

Notices

Federal Register

Vol. 70, No. 102

Friday, May 27, 2005

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

Food Safety and Inspection Service

[Docket No. 05-003N]

International Standard-Setting Activities

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the sanitary and phytosanitary standard-setting activities of the Codex Alimentarius Commission (Codex), in accordance with section 491 of the Trade Agreements Act of 1979, as amended, and the Uruguay Round Agreements Act, Public Law 103-465, 108 Stat. 4809. This notice also provides a list of other standard-setting activities of Codex, including commodity standards, guidelines, codes of practice, and revised texts. This notice, which covers the time periods from June 1, 2004, to May 31, 2005, and June 1, 2005, to May 31, 2006, seeks comments on standards currently under consideration and recommendations for new standards.

ADDRESSES: Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD-ROM's, and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.

All submissions received must include the Agency name and docket number 05-003N. Please state that your comments refer to Codex and, if your comments relate to specific Codex committees, please identify those committees in your comments and submit a copy of your comments to the delegate from that particular committee. All comments submitted will be

available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at http://www.fsis.usda.gov/regulations/2005_notices_index/.

FOR FURTHER INFORMATION CONTACT: F. Edward Scarbrough, Ph.D., United States Manager for Codex, U.S. Department of Agriculture, Office of the Under Secretary for Food Safety, Room 4861, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250-3700; (202) 205-7760. For information pertaining to particular committees, the delegate of that committee may be contacted. (A complete list of U.S. delegates and alternate delegates can be found in Attachment 2 to this notice.) Documents pertaining to Codex are accessible via the World Wide Web at the following address: <http://www.codexalimentarius.net/current.asp>. The U.S. Codex Office also maintains a Web site at http://www.fsis.usda.gov/Regulations_&Policies/Codex_Alimentarius/index.asp.

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established on January 1, 1995, as the common international institutional framework for the conduct of trade relations among its members in matters related to the Uruguay Round Trade Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade (GATT). U.S. membership in the WTO was approved and the Uruguay Round Agreements Act was signed into law by the President on December 8, 1994. The Uruguay Round Agreements became effective, with respect to the United States, on January 1, 1995. Pursuant to section 491 of the Trade Agreements Act of 1979, as amended, the President is required to designate an agency to be responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization, Codex, World Organization for Animal Health, and the International Plant Protection Convention. The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the U.S. Department of Agriculture as the agency

responsible for informing the public of SPS standard-setting activities of each international standard-setting organization. The Secretary of Agriculture has delegated to the Administrator, Food Safety and Inspection Service (FSIS), the responsibility to inform the public of the SPS standard-setting activities of Codex. The FSIS Administrator has, in turn, assigned the responsibility for informing the public of the SPS standard-setting activities of Codex to the U.S. Codex Office, FSIS.

Codex was created in 1962 by two U.N. organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the principal international organization for encouraging fair international trade in food and protecting the health and economic interests of consumers. Through adoption of food standards, codes of practice, and other guidelines developed by its committees and by promoting their adoption and implementation by governments, Codex seeks to ensure that the world's food supply is sound, wholesome, free from adulteration, and correctly labeled. In the United States, the United States Department of Agriculture (USDA); the Food and Drug Administration (FDA), Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA) manage and carry out U.S. Codex activities.

As the agency responsible for informing the public of the SPS standard-setting activities of Codex, FSIS publishes this notice in the **Federal Register** annually. Attachment 1 (Sanitary and Phytosanitary Activities of Codex) sets forth the following information:

1. The SPS standards under consideration or planned for consideration; and
2. For each SPS standard specified:
 - a. A description of the consideration or planned consideration of the standard;
 - b. Whether the United States is participating or plans to participate in the consideration of the standard;
 - c. The agenda for United States participation, if any; and
 - d. The agency responsible for representing the United States with respect to the standard.

To obtain Copies of those Standards listed in Attachment 1 that are under

consideration by Codex, please contact the Codex delegate or the U.S. Codex Office. This notice also solicits public comment on those standards that are currently under consideration or planned for consideration and recommendations for new standards. The delegate, in conjunction with the responsible agency, will take the comments received into account in participating in the consideration of the standards and in proposing matters to be considered by Codex.

The United States' delegate will facilitate public participation in the United States Government's activities relating to Codex Alimentarius. The United States' delegate will maintain a list of individuals, groups, and organizations that have expressed an interest in the activities of the Codex committees and will disseminate information regarding United States' delegation activities to interested parties. This information will include the current status of each agenda item; the United States Government's position or preliminary position on the agenda items; and the time and place of planning meetings and debriefing meetings following Codex committee sessions. In addition, the U.S. Codex Office makes much of the same information available through its web page, http://www.fsis.usda.gov/Regulations_&Policies/Codex_Alimentarius/index.asp. Please visit the web page or notify the appropriate U.S. delegate or the Office of U.S. Codex Alimentarius, Room 4861, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250-3700, if you would like to access or receive information about specific committees.

The information provided in Attachment 1 describes the status of Codex standard-setting activities by the Codex Committees for the time periods from June 1, 2004 to May 31, 2005, and June 1, 2005 to May 31, 2006. In addition, the following attachments are included:

- Attachment 2 List of U.S. Codex Officials (includes U.S. delegates and alternate delegates)
- Attachment 3 Timetable of Codex Sessions (June 2004 through June 2006)
- Attachment 4 Definitions for the Purpose of Codex Alimentarius
- Attachment 5 Part 1—Uniform Procedure for the Elaboration of Codex Standards and Related Texts
Part 2—Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts
- Attachment 6 Nature of Codex Standards

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS web page located at http://www.fsis.usda.gov/regulations/2005_Notices_Index/.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/ and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

Done at Washington, DC on May 24, 2005.

F. Edward Scarbrough,
United States Manager for Codex.

Attachment 1: Sanitary and Phytosanitary Activities of Codex

Codex Alimentarius Commission and Executive Committee

The Codex Alimentarius Commission will hold its Twenty-Eighth Session July 4-9, 2005 in Rome, Italy. At that time it will consider procedural matters, and the standards, codes of practice, and related matters brought to its attention by the general subject committees, commodity committees, *ad hoc* Task Forces and member delegations. It will also consider options to implement recommendations from the review of

Codex committee structure and mandates of Codex committees and task forces, as well as budgetary and strategic planning issues. At this Session, the Commission will elect a Chair and three Vice Chairs. The issue of Codex interaction with other international organizations will be discussed.

Prior to the Commission meeting, the Executive Committee will have met at its Fifty-fifth Session on February 9-11, 2005 and its Fifty-sixth Session on June 30-July 2, 2005. It is composed of the chairperson, vice-chairpersons, seven members elected from the Commission, one from each of the following geographic regions: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, and South-West Pacific. In addition, regional coordinators from the six regional committees attend as observers. It will consider the Codex Strategic Plan 2008-2013; review the Codex committee structure and mandate of Codex committees and task forces; review matters arising from reports of Codex Committees, proposals for new work, and standards management issues; consider the implementation of the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards; and review the Trust Fund for the Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius.

Responsible Agency: USDA/FSIS.
U.S. Participation: Yes.

Codex Committee on Residues of Veterinary Drugs in Foods

The Codex Committee on Residues of Veterinary Drugs in Foods determines priorities for the consideration of residues of veterinary drugs in foods and recommends Maximum Residue Limits (MRLs) for veterinary drugs. A veterinary drug is defined as any substance applied or administered to a food producing animal, such as meat or dairy animals, poultry, fish or bees, for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behavior.

A Codex Maximum Limit for Veterinary Drugs (MRLVD) is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is adopted by the Codex Alimentarius Commission to be permitted or recognized as acceptable in or on a food. An MRLVD is based on the Acceptable Daily Intake (ADI) and indicates the amount of residue in food that is considered to be without appreciable toxicological hazard. An MRLVD also takes into account other

relevant public health risks as well as food technological aspects. When establishing an MRLVD, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRLVD may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

Acceptable Daily Intake (ADI): An estimate by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg).

The committee met in Arlington, VA (USA), October 25–28, 2004. The following will be under consideration by the Commission at its 28th Session in July 2005. The relevant document is ALINORM 5/28/31.

Draft MRLs at Step 8:

- Cyhalothrin.
- Flumequine.
- Neomycin.
- Dicyclanil.

Proposed Draft MRLs at Step 5/8:

- Imidocarb.

Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance at Step 5/8.

Proposed Draft MRLs at Step 5:

- Flumequine (in black tiger shrimp).
- Pirlimycin.
- Cypermethrin and alpha-cypermethrin.

- Doramectin (in cow's milk).

The Committee continues to work on:

- Draft MRLs for Trichlorfon (metrifonate) at step 7.
- Proposed Draft MRLs for Ractopamine at step 4.
- Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for Control of Veterinary Drug Residues in Foods.
 - Discussion paper on Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods.
 - Proposed Draft Revised Part I, II, III of Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods.
 - Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation.
 - List of Methods of Analysis for Veterinary Drug Residues and Identification of Routine Methods of Analysis.
 - Recommendations on Residues of Veterinary Drugs without ADI/MRL (Prioritization of work).

Responsible Agency: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Additives and Contaminants

The Codex Committee on Food Additives and Contaminants (CCFAC) (a) establishes or endorses permitted maximum or guideline levels for individual food additives, contaminants, and naturally occurring toxicants in food and animal feed; (b) prepares priority lists of food additives and contaminants for toxicological evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); (c) recommends specifications of identity and purity for food additives for adoption by the Commission; (d) considers methods of analysis for food additives and contaminants; and (e) considers and elaborates standards and codes for related subjects such as labeling of food additives when sold as such and food irradiation. The committee met in The Hague, The Netherlands, April 25–29, 2005. The following matters are under consideration by the Commission at its 28th Session in July 2005. The relevant document is ALINORM 5/28/12.

- Revised Terms of Reference of the Codex Committee on Food Additives and Contaminants.

- Terms of Reference for the FAO/WHO Joint Expert Consultation to Conduct a Comprehensive Assessment of Use of Active Chlorine.

Food Additives

To be considered at Step 8:

- General Standard for Food Additive (GSFA): Draft Food Additive Provisions in Tables 1 and 2.

- Amendment to Annex B (Food Category System) of the GSFA (coconut water).

To be considered at Step 5/8:

- General Standard for Food Additives: Proposed Draft Food Additive Provisions in Tables 1, 2 and 3.

- Advisory Specifications for the Identity and Purity of Food Additives.

- Proposed Draft Revisions to the Codex International Numbering System for Food Additives.

To be considered at Step 5:

- Proposed Draft Revised Preamble to the GSFA, including diagram.

To be considered for Revocation and Discontinuation of work:

- General Principles for the Use of Food Additives.
- Proposed Amendments to the Codex Procedural Manual related to the revocation of the General Principles for the Use of Food Additives.
- Proposed Draft and Draft Food Additive Provisions in the GSFA.

To be considered for New Work:

- Revision of Class Names and the International Numbering System for Food Additives.

The Committee is continuing work on:

- General Standard for Food Additives: Draft Food Additive Provisions (in Tables 1, 2 and 3).
- General Standard for Food Additives: Revisions to the Preamble to clarify relationship between the General Standard and commodity standards.
 - International Numbering System.
 - Specifications for the Identity and Purity of Food Additives.
 - Inventory of Processing Aids.
 - Discussion Paper on Flavoring Agents.

Contaminants

To be considered at Step 8:

- Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts.

- Draft Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods.

- Draft Maximum Levels for Cadmium in wheat grain, potato, stem and root vegetables, leafy vegetables, and other vegetables.

To be considered at Step 5/8:

- Proposed Amendment to the Preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF).

To be considered at Step 5:

- Proposed Draft Maximum Level for Aflatoxin in unprocessed almonds, hazelnuts and pistachios.
- Proposed Draft Maximum Levels for Cadmium in rice, cephalopod (excluding viscera), and marine bivalve mollusks (excluding oysters and scallops).

To be considered for Revocation:

- List of Maximum Levels for Contaminants and Toxins Contained in Codex Commodity Standards and Relevant Standards and Texts.

To be considered for New Work:

- Appendix to the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts to address additional measures for the prevention and reduction of aflatoxins in Brazil nuts.

The Committee is continuing work on:

- Maximum levels for aflatoxin in processed almonds, hazelnuts, and pistachios.
- Discussion Paper on Aflatoxin Contamination in Brazil Nuts.
- Proposed draft sampling plan for Aflatoxin contamination in Almonds, Brazil nuts, Hazelnuts and Pistachios.

• Discussion paper on Deoxynivalenol (DON) Contamination in Cereals.

• Maximum Level for lead in fish.
• Proposed Draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin-like PCB Contamination in Foods.

• Discussion paper with proposals for maximum levels for 3-mono-chloropropanediol in acid-hydrolyzed vegetable protein (acid-HVP) and acid-HVP containing foods.

• Discussion paper on acrylamide, including a project paper for new work and an outline of a proposed draft code of practice.

• Draft Revised Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade, Including Guideline Levels for Long-Term Use.

• Discussion paper on polyaromatic hydrocarbons, including a project paper for new work and an outline of a proposed draft code of practice.

• Discussion paper on methylmercury in fish.

• Discussion paper on Code of Practice for the Prevention and Reduction of Ochratoxin A (OTA) Contamination in Coffee and Cocoa.

• Discussion paper on Maximum level of Ochratoxin A in Wine.

General Issues

• Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA.

Responsible Agency: HHS/FDA

U.S. Participation: Yes.

Codex Committee on Pesticide Residues

The Codex Committee on Pesticide Residues recommends to the Codex Alimentarius Commission establishment of maximum limits for pesticide residues for specific food items or in groups of food. A Codex Maximum Residue Limit for Pesticide (MRLP) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. Foods derived from commodities that comply with the respective MRLPs are intended to be toxicologically acceptable, that is, consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI,* should indicate that foods complying with Codex MRLPs are safe for human consumption.

Codex MRLPs are primarily intended to apply in international trade and are

derived from reviews conducted by the Joint Meeting on Pesticide Residues (JMPR) following:

(a) Review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices (GAP). Data from supervised trials conducted at the highest nationally recommended, authorized, or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLPs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices, and

(b) Toxicological assessment of the pesticide and its residue.

The committee met in The Hague, The Netherlands, April 18–23, 2005. The following items will be considered by the Commission at its 28th Session in July 2005. The relevant document is ALINORM 05/28/24.

To be considered at Step 8:

• Draft and Draft Revised Maximum Residue Limits.

To be considered at Step 8(I):

Bifenazate.

Fludioxonil.

Trifloxystrobin.

To be considered at Step 5/8:

• Proposed Draft and Proposed Draft Revised Maximum Residue Limits including Proposed Draft MRLs for Spices.

• Proposed Draft Guidelines for the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues.

• Proposed New Food Classification Codes for Commodities with Adopted MRLs.

To be considered at Step 5:

• Proposed Draft and Proposed Draft Revised Maximum Residue Limits including Proposed Draft MRLs for Dried Chili Peppers.

• Proposed Draft Guidelines on Estimation of Uncertainty of Results.

• Proposed Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues.

To be considered for Revocation:

• Codex CLX–Ds.

The committee is continuing work on:
• Pilot Project for the examination of national MRLs as Interim Codex MRLs for safer replacement pesticides.

• Revision of the List of Recommended Methods of Analysis for Pesticide Residues.

• Criteria for Prioritization Process to Recommend Compounds for Evaluation by JMPR.

• Revision of the Codex Priority List of Pesticides for review by JMPR.

• MRLs for Processed or Ready-to-Eat Foods.

*Acceptable Daily Intake (ADI) of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the Joint FAO/WHO Meeting on Pesticide Residues. It is expressed in milligrams of the chemical per kilogram of body weight.

Responsible Agency: EPA, USDA/AMS.

U.S. Participation: Yes.

Codex Committee on Methods of Analysis and Sampling

The Codex Committee on Methods of Analysis and Sampling:

(a) Defines the criteria appropriate to Codex Methods of Analysis and Sampling;

(b) Serves as a coordinating body for Codex with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories;

(c) Specifies, on the basis of final recommendations submitted to it by the other bodies referred to in (b) above, Reference Methods of Analysis and Sampling appropriate to Codex Standards which are generally applicable to a number of foods;

(d) Considers, amends, if necessary, and endorses, as appropriate, methods of analysis and sampling proposed by Codex (Commodity) Committees, except that methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives do not fall within the terms of reference of this Committee;

(e) Elaborates sampling plans and procedures, as may be required;

(f) Considers specific sampling and analysis problems submitted to it by the Commission or any of its Committees; and

(g) Defines procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.

The 26th Session of the Committee met in Budapest, Hungary, on April 4–8, 2005. The relevant document is ALINORM 05/28/23. The following will be considered by the Commission at its 28th Session in July 2005.

To be considered at Step 5:

• Proposed Draft Guidelines for Evaluating Acceptable Methods of Analysis.

The Committee will continue work on:

• Criteria for Evaluating Acceptable Methods of Analysis.

- Proposed Draft Guidelines for Settling of Disputes on Analytical (test) Results.

- Consideration of the Fitness-For-Purpose Approach to Evaluating Methods of Analysis.

- Further Review of the *Analytical Terminology for Codex Use* in the Procedural Manual.

- Endorsement of Methods of Analysis and Sampling Provisions in Codex Standards.

- Criteria for Methods of Analysis for the Detection and Identification of Foods derived from Biotechnology

- Methods of Analysis for the determination of dioxins and PCBs.

Responsible Agency: HHS/FDA; USDA/MRP.

U.S. Participation: Yes.

Codex Committee on Food Import and Export Inspection and Certification Systems

The Codex Committee on Food Import and Export Inspection and Certification Systems is charged with developing principles and guidelines for food import and export inspection and certification systems to protect consumers and to facilitate trade. Additionally, the Committee develops principles and guidelines for the application of measures by competent authorities to provide assurance that foods comply with essential requirements, especially statutory health requirements. This encompasses work on: Equivalence of food inspection systems including equivalence agreements, processes and procedures to ensure that sanitary measures are implemented; guidelines on food import control systems; and guidelines on food product certification and information exchange. The development of guidelines for the appropriate utilization of quality assurance systems to ensure that foodstuffs conform to requirements and to facilitate trade also are included in the Committee's terms of reference. The reference document is ALINORM 05/28/30. The committee met in Melbourne, Australia, on December 6–10, 2004. The following will be considered for adoption by the Commission at its 28th Session in July 2005.

To be considered at step 5/8:

- Draft Principles for Electronic Certification.

The committee is continuing work on:

- Proposed Draft Appendices to the *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*.

(a) Determining an “objective basis of comparison”

(b) Details on the process of determining equivalence.

(c) Documentation for evaluation of submissions of requests for equivalence determinations.

- Proposed Draft Guidelines for Risk-based Inspection of Imported Foods.

New work:

- Develop principles for product tracing/traceability within the context of food inspection and certification systems.

- Revise the *Codex Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certification*.

Responsible Agency: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on General Principles

The Codex Committee on General Principles deals with procedure and general matters as are referred to it by the Codex Alimentarius Commission. The 21st Session addressed issues related to decisions made by the Commission regarding the FAO/WHO Codex Evaluation. The 22nd Session which met on April 11–15, 2005 in Paris, France, considered the regular work of the Committee. The relevant documents are ALINORM 05/28/33 and ALINORM 05/28/33A. Matters to be considered for adoption by the 28th Commission in July 2005:

To be considered at Step 8:

- Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants (CCFAC).

- Draft CCFAC Policy for Exposure Assessment.

For consideration by the Commission: *Amendments to the Rules of Procedure:*

- Proposed amendments concerning the enlargement of the Executive Committee, the functions of the Executive Committee and matters related to budget and expenses.

- Proposed Amendments to Rule VIII.5—Observers.

- Proposed Amendment on the Right to Address the Chair.

Amendments to the Procedure Manual:

- Draft Revised Criteria for the Establishment of Work Priorities.

- Draft Guidelines on Physical Working Groups.

- Draft Guidelines on Electronic Working Groups.

- Draft Revised Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission.

- Proposed Amendments to the Procedural Manual to eliminate the

acceptance procedures for Codex Standards.

- Draft Guidelines for Cooperation with International Intergovernmental Organizations.

The Committee continued work on:

- Proposed Draft Working Principles for Risk Analysis for Food Safety (Guidance to National Governments).

- Proposed amendments to the Rules of Procedure: Duration of the terms of the Members of the Executive Committee.

- Possible reorganization of the structure, content and presentation of the Procedural Manual.

- Changes in the Elaboration Procedures.

- Clarification of the term “interim” as used for the adoption of Codex standards at Step 8.

- Possible definitions of “science-based” and “risk-based”.

- Management of the work in the Codex Committee on Food Hygiene.

Responsible Agency: USDA/FSIS, FDA/CFSAN.

U.S. Participation: Yes.

Codex Committee on Food Labelling

The Codex Committee on Food Labelling is responsible for drafting provisions on labelling issues assigned by the Codex Alimentarius Commission. The reference document is ALINORM 04/27/22. The Committee held its Thirty-third Session in Kota Kinabalu, Malaysia, on May 9–13, 2005. It considered the following items:

- Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods Proposed Revised Sections: Annex 2—Tables 3 and 4, Revision to Table 1 (Natural Sodium Nitrate).

- Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*—(Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering) Section 2. (Definitions).

- Proposed Draft Guidelines for the Labelling of Food and food Ingredients obtained through certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions.

- Proposed Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients*.

- Country of Origin Labelling.

- Discussion paper on Advertising.

Responsible Agency: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Hygiene

The Codex Committee on Food Hygiene has four primary responsibilities. First, to draft basic provisions on food hygiene applicable to all food. These provisions normally take the form of Codes of Hygienic Practice for a specific commodity (e.g. bottled water) or group of commodities (e.g., milk and milk products). Second, to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to consider microbiological risk management matters in relation to food hygiene and in relation to the risk assessment activities of FAO and WHO. Third, to consider, amend if necessary, and endorse food hygiene provisions that are incorporated into specific Codex commodity standards by the Codex commodity committees. Fourth, to provide such other general guidance to the Commission on matters relating to food hygiene as may be necessary. The following items will be considered by the Codex Alimentarius Commission at its 28th Session in Rome, Italy, July 4–9, 2005. The relevant document is ALINORM 05/28/13.

To be considered at Step 5:

- Proposed Draft Guidelines on the Application of the General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods.

- Proposed Draft Code of Hygienic Practice for Eggs and Egg Products.

- Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

The committee continues to work on:

- Proposed Draft Guidelines for Validation of Food Hygienic Control Measures.

- Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Children.

- Endorsement of Hygiene Provisions in Codex Standards and Codes of Practice.

- Annexes to the step 5 documents.
- Proposals/risk profiles:

- Guidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of Enterohemorrhagic *E. coli* in Ground Beef and Fermented Sausages.

- Guidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of Salmonella spp. in Broiler Chickens.

- Guidelines for Risk Management Options for *Campylobacter* in Broiler Chickens.

- *Vibrio* spp. in Seafood.

- Viruses in Food.

Responsible Agency: HHS/FDA; FSIS/USDA.

U.S. Participation: Yes.

Codex Committee on Fresh Fruits and Vegetables

The Codex Committee on Fresh Fruits and Vegetables is responsible for elaborating world-wide standards and codes of practice for fresh fruits and vegetables. The Committee met in Mexico City, Mexico, on May 16–20, 2005. At the session they discussed the following items:

- Draft Standard for Tomatoes at Step 7.

- Draft Standard for Table Grapes retained at Step 7.

- Proposed Draft Standard for Rambutan at Step 3.

- Proposed Draft Standard for Apples at Step 3.

- Section 2.1.1 (Maturity Requirements) and Annex on Small-berry Varieties (Section 3.1) (draft Codex Standard for Table Grapes).

- Guidelines for the Quality Control of Fresh Fruits and Vegetables.

- Standard Layout for Codex Standards for Fresh Fruits and Vegetables.

- Priority List.

Responsible Agency: USDA/AMS.

U.S. Participation: Yes.

Codex Committee on Nutrition and Foods for Special Dietary Uses

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is responsible for studying nutritional problems referred by the Codex Alimentarius Commission. The Committee also drafts general provisions, as appropriate, on nutritional aspects of all foods and develops standards, guidelines, or related texts for foods for special dietary uses. The committee met in Bonn, Germany, November 1–4, 2004. The relevant document is ALINORM 05/28/26. The following items will be considered by the 28th Session of the Commission in June 2005.

To be adopted at Step 8:

- Draft Guidelines for Vitamin and Mineral Food Supplements.

The Committee continues work on:

- Draft Revised Standard for Gluten-Free Foods at Step 7.

- Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children at Step 6.

- Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants at Steps 3 (Section A) and 6 (Section B).

- Guidelines for Use of Nutrition Claims Draft Table of Conditions for Nutrient Content Claims (Part B containing Provisions on Dietary Fibre) at Step 6.

- Proposed Draft Revision of the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children.

- Proposed Draft Recommendations on the Scientific Basis of Health Claims.

- Discussion Paper on the Application of Risk Analysis to the Work of the CCNFSDU.

- Discussion Paper on Proposals for Additional or Revised Nutrient Reference Values (NRVs).

Responsible Agency: HHS/FDA; FNS/USDA.

U.S. Participation: Yes.

Codex Committee on Fish and Fishery Products

The Fish and Fishery Products Committee is responsible for elaborating standards for fresh, frozen and otherwise processed fish, crustaceans and mollusks. The committee met in Capetown, South Africa, February 28–March 4, 2005. The following will be considered by the 28th Session of the Commission when it meets in July 2005. The relevant document is ALINORM 05/28/18.

To be considered at Step 8:

- Draft Code of Practice for Fish and Fishery Products (Aquaculture).

- Draft Amendment to the Standard for Salted Fish and Dried Salted Fish.

To be considered at Step 5/8:

- Proposed Draft Code of Practice for Fish and Fishery Products (Shrimps and Prawns; Cephalopods; Transport; Retail; and relevant Definitions).

To be considered at Step 5:

- Proposed Draft Standard for Sturgeon Caviar New work:

- Revision of the Procedure for the Inclusion of Species.

- Amendment of the Standard for Canned Sardines and Sardine-Type Products.

The Committee continues work on the following:

- Proposed Draft Standard for Live and Processed Bivalve Mollusks.

- Proposed Draft Standard for Smoked Fish.

- Proposed Draft Standard for Quick Frozen Scallop Adductor Muscle Meat.

- Proposed Draft Code of Practice on the Processing of Scallop Meat.

- Proposed Draft Code of Practice for Fish and Fishery Products (other sections).

- Proposed Draft Amendment of the Standard for Canned Sardines and Sardine-Type Products (*Clupea bentincki*).

Responsible Agency: HHS/FDA; USDC/NOAA/NMFS.

U.S. Participation: Yes.

Codex Committee on Milk and Milk Products

The Codex Committee on Milk and Milk Products is responsible for establishing international codes and standards for milk and milk products. The Committee held its 6th Session in Auckland, NZ on April 26–30, 2004. The relevant document is ALINORM 04/27/11.

For discussion at the 28th Session of the Codex Alimentarius Commission in July 2005.

• Proposal for a new standard for Parmesan Cheese At its 7th Session, the Committee will continue work on the following:

At Step 6:

• Draft Standard for a Blend of Evaporated Skimmed Milk and Vegetable Fat.

• Draft Standard for a Blend of Skimmed Milk and Vegetable Fat in Powdered Form.

• Draft Standard for a Blend of Sweetened Condensed Skimmed Milk and Vegetable Fat.

• Draft Revised Standard for Whey Cheese.

• Draft Revised Standards for Cheddar (C–1) and Danbo (C–3).

Other work of the committee:

• Proposed Draft Revised Standards for Individual Cheeses at Step 4.

• Proposed Template for Fermented Milk Drinks Provisions.

• Proposed Draft Model Export Certificate for Milk and Milk Products.

• Methods of Analysis and Sampling for Milk Products.

• Proposed Draft Revised Standard for Processed Cheese.

• Proposed Draft Revised Standard for Dairy Spreads.

• Discussion paper on Proposed Revision of the Codex Standard for Extra Hard Grating Cheese.

• Discussion paper on the Issue of Naming Non-standardized Dairy Products.

Responsible Agency: USDA/AMS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Fats and Oils

The Codex Committee on Fats and Oils is responsible for elaborating standards for fats and oils of animal, vegetable, and marine origin. The committee met in London, U.K., February 21–25, 2005. The relevant document is 05/28/17. The following will be considered by the Commission at its July 2005 session.

To be considered at Step 5/8:

• Proposed Draft Amendments to the Standard for Named Vegetable Oils: Sesameseed Oil.

To be considered at Step 5:

• Proposed Draft Amendments to the Standard for Named Vegetable Oils: Rice Bran Oil.

To be considered at Step 5 of the Accelerated Procedure:

• Proposed Draft Revised Table 1 of the Recommended International Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk.

New Work:

• Amendment of the Standard for Named Vegetable Oils.

• Mid-oleic sunflowerseed oil.

• Mid-oleic acid soya bean oil.

• Low linolenic acid soya bean oil.

• Unbleached palm oil: total carotenoids.

The Committee continues work on:

• Draft Standard for Fat Spreads and Blended Spreads: Food additives.

• Draft List and Proposed Draft List of Acceptable Previous Cargoes.

• Proposed Draft Amendment to the Standard for Olive Oil: Linolenic Acid content.

• Criteria for the Revision of Named Vegetable oils.

• Consideration of ISO proposal to amend the nomenclature of oils.

Responsible Agency: HHS/FDA; USDA/ARS.

U.S. Participation: Yes.

Codex Committee on Processed Fruits and Vegetables

The Codex Committee on Processed Fruits and Vegetables is responsible for elaborating standards for Processed Fruits and Vegetables. After having been adjourned *sine die*, the Committee reconvened in Washington, DC, in March 1998 to begin work revising the standards. The Committee held its most recent session on September 27 October 1, 2004. The relevant document is ALINORM 05/28/27.

To be considered at Step 5:

• Processed Tomato Concentrates.

• Preserved (Canned) Tomatoes.

• Certain Canned Citrus Fruits.

The committee is continuing work on:

• Draft Codex Standard for Pickled Fruits and Vegetables.

• Proposed Draft Codex Standards for:

• Jams, Jellies and Marmalades.

• Certain Canned Vegetables and Guidelines for Packing Media for Canned Vegetables.

Other work:

• Methods of Analysis for Processed Fruits and Vegetables.

• Priority List for the Standardization of Processed Fruits and Vegetables.

Discontinued work in this committee:

• Proposed Draft Standard for Soy Sauce.

Responsible Agency: USDA/AMS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Meat Hygiene

The 24th Session of the Commission decided to reactivate the Codex Committee on Meat Hygiene with New Zealand as Host Government. The Terms of Reference were amended to reflect the inclusion of poultry in its mandate. The Committee completed its work at its 11th Session and requested the Commission that it be adjourned *sine die*. The relevant document is ALINORM 05/28/16.

To be considered at Step 8:

• Draft Code of Hygienic Practice for Meat.

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Cereals, Pulses, and Legumes

The 26th Session of the Codex Alimentarius Commission adopted the Proposed Draft Standard for Instant Noodles at Step 5, on the recommendation of the Coordinating Committee for Asia, and advanced it to Step 6 for consideration by the Committee on Cereals, Pulses and Legumes by correspondence. The United States, as host government, has circulated the Draft Standard for two rounds of comments. Consideration of the additives provisions will take place in the Codex Committee on Food Additives and Contaminants.

Responsible Agency: HHS/FDA; USDA/GIPSA.

U.S. Participation: Yes.

Certain Codex Commodity Committees

Several Codex Alimentarius Commodity Committees have adjourned *sine die*. The following Committees fall into this category:

• *Cocoa Products and Chocolate.*

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

• *Natural Mineral Water.*

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

• *Sugars.*

Responsible Agency: USDA/ARS; HHS/FDA.

U.S. Participation: Yes.

• *Vegetable Proteins.*

Responsible Agency: USDA/ARS; HHS/FDA.

U.S. Participation: Yes.

Ad Hoc Intergovernmental Task Force on Animal Feeding

The Commission at its 23rd Session established the Ad Hoc Intergovernmental Task Force on Animal Feeding to develop guidelines or standards as appropriate on good animal feeding practices. The Revised

Draft Code of Practice for Good Animal Feeding was held at Step 8 by the Commission at its 26th Session in June 2003, with the exception that the definition of "feed additive" and paragraphs 11, 12, and 13 were advanced to step 6. The Task Force held its 5th Session on May 17–19, 2004 and discussed:

- Revised Draft Code of Practice for Good Animal Feeding (definition of "feed additive" and paragraphs 11, 12, and 13).

Responsible Agency: HHS/FDA; USDA/APHIS.

U.S. Participation: Yes.

Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices

The Commission at its 23rd Session established this Task Force to revise and consolidate the existing Codex standards and guidelines for fruit and vegetable juices and related products, giving preference to general standards. These standards were originally developed by the Joint UNECE/Codex Group of Experts on the Standardization of Fruit Juices which had been abolished by its parent organizations. The Task Force held its fourth and final session in Fortaleza, Brazil, on October 11–15, 2004. The Task Force completed the work assigned to the Task Force in its Terms of Reference.

For Adoption at Step 8:

- Draft Codex General Standard for Fruit Juices and Nectars.
- Draft Minimum Brix Level for Reconstituted Juice and Reconstituted Pure and Minimum Juice and/or Pure Content for Fruit Nectars (%v/v)—grapes, guava, mandarine/tangerine, mango, passion fruit and tamarind (Indian date) juices/nectars.

For Adoption at Step 5/8:

- Proposed Draft Minimum Brix Level for Reconstituted Juice and Reconstituted Pure and Minimum Juice and/or Purée Content for Fruit nectars (%v/v)—orange, lemon, lime, and pineapple juices/nectars.

Responsible Agency: HHS/FDA; USDA/AMS.

U.S. Participation: Yes.

FAO/WHO Regional Coordinating Committees

The Codex Alimentarius Commission is made up of an Executive Committee, as well as approximately 30 subsidiary bodies. Included in these subsidiary bodies are coordinating committees for groups of countries located in proximity to each other who share common concerns. There are currently six Regional Coordinating Committees:

- Coordinating Committee for Africa.
- Coordinating Committee for Asia.

- Coordinating Committee for Europe.

- Coordinating Committee for Latin America and the Caribbean.

- Coordinating Committee for the Near East.

- Coordinating Committee for North America and the South-West Pacific.

The United States participates as an active member of the Coordinating Committee for North America and the South-West Pacific, and is informed of the other coordinating committees through meeting documents, final reports, and representation at meetings. Each regional committee:

- Defines the problems and needs of the region concerning food standards and food control;

- Promotes within the committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures;

- Recommends to the Commission the development of world-wide standards for products of interest to the region, including products considered by the committee to have an international market potential in the future; and

- Serves a general coordinating role for the region and performs such other functions as may be entrusted to it by the Commission.

Codex Coordinating Committee for North America and the South-West Pacific

The Coordinating Committee is responsible for defining problems and needs concerning food standards and food control of all Codex member countries of the region. Items coming before the Commission in July include the following. The committee met in Apia, Samoa, on October 19–22, 2004. The relevant document is ALINORM 05/28/32.

- Recommendation that Samoa be reappointed as Regional Coordinator.

- Support the development of a new Standard for Parmesan cheese and adopt the amendment of the Codex Standard for Canned Sardines and Sardine-Type Products.

Items on the agenda for the next meeting may include:

- Codex working documents of special interest to regional member states.

- Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards.

- Strategic Plan for the Coordinating Committee for North America and the Southwest Pacific.

- Trust Fund for the participation of Developing Countries in Codex.

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

Codex Coordinating Committee for Asia

The Coordinating Committee met in Jeju-Do, Republic of Korea on September 7–10, 2004. The relevant document is ALINORM—5/15.

To be considered at Step 5:

- Proposed Draft Standard for Ginseng Products.

New work:

- Refrigerated, Non-fermented Soybean Products.

Attachment 2—U.S. Codex Alimentarius Officials Codex Committee Chairpersons

Codex Committee on Food Hygiene

Dr. Karen Hulebak, Chief Scientist, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 3130, South Building, Washington, DC 20250–3700. Phone: (202) 720–5735, Fax: (202) 720–2980. E-mail: karen.hulebak@fsis.usda.gov.

Codex Committee on Processed Fruits and Vegetables

Mr. David L. Priester, Head, Standardization Section, AMS Fruit & Vegetable Programs, Fresh Products Branch, U.S. Department of Agriculture, Room 1661, South Building, 1400 Independence Avenue, SW., Washington, DC 20250–0240. Phone: (202) 720–2185. Fax: (202) 720–8871. E-mail: david.priester@usda.gov.

Codex Committee on Residues of Veterinary Drugs in Foods

Dr. Stephen F. Sundlof, Director, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place (HFV–1), Rockville, MD 20855, Phone: (301) 827–2950, Fax: (301) 827–8401, E-mail: ssundlof@cvm.fda.gov.

Codex Committee on Cereals, Pulses and Legumes (Adjourned sine die)

Mr. Steven N. Tanner, Director, Technical Services Division, Grain Inspection, Packers & Stockyards Administration, U.S. Department of Agriculture, 10383 N. Executive Hills Boulevard, Kansas City, MO 64153–1394, Phone: (816) 891–0401, Fax: (816) 891–0478, E-mail: tanner@tsd.fgiskc.usda.gov.

Listing of U.S. Delegates and Alternates Worldwide General Subject Codex Committees

Codex Committee on Residues of Veterinary Drugs in Foods (Host Government—United States)

U.S. Delegate

Dr. Steven D. Vaughn, Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, Phone: (301) 827-1796, Fax: (301) 594-2297, E-mail: SVaughn@cvm.fda.gov.

Alternate Delegate

Dr. Alice Thaler, Staff Director, Animal and Egg Production Food Safety Staff, Food Safety and Inspection Service, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 690-2683, Fax: (202) 720-8213, E-mail: alice.thaler@fsis.usda.gov.

Codex Committee on Food Additives and Contaminants (Host Government—The Netherlands)

U.S. Delegate

Dr. Terry C. Troxell, Director, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1700, Fax: (301) 436-2632, E-mail: Terry.Troxell@cfstan.fda.gov.

Alternate Delegate

Dr. Dennis M. Keefe, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1284, Fax: (301) 436-2972, E-mail: dennis.keefe@cfstan.fda.gov.

Codex Committee on Pesticide Residues (Host Government—The Netherlands)

U.S. Delegate

Lois Rossi, Director of Registration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, Phone: (703) 305-5035, Fax: (703) 305-5147, E-mail: Rossi.Lois@epamail.epa.gov.

Alternate Delegate

Dr. Robert Epstein, Associate Deputy Administrator, Science and Technology, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box

96456, Room 3522S, Mail Stop 0222, 1400 Independence Avenue, SW., Washington, DC 20090, Phone (202) 720-2158, Fax: (202) 720-1484, E-mail: Robert.Epstein@usda.gov.

Codex Committee on Methods of Analysis and Sampling (Host Government—Hungary)

U.S. Delegate

Dr. Gregory Diachenko, Director, Division of Chemistry Research and Environmental Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (HFS-245), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone (301) 436-1898, Fax: (301) 436-2364, E-mail: Gregory.Diachenko@cfstan.fda.gov.

Alternate Delegate

Mr. Donald C. Kendall, Technical Services Division, Grain, Inspection, Packers & Stockyards Administration, U.S. Department of Agriculture, 10383 N. Ambassador Drive, Kansas City, MO 64153-1394, Phone: (816) 891-0463, Fax: (816) 891-0478, E-mail: Donald.C.Kendall@usda.gov.

Codex Committee on Food Import and Export Inspection and Certification Systems (Host Government—Australia)

U.S. Delegate

Dr. Catherine Carnevale, Director, Office of Constituent Operations, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-550), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-2380, Fax: (301) 436-2612, E-mail: Catherine.Carnevale@cfstan.fda.gov.

Alternate Delegate

Karen Stuck, Chief, International Policy Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 2137, South Building, 1400 Independence Avenue, SW., Washington, DC 20250-3700, Phone: (202) 720-3470, Fax: (202) 720-7990, E-mail: Karen.Stuck@fsis.usda.gov.

Codex Committee on General Principles (Host Government—France)

U.S. Delegate

Note: A member of the Steering Committee heads the delegation to meetings of the General Principles Committee.

Codex Committee on Food Labeling (Host Government—Canada)

U.S. Delegate

Leslye Fraser, J.D., Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Parkway (HFS-004), College Park, MD 20740, Phone: (301) 436-2378, Fax: (301) 436-2637, E-mail: leslye.fraser@fda.hhs.gov.

Alternate Delegate

Ms. Danielle Schor, Chief of Staff, Office of the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250-1400, Phone: (202) 720-6618, Fax: (202) 720-7771, E-mail: danielle.schor@fsis.usda.gov.

Codex Committee on Food Hygiene (Host Government—United States)

U.S. Delegate

Dr. Robert L. Buchanan, Director, Office of Science, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-006), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-2369, Fax: (301) 436-2642, E-mail: Robert.Buchanan@cfstan.fda.gov.

Alternate Delegates

Dr. Daniel Engeljohn, Deputy Assistant Administrator, Office of Policy, Program, and Employee Development, Room 3149, South Building, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 205-0495, Fax: (202) 401-1760, E-mail: Daniel.engeljohn@fsis.usda.gov.

Dr. Rebecca Buckner, Consumer Safety Officer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Room 3B-0033 Harvey Wiley Building, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436-1486, Fax: (301) 436-2632, E-mail: Rebecca.Buckner@cfstan.fda.gov.

Codex Committee on Nutrition and Food for Special Dietary Uses (Host Government—Germany) U.S. Delegate

Barbara O. Schneeman, PhD, Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Highway, College Park, MD 20740, Tel: (301) 436-2373, Fax: (301) 436-2636, E-mail: Barbara.Schneeman@cfstan.fda.gov.

Alternate Delegate

Patricia McKinney, Senior Program Analyst, Office of Analysis, Nutrition Service, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302, Tel: (703) 305-2126, Fax: (703) 305-2576, E-mail: Pat.Mckinney@fns.usda.gov.

Worldwide Commodity Codex Committees Codex Committee on Fresh Fruits and Vegetables (Host Government—Mexico)

U.S. Delegate

Dorian LaFond, International Standards Coordinator, Fruit and Vegetables Program, Agricultural Marketing Service, Room 2086, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone (202) 690-4944, Fax: (202) 720-4722, E-mail: dorian.lafond@usda.gov.

Alternate Delegate

Vacant.

Codex Committee on Fish and Fishery Products (Host Government—Norway)

U.S. Delegate

Mr. Philip C. Spiller, Director, Office of Seafood, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-400), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-2300, Fax: (301) 436-2599, E-mail: Philip.Spiller@cfsan.fda.gov.

Alternate Delegate

Mr. Richard V. Cano, Acting Director, National Seafood Inspection Program, NOAA, U.S. Department of Commerce, 1315 East-West Highway, Silver Spring, MD 20910, Phone: (301) 713-2355, Fax: (301) 713-1081, E-mail: richard.cano@noaa.gov.

Codex Committee on Cereals, Pulses and Legumes (Host Government—United States)

U.S. Delegate

Mr. Charles W. Cooper, Director, International Activities Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-585), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1714, Fax: (301) 436-2612, E-mail: Charles.Cooper@cfsan.fda.gov.

Alternate Delegate

Mr. David Shipman, Deputy Administrator, Federal Grain Inspection Division, Grain Inspection, Packers and Stockyards Administration, U.S.

Department of Agriculture, Room 1661, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720-9170, Fax: (202) 205-9237, E-mail:

dshipman@gipsadc.usda.gov.

Codex Committee on Milk and Milk Products (Host Government—New Zealand)

U.S. Delegate

Mr. Duane Spomer, Associate Deputy Administrator for Standards and Grading, Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2746, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720-3171, Fax: (202) 720-2643, E-mail: duane.spomer@usda.gov.

Alternate Delegate

John F. Sheehan, Director, Division of Dairy and Egg Safety, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436-1488, Fax: (301) 436-2632, E-mail: john.sheehan@cfsan.fda.gov.

Codex Committee on Fats and Oils (Host Government—United Kingdom)

U.S. Delegate

Mr. Charles W. Cooper, Director, International Activities Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-585), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1714, Fax: (301) 436-2612, E-mail: Charles.Cooper@cfsan.fda.gov.

Alternate Delegate

Ms. Kathleen Warner, U.S. Department of Agriculture, 1815 N. University Street, Peoria, IL 61604, Phone (309) 681-6584, Fax: (309) 681-6668, E-mail: warnerk@ncaur.usda.gov.

Codex Committee on Cocoa Products and Chocolate (Host Government—Switzerland)

U.S. Delegate

Mr. Charles W. Cooper, Director, International Activities Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-585), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1714, Fax: (301) 436-2612, E-mail: Charles.Cooper@cfsan.fda.gov.

Alternate Delegate

Dr. Michelle Smith, Food Technologist, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-306), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: 301-436-2024, Fax: 301-436-2651, E-mail: Michelle.Smith@cfsan.fda.gov.

Codex Committee on Sugars (Host Government—United Kingdom)

U.S. Delegate

Dr. Thomas L. Tew, Research Geneticist, Sugarcane Research Unit, Agricultural Research, USDA—FSIS, 5883 USDA Road, Houma, LA 70360, Phone: (504) 872-5042, Fax: (504) 868-8369, E-mail: ttew@nola.srrc.usda.gov.

Alternate Delegate

Dr. Dennis M. Keefe, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-265), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1284, Fax: (301) 436-2972, E-mail: dennis.keefe@cfsan.fda.gov.

Codex Committee on Processed Fruits and Vegetables (Host Government—United States)

U.S. Delegate

Dorian Lafond, International Standards Coordinator, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2086, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 690-4944, Fax: (202) 720-0016, E-mail: Dorian.Lafond@usda.gov.

Alternate Delegate

Mr. Charles W. Cooper, Director, International Activities Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-585), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1714, Fax: (301) 436-2612, E-mail: Charles.Cooper@cfsan.fda.gov.

Codex Committee on Vegetable Proteins (Host Government—Canada)

U.S. Delegate

Dr. Wilda H. Martinez, Area Director, ARS North Atlantic Area, Agricultural Research Service, USDA, 600 E. Mermaid Lane, Wyndmoor, PA 19038, Phone: (215) 233-6593, Fax: (215) 233-6719, E-mail: wmartinez@ars.usda.gov.

Alternate Delegate

Dr. Jeanne Rader, Director, Division of Research and Applied Technology, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1786, Fax: (301) 436-2640, E-mail: Jeanne.Rader@cfstan.fda.gov.

Codex Committee on Meat Hygiene (Host Government—New Zealand)

U.S. Delegate

Dr. Perfecto Santiago, Deputy Assistant Administrator, Office of Food Security and Emergency Preparedness, Room 3130, South Building, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 205-0452, Fax: (202) 690-5634. Perfecto.Santiago@fsis.usda.gov.

Alternate Delegate

Dr. William O. James, Deputy Assistant Administrator, Office of International Affairs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 3143, South Building, Washington, DC 20250-3700, Phone: (202) 720-5362, Fax: (202) 690-3856, E-mail: william.james@fsis.usda.gov.

Codex Committee on Natural Mineral Waters (Host Government—Switzerland)

U.S. Delegate

Dr. Terry C. Troxell, Director, Office of Plant and Dairy Foods and Beverages,

Center for Food Safety & Applied Nutrition, Food and Drug Administration (HFS-300), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1700, Fax: (301) 436-2632, E-mail: Terry.troxell@cfstan.fda.gov.

Alternate Delegate

Ms. Shellee Anderson, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-830), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1491, Fax: (301) 436-2636, E-mail: Shellee.Anderson@cfstan.fda.gov.

Ad Hoc Intergovernmental Task Forces; Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices (Host Government—Brazil)

U.S. Delegate

Mr. Martin Stutsman, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-306), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Phone: (301) 436-1642, Fax: (301) 436-2651, E-mail: Martin.Stutsman@cfstan.fda.gov.

Alternate Delegate

Vacant.

Ad Hoc Intergovernmental Task Force on Foods Derived From Modern Biotechnology (Host Government—Japan)

U.S. Delegate

Bernice Slutsky, Ph.D., Special Assistant to the Secretary for Biotechnology, Office of the Secretary, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720-3631, Fax: (202) 720-6314, E-mail: Bernice.Slutsky@usda.gov.

Alternate Delegate

Eric Flamm, Ph.D., Senior Advisor, Office of the Commissioner, Food and Drug Administration, Room 1561 Parklawn Building, Rockville, MD 20857, Phone: (301) 827-0591, FAX: (301) 827-4774, E-mail: EFLAMM@OC.FDA.GOV.

There are six regional coordinating committees:

Coordinating Committee for Africa
Coordinating Committee for Asia
Coordinating Committee for Europe
Coordinating Committee for Latin America and the Caribbean
Coordinating Committee for the Near East
Coordinating Committee for North America and the South-West Pacific

Contact: Paulo Almeida, Office Manager, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue, SW., Washington, DC 20250-3700, Phone (202) 205-7760, Fax (202) 720-3157, E-mail: Paulo.Almeida@fsis.usda.gov.

ATTACHMENT 3.—TIMETABLE OF CODEX SESSIONS

[June 2004 through June 2006]

2004:			
CX 702-54	Executive Committee (54th session)	24-26 June	Geneva (Switzerland).
CX 701-27	Codex Alimentarius Commission (27th Session)	28 June-2 July	Geneva (Switzerland).
CX 727-14	Regional Coordinating Committee for Asia (14th Session).	7-10 September	Jeju (City) Republic of Korea.
CX 706-24	Regional Coordinating Committee for Europe (24th Session).	20-23 September	Bratislava (Slovak Republic).
CX 713-22	Codex Committee on Processed Fruits and Vegetables (22nd Session).	27 September-1 October	Arlington, VA (USA).
CX 801-03	Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices (3rd Session).	11-15 October	Fortaleza (Brazil).
CX 732-08	Regional Coordinating Committee for North America and South West Pacific (8th Session).	19-22 October	Apia (Samoa).
CX 730-15	Codex Committee on Residue of Veterinary Drugs in Foods (15th Session).	25-28 October	Arlington, VA (USA).
CX 720-26	Codex Committee on Nutrition and Foods for Special Dietary Uses (26th Session).	1-5 November	Bonn (Germany).
CX 716-21	Codex Committee on General Principles (21st Session).	15-19 November	Paris (France).
CX 725-14	Regional Coordinating Committee for Latin America and the Caribbean (14th Session).	29 November-3 December ...	Buenos Aires (Argentina).
CX 733-13	Codex Committee on Food Import and Export Certification Systems (13th Session).	6-10 December	Melbourne (Australia).

ATTACHMENT 3.—TIMETABLE OF CODEX SESSIONS—Continued
[June 2004 through June 2006]

2005:			
CX 707-16	Regional Coordinating Committee for Africa (16th Session).	25-28 January	Rome (FAO) (Italy).
CX 702-55	Executive Committee (55th Session)	9-11 February	Rome (FAO) (Italy).
CX 723-11	Codex Committee on Meat and Poultry Hygiene (11th Session).	14-18 February	Christchurch (New Zealand).
CX 709-19	Codex Committee on Fats and Oils (19th Session)	21-25 February	London (United Kingdom).
CX 722-27	Codex Committee on Fish and Fishery Products (27th Session).	28 February-4 March	Capetown (South Africa).
CX 734-03	Regional Coordinating Committee for Near East (3rd Session).	7-10 March	Amman (Jordan).
CX 712-37	Codex Committee on Food Hygiene (37th Session)	14-19 April	Buenos Aires (Argentina).
CX 715-26	Codex Committee on Methods of Analysis and Sampling (26th Session).	4-8 April	Budapest (Hungary).
CX 716-22	Codex Committee on General Principles (22nd Session).	11-15 April	Paris (France).
CX 718-37	Codex Committee on Pesticide Residues (37th Session).	18-23 April	The Hague (The Netherlands).
CX 711-37	Codex Committee on Food Additives and Contaminants (37th Session).	25-29 April	The Hague (The Netherlands).
CX 714-33	Codex Committee on Food Labelling (33rd Session)	9-13 May	Kota Kinabalu (Malaysia).
CX 731-12	Codex Committee on Fresh Fruits and Vegetables (12th Session).	16-20 May	Mexico City Mexico).
CX 702-56	Executive Committee (56th Session)	6 June-2 July	Rome (Italy).
CX 701-28	Codex Alimentarius Commission (28th Session)	4-9 July	Rome (Italy).
CX 804-1	Ad Hoc Task Force on Biotechnology	19-23 September	TBA (Japan).
CX 720-14	Codex Committee on Nutrition and Foods for Special Dietary Uses (27th Session).	21-25 November	Bonn (Germany).
CX 733-14	Codex Committee on Food Import and Export Inspection and Certification Systems (14th Session).	28 November-2 December	TBA (Australia).
CX 702-57	Executive Committee (57th Session)	30 November-2 December	Geneva (Switzerland).
2006:			
CX 703-7	Codex Committee on Milk and Milk Products (7th Session).	27-31 March	TBA (New Zealand).
CX 718-38	Codex Committee on Pesticide Residues (38th Session).	3-8 April	TBA (Brazil).
CX 716-23	Codex Committee on General Principles (23rd Session).	9-13 April	Paris (France).
CX 711-38	Codex Committee on Food Additives and Contaminants (38th Session).	24-28 April	The Hague (The Netherlands).
CX 714-34	Codex Committee on Food Labelling (34th Session)	1-5 May	Ottawa (Canada).
CX 730-16	Codex Committee on Residue of Veterinary Drugs in Food (16th Session).	8-12 May	Washington, DC (USA).
CX 715-27	Codex Committee on Methods of Analysis and Sampling (27th Session).	15-19 May	Budapest (Hungary).
CX 702-58	Executive Committee (58th Session)	28-30 June	Geneva (Switzerland).
CX 201-29	Codex Alimentarius Commission (29th Session)	3-8 July	Geneva (Switzerland).

Attachment 4—Definitions for the Purpose of Codex Alimentarius

Words and phrases have specific meanings when used by the Codex Alimentarius.

For the purposes of Codex, the following definitions apply:

1. *Food* means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum, and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.

2. *Food hygiene* comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure

a safe, sound, wholesome product fit for human consumption.

3. *Food additive* means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport, or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The food additive term does not include "contaminants" or substances

added to food for maintaining or improving nutritional qualities.

4. *Contaminant* means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry, and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matters.

5. *Pesticide* means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production,

storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant-growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term pesticides excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

6. *Pesticide residue* means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

7. *Good Agricultural Practice in the Use of Pesticides (GAP)* includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner that leaves a residue, which is the smallest amount practicable.

Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.

8. *Codex Maximum Limit for Pesticide Residues (MRLP)* is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLPs are based on their toxicological affects and on GAP data and foods derived from commodities that comply with the respective MRLPs are intended to be toxicologically acceptable.

Codex MRLPs, which are primarily intended to apply in international trade, are derived from reviews conducted by the JMPR following:

(a) Toxicological assessment of the pesticide and its residue, and

(b) Review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized, or registered uses are

included in the review. In order to accommodate variations in national pest control requirements, Codex MRLPs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

Consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with Codex MRLPs are safe for human consumption.

9. *Veterinary Drug* means any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behavior.

10. *Residues of Veterinary Drugs* include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned.

11. *Codex Maximum Limit for Residues of Veterinary Drugs (MRLVD)* is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on food.

An MRLVD is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. An MRLVD also takes into account other relevant public health risks as well as food technological aspects.

When establishing an MRLVD, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRLVD may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical and analytical methods are available.

12. *Good Practice in the Use of Veterinary Drugs (GPVD)* is the official recommended or authorized usage including withdrawal periods approved by national authorities, of veterinary drugs under practicable conditions.

13. *Processing Aid* means any substance or material, not including apparatus or utensils, not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a

certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

Definitions of Risk Analysis Terms Related to Food Safety Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Dose-Response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components: Risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) Hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk Assessment Policy: Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

Risk Characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard

characterization and exposure assessment.

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, related risk factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk Estimate: The quantitative estimation of risk resulting from risk characterization.

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk Profile: The description of the food safety problem and its context.

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.

Attachment 5

Part 1—Uniform Procedure for the Elaboration of Codex Standards and Related Texts

Steps 1, 2 and 3

(1) The Commission decides, taking into account the “Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies,” to elaborate a Worldwide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a Worldwide Codex Standard may also be taken by subsidiary bodies of the Commission in accordance with the above-mentioned criteria, subject to subsequent approval by the Commission or its Executive Committee at the earliest possible opportunity. In the case

of Codex Regional Standards, the Commission shall base its decision on the proposal of the majority of members belonging to a given region or group of countries submitted at a session of the Codex Alimentarius Commission.

(2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Panel of Experts on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).

(3) The proposed draft standard is sent to members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

Step 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

Step 5

The proposed draft standard is submitted through the Secretariat to the Commission or to the Executive Committee with a view to its adoption as a draft standard. When making any decision at this step, the Commission or the Executive Committee will give due consideration to any comments that may be submitted by any of its members regarding the implications which the proposed draft standard or any provisions of the standard may have for their economic interests. In the case of Regional Standards, all members of the Commission may present their comments, take part in the debate and propose amendments, but only the majority of the Members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. When making any decisions at this step, the members of the region or group of countries concerned will give due consideration to any comments that may be submitted by any of the members of the Commission regarding the implications which the proposed draft standard or any provisions of the proposed draft

standard may have for their economic interests.

Step 6

The draft standard is sent by the Secretariat to all members and interested international organizations for comment on all aspects, including possible implications of the draft standard for their economic interests.

Step 7

The comments received are sent by the Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the draft standard.

Step 8

The draft standard is submitted through the Secretariat to the Commission together with any written proposals received from members and interested international organizations for amendments at Step 8 with a view to its adoption as a Codex Standard. In the case of Regional standards, all members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of members of the region or group of countries concerned attending the session can decide to amend and adopt the draft.

Part 2—Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts

Steps 1, 2 and 3

(1) The Commission or the Executive Committee between Commission sessions, on the basis of a two-thirds majority of votes cast, taking into account the “Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies”, shall identify those standards which shall be the subject of an accelerated elaboration process. The identification of such standards may also be made by subsidiary bodies of the Commission, on the basis of a two-thirds majority of votes cast, subject to confirmation at the earliest opportunity by the Commission or its Executive Committee by a two-thirds majority of votes cast.

(2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Panel of Experts on Pesticide Residues

(JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).

(3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests. When standards are subject to an accelerated procedure, this fact shall be notified to the Members of the Commission and the interested international organizations.

Step 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

Step 5

In the case of standards identified as being subject to an accelerated elaboration procedure, the draft standard is submitted through the Secretariat to the Commission together with any written proposals received from Members and interested international organizations for amendments with a view to its adoption as a Codex standard. In taking any decision at this step, the Commission will give due consideration to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

Attachment 6—Nature of Codex Standards

Codex standards contain requirements for food aimed at ensuring for the consumer a sound, wholesome food product free from adulteration, and correctly labelled. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the criteria listed therein.

Format for Codex Commodity Standards Including Standards Elaborated Under the Code of Principles Concerning Milk and Milk Products

Introduction

The format is also intended for use as a guide by the subsidiary bodies of the Codex Alimentarius Commission in presenting their standards, with the object of achieving, as far as possible, a uniform presentation of commodity

standards. The format also indicates the statements which should be included in standards as appropriate under the relevant headings of the standard. The sections of the format required to be completed for a standard are only those provisions that are appropriate to an international standard for the food in question.

Name of the Standard
Scope
Description
Essential Composition and Quality Factors
Food Additives
Contaminants
Hygiene
Weights and Measures
Labelling
Methods of Analysis and Sampling

Format for Codex Standards

Name of the Standard

The name of the standard should be clear and as concise as possible. It should usually be the common name by which the food covered by the standard is known or, if more than one food is dealt with in the standard, by a generic name covering them all. If a fully informative title is inordinately long, a subtitle could be added.

Scope

This section should contain a clear, concise statement as to the food or foods to which the standard is applicable unless the name of the standard clearly and concisely identifies the food or foods. A generic standard covering more than one specific product should clearly identify the specific products to which the standard applies.

Description

This section should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which the product or products are derived and any necessary references to processes of manufacture. The description may also include references to types and styles of product and to type of pack. The description may also include additional definitions when these additional definitions are required to clarify the meaning of the standard.

Essential Composition and Quality Factors

This section should contain all quantitative and other requirements as to composition including, where necessary, identity characteristics, provisions on packing media and requirements as to compulsory and optional ingredients. It should also include quality factors that are essential for the designation, definition, or

composition of the product concerned. Such factors could include the quality of the raw material, with the object of protecting the health of the consumer, provisions on taste, odor, color, and texture which may be apprehended by the senses, and basic quality criteria for the finished products, with the object of preventing fraud. This section may refer to tolerances for defects, such as blemishes or imperfect material, but this information should be contained in appendix to the standard or in another advisory text.

Food Additives

This section should contain the names of the additives permitted and, where appropriate, the maximum amount permitted in the food. It should be prepared in accordance with guidance given on page of the Codex Procedural Manual and may take the following form:

“The following provisions in respect of food additives and their specifications as contained in section * * * of the Codex Alimentarius are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives and Contaminants.”

A tabulation should then follow, viz.:
“*Name of additive, maximum level* (in percentage or mg/kg).”

Contaminants

(a) *Pesticide Residues*: This section should include, by reference, any levels for pesticide residues that have been established by the Codex Committee on Pesticide Residues for the product concerned.

(b) *Other Contaminants*: In addition, this section should contain the names of other contaminants and where appropriate the maximum level permitted in the food, and the text to appear in the standard may take the following form:

“The following provisions in respect of contaminants, other than pesticide residues, are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives and Contaminants.”

A tabulation should then follow, viz.:
“*Name of contaminant, maximum level* (in percentage or mg/kg).”

Hygiene

Any specific mandatory hygiene provisions considered necessary should be included in this section. They should be prepared in accordance with the guidance given in the Codex Procedural Manual. Reference should also be made to applicable codes of hygienic practice. Any parts of such codes, including in

particular any end-product specifications, should be set out in the standard, if it is considered necessary that they should be made mandatory. The following statement should also appear:

“The following provisions in respect of the food hygiene of the product are subject to endorsement [have been endorsed] by the Codex Committee on Food Hygiene.”

Weights and Measures

This section should include all provisions, other than labelling provisions, relating to weights and measures, *e.g.*, where appropriate, fill of container, weight, measure or count of units determined by an appropriate method of sampling and analysis. Weights and measures should be expressed in S.I. units. In the case of standards which include provisions for the sale of products in standardized amounts, *e.g.* multiples of 100 grams, S.I. units should be used, but this would not preclude additional statements in the standards of these standardized amounts in approximately similar amounts in other systems of weights and measures.

Labelling

This section should include all the labelling provisions contained in the standard and should be prepared in accordance with the guidance given in the Codex Procedural Manual. Provisions should be included by reference to the General Standard for the Labelling of Prepackaged Foods. The section may also contain provisions which are exemptions from, additions to, or which are necessary for the interpretation of the General Standard in respect of the product concerned provided that these can be justified fully. The following statement should also appear:

“The following provisions in respect of the labelling of this product are subject to endorsement [have been endorsed] by the Codex Committee on Food Labelling.”

Methods of Analysis and Sampling

This section should include, either specifically or by reference, all methods of analysis and sampling considered necessary and should be prepared in accordance with the guidance given in the Codex Procedural Manual. If two or more methods have been proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives and included in this section either specifically or by reference. The following statement should also appear:

“The methods of analysis and sampling described hereunder are to be endorsed [have been endorsed] by the Codex Committee on Methods of Analysis and Sampling.”

[FR Doc. 05-10636 Filed 5-26-05; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest, Bearlodge Ranger District, Wyoming, Dean Project Area Proposal and Analysis

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement on a proposal to implement multiple resource management actions within the Dean Area as directed by the Black Hills National Forest Land and Resource Management Plan. The Dean Project Area covers about 12,468 acres of National Forest System land and about 2,256 acres of interspersed private land within the Redwater Creek watershed directly north of Sundance, Wyoming. Proposed actions would modify the structure of forest stands across the planning area to reduce fuel loads, potential for uncharacteristically intense wildfire behavior, and risk of insect outbreaks; provide for diverse wildlife habitat and restore hardwood; and provide a mix of motorized and non-motorized use opportunities. This revised Notice of Intent is being issued because of a change in the designated responsible official.

DATES: Scoping was conducting as described in the Notice of Intent of November 24, 2004 (69 FR 68303). Comments submitted during scoping for the proposed action are part of the project record and were considered in developing the Draft EIS. The Draft EIS was issued in March 2005 (70 FR 12211), and the comment period was extended once (70 FR 19951). Comments were accepted through May 2, 2005. These comments are being considered during completion of the Final EIS. The Final environmental impact statement is expected in June 2005.

FOR FURTHER INFORMATION CONTACT: Janis Bouma, Project Coordinator, Black Hills National Forest, Bearlodge Ranger District, 121 S. 21st Street, Sundance, Wyoming 82729, phone (307) 283-1361.

SUPPLEMENTARY INFORMATION: The actions are proposed in direct response to management direction provided by

the Black Hills National Forest Land and Resource Management Plan (Forest Plan). The site-specific actions are based on Forest Plan Standards and Guidelines to promote existing resource conditions in the Dean Project Area toward meeting Forest Plan Goals and Objectives. The project area lies in the Bear Lodge Mountains in the Black Hills National Forest, directly north of Sundance, Wyoming. Issues considered include: Fire and fuel hazard reduction; impacts of vegetation treatment and multiple forest uses on wildlife and fish habitat; and travel management and recreation.

Purpose of and Need for Action

There is a need to reduce the potential for uncharacteristically intense wildfire behavior and insect infestation, provide diverse wildlife habitat, and manage motorized recreation in the Dean Project Area. This project will address Forest Plan Goal 2 (providing for biologically diverse ecosystems) and Goal 3 (providing for sustained commodity uses) consistent with Forest Plan Standards and Guidelines.

Proposed Action

Actions proposed in the Dean Project Area include:

- Modifying stand structure across the planning area to reduce potential for uncharacteristically intense wildfire behavior and benefit wildlife. This action includes thinning the forest, removing conifers from stands of hardwoods such as aspen, bur oak, and birch, and expanding and/or creating meadows.
- Reducing fuel loads by decreasing the volume and arrangement of both existing fuels and those resulting from other vegetation treatment activities. Treatment could include lopping, chipping, crushing, piling and burning, and prescribed burning on up to 2,971 acres.
- Reducing the density of pine stands on up to 4,840 acres to decrease the potential for spreading crown fires, increase tree growth and vigor, and lessen the risk of insect infestation and disease. This may be done by using commercial timber harvest to thin out merchantable trees and using other methods to thin small, unmerchantable trees. These actions would provide wood fiber to local industry and would require construction of up to 5.7 miles of new specified roads.
- Modifying the Forest Plan through a non-significant amendment to change Management Area (MA) designation in part of the project area to better reflect actual conditions. The entire project area is currently in MA 5.4 (Big Game