HARMONIZATION ALERT

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HARMONIZATION ALERT, a publication of Public Citizen, seeks to promote open and accountable policy-making relating to public health, natural resources, consumer safety, and economic justice standards in the era of globalization.

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HEALTH & ENVIRONMENT

Topic: *Canadian Corporation Uses NAFTA to Sue U.S. for California MTBE Ban*
Venue: NAFTA Chapter 11 Tribunal
Contact: The California Executive Order banning MTBE can be downloaded from www.ca.gov/s/governor/d599.html; the University of California report on which the ban is based is available at http://tsrtp.ucdavis.edu/mtberpt/homepage.html. To view Methanex Corporation's arguments, visit www.methanex.com. There is no mechanism for citizen input into NAFTA Chapter 11 cases. The U.S. Trade Representative and the Department of Justice handle NAFTA Chapter 11 cases; however, they have yet to release the names of the officials in charge of this case.

The Canadian corporation Methanex is suing the U.S. government for $970 million, using the North American Free Trade Agreement (NAFTA). Methanex claims that California's ban on methyl tertiary butyl ether (MTBE) violates new investor rights granted to Methanex under NAFTA's Chapter 11 rules by limiting the corporation's ability to sell MTBE. If a NAFTA tribunal finds the regulation to be a "regulatory taking," as claimed by

Methanex, the U.S. government can be held liable for the corporation's lost profits.

On March 25, 1999, California, by executive order, required the removal of MTBE from gasoline sold in the state by December 31, 2002. California Governor Gray Davis declared that "on balance, there is significant risk to the environment from using MTBE in gasoline in California."[1] The chemical also has been associated with human neurotoxicological effects, such as dizziness, nausea, and headaches, and has been found to be an animal carcinogen with the potential to cause human cancer.[2]

The ban is based on a 1998 University of California-Davis report which found, "There are significant risks and costs associated with water contamination due to the use of MTBE."[3] The report noted, "MTBE is highly soluble in water and will transfer readily to groundwater from gasoline leaking from underground storage tanks, pipelines and other components of the gasoline distribution system."[4] The report also noted that the use of MTBE gas in motor boats results in contamination of surface water.[5] It concluded, "We are placing our limited water resources at risk by using MTBE."[6]

Methanex claims that MTBE provides cleaner air.[7] However, the U.C.-Davis report found that "there is no significant additional air quality benefit to the use of oxygenates such as MTBE in reformulated gasoline. . . ."[8] The report also found no economic benefit from the use of MTBE. In comparing the costs of gas with MTBE added to gas with ethanol added and gas without any oxygenate added, the report concluded that MTBE gas "has the highest net annual cost due primarily to the costs of treating contaminated water supplies, higher fuel prices, and lower fuel efficiency."[9]

Methanex filed its suit under NAFTA's Chapter 11 Expropriation and Compensation provisions. These provisions allow private investors to sue NAFTA nations directly in NAFTA tribunals for cash compensation for government actions judged by the tribunal to undermine an investor's future profitability. Specifically NAFTA guarantees foreign investors compensation from NAFTA nation governments for any government action "tantamount to" an "indirect expropriation."[10] This provision has been criticized as establishing a broad regulatory takings mechanism.

Critics have accused Methanex of using NAFTA to override the Governor, State Senate, and people of California. The case is being watched closely by many Members of the U.S. Congress, including those who supported and opposed NAFTA, as a test of NAFTA's ability to undermine the legislative process and the public health and environmental legislation resulting from it.

The California case has drawn comparisons to the 1998 case brought against Canada by the U.S.-based Ethyl Corporation under NAFTA's Chapter 11 provisions. In that case, Ethyl sued Canada for $250 million after Canada banned the gasoline additive MMT because of health risks. Ethyl claimed the ban violated NAFTA because it "expropriated" future profits and damaged Ethyl's reputation. After learning that the NAFTA tribunal was likely to rule against its position, the Canadian government revoked the ban, paid Ethyl $13 million, and issued a public statement declaring there was no evidence that MMT posed health or environmental risks.

CODEX COMMITTEES

On May 26, 1999, the Food Safety and Inspection Service (FSIS) published in the *Federal Register* (at 64 *Fed. Reg.* 28428) a list of all the committees of the Codex Alimentarius Commission, the international organization designated by the World Trade Organization to set food safety standards. The list contains contact information and the committees' sanitary and phytosanitary (food and agricultural) standard-setting activities.

Although official representation at Codex is through governments, corporations play an active role. One study found that 26% of all participants on Codex working committees represented business interests while less than 1% represented consumer interests.[11] The list of corporations with formal roles as members of country delegations includes Nestle, Coca-Cola, Bayer, Monsanto, Kraft, BASF, Pepsico, M&M Mars, Dupont, Shell, Hershey, Dole, Pfizer, and Tyson Foods.[12]

Submit written comments regarding any of the

Harmonization Alert is a monthly publication of Public Citizen Foundation. It aims to inform a wide audience of interested parties about international standardization activities. Additional information and materials for many of this publication's listings are available through our harmonization clearing house. If you have information on harmonization-related issues, please contact us so we can share your information with other readers. ***Harmonization Alert*** is available free of charge by mail, list serve, and on the Internet at www.harmonizationalert.org. Please contact Dion Casey at dcasey@citizen.org or Mary Bottari at mbottari@citizen.org, or call (202) 546-4996 to subscribe or for clearinghouse requests. Public Citizen's Harmonization Project is supported by grants from the Ford Foundation, the National Association for Public Interest Law, and the Cummings Foundation.

committees to: FSIS Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 1400 Independence Avenue, SW, Washington, D.C. 20250-3700. You must state that your comments refer to Codex and identify the committee to which they relate. You also must submit a copy of your comments to the delegate from that committee. All submitted comments will be available to the public at the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Please note the following abbreviations: U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), and U.S. Environmental Protection Agency (EPA).

Codex Cmte: *Codex Executive Committee*

Contact: F. Edward Scarbrough, Ph.D., U.S. Manager for Codex Alimentarius, USDA, Office of the Undersecretary for Food Safety, Room 4861, South Agriculture Building, 1400 Independence Avenue, SW, Washington, DC 20250-3700; Phone: (202) 205-7760.

The Codex Executive Committee is composed of the chairperson, vice-chairpersons, and six members elected from the complete Codex Alimentarius Commission, one from each of geographic region - Africa, Asia, Europe, Latin America and the Caribbean, North America, and the South-West Pacific. This committee last met June 24-25, 1999, and considered the following issues: (1) the financial situation of the Food Standards Programme for 1999-99 and 2000-01; (2) principles of risk analysis; (3) matters arising from Codex Committees' reports; (4) designation of host governments for Codex Committees and ad hoc intergovernmental task forces; (5) criteria for new work and guidelines for establishing inclusive standards; and (6) documentation, translation, and interpretation services for Codex Committees. Thomas Billy, administrator of the USDA Food Safety and Inspection Service, was elected to chair of this committee, but Ed Scarbrough will continue to represent the U.S.

Codex Cmte: *Residues of Veterinary Drugs in Foods*

Contact: Dr. Robert C. Livingston, Center for Veterinary Medicine (HFV-1), FDA, 7500 Standish Place, Rockville, MD 20855; Phone: (301) 594-5903; Fax: (301) 594-1830; or Dr. Pat Basu, Director, Chemistry and Toxicology Division, Office of Public Health and Science, FSIS, USDA, 6912 Franklin Court, 1099 14th Street, NW, Washington, DC 20250-3700; Phone: (202) 501-7319; Fax: (202) 501-7639.

The Codex Committee on Residues of Veterinary Drugs (CCRVD) recommends maximum residue limits for veterinary drugs (MRLVDs) in foods for consideration by the full Codex Alimentarius Commission. A Codex MRLVD is the maximum concentration of a veterinary drug residue in food recommended by Codex. It 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). An ADI is an estimate of the amount of a veterinary drug that can be ingested daily over a lifetime without appreciable health risk.

The CCRVD's next meeting is scheduled for March 28-31, 2000, in Washington, D.C. Subjects for consideration include: (1) risk analysis principles; (2) guidelines on residues at injection sites; (3) guidelines on the control of veterinary drugs in milk and milk products; (4) methods of analysis and sampling; (5) draft code for good animal feeding; and (6) MRLs for several veterinary drugs.

Codex Cmte: *Food Additives and Contaminants*

Contact: Dr. Alan Rulis, Director, Office of Premarket Approval, CFSAN, FDA, 200 C Street,

SW, (HFS-200), Washington, DC 20204; Phone: (202) 418-3100; Fax: (202) 418-3131; or Dr. Terry C. Troxell, Director, Division of Programs and Enforcement Policy, CFSAN, FDA, 200 C Street, SW, (HFS-456), Washington, DC 20204; Phone: (202) 205-5321; Fax: (202) 205-4422.

The Codex Committee on Food Additives and Contaminants (CCFAC) performs the following: (1) sets maximum levels for individual food additives, contaminants, and naturally-occurring toxic substances in food and animal feed; (2) prepares priority lists of food additives and contaminants for toxicological evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); (3) recommends specifications of identity and purity for food additives for adoption by the full Codex Commission; (4) considers methods of analysis for food additives and contaminants; and (5) considers standards and codes for related subjects, such as food irradiation and labeling issues. A food additive is any substance not normally consumed as a food by itself, whether or not it has nutritive value, which is intentionally added to a food for a technological purpose and becomes a component of or otherwise affect the characteristics of the food.

The CCFAC last met March 22-26, 1999, in The Hague, The Netherlands. The next session is tentatively scheduled for March 20-24, 2000, in Beijing, People's Republic of China. Topics for consideration include risk analysis principles, specifications for dozens of food additives, maximum levels for several toxins, and a general standard for irradiated foods.

Codex Cmte: *Pesticide Residues*

Contact: Fred Ives, Health Effects Division (7509C), Office of Pesticide Programs, EPA, 401 M Street, SW, Washington, DC 20460; Phone: (703) 305-6378; Fax: (703) 305-5147; or Dr. Richard Parry, Jr., Assistant Administrator, Cooperative Interactions, Agricultural Research Service, USDA, Room 358-A, Jamie L. Whitten Federal Bldg., Washington, DC 20250-3700; Phone: (202) 720-3973; Fax: (202) 720-5427.

The Codex Committee on Pesticide Residues (CCPR) recommends to the full Codex Commission maximum limits for pesticide residues for specific foods or in food groups. A Codex Maximum Limit for Pesticide Residues (MRLP) is the maximum concentration of a pesticide residue suggested by Codex to be allowed in or on foods or animal feeds.

Codex MRLPs are primarily intended to apply in international trade. Codex standards are given a presumption of NAFTA and WTO conformity. Countries with standards higher than Codex standards bear the burden of justifying them. Agribusiness has advocated that food meeting Codex standards be given full access to all WTO-member nations' markets regardless of compliance with domestic standards.

The CCPR will meet May 1-8, 2000, in The Hague, The Netherlands. The Committee will consider MRLPs for several pesticides, including: Abamectin, Acephate, Aldicarb, Aminomethyl-Phosphon, Bifenthrin, Captan, Carbofuran, Carbosulfan, Clethodim, Chlormequat, Chloro-Thalonil, Chlorpyrifos, DDT, Diazinon, Dicofol, Diquat, Disulfoton, Ethephon, Dithio-Carbamates, Fenarimol, Fenbuconazole, Fenthion, Flumethrin, Glyphosphate, Haloxyfop, Methamidophos, Methidathion, Mevinphos, Myclobutanil, Parathion, Parathion-Methyl, Phorate, Phosmet, Proxpoxur, Tebuconazole, Tebufenozide, Teflubenzuron, and Thiabendazole.

Codex Cmte: *Methods of Analysis and Sampling*

Contact: Dr. William Horwitz, Scientific Advisor, CFSAN (HFS-500), FDA, Room 3832, 200 C Street, SW, Washington, DC 20204; Phone: (202) 205-4346; Fax: (202) 401-7740; or William Franks, Deputy Administrator, Science and Technology, Agricultural Marketing Service, USDA, Room 3507, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20250; Phone: (202) 720-5231; Fax: (202) 720-6496.

The Codex Committee on Methods of Analysis and Sampling (CCMAS): (1) defines the criteria appropriate to Codex sampling and analysis methods; (2) coordinates with other international groups working in sampling and analysis methods and quality assurance systems for laboratories; (3) recommends methods of sampling and analysis standards for foods; and (4) defines procedures, protocols, guidelines, and related texts for the assessment of food laboratory proficiency and quality assurance systems for laboratories.

The CCMAS will meet February 26 - March 2, 2001, in Budapest. Subjects for consideration will include harmonization of analytical terminology, amendments to the Codex Procedural Manual, and endorsement of methods of analysis and sampling provisions in Codex standards.

Codex Cmte: *Food Import and Export Inspection and Certification Systems*

Contact: L. Robert Lake, Director, Office of Regulations and Policy, FDA, 200 C Street, SW, Washington, DC 20204; Phone: (202) 205-4160; Fax: (202) 401-7739; or Mark Manis, Director, International Policy Development Division, Office of Policy, Program Development, and Evaluation, FSIS, USDA, Room 4434, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20250-3700; Phone: (202) 720-6415; Fax: (202) 720-7990.

The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFIEICS) develops principles and guidelines for food import and export inspection and certification systems in order to expedite trade in food. This committee also establishes criteria for WTO-member nations to determine whether other WTO-member nations' food inspection systems are equivalent and procedures to ensure that sanitary measures are properly implemented.

The CCFIEICS's next meeting is scheduled for February 21-25, 2000, in Adelaide, Australia. Topics for consideration include: (1) guidelines for import control systems; (2) criteria for official certificate formats and rules relating to the production and issue of certificates; (3) guidelines for the judgement of equivalence of sanitary measures associated with food inspection and certification systems; and (4) guidelines for the utilization and promotion of quality assurance systems.

Codex Cmte: *General Principles*

Contact: F. Edward Scarbrough - information available above under Executive Committee.

The Codex Committee on General Principles (CCGP) deals with Codex's administrative rules and procedures. Its next meeting will be held April 10-14, 2000, in Paris, France. Topics of discussion will include: (1) definitions for risk management and communication; (2) guidelines for the participation of international non-governmental organizations in the work of Codex; (3) measures for facilitating consensus; (4) consideration of legitimate factors other than science in Codex decision-making; and (5) revision of the code of ethics for international trade in food.

Codex Cmte: *Food Labeling*

Contact: L. Robert Lake - information available above under Food Import and Export Certification and Inspection Systems; or Dr. Robert Post, Director, Labeling and Additive Policy Division, Office of Policy, Program Development and Evaluation, FSIS, USDA, Cotton Annex, Room 602, 1400 Independence Avenue, SW, Washington, DC 20250-3700; Phone: (202) 205-0279; Fax: (202) 205-3625.

The Codex Committee on Food Labeling (CCFL) drafts Codex rules on labeling issues. For example, the CCFL is in charge of developing labeling provisions for organic and genetically-engineered foods. The CCFL will meet May 9-12,

2000, in Ottawa, Canada to discuss: (1) guidelines for the production, processing, labeling, and marketing of organically-produced foods; (2) guidelines for labeling foods that can cause hypersensitivity; (3) amendments to the guidelines on nutrition labeling; (4) suggestion on labeling genetically-engineered foods; and (5) recommendations for the use of health claims.

Codex Cmte: *Food Hygiene*

Contact: Dr. Robert Buchanan, Senior Science Advisor, FDA, 200 C Street, SW, Washington, DC 20204; Phone: (202) 205-5053; Fax: (202) 205-4970.

The Codex Committee on Food Hygiene (CCFH) drafts Codes of Hygienic Practice for foods and recommends food hygiene provisions to the full Codex Commission. The CCFH will meet November 29 - December 3, 1999, in Washington, DC. Subjects of consideration will include: (1) draft Codes of Hygienic Practice for bottled water, milk and milk products, and pre-cut raw fruits and vegetables; (2) principles for the conduct of microbiological risk management; (3) antibiotic resistance in bacteria in food; (4) food viruses; and (5) recommendations for the control of Listeria monocytogenes in foods in international trade.

Codex Cmte: *Fresh Fruits and Vegetables*

Contact: David L. Priester, International Standards Coordinator, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, PO Box 96456, Room 2069, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20090-6456; Phone: (202) 720-2184; Fax: (202) 720-0016; or Larry B. Lace, Branch Chief, Room 2049 (same address); Phone: (202) 720-5870; Fax: (202) 720-0393.

The Codex Committee on Fresh Fruits and Vegetables (CCFFV) develops standards and codes of practice for fresh fruits and vegetables. The CCFFV's next meeting is scheduled for September 4-8, 2000, in Mexico City. Topics of discussion will include: (1) codes of practice for the quality inspection and certification of fresh fruits and vegetables; and (2) draft standards for pineapples, grapefruit, papaya, oranges, asparagus, apples, grapes, and tomatoes.

Codex Cmte: *Nutrition and Foods for Special Dietary Uses*

Contact: Dr. Elizabeth Yetley, Director, Office of Special Nutritionals, CFSAN, FDA, 200 C Street, SW (HFS-450), Washington, DC 20204; Phone: (202) 205-4168; Fax: (202) 205-5295; or Dr. Robert J. Moore, Senior Regulatory Scientist, CFSAN, FDA, 200 C Street, SW (HFS-456), Washington, DC 20204; Phone: (202) 205-4605; Fax: (202) 260-8957.

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) studies nutritional problems referred to it by the full Codex Commission, drafts provisions on nutritional aspects for all foods, and develops guidelines and standards for foods for special dietary uses. The CCNFSDU will meet June 19-23, 2000, in Berlin, Germany, to discuss (1) guidelines for nutrient claims; (2) standards for processed cereal-based foods for infants and young children; (3) standards for infant formula; and (4) guidelines for vitamin and mineral supplements.

Codex Cmte: *Fish and Fishery Products*

Contact: Philip C. Spiller, Director, Office of Seafood (HFS-400) VERB, CFSAN, FDA, 200 C Street, SW, Washington, DC 20204; Phone: (202) 418-3133; Fax: (202) 418-3198; or Samuel W. McKeen, Director, Office of Trade and Industry Services, National Oceanic and Atmospheric Administration, NMFS 1335 East-West Highway, Room 6490, Silver Spring, MD 20910; Phone (301) 713-2362; Fax: (301) 713-1081.

The Codex Committee on Fish and Fishery Products (CCFFP) develops standards for fresh and frozen fish, crustaceans, and mollusks. Its next meeting will be held June 5-9, 2000, in Aalesund, Norway. Subjects for consideration will include: (1) guidelines for the sensory evaluation of fish and shellfish in laboratories; (2) draft code of practice for fish and fishery products; and (3) draft standards for smoked fish, molluscan shellfish, dried salted anchovies, salted Atlantic herring, and salted sprats.

Codex Cmte: *Milk and Milk Products*

Contact: Duane Spomer, Chief, Dairy Standardization Branch, USDA, Agricultural Marketing Service, Room 2750, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20250-0230; Phone: (202) 720-9382; Fax: (202) 720-2643; or John C. Mowbray, Division of Programs and Enforcement Policy, CFSAN, FDA, 200 C Street, SW, (HFS-306), Washington, DC 20204; Phone: (202) 205-1731; Fax: (202) 205-4422.

The Codex Committee on Milk and Milk Products (CCMMP) establishes codes and standards for milk and milk products. Its next meeting is scheduled for February 28 - March 3, 2000, in Wellington, New Zealand. Topics of discussion will include: (1) heat treatment definitions; (2) model export certificates for milk products; and (3) standards for butter, cheese, evaporated milks, cream, and dairy spread.

Codex Cmte: *Fats and Oils*

Contact: Charles W. Cooper, Director, International Activities Staff, CFSAN, FDA, 200 C Street, SW, Room 5823 (HFS-585), Washington, DC 20204; Phone (202) 205-5042; Fax: (202) 401-7739; or Dr. Dwayne Buxton, National Program Leader for Oilseeds and Bioscience, Agricultural Research Service, Room 212, Building 005, Barc West, Beltsville, MD 20705; Phone: (301) 504-5321; Fax: (301) 504-5467.

The Codex Committee on Fats and Oils (CCFO) develops standards for fats and oils of animal, vegetable, and marine origin. It will meet March 26-30, 2001, in London, England, to discuss standards for animal fats, edible fats and oils, vegetable oils, fat spreads, and olive oils, as well as a draft revised code of practice for the storage and transport of fats.

Codex Cmte: *Cocoa Products and Chocolate*

Contact: Charles W. Cooper - information available under Fats and Oils; or Dr. Michelle Smith, Food Technologist, Office of Food Labeling, CFSAN, FDA (HFS-158), 200 C Street, SW, Washington, DC 20204; Phone: (202) 205-5099; Fax: (202) 205-4594.

The Codex Committee on Cocoa Products and Chocolate sets standards for cocoa products and chocolates. Its next meeting will be held November 2-4, 2000, in Bern, Switzerland. Topics of discussion will include standards for cocoa butter, cocoa mass, cocoa powders, chocolate, and chocolate products.

Codex Cmte: *Processed Fruits and Vegetables*

Contact: James Rodeheaver, Chief, Processed Products Branch, Fruits and Vegetables Program, Agricultural Marketing Service, USDA, PO Box 96456, Room 0709, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20090-6456; Phone: (202) 720-4693; Fax: (202) 690-1527; or Charles W. Cooper - information available under Fats and Oils.

The Codex Committee on Processed Fruits and Vegetables (CCPFV) elaborates standards for processed fruits and vegetables. The CCPFV last met in March, 1998, in Washington, DC, and will meet again September 11-15, 2000, in Washington, DC. Subjects for consideration will include standards for canned pears, pineapple, fruit cocktail, citrus fruits, applesauce, vegetables, tomatoes, mushrooms, and chestnuts; pickles, raisins, and table olives; and jams, jellies, and marmalades.

Codex Cmte: *Soups and Broths*

Contact: Charles Edwards, Director, Labeling, Products and Technology Standards Division, Office of Policy, Program Development and Evaluation, FSIS, USDA, Room 405, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700; Phone: (202) 205-0675; Fax: (202) 205-0080; or Dr. Robert Post, Director, Labeling and Compounds Review Division, Office of Policy, Program Development and Evaluation, FSIS, USDA, Room 602, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700; Phone: (202) 205-0279; Fax: (202) 205-3625.

The Codex Committee on Soups and Broths (CCSB) set standards for soups, broths, bouillons, and consommes. The CCSB adjourned *sine die* (without fixing a date for future action), and has no further meetings scheduled. However, the committee is planning to continue work on revising the standard for bouillons and consommes. The FSIS notice did not specify when or where this action will take place.

Codex Cmte: *Sugars*

Contact: Dr. Benjamin Legendre, Agricultural Research Service, USDA, SRRC, Sugarcane Research Unit, 800 Little Bayou Black Drive, PO Box 470, Houma, LA 70361-0470; Phone: (504) 872-5042; Fax: (504) 868-8369; or Dr. Dennis M. Keefe, Office of Premarket Approval, CFSAN, FDA, 200 C Street, SW (HFS-206), Washington, DC 20204; Phone: (202) 418-3113; Fax: (202) 418-3131.

The Codex Committee on Sugars (CCS) developed standards for all types of sugars and sugar products. The CCS adjourned *sine die*, but the full Codex Commission asked it to revise the standards for sugar and honey. Thus, the CCS is continuing its work on those standards, but has not released a time or place for its future work.

Codex Cmte: *Natural Mineral Waters*

Contact: Dr. Terry C. Troxell, Director, Office of Plant and Dairy Foods and Beverages, CFSAN, FDA, 200 C Street, SW (HFS-305), Washington, DC 20204; Phone: (202) 205-5321; Fax: (202) 205-4422; or Shellee Davis, Division of Programs and Enforcement Policy, CFSAN, FDA, 200 C Street, SW (HFS-306), Washington, DC 20204; Phone: (202) 205-4681; Fax: (202) 205-4422.

The Codex Committee on Natural Mineral Waters (CCNMW) sets standards for natural mineral waters. The CCNMW's next meeting is scheduled for October 30 - November 1, 2000, in Bern, Switzerland.

Codex Cmte: *North America and the South-West Pacific*

Contact: Patrick Clerkin, Director, U.S. Codex Office, FSIS, USDA, Room 4861, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20250-3700; Phone: (202) 205-7760; Fax: (202) 720-3157.

The Codex Coordinating Committee for North America and the South-West Pacific, of which the U.S. is a member, is charged with defining problems and needs regarding food standards and food control of all Codex member nations in that region. This committee last met October 6-9, 1998, in Seattle, Washington, and will meet next December 5-8, 2000, in Australia. Topics of discussion will include: (1) general standards for genetically-engineered foods; (2) consumer participation in Codex work; and (3) acceptance of Codex standards and maximum residue limits for pesticides by nations in the region.

Codex Cmte: *Cereals, Pulses, and Legumes*

Contact: Charles W. Cooper - information available above under Fats and Oils; or David Shipman, Deputy Administrator, Grain Inspection Packers and Stockyards, Administration, USDA, Room 1092, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20250-3601; Phone: (202) 720-9170; Fax: (202) 720-1015. This committee has adjourned *sine die*.

Codex Cmte: *Vegetable Proteins*

Contact: Dr. Wilda H. Martinez, Associate Deputy Administrator, Aqua Products and Human Nutrition Sciences, USDA, Agricultural Research Service, Room 107, B-005, Beltsville, MD 20705; Phone: (301) 504-6275; Fax: (301) 504-6699. This committee has adjourned *sine die.*

Codex Cmte: *Meat Hygiene*

Contact: Dr. John Prucha, Assistant Deputy Administrator, International and Domestic Policy, FSIS, USDA, Room 4866, South Agriculture Bldg., 1400 Independence Avenue, SW, Washington, DC 20250-3700; Phone (202) 720-3473; Fax: (202) 690-3856. This committee has adjourned *sine die*.

Codex Cmte: *Processed Meat and Poultry Products*

Contact: Dr. Daniel Engeljohn, Director, Regulations Development and Analysis Division, Office of Policy, Program Development and Evaluation, FSIS, USDA, Room 112, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700; Phone: (202) 720-5627; Fax: (202) 690-0486; or Charles Edwards - information available above under Soups and Broths. This committee has adjourned *sine die*.

HARMONIZATION

Topic: *TransAtlantic Business Dialogue (TABD) Mid-Year Report*

Contact: The complete report is available at www.tabd.com/about/MYMTechnicalAnnex.html. A summary of the report is available at www.tabd.com/about/MYMExecSummary1.html. More information on the TABD is available at www.tabd.com.

In May 1999, the TransAtlantic Business Dialogue (TABD), a coalition of U.S. and European business interests created by the U.S. and European governments in 1995, released its Mid-Year Report. The report contains TABD's analysis of the progress the U.S. and European governments have made on past TABD recommendations for deregulation, harmonization, and greater economic integration. The Mid-Year Report is TABD's scorecard on government implementation of its requested policy changes and a list of future demands.

TABD has been criticized as a circumvention of the normal policy-making process which requires openness and public input. It provides high-level contacts with U.S. and EU government officials for industry representatives combined with a commitment to considering each item the industry coalition presents. Indeed, in the U.S. an interagency process has been developed simply to respond to TABD demands. The government team issues its own scorecard documenting how many of the industry requests it has satisfied.

The TABD report proposes harmonization or deregulation in dozens of areas, including: product liability, economic sanctions, climate change, intellectual property, taxation, services, government procurement, privacy in electronic commerce transactions, dietary supplements, medical devices, pharmaceuticals, chemicals, and automobile and aviation standards. A summary of TABD's recommendations in some of those areas follows.

Conformity Assessment - Industry Self-Certification and Third-Party Certification are the dominant themes in the TABD report. TABD proposes market access systems based on "suppliers' declaration of conformity" and third-party

certification. This would allow manufacturers to market their products in the U.S. and Europe without their being subject to government inspection. Rather, corporations would be able to certify themselves or pay a private third party to certify them as complying with all appropriate regulations.

Aviation Safety - TABD encourages the harmonization of U.S. and European aviation regulations and compliance determinations. TABD proposes the harmonization of most transport airplane requirements by December 1999 and safety-related provisions by June 2000. TABD also has set October 1999 as the deadline for the U.S. Federal Aviation Administration (FAA) and the European Union (EU) Joint Airworthiness Authorities (JAA) to harmonize regulations which have been forwarded by TABD's Aviation Rulemaking Advisory Committee for implementation. Finally, TABD recommends the EU establish a single aviation authority by May 2000.

Automotive Standards - TABD suggests that the EU and U.S. governments begin to harmonize motor fuel specifications and environmental regulations by October 1999. TABD also has recommended a global tire standard (GTS-2000) to both governments, and is awaiting their responses.

Dietary Supplements - TABD wants to establish a harmonized definition of dietary supplements and common principles for their regulation to allow market access on both sides of the Atlantic. Industry members are proposing good manufacturing practices (GMP) standards as well as labeling and advertising rules. TABD plans to establish a joint government and industry working group to work on these issues.

Pharmaceuticals - TABD urges the U.S. Food and Drug Administration (FDA) to complete equivalency assessments of each of the 15 EU member nations, as required by the U.S. - EU Mutual Recognition Agreement. TABD also wants to work with both governments to develop exemptions to the EU's Data Privacy Directive, which prohibits the transfer of consumers' personal data from EU nations to nations that do not have similar privacy protections, for pharmaceutical industry "research and development."[13] Finally, TABD encourages both governments to take "a non-regulatory approach and encourage private sector leadership of technical standards and development" for direct-to-consumer advertising of pharmaceuticals.[14]

Economic Sanctions - TABD encourages the withdrawal of boycotts and other sanctions with extraterritorial effects. It supports bills proposed in the U.S. Senate and House of Representatives that would create national interest waivers and apply economic sanctions only as a last resort. TABD "strongly reaffirms its request to the U.S. government to obtain the immediate cessation of economic sanctions" at the state and local levels.[15]

Product Liability - TABD supports the "reform" of U.S. product liability laws at the federal and state levels. Specifically, TABD desires a cap on punitive damages and joint and several liability; re-working of statutes of repose and statutes of limitation; and more widely-available affirmative defenses. However, to date TABD has been unable to persuade Congress to enact any of these "reforms" into federal law.

For a more thorough description of TABD's efforts, see the complete Mid-Year Report, available on the Internet at the address listed above.

OTHER NEWS

Topic: *USDA Finds GM Crops Do Not Increase Yields or Lower Pesticide Costs*

Contact: A summary of the U.S. Department of Agriculture's survey results is available on the Internet at www.econ.ag.gov/whatsnew/issues/biotech/index.htm.

The U.S. Department of Agriculture (USDA) recently released the results of a 1997 Agricultural Resource Management Study comparing the costs and yields of genetically-modified (GM) and traditional crops. The study found that, contrary to biotechnology industry claims, GM crops, on average, do not substantially increase yields or lower pesticide costs for cotton and soybean farmers.[16] According to Nora Brooks of USDA's Economic Research Service, at a June 24, 1999, conference on agricultural biotechnology in Washington, DC, "A comparison of costs and yields did not show a clear economic advantage for herbicide-tolerant soy and cotton, nor for Bt cotton."[17]

The study surveyed farmers in soybean-growing states which represent 93% of U.S. soybean acreage, and cotton-growing states which account for 95% of the U.S. cotton acreage.[18] Although farmers using GM seeds averaged fewer pesticide treatments, their treatment costs still were higher because GM seeds cost more than traditional seeds, and farmers must pay technology fees to use the GM seeds.[19]

The study did find that yields for Bt cotton were increased in four of seven regions, and yields for Bt corn were higher in two of five regions. The report stated, "For the case of herbicide-tolerant crops, the results are mixed:

only for a few regions and in some years are yields higher for adopters."[20]

The study noted several shortcomings in its methods. One was the time lag between use of GM crops and publication of the study's results. Another was its failure to include the cost of European consumers' opposition to GM foods in its economic analysis. For instance, in 1998, European consumers' opposition cost U.S. corn growers around $200 million in lost corn sales to the European Union.[21]

Topic: *Report from 23rd Session of Codex Alimentarius in Rome June 28-July3: U.S.Retreats from Position on BST Hormone*

Contact: F. Edward Scarbrough, Ph.D., U.S. Manager for Codex Alimentarius, USDA, Office of the Undersecretary for Food Safety, Room 4861, South Agriculture Building, 1400 Independence Avenue, SW, Washington, DC 20250-3700, Phone: (202) 205-7760.

The U.S. will no longer insist that the Codex Alimentarius Commission (Codex) certify Bovine Somatotropin (BST), a hormone injected into dairy cows to increase their milk production, as safe to use, thus ending a decade-long struggle with the European Union over the hormone.[22] For ten years, the U.S. has tried to compel Codex, the international body designated by the World Trade Organization to set food safety standards, to approve BST as safe.[23] If Codex had done so, other nations would have been forced to accept imports of milk from cows treated with BST, or face a WTO challenge and the prospect of paying millions of dollars in compensation to the U.S. if they lost.

The U.S. abandoned its stance after concluding that no consensus existed on the issue at the 23rd meeting of the Codex in Rome.[24] Codex generally passes rules and standards by consensus. The U.S. twice pushed votes on BST in Codex, but lost both times. The European Union and Canada, where the use of BST is prohibited, both opposed the U.S. position.[25] The U.S. Food and Drug Administration (FDA) approved BST in 1993, claiming it posed no significant human or animal health risks. However, in April 1998, the Canadian Department of Health released a report pointing out several gaps in the FDA's analysis of BST.[26] For example, the FDA ignored a rat study - performed by Monsanto, the corporation that manufactures BST - which showed possible absorption of the hormone, simply because Monsanto characterized the study as "non-pivotal."[27]

In addition, since FDA's approval of the hormone, several studies have shown that a biochemical in milk from cows injected with BST survives digestion.[28] The biochemical, Insulin-like Growth Factor (IGT-1), is believed to be a significant factor in breast, prostate, and colon cancer.[29] The Center for Food Safety and two dozen other U.S. public interest groups filed a petition requesting withdrawal of BST from the U.S. market with the FDA on December 15, 1998.[30]

The hormone also has been linked to animal health problems. On January 14, 1999, the Canadian Department of Health rejected Monsanto's application for the sale of BST in Canada, arguing it poses too many risks to the health of cows.[31] Health Canada's veterinary committee studied BST for nine years and found that cows treated with the hormone had a 25% greater risk of mastitis, a painful udder infection that requires antibiotic treatment; an 18% greater risk of infertility; a 50% greater risk of lameness; and a 20-25% greater chance of being culled from a herd than cows that were not injected with the hormone.[32]

Many other important decisions were made at this meeting which was attended by a handful of U.S. consumer organizations. There is increased interest in the activities of Codex on the part of U.S. consumers because under the WTO's Agreement on Sanitary and Phytosanitary Measures (SPS) only international standards like those developed by the Codex Alimentarius are presumed to be WTO-legal. As a consequence the U.S. could be forced to weaken current food-safety regulations that are more stringent than Codex standards or face sanctions in the WTO.

At this recent Codex session delegates also:

- approved pesticide residue levels that do not take into account the effects on children, as mandated by U.S. law;
- approved an amended standard permitting higher levels of lead and nitrates in natural mineral water than the FDA currently allows;
- approved a standard that does not require pasteurization of dairy products as is now required by the FDA;
- sanctioned the use of five food additives which, while presumably safe, have not been approved by the FDA for use in the U.S.;
- created a task force to draft animal feeding standards in the wake of the recent Belgian food-scare when dioxin was discovered in chicken and

eggs products;

- approved international guidelines for the production, processing and labeling of organic foods;
- created a task force on genetically modified food, which is expected to establish procedures for approval and labeling of GMOs;
- considered recommendations to increase consumer participation in the Codex, including: developing guidelines on consumer participation and benchmarks for improvement, improving dissemination of Codex information, inviting consumer organizations to participate in national and sub regional workshops;
- adopted draft principles on the definition and role of "observer status" for international non-governmental organizations (NGOs);
- recommended further clarification of risk analysis principles.

In addition Thomas Billy, administrator of the USDA Food Safety and Inspection Service, was elected to chair of the Codex.[33] See page 17 for information on a USDA briefing on what took place at the 46th Session of the Codex Executive Committee and the 23rd Session of the full Codex Alimentarius Commission.

-- Bruce Silverglade from the Center for the Science in the Public Interest and Rod Leonard from the Community Nutrition Institute contributed to this report.

FEDERAL REGISTER ALERTS

For more timely notice of these alerts, please visit our website at www.harmonizationalert.org and sign up for one of our four listservers.

Topic: *ICH Guidance on the Duration of Chronic Toxicity Testing in Animals*
Action: Notice of public availability
Venue: Food and Drug Administration
FR Cite: 64 *Federal Register* 34259 (June 25, 1999)
Deadline: Submit written comments at any time
Contact: For more information on the guidance, Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; Phone: (301) 594-6758. For more information on the International Conference on Harmonization, Janet J. Showalter, Office of Health Affairs (HFY-20), FDA, 5600 Fishers Lane, Rockville, MD 20857; Phone: (301) 827-0864. Submit 2 copies of written comments (identified with Docket No. 97D-0444) on the guidance to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available by mail from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, MD 20857; by calling the Center for Biologics Evaluation and Research's Voice Information System at 1-800-835-4709; or on the Internet at www.fda.gov/cder/guidance/index.htm.

The Food and Drug Administration (FDA) is publishing a guidance document entitled "S4A Duration of

Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)." This guidance was prepared under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for the purpose of providing guidance in the safety evaluations of drug products.

The FDA also notes circumstances in which it may accept durations of chronic toxicity testing in nonrodents that differ from the duration recommended by the ICH. The ICH generally recommends 9-month chronic toxicity studies in nonrodents. However, the FDA considers 6-month studies acceptable for indications of chronic conditions associated with short-term, intermittent drug exposure (e.g. bacterial infections, migraines, erectile dysfunction, and herpes); and for drugs intended for indications of life-threatening diseases for which substantial long-term human clinical data are available (e.g. cancer chemotherapy). The FDA considers 12-month studies more appropriate for chronically used drugs to be approved on the basis of short-term clinical trials employing efficacy surrogate markers where safety data from humans are limited to short-term exposure (e.g. some AIDS therapies); and for new molecular entities acting at new molecular targets where post-marketing experience is not available for the pharmacological class.

The ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The EU, Japan, and the U.S. The ICH is sponsored by government agencies and industry associations, including: The European Federation of Pharmaceutical Industries Associations, the Japanese Pharmaceutical Manufacturers Association, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee is made up of representatives of the sponsors and the Secretariat. Officials from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area are allowed as "observers."

Topic: *Economic and Environmental Effects of Tariff Elimination on Forest Products*

Action: Request for public comments

Venue: Office of the U.S. Trade Representative and Council on Environmental Quality

FR Cite: 64 *Federal Register* 34304 (June 25, 1999)

Deadline: July 24, 1999

Contact: For more information, Office of the U.S. Trade Representative, Environment and Natural Resources Section, at (202) 395-7320; or the Council on Environmental Quality, International Affairs, at (202) 456-6224. Submit 20 copies of written comments to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Attn: Forest Products ATL, Office of the U.S. Trade Representative, Room 122, 600 17th Street, NW, Washington, D.C. 20508.

The U.S. Trade Representative (USTR) and the Council on Environmental Quality (CEQ) are writing an analysis of the possible economic and environmental effects of eliminating tariffs and regulatory standards on forest products. The Clinton administration has been pushing for tariff and non-tariff liberalization in seven sectors, including forestry, fisheries, and mining in the context of the Asia Pacific Economic Cooperation (APEC) negotiations. Opposition to this proposal at APEC has resulted in it remaining "voluntary" for APEC nations.

Now the U.S. seeks to multilateralize the proposal by pushing for an "early harvest" agreement for the Seattle WTO Ministerial. This would mean the actual signing of an agreement rather than just the beginning of future negotiations. Opposition by forest conservation groups worldwide has made the "Global Free Logging Agreement" aspect of the proposal controversial. So far, other countries have not agreed to allow the proposal to be signed at Seattle.

The agencies invite public comment on the issues raised by the proposal.

Topic: *International Cooperation on Harmonization's Guidance for Veterinary Medicinal Products*
Action: Notice of public availability and request for comments
Venue: Food and Drug Administration (FDA)
FR Cite: 64 Federal Register 38445 (July 16, 1999)
Deadline: For written comments, August 16, 1999
Contact: For more information, Sharon R. Thompson (HFV-3), Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855; Phone: (301) 594-1798; E-mail: sthompso@cvm.fda.gov; or Thomas Letonja (HFV-130), same address; Phone: (301) 827-7576; e-mail: tletonja@cvm.fda.gov. Submit written comments - identified with Docket No. 99D-2248 and the full title of the draft guidance documents to which the comments refer - to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, room 1061, Rockville, MD 20852.

The Food and Drug Administration (FDA) is releasing four draft guidance documents for public review and comment: "Efficacy of Anthelmintics: General Recommendations (#90)"; "Efficacy of Anthelmintics: Specific Recommendations for Bovines (#95)"; "Efficacy of Anthelmintics: Specific Recommendations for Ovines (#96)"; and "Efficacy of Anthelmintics: Specific Recommendations for Caprines (#97)." These documents were prepared by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), and are intended to harmonize methods used in the evaluation of new anthelmintics submitted for approval to the U.S., Japan, and the European Union.

MEETINGS/EVENTS

Event: *President's Council on Food Safety Public Meeting*
Date: July 15, 1999, from 8:30 a.m. to 5 p.m.
Location: The Washington Plaza Hotel, 10 Thomas Circle, Massachusetts Avenue and 14th Street, Washington, D.C.
Deadline: Comments should be submitted by September 1, 1999.
Contact: For more information, Robert Tynan, U.S. Department of Agriculture, at (202) 205-7393 or robert.tynan@usda.gov; to register for the meeting, call Sheila Johnson at (202) 501-7305. Submit 3 copies of written comments to USDA/FSIS Hearing Clerk, 300 12th Street, S.W., Rm. 102 Cotton Annex, Washington, D.C. 20250-3700; or FDA/Dockets Management Branch (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Comments submitted to the USDA must identify Docket No. 98-045N, and comments submitted to the FDA must identify Docket No. 97N-0074. Comments may be submitted electronically, as an ASCII file, to oppts.homepage@epa.gov. Electronic comments must identify Docket No. OPP-00550.

The President's Council on Food Safety, comprised of the U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), was established in August 1998 by Executive Order 13100 to develop a "comprehensive national food safety strategic plan." The stated purpose of the plan is to reduce food- and water-borne illnesses. The three agencies are holding this public meeting to discuss the development of the plan and are establishing public dockets to receive public comments on the plan and the planning process. Summaries of the public meeting will be posted on the Internet within 30 days at www.foodsafety.gov. The complete public docket will be made available on the EPA's web site at

www.epa.gov/opptsfrs/home/rules.htm#docket.

Event: *FDA Public Meeting on Dietary Supplements Regulation*

Date: July 20, 1999, from 9 a.m. to 5 p.m.

Location: Oakland Federal Bldg., 3rd Floor Auditorium, North Tower, 1301 Clay St., Oakland, CA.

Deadline: Persons wishing to attend the meeting must register with the contact person below by July 9, 1999. Written comments must be submitted by August 20, 1999.

Contact: For more information, Janet B. McDonald, Office of Regulatory Affairs (HFR-PA-145), Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502-7070; Phone: (510) 337-6845; Fax: (510) 337-6708; E-mail: jmcdonal@ora.fda.gov. Submit 2 copies of written comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments also may be submitted electronically to FDADockets@bangate.fda.gov or via the FDA's web site at www.fda.gov. Comments must identify Docket No. 99N-1174.

The Food and Drug Administration's Center for Food Safety and Applied Nutrition is holding a public meeting to solicit input on the development of regulations for dietary supplements. Issues to be discussed at the meeting include: the boundaries between dietary supplements and drugs, cosmetic products, and conventional foods; good manufacturing practices; adverse event reporting; research and resource needs; and enforcement.

The FDA requests that comments address the following questions: (1) Besides ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include? (2) What specific tasks should the FDA undertake first? (3) What factors should the FDA consider in determining how best to implement a task? (4) What tasks should be included under the various dietary supplement program elements in the DFSAN 1999 Program Priorities document? (5) Are there current safety, labeling, or other marketplace issues that the FDA should address through enforcement actions? (6) Toward what type or area of research on dietary supplements should the FDA allocate its research resources? (7) What mechanisms are available to leverage the FDA's resources to meet the strategy's objectives?

Transcripts of the meeting will be available within 15 days of the meeting at the FDA's web site at www.fda.gov, or vm.cfsan.fda.gov/dms/cfsan199.html.

Event: *FDA Public Meeting on Structure/Function Claims for Dietary Supplements*

Date: August 4, 1999, 8 a.m. - 6 p.m.

Location: Jefferson Auditorium, U.S. Department of Agriculture, 1400 Independence Avenue, SW, Washington, DC.

Deadline: For written comments, August 4, 1999

Contact: For more information, Lisa Barclay, Office of Policy, Planning and Legislation (HF-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; Phone: (301) 827-3360. Submit written comments - with Docket No. 98N-0044 - to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852, or via e-mail to FDADockets@oc.fda.gov.

The Food and Drug Administration (FDA) is holding a public meeting to receive additional comments on three controversial issues raised by FDA's proposed rule on claims made for dietary supplements concerning the effect of the supplements on the human body's structure or function. The FDA also is re-opening the comment period for the proposed rule.

On April 29, 1998, the FDA published the proposed rule on the types of claims that could be made for dietary supplements without prior authorization from

the FDA (63 *Federal Register* 23624). Under current federal law, a dietary supplement may carry a statement describing "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that "characterizes the documented mechanism by which it acts to maintain such structure or function." These statements are called "structure/function claims." However, a dietary supplement may not make a "disease claim," which is a statement claiming "to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."

In the proposed rule, the FDA attempted to differentiate disease claims from structure/function claims and define the term "disease" differently than the FDA had defined it in other regulations. The FDA received over 100,000 comments, most of them objecting to the proposed definition of "disease" or to the criteria for identifying disease claims. Thus, the FDA is seeking additional comments focusing on three issues: (1) whether it should use the already-existing or the proposed new definition of "disease;" (2) whether certain common conditions associated with natural states, such as hot flashes associated with menopause, should be considered "diseases;" and (3) whether dietary supplements may carry implied disease claims.

Event: *U.S. Codex Alimentarius Commission Meeting*

Date: August 17, 1999, 1 p.m. - 4 p.m.

Location: Room 107A, Jamie L. Whitten Bldg, 12th Street and Jefferson Drive, SW, Washington, DC

Contact: F. Edward Scarbrough, Ph.D., U.S. Manager for Codex Alimentarius, Room 4861, South Building, U.S. Department of Agriculture, 14th and Independence Avenue, SW, Washington, DC 20250; Phone: (202) 205-7760. Send an original and 2 copies of written comments to FSIS Docket Clerk, Docket #99-040N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. All comments will be available to the public at the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

The Office of Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), is holding this public meeting to provide information about decisions on issues considered at the 46th Session of the Codex Executive Committee and the 23rd Session of the full Codex Alimentarius Commission, which took place in Rome, Italy, June 24-25 and June 28-July 3, 1999, respectively. USDA also is soliciting public comment on the future direction of U.S. efforts in Codex.

The following issues will be discussed at the meeting: (1) election of officers of the Commission and appointment regional coordinators; (2) report on the financial situation of the Joint FAO/WHO Food Standards Program for 1998/99 and 2000/01; (3) consideration of the draft medium-term plan for 1998 - 2000; (4) consumers' involvement in Codex work; (5) principles of risk analysis; (6) consideration of amendments to the Codex procedure manual; (7) consideration of draft standards and related text; (8) consideration of proposals to elaborate new standards; (9) matters arising from reports of Codex Committees; and (10) designation of host governments for Codex Committees. See page 12 for a report on the 23rd Session of Codex.

Event: *U.S. Codex Committee on Pesticide Residue Meeting*

Date: August 26, 1999, 9 a.m. - 12 p.m.

Location: Building 1050, BARC-East, Beltsville, MD

Contact: U.S. Codex Office, Phone: (202) 205-7760; Fax: (202) 720-3157; E-mail: uscodex@usda.gov. No agenda has been released. For more information on what types of issues this committee considers, see the above listing for the corresponding Codex Committee

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Event: *EPA/USDA Public Workshop on Bt Crop Resistance Management*

Date: August 26, 1999, 8 a.m. - 5:30 p.m.
Location: Sheraton Four Points Hotel, Memphis International Airport, 2240 Democrat Road, Memphis, TN; Phone: (901) 332-1130
Deadline: For written comments, September 30, 1999
Contact: Sharlene R. Matten, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; Phone: (703) 605-0514; E-mail: matten.sharlene@epa.gov; Fax: (703) 308-7026. If you plan on attending the workshop, EPA suggests that you preregister by visiting the workshop website at www.epa.gov/pesticides/biopesticides/btworkshop826.htm and filling out the registration form there, or by contacting Teresa Bullock at (815) 753-9347 or tbullock@niu.edu. There is no registration fee, and EPA has reserved a block of rooms at the hotel at a special rate. To reserve a room at the hotel, call (901) 332-1130. Submit written comments - with Docket No. OPP-00615 on the first page - to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, EPA, 401 M Street, SW, Washington, DC 20460.

The Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) will conduct a joint public workshop on managing the emergence of insect populations resistant to Bacillus thuringiensis (Bt) plant-pesticides. The two agencies are soliciting public comment to help them develop and implement plans for managing such resistance in insects. Topics to be discussed include: environmental protection, Bt cotton, Bt crops, pesticides, plant-pesticides, biopesticides, and resistance management.

Bt is an insect toxin that occurs naturally in soil. Organic farmers use Bt sprays to control insect pests. Several corporations, such as Monsanto, have begun genetically modifying cotton and corn seeds to produce the Bt toxin internally, claiming this reduces the need for pesticide sprays. However, this has led organic farmers and some scientists to argue that such genetically-modified crops will promote insect resistance to Bt, thus robbing organic farmers of their ability to control insect pests naturally.[34]

Event: *International Conference on Biotechnology in the Global Economy*
Dates: September 2-3, 1999
Location: Harvard University, Cambridge, MA
Contact: Calestous_Juma@Harvard.Edu.; Phone: (617) 496-0433; Fax: (617) 496-8753.

The Center for International Development and the Belfer Center for Science and International Affairs at Harvard University are organizing this international conference to address biotechnology's implications on international trade, intellectual property rights, biodiversity prospecting, developing countries, human and environmental safety, and social values. The conference will foster dialogue among researchers, entrepreneurs, political leaders, policy makers, practitioners, and civil society through roundtable sessions. Discussions will use case studies to promote the sharing of experiences and information. The outcomes of these discussions will be used to formulate research agendas, guide further policy discussions, and contribute to the development of training and educational materials on biotechnology and public policy.

Event: *50 Years Is Enough Network's 4th Activists' Conference*
Dates: September 23-26, 1999
Location: Washington, D.C.
Contact: 50 Years Is Enough Network, 1247 E Street, SE, Washington, D.C. 20003; Phone: (202) 463-2265; E-mail: wb50years@igc.org; Internet: www.50years.org. Registration fees: before

September 10th - $45, afterwards - $55.

The 50 Years Is Enough Network is a coalition of 205 grassroots, faith-based, policy, women's, environmental, labor, and social and economic justice organizations dedicated to making the World Bank and the International Monetary Fund (IMF) democratic and accountable to those who have to live with the effects of their policies and practices. The Network, founded on the 50th anniversary of the founding of the World Bank and the IMF, is made up of such organizations as Friends of the Earth, Greenpeace, the Institute for Agriculture and Trade Policy, Pesticide Action Network, Sierra Club, Progressive Student Network, International Labor Rights Fund, Women's Environment & Development Organization, and Africa Faith and Justice Network.

The conference is targeted toward activists fighting for economic justice, and will provide substantive briefings and strategic sessions on issues such as developing nations' debt, sweatshops, and international financial institutions. It will critique the global economy and develop real-world alternatives to globalization. The conference will culminate in a public demonstration at the headquarters of the IMF during its interim committee meeting.

NOTES

1. California Executive Order D-5-99, Mar. 25, 1999, *available at* www.ca.gov/s/governor/d599.html, at 1.

2. Keller, Arturo, *et. al*, Health & Environmental Assessment of MTBE, Vol. 1, Summary & Recommendations, Nov. 1998, *available at* http://tsrtp.ucdavis.edu.mtberpt, at 23-24.

3. University of California at Davis Report: MTBE Fact Sheet, Nov. 12, 1998, *available at* http://tsrtp.ucdavis.edu/mtberpt, at 1.

4. *Id.*

5. *Id.*

6. *Id.*

7. *See* Bullet Point Background on Methanex's NAFTA Claim and MTBE, *available at* www.methanex.com, at 1; site visited on July 21, 1999.

8. UC Report, *supra* note 3, at 1.

9. *Id.*

10. *See* North American Free Trade Agreement, Part Five - Investment, Services and Related Matter, Ch. Eleven, Article 1110: Expropriation and Compensation, *available at* www.sice.oas.org/trade/nafta/chap-111.stm.

11. *See* Natalie Avery, Martine Drake, and Tim Lang, CRACKING THE CODEX: AN ANALYSIS OF PARTICIPATION ON CODEX ALIMENTARIUS COMMISSIONS WHICH SET INTERNATIONAL FOOD STANDARDS, (1993), at 1.

12. *See id.*, at 19.

13. Transatlantic Business Dialogue, *TABD Mid Year Report*, May 10, 1999, at 36, *available at* www.tabd.com/about/MYMTechnicalAnnex.html.

14. *Id.* at 38.

15. *Id.* at 52.

16. "Biotech Crops Do Not Improve Yield or Cut Pesticide Costs, USDA Finds," *World Food Chemical News*, July 7, 1999, at 21.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*, at 23.

21. *Id.*

22. *See*, Leonard, Rod, "U.S. Backs Off On Trade Tiff With EU On BST Hormone," *Nutrition Week*, July 2, 1999.

23. *See id.*

24. *See id.*

25. *See id.*

26. *See* rBST Internal Review Team, Health Protection Branch, Health Canada, "rBST (Nurtilac) 'Gaps Analysis' Report," Apr. 21, 1998.

27. *See* Petition Seeking the Withdrawal of the New Animal Drug Application Approval for Posilac - Recombinant Bovine Growth Hormone (rBGH), Docket No. 98P-1194, Dec. 15, 1998, at 15.

28. *See id.*, at 12-13.

29. *See id.*, at 14.

30. *See* Petition Seeking the Withdrawal of the New Animal Drug Application Approval for Posilac - Recombinant Bovine Growth Hormone (rBGH), Docket No. 98P-1194, Dec. 15, 1998.

31. *See* "Canadian Health Department rejects rBST, cites 'too many health risks for cows,'" *World Food Chemical News*, Jan. 20, 1999, at 1.

32. *See id.*

33. Some of the information for this report was taken from Hart, Kathleen, "Codex Meeting," *World Food Chemical News*, July 7, 1999, 11-17.

34. *See* Silverglade, Bruce, Comments on behalf of the International Association of Consumer Food Organizations to Japan's Ministry of Agriculture, Forestry and Fisheries, Food Marketing Bureau, Office of Food Labeling, Oct. 9, 1998. *See also* "The Risks of Genetic Engineering," *St. Louis Post-Dispatch*, Mar. 17, 1999.