

Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent to Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to BTG USA Inc. of Gulph Mills, Pennsylvania, an exclusive license to U.S. Patent No. 5,496,732 (Serial No. 08/054,985) issued on March 5, 1996, and to U.S. Patent Application Serial No. 08/609,320 filed on March 1, 1996, both entitled "Enhanced Inset Resistance in Plants Genetically Engineered with a Plant Hormone Gene Involved in Cytokinin Biosynthesis." Notice of Availability for Serial No. 08/054,985 was published in the **Federal Register** on July 23, 1993. Serial No. 08/608,320 is a continuation of Serial No. 08/054,985.

DATES: Comments must be received on or before June 30, 1997.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, Room 415, Building 005, BARC-West, Beltsville, Maryland 20705-2350.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; telephone: 301-504-5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as BTG USA Inc. has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective

exclusive license may be granted unless, within sixty days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which established that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard M. Parry, Jr.,

Assistant Administrator.

[FR Doc. 97-11254 Filed 4-30-97; 8:45 am]

BILLING CODE 3410-03-M

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent to Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to NOBL Laboratories, Inc. of Sioux Center, Iowa, an exclusive license to U.S. Patent Application Serial No. 08/609,334 filed on March 1, 1996, entitled "Restriction Enzyme Screen for Differentiating Porcine Reproductive and Respiratory Syndrome Virus Strains." Notice of Availability was published in the **Federal Register** on July 18, 1996.

DATES: Comments must be received on or before June 30, 1997.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, Room 415, Building 005, BARC-West, Beltsville, Maryland 20705-2350.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; telephone: 301-504-5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as NOBL Laboratories, Inc., has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective

exclusive license may be granted unless, within sixty days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard M. Parry, Jr.,

Assistant Administrator.

[FR Doc. 97-11253 Filed 4-30-97; 8:45 am]

BILLING CODE 3410-03-M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 97-027N]

Codex Strategic Planning Meeting

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; public hearing and request for comments.

SUMMARY: This notice informs the public of a strategic planning activity relating to the U.S. Government's representation on the Codex Alimentarius Commission, an international food standard-setting program. The notice includes a description of Codex activities; identifies five issues to be addressed; identifies specific objectives, methods, timeframes, and persons or agencies responsible for addressing them. A public hearing will be held in Washington, DC on May 8, 1997, to allow a dialogue on the identified issues. U.S. Government agencies plan to use the record of that hearing and of comments received in finalizing their planned approaches to achieving U.S. goals for Codex standard-setting activities.

DATES: The public meeting will be held on May 8, 1997, from 9:30 a.m. until 12:30 p.m.

ADDRESSES: The conference will be held at the Holiday Inn Rosslyn-Westpark, 1900 N. Fort Myer Drive, Arlington, VA 22207. Send an original and two copies of written comments to: FSIS Docket Clerk, DOCKET NO. 97-027N, Room 102, Cotton Annex, 300 12th Street SW, Washington, DC, 20250-3700. All comments submitted and a transcript of the hearing will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 1:00 p.m., and

2:00 p.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Patrick J. Clerkin, Director, U.S. Codex Office, United States Department of Agriculture, Food Safety and Inspection Service, West End Court, Room 311, Washington, DC 20250; (202) 418-8852.

SUPPLEMENTARY INFORMATION: The Codex Alimentarius Commission (Codex) is an international governmental organization with current membership from the national governments of 156 countries, including the United States. It was formed in 1962 to facilitate world trade in foods and to promote consumer protection.

Codex is a subsidiary of two United Nations groups, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). It has worked to develop international food standards that protect consumers' health as well as promote fair trade. Food production practices all over the world have been upgraded as a result.

The United States participates in Codex Alimentarius activities through U.S. Codex, which consists of federal government officials assisted by representatives of non-government interests.

How Codex Currently Operates

Codex provides a forum in which member countries and international organizations can cooperate to achieve the dual goals of consumer protection and fair food trade practices. The Commission meets every other year; its Executive Committee meets between sessions.

Codex Committees

Codex has established several types of committees. The ones that draft standards and codes of practice and guidelines are commodity committees and general-subject committees.

Fifteen commodity committees have operated from time to time. Those currently active are Fats and Oils, Fish and Fishery Products, Nutrition and Foods for Special Dietary Uses, Milk and Milk Products, Fresh Fruits and Vegetables, Cereals, Pulses and Legumes, Natural Mineral Waters, Cocoa and Chocolate Products, Sugars, and Processed Fruits and Vegetables. Meat Hygiene, which had been inactive, was reconvened in 1991 to update the codes of practice under its jurisdiction. It adjourned in 1993 after completing this task.

There are eight committees which deal with general subjects rather than with particular commodities. They are: Food Labeling; Food Additives and

Contaminants; Food Hygiene; Pesticide Residues; Residues of Veterinary Drugs in Foods; Methods of Analysis and Sampling; Food Import and Export Inspection and Certification Systems; and General Principles, which sets rules and procedures for Codex.

There are also five regional coordinating committees representing Africa, Asia, Europe, Latin America and the Caribbean, and North America and the South-West Pacific. They define the regions' problems and needs concerning food standards and food control.

The United States serves on all the commodity and general subject committees that are currently active, and on the regional committee that includes North America.

Two independent committees of experts work closely with Codex: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). These expert committees perform the scientific evaluations which support Codex standards, guidelines, Maximum Residue Levels (MRLs), and codes of practice.

A comprehensive notice, detailing the sanitary and phytosanitary standard-setting activity of Codex, is published annually in the **Federal Register** (FR) (see June 4, 1996 (61 FR 28132)). It also details other standard-setting activities of Codex, including commodity standards, guidelines, codes of practice, and revised texts. Included as an Appendix to that notice is a description of the system for elaborating standards within the Codex Commission and its Committees. A reading of that notice will enhance an understanding of the issues identified in this strategic planning document.

In 1994, the United States signed and ratified the Uruguay Round Agreements Act, and thereby became a signatory member of the World Trade Organization (WTO). The agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) requires members to use international standards as the basis for sanitary and phytosanitary measures when such international standards meet the member's appropriate level of protection. The SPS Agreement explicitly recognizes Codex as an organization that develops such standards. In this context, Codex standards will play a significant role with regard to food safety and agricultural trade.

In anticipation of the emerging importance of Codex standards, Codex inaugurated a review of the policies, processes, and procedures established

over the course of its more than 30-year history. This examination grew out of an international conference held in Rome in 1991 to address three major areas of concern: (1) The heightened status and responsibility that would be given to Codex standards under what was then a draft proposal of the General Agreement on Tariffs and Trade (GATT);

(2) advances in food production technologies; and (3) changing consumer expectations about food safety and composition. U.S. Codex also engaged in a process of self-examination as a prelude to change.

In February 1995, U.S. Codex issued a draft report setting forth the results of work initiated in October 1992, by a Strategic Planning Group to recommend a new course for United States participation in Codex Alimentarius. The group was asked to consider how U.S. Codex can become more effective in:

- maintaining and improving public health protection;
- encouraging changes in Codex to enhance its public health mission;
- broadening the involvement of public, consumer, and environmental organizations as well as the chemical and food industries in developing international food safety standards;
- prioritizing its activities and using its resources more efficiently; and
- facilitating trade.

The Strategic Planning Group identified five critical issues to be addressed. The first two issues deal with changes in Codex itself; the other three issues deal with internal U.S. changes. The Group subsequently identified specific actions or approaches that the U.S. Codex might take to address these issues. (The Group did not address those parts of Codex standards that are not related to food safety; e.g., food composition/identity standards which are subject to the WTO Agreement on Technical Barriers to Trade. It might be useful for another group to consider systematically the strategic issues concerning these standards.) A brief description of each issue and related actions is presented below.

Issue 1: U.S. Support for Strengthening the Scientific Basis for Codex Decisions

Codex health and safety standards have been and must continue to be based on scientific analysis and evidence. The procedures by which those standards are elaborated should be transparent and consistently applied. In many cases scientific work in support of Codex's elaboration of standards is performed by Expert Committees that

are independent of Codex. In other cases, work is performed internally by Codex Committees. In the latter case, those committees are termed, "process committees." In all cases, criteria for making decisions on standards should be clear and science-based. The United States should support the efforts of Codex and other international organizations to improve the scientific basis for Codex standards to meet these goals.

Expert Committees

With regard to the elaboration of standards, primary responsibility for performing the scientific evaluations that underlie most Codex health and safety standards rests with FAO, and with WHO through the International Programme for Chemical Safety (IPCS). This work is done through two expert committees, The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In addition, FAO and WHO sponsor ad hoc expert consultations on specific topics related to food safety.

Governments and non-governmental organizations have no routine, direct working relationship with JMPR and JECFA, although both EPA and FDA have provided funds and support in kind to FAO and WHO/IPCS. While the work of JECFA and JMPR has been of high quality, the procedures under which they operate should be enhanced to assure that decisions are firmly based in science, and that their operations are transparent to all interested parties. The same would hold true for other expert consultations.

FAO and WHO/IPCS have begun to make changes in the way they conduct scientific evaluations of chemicals. However, with demands and expectations for change coming from many sources, a broader and more systematic look is needed at the scientific framework, and the processes of international chemical safety evaluation.

The expert committees need effective processes that would allow broader

consideration of the views of countries, consumer and public interest groups, the chemical industry, food producers, international organizations involved in chemical safety, and any other interested party.

Codex and member countries should encourage the FAO/WHO to initiate necessary changes internally or support development of and adoption of such relevant and suitable procedures, as may be internationally agreed on by other international organizations which will improve the quality, consistency, integrity, and transparency of expert committee evaluations.

Issues that might be considered include:

- establishment of minimum data sets for evaluation,
- establishment of guidelines for data development,
- establishment of standard data evaluation and reporting procedures,
- development and application of good laboratory practice standards,
- development and application of data quality standards (factors which might render a study acceptable or unacceptable for review),
- establishment of harmonized and articulated approaches to risk assessment,
- use of national evaluations which meet international standards instead of creating new international evaluations,
- tailoring evaluations to meet the practical needs of countries and other international organizations,
- establishment of processes and time frames for updating previous evaluations as new scientific information emerges,
- maintenance of administrative records,
- establishment of roles and responsibilities of member countries and non-governmental organizations,
- development of guidelines how to establish priorities for chemical evaluation work,
- improved mechanisms to ensure FAO/WHO awareness of all relevant

data, including adverse effects data, are provided,

- establishment of selection criteria for JMPR/JECFA experts, and
- improvement in communicating of the results of all work that supports the elaboration of Codex standards.

Process Committees

Codex committees performing work primarily related to food production and inspection activities, notably the Meat Hygiene and Food Hygiene committees and the Committee on Food Import and Export Inspection and Certification Systems, are sometimes known as "process" committees. They do not use JECFA or JMPR evaluations as part of their deliberation. They develop Codes of Practice through discussion and assignment of working groups. Codes of Practice are not considered official standards by Codex in that countries are not requested to provide a formal acknowledgment of acceptance or rejection. However, they are established through the Codex step process and will probably be considered as standards under WTO, NAFTA and future trade agreements.

Criteria for decision-making relating to such standards within Codex should be clearly articulated to allow consideration of only those factors relevant to the health protection of consumers and to the promotion of fair practices in trade. Such criteria for decision making should be used in all Codex committees and in the Commission itself. The decisions should be arrived at through an open process, with a clearly defined rationale. Previous decisions should be revisited if new scientific information becomes available.

Availability of information on Codex activities and on work performed in support of Codex activities, in the form of working documents and standards, is critical to achieving the transparency necessary to assure the public's confidence in Codex. Mechanisms to improve communications must be sought by Codex and all member states.

ACTOPM PLAN—ISSUE #1: U.S. SUPPORT FOR STRENGTHENING THE SCIENTIFIC BASIS FOR CODEX DECISIONS

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
A. Develop and promote criteria to be used by WHO/FAO in selecting experts to serve on the JMPR/JECFA which will be based on the following: (1) Open process for the submission of nominations/acceptance and tenure;	(1) U.S. will develop paper	U.S. Codex Office to establish an inter-agency group.	2/1/97	(1)

ACTOPM PLAN—ISSUE #1: U.S. SUPPORT FOR STRENGTHENING THE SCIENTIFIC BASIS FOR CODEX DECISIONS—
Continued

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
(2) Conflict of interest disclosure; and;.	(2) Paper will be circulated to U.S. Government/ NGO's as well as other countries for input.				
(3) Technical Qualifications	(3) Document will be intro- duced in appropriate Codex forum and will form basis for U.S. Posi- tion in any related delib- erations of any Codex Committee.				
B. Establish better communication mechanisms to ensure that infor- mation on Codex activities is read- ily and easily available.	(1) U.S. Codex establish Codex Home Page. (2) Encourage Codex to expand use of the Internet (See item 2(A)).	U.S. Codex Office	11/01/96 ..	7/1/96
C. Develop and promote the estab- lishment of minimum/adequate data sets for expert bodies (JECFA/JMPR).	(1) U.S. Develop paper (2) Circulate document to Government officials as well as other countries for input. (3) Document will be intro- duced in appropriate Codex forum and will form basis for U.S. Posi- tion in any related delib- erations of any Codex Committee.	U.S. Codex Office to es- tablish an inter-agency technical working group.	2/1/97	10/15/97

¹ Ongoing.

Issue 2: U.S. Support for Codex Efforts to Improve its Management Processes

U.S. Codex should support the revitalization of Codex. Revitalization of Codex should include conducting a systematic review of priorities, streamlining the decision-making processes, increasing transparency, and improving communication. These steps will enhance the credibility of Codex with national regulatory authorities and consumers.

FAO/WHO began a formal reevaluation of Codex procedures and guiding principles in March 1991 at the Conference on Food Standards, Chemicals in Foods and Food Trade. Codex is now streamlining its standards to concentrate on essential health-related aspects. This represents a shift in emphasis. Now that over 100 countries have become members of the WTO, it is important that Codex again re-examine its operation with particular attention to the following areas:

1. Codex should conduct a formal strategic planning exercise, including a systematic review of Codex priorities. This would provide a framework for major policy decisions and serve as a basis for refocusing priorities. Codex needs to strengthen its links with other international food safety organizations and ensure that its activities are integrated with and do not duplicate the activities of others in the broad area of chemical safety.

2. Codex decision-making procedures should be clearly defined and transparent so that interested parties can more fully understand, evaluate, and participate in the process.

3. Codex needs to streamline its processes so that standards can be developed and adopted more rapidly. In addition, it needs a process, including an emergency procedure, to reevaluate and update its standards as new scientific information emerges.

4. The public needs to understand how Codex operates in order to work

within the system and use it effectively. Codex should more frequently and more broadly communicate information on its activities and on how to obtain standards, meeting reports and other documents.

5. Codex should review the terms of reference of the Executive Committee to expand its area of responsibility to include strategic planning and better ensuring that priority areas of work are on target in terms of time and other considerations. The Executive Committee must refocus itself to become the "Board of Directors" of the organization, responsible for making decisions on significant issues occurring between Commission meetings such as establishing work priorities and directing issues to the appropriate committees for action.

6. Codex should examine its use of resources to determine whether increased efficiency is possible. If appropriate, additional resources should be identified.

ACTION PLAN—ISSUE #2: U.S. SUPPORT FOR CODEX EFFORTS TO IMPROVE ITS MANAGEMENT PROCESSES

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
A. Encourage Codex to establish standard procedures for handling Codex documents to ensure timeliness and opportunity for adequate review by member countries.	U.S. submit a proposal to the Executive Committee for discussion.	U.S. Codex Office	2/1/97	5/15/97
	One recommendation is that Codex move expeditiously to put Committee documents on the World Wide Web so that countries could have immediate access to the working documents.	(¹)
B. Codex review its policies for drafting the Committee reports to assure adequate information is provided on assignments and history of evolving standards.	U.S. submit a proposal to the Executive Committee for discussion.	U.S. Codex Office	2/1/97	5/97
C. Commission meeting operating practices be reviewed to assure the most efficient/effective use of members time.	U.S. submit a proposal to the Executive Committee for discussion.	U.S. Codex Office	2/1/97	5/15/97
D. Encourage Codex review of operating practices to utilize strategic thinking in developing the work plan and to determine if additional efficiencies can be realized. This could include related changes to the Executive Committee's terms of reference.	Develop appropriate follow-up to 1995 Executive Committee discussion of this issue.	U.S. Codex Office	3/1/97	5/97
E. In the appropriate Codex Committee promote the development of a process for establishing emergency procedures (developing, revising or elaborating Codex standards where warranted to protect public health by newly developed food safety scientific information which invalidates the existing standard).	1. U.S. develop paper 2. Circulate document to government officials as well as other countries for input. 3. Present paper in appropriate Codex Committee.	U.S. Codex Office	2/97	11/97

¹ Ongoing.**Issue 3: U.S. Acceptance of Codex Standards**

To facilitate U.S. decisions on increased acceptance of Codex standards related to food safety, U.S. Codex should develop processes for systematically evaluating such existing Codex standards and proposed new Codex standards using established U.S. approaches to risk assessment.

Historically, two factors have worked against U.S. Acceptance of Codex Standards. These are:

—current U.S. workloads, which force the regulatory agencies to place a low

priority on reaching decisions on whether they can accept proposed Codex standards, and;

—differences between the Codex standards and U.S. regulations.

Under current Codex rules and procedures, Codex member countries are obligated to consider for acceptance all pesticide and veterinary drug MRLs as well as all food additive, commodity and general standards adopted by Codex. Current U.S. acceptance procedures vary among agencies having responsibilities for each of these categories of standards. The agencies

include EPA, FDA and USDA. These agencies need to harmonize their processes for considering Codex Standards and for developing U.S. standards with the Codex processes for data evaluation and standard development. Where methods supporting the Codex processes pose impediments to harmonization, the U.S. Codex needs to address those processes in all appropriate forums. The Food Quality Protection Act of 1996 provides for consideration by the U.S. Government of Codex pesticide MRLs.

ACTION PLAN—ISSUE #3: U.S. ACCEPTANCE OF CODEX STANDARDS

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
A. Agencies shall consider Codex Standards in the development of U.S. Standards for food.	(1) Develop model SOP with examples. (The model should accommodate the variable complexity of different type standards.). (2) Have model Standard Operating Practice endorsed by Steering Committee. (3) Distribute to relevant agencies for implementation	U.S. Codex Office with input from agencies. U.S. Codex Office Steering Committee. U.S. Codex Office	Individual agency resources (to be determined). 	2/1/97	10/97
B. Improve understanding and level of quality input into all phases of Codex standards development by stakeholders (government, non-government organizations).	—Establish and implement an outreach program including elements such as: —Home page —Workshops —Paper distribution	U.S. Codex Office	1/1/97	06/97
C. Encourage U.S. industry to submit data relevant to U.S. consideration of acceptance of Codex standards.	Enhance dialog with U.S. industry.	U.S. Manager for Codex	1/1/97	(¹)
D. Establish and codify process for routine review of Codex standards, guidelines, and recommendations for consideration for acceptance.	Agencies develop their own model.	Individual agencies	Implementation of the objective will require substantial resources by individual agencies (to be determined). 	01/96 6/97	3/1/98 08/97
E. In recognition of the obligations under Article 3 of the SPS Agreement, issue policy statement regarding acceptance of Codex standards, guidelines and recommendations.	Issue joint policy statement across all agencies.	Steering Committee U.S. Manager for Codex.	6/97	08/97
F. Establish model format for U.S. positions on proposed Codex standards at Step 3 to specifically identify: (a) whether acceptance of the Codex standard would affect U.S. consumer health and safety. (b) whether acceptance of the Codex standard would require changes in U.S. food production, marketing and regulatory practices. (c) steps which need to be initiated to harmonize the relevant U.S. standard and the proposed Codex standard.	(1) Prepare format for U.S. positions to address issues "a"—"c" to be applied by committees. —for any document going through step procedures. (2) Train U.S. delegates in implementation of format. (3) Implement new format	Steering Committee U.S. Manager for Codex EPA, USDA, FDA, DOC. U.S. Codex Office Individual agencies Substantial resources (to be determined.).	2/11/97 02/97 06/97	03/97

¹ Ongoing.**Issue 4: Effective Participation of Non-Governmental Organizations in U.S. Codex**

Balanced non-governmental participation is needed and will help ensure that the positions taken by U.S. Codex have broad support. In line with this objective, the process of gathering information and developing positions

should be transparent—open to public scrutiny.

Codex delegations are led by U.S. government officials, primarily managers and scientists, who serve as the formal U.S. representatives in Codex committee meetings. Nevertheless, in the development of U.S. positions, parties outside the government have traditionally provided technical

information and support to such representatives, in some cases serve as members of the delegation. These experts primarily from the regulated industry, serve a useful purpose because of their expertise in specific technical matters before the various Codex committees. In addition to providing technical information, they convey the views of their constituents to the

committees and relay information about U.S. Codex activities to those constituents.

U.S. Codex should involve a greater variety of groups in its activities and, for all of its activities, should expand their criteria for participation. In addition, U.S. Codex's entire process of gathering information and developing positions must be transparent.

U.S. Codex must develop and implement mechanisms to involve a far

broader range of interests in U.S. Codex activities. This expanded participation can occur on many levels, ranging from simply receiving written information on Codex activities to actively participating in the development of U.S. positions.

U.S. Codex should conduct an extensive outreach effort to include national, regional, and local organizations and individuals with a stake in the establishment of international food standards. U.S. Codex should explore

the possibility of creating a network of scientists and food and nutrition technologists interested in Codex issues.

In order for the U.S. Government to formally accept standards adopted by Codex, it is essential that such standards not only provide adequate public health protection, but that non-governmental organizations (public interest, industry, professional, etc.) have confidence in the integrity of all aspects of the standard elaboration process.

ACTION PLAN—ISSUE #4: EFFECTIVE PARTICIPATION OF NON-GOVERNMENTAL ORGANIZATIONS (NGOs) IN U.S. CODEX

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
A. Establish guidelines and criteria for consistency in the operations of U.S. Codex delegations including the selection process of NGOs on delegations and participation of NGOs in U.S. Codex.	Develop guidelines and provide training for all U.S. delegates to ensure awareness of operating procedures for delegations (See Item 5 (E)).	U.S. Codex Office and agency representatives	Started Operations	(¹)
B. Establish a system for timely distribution of papers to allow for routine and early opportunity for public comment on U.S. positions as well as papers from the Codex Secretariat.	Papers should be posted on Internet and a cut-off date should be established for submissions of papers by all Codex Committees. (Discussed in Executive Committee, June 1996).	U.S. Codex Office	4/5/96	(¹)
C. Request the establishment of a procedure for increased participation of NGO's in Expert Consultations. Specifically recommend that NGO's attend Expert Consultations as participants.	U.S. will request that names be submitted to the Codex Office by public interest groups to facilitate participation in Expert Consultations. Bring to the attention of FAO/WHO the need to notify interested officials when such expert consultations are planned.	U.S. Codex Office Codex Secretariat	6/96	(¹)
D. Continue to work with other Codex members to promote effective NGO participation.	The United States will continue to provide strong support for NGO participation in appropriate Codex forums.	U.S. Codex Office	(¹)
E. Continue to provide opportunities for NGOs to increase awareness of the Codex Alimentarius Food Standards Programme.	U.S. will develop regular briefings and public meetings and utilize USDA's Communications Office and the Office of Intergovernmental Relations, as well as FR notices Internet, consumer and industry-sponsored forums and interagency communications to promote awareness.	U.S. Codex Office	(¹)

¹ Ongoing.

Issue 5: Management and Effectiveness of U.S. Codex

To enhance its effectiveness in Codex, the U.S. government should consider a larger role for U.S. Codex, including a senior executive position for the U.S. Manager, staffing, and funding.

The United States has actively participated in and been considered a leader in Codex since the organization was established. Its contributions have centered around science and technology. It is now clear that to capitalize on its scientific and technical capabilities and increase the effectiveness of its participation, the

United States must expand its focus and investment.

The following points need to be addressed to enhance the effectiveness of current U.S. participation:

1. U.S. Codex needs to take into account the changing Codex dynamics and develop increased social, political and economic sensitivity and awareness

of the global implications of such change. U.S. representatives must be fully informed about the needs of other countries as well as domestic needs. The United States must function as a team player, sharing information, seeking coalitions and engaging in partnerships to advance and support proposals of mutual concern. It must be well-prepared to step into a leadership role when the situation warrants, and be willing to negotiate in support of the development of science-based standards for all member countries.

2. The U.S. government should provide adequate resources for effective

participation in Codex and consider a larger organizational role for U.S. Codex, thus promoting increased efficiency, effectiveness, and participation. Full support from all management levels is needed to ensure that Codex activities receive high priority, with full time staff, targeted funding, and a senior executive position for the U.S. Manager.

3. The federal managers and scientists in U.S. Codex need training in international negotiations and intercultural relations. There should be regular interaction among them to strengthen their sense of identity,

improve awareness of cross-cutting issues, and identify at an early stage controversial issues that need attention by the coordinator of U.S. Codex. Early identification of emerging issues will allow effective coalition building with other countries' delegates to promote mutual interests.

4. U.S. Codex needs a mechanism to allow it to routinely evaluate the results of its efforts.

5. The makeup of U.S. Codex should reflect a balance between trade and regulatory perspectives.

ACTION PLAN—ISSUE #5: MANAGEMENT AND EFFECTIVENESS OF U.S. CODEX

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
A. Establish and recruit/select a U.S. Manager for Codex Alimentarius in the Office of the Under Secretary for Food Safety in order to better facilitate interagency process.	—Included in FSIS reorganization package. —Announce position —Designate a review panel.	Under Secretary for Food Safety.	4/30/96	1/30/97.
B. Provide adequate staffing for the U.S. Codex Office.	—Appropriately classify and staff positions consistent with Strategic Plan and Action Plan assumptions.	Administrator for FSIS	8/31/96	Ongoing.
Further enhance technical and policy expertise in U.S. Codex Office.	—Detail staff from relevant U.S. Government agencies.	U.S. Codex Office Steering Committee.	No new resources—FTE would be borne by participating agencies.	4/1/97	Ongoing.
	—Internship Programs —e.g. George Washington University Program/School for Advanced Studies at John Hopkins/investigate other interagency fellowship possibilities.	U.S. Codex Office	08/05/97	Ongoing.
C. Seek appropriations to establish specific funding for U.S. Codex Office and funding for U.S. hosted meetings.	Prepare estimates of needed resources.	Under Secretary for Food Safety, Steering Committee, U.S. Manager for Codex, U.S. Codex Office.	1/1/97	FY-1999.
	Develop appropriation package to include in FY-99 appropriation submission.	1/1/97	
D. Seek Congressional funding for individual Federal Agency activities in the development, review, and acceptance of Codex standards.	Prepare estimate of resources needed.	—Policy level Steering Committee. —U.S. Manager for Codex.	2/1/97.	12/97.
E. Provide training for all U.S. Codex officials to ensure awareness of operating procedures for delegations and to enhance knowledge and skills. (Include training modules which distinguish between food safety and quality requirements in Codex standards and the implications under WTO). See 4(A).	Interagency working group to define training requirements and plan. (FDA, EPA, USDA, USTR, DOC, State).	U.S. Codex Office	2/1/97	Ongoing.

ACTION PLAN—ISSUE #5: MANAGEMENT AND EFFECTIVENESS OF U.S. CODEX—Continued

Objective	Method	Responsibility (person/area)	Resources	Initiation date	Completion date
F. Reorganize current Codex Steering Committee to better manage and provide oversight in a timely manner to Codex issues, e.g. form separate policy and technical committees. (1 senior-level policy committee) (1 senior-level technical committee).	Discuss proposal w/current Steering Committee.	—Under Secretary for Food Safety. —Existing Steering Committee. —U.S. Manager for Codex.	2/96	5/1/97.
	Review Steering Committee comments and get Steering Committee endorsement.	—Under Secretary for Food Safety. —Steering Committee .. —U.S. Manager for Codex.	6/1/97	8/1/97.
	Prepare draft terms of reference for new committees and determine membership.	—Under Secretary for Food Safety. —Steering Committee .. —U.S. Manager for Codex.	8/1/97	10/1/97.
G. Develop a process to define inter/intra agency communication problems and necessary steps to resolve them. Such steps should be oriented toward sharing information with a view toward identifying significant cross-cutting or controversial issues to Codex Steering Committee.	Agencies document current procedures of inter/intra process to U.S. Codex office and identify steps taken to resolve problems. Manager routinely participate as member.	—FDA, USDA, EPA, DOC, USTR. —Policy level Steering Committee. —U.S. Manager for Codex.	To be determined	2/1/97	Ongoing.
H. Establish relationship with SPS Committee.	Share data on acceptance of standards.	—U.S. Manager for Codex. —U.S. Codex Office	To be determined	2/1/97	10/1/97.
I. Establish Homepage on Internet in the U.S. Codex Office and utilize electronic transmission of documents: • transmitting U.S. response to request for country comments. • receiving working Codex documents.	—FSIS Administrator ... —U.S. Codex Office	2/1/97	7/1/97.
J. Ensure that Codex duties are reflected in Codex managers (delegates/alternates) position descriptions/performance plans.	U.S. Codex office to introduce subject/need to the Steering Committee.	Individual Agencies	2/1/97	7/1/97.
Develop generic performance standards.	Codex office to provide agencies generic statement of duties of U.S. Delegates.	10/1/97.	
	Steering Committee to contact individual agencies to request initiation of this objective.	10/1/97.

Public Hearing

A public hearing is scheduled for May 8, 1997, from 9:30 AM to 12:30 PM, at the Holiday Inn Rosslyn-Westpark, 1900 N. Fort Myer Drive, Arlington, VA 22207. Attendees will hear brief descriptions of the issues and action plans, and will have the opportunity to pose questions and offer comments. A transcript will be made of the

proceedings. The Agencies plan to use the record of this hearing and of comments received in finalizing their planned approaches to achieving U.S. goals for Codex standard-setting activities.

Comments regarding the Codex standard-setting activities may be sent to the FSIS Docket Room (see ADDRESSES). Please state that your

comments relate to Codex activities and specify which issues and objectives your comments address.

Done at Washington, DC on: April 25, 1997.

Thomas J. Billy,

Administrator, Food Safety and Inspection Service.

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