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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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ENVIRONMENT

Topic: *U.S. Court Rejects Weakened Standards on "Dolphin Safe" Labeling for Tuna*

Contact: Christopher Fanning, National Marine Fisheries Service, Southwest Region, Sustainable Fisheries Division, 562-980-4030; or J. Allison Routt, NMFS, Southwest Region, Protected Resources Division, 562-980-4020.

On April 11, 2000, the U.S. District Court for the Northern District of California rejected the U.S. Department of Commerce's attempt to weaken standards on "dolphin safe" labeling for tuna.[1] Judge Thelton Henderson held that Commerce Secretary William Daley "acted contrary to the law and abused his discretion when he triggered a change in the dolphin safe label standard."[2]

The decision was hailed by environmental groups and lawmakers who had worked to establish the "dolphin safe" tuna label. David Phillips, Director of the International Marine Mammal Project at Earth Island Institute, one of the environmental groups that filed the suit, called the decision a "tremendous rebuke" of Clinton administration officials "who sold out dolphin protections to accommodate a handful of foreign fishing companies."[3] Senator Barbara Boxer (D-CA), co-author of the law establishing the "dolphin safe" label,[4] said, "This is a victory for those who believe that dolphins deserve to be protected. They have insisted that the 'dolphin safe' label on every can of tuna must represent the highest possible level of protection for these unique and beautiful marine mammals, and they have been vindicated."[5]

The events leading up to this case go back to 1959, when fishermen in the Eastern Tropical Pacific Ocean (ETP), which covers approximately seven million square miles of ocean between the coast of Southern California to South America, began to use mile-long "purse seine" nets to catch yellowfin tuna. For undetermined reasons, schools of tuna in the ETP tend to congregate under schools of dolphins. Thus, tuna fishermen deliberately chased and encircled dolphins in their nets to catch the tuna below. Between 1959 and 1972, millions of dolphins drowned in tuna fishermen's nets.[6]

In 1972, Congress passed the Marine Mammal Protection Act (MMPA),[7] which prohibited U.S. tuna

fishermen from using fishing methods that resulted in dolphin deaths. In 1988, Congress passed amendments to the MMPA banning tuna imports from countries whose fishermen used purse seine nets to catch tuna. Under the MMPA, the National Marine Fisheries Services (NMFS) studied dolphin populations in the ETP and found that three stocks of dolphins - the coastal, northeastern offshore spotted, and eastern spinner - were "depleted" due to purse seine fishing methods.[8] In 1990, Congress passed the Dolphin Protection Consumer Information Act (DPCIA), which created the popular "dolphin safe" label and prevented tuna sold in the U.S. from displaying this label if the tuna was caught with purse seine nets deliberately deployed to encircle dolphins.[9] As a result of this legislation, dolphin deaths in the ETP dropped dramatically - from 423,678 deaths per year in 1972 to 15,550 per year in 1992.[10]

In 1991, Mexico challenged the provisions of the MMPA excluding tuna from the U.S. market if it was caught using purse seine nets in a General Agreement on Tariffs and Trade (GATT) case.[11] In 1994 the European Community (EC) brought a similar GATT challenge.[12] In both cases, the U.S. argued that because dolphin protection is a legitimate environmental objective and the ban was applied to both domestic and foreign fishermen, the MMPA provisions were non-discriminatory and thus GATT-legal. In both cases, the GATT panel ruled that a policy which treats physically-identical goods differently based on their production or processing methods violated GATT rules. The U.S. also argued that a GATT exception allowed the U.S. to maintain the policy, but the GATT panel rejected this argument and held that the MMPA provisions were not "necessary" to protect dolphins.[13]

In contrast to WTO rules, GATT procedures required consensus of all GATT nations to adopt a dispute panel ruling. Given the U.S. and Mexican governments agreed that adoption of a GATT panel ruling against dolphin protections would politically doom the already precarious passage of the North American Free Trade Agreement (NAFTA), the two countries jointly blocked the adoption of the ruling.

However, in 1995, after the U.S. entered the World Trade Organization (WTO), Mexico threatened a WTO enforcement case against the U.S. for refusing to implement the 1991 GATT ruling. Under WTO rules, consensus is required to *stop* implementation of a dispute panel ruling. Consequently, President Clinton promised Mexican President Ernesto Zedillo that weakening the dolphin protection standard was "a top priority for [his] Administration and for [him] personally."[14]

On August 15, 1997, after one failed attempt to implement the GATT ruling and intensified Clinton Administration lobbying, Congress passed the International Dolphin Conservation Program Act (IDCPA),[15] which amended the MMPA to allow tuna imports from countries that permit fishermen to use purse seine nets. The amendment also allowed tuna caught with purse seine nets to be labeled "dolphin safe" if monitors on fishing boats did not actually observe any dolphins killed or seriously injured during the setting of the nets.

The original champions of the DPCIA, joined by the Dolphin Safe Fair Trade Coalition, fought against the weakening of the law. However, their warnings that observers could not possibly monitor all the activities on ships the length of football fields resulted only in the inclusion of a follow-up study as part of the law.

The issue to be studied was whether the use of purse seine nets to chase and ensnare dolphins was causing physiological stress that impeded the rebound of dolphin stocks even if monitors did not observe dolphins being killed or seriously injured during the setting of the nets. Congress ordered the Secretary of Commerce, prior to making any changes in the dolphin safe label, (1) to perform population studies of the depleted dolphin stocks, and (2) to research whether the physiological stress effects of being repeatedly chased and encircled by purse seine nets was adversely affecting depleted dolphin stocks.[16]

Pending this research, Congress mandated that the existing dolphin safe label standards for tuna marketed in the U.S. remain in force. If the Secretary found that the use of purse seine nets on dolphins was causing physiological stress contributing to the depletion of dolphin populations, the existing label standards would remain in force. If, however, the Secretary concluded that there was no such adverse impact, the label standard would change to allow tuna caught with purse seine nets to be labeled "dolphin safe" if no dolphins were observed being killed or seriously injured during a particular net set.[17]

NMFS conducted this research, and on March 25,

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1999, submitted a report to Congress. NMFS found that two of the three depleted dolphin populations (the northeastern offshore spotted and eastern spinner dolphins) were not recovering at the expected rate given the reduced death rates since 1992.[18] In fact, NMFS found that the population of the northeastern offshore spotted dolphin continued to decline from 1991 to 1998, and that the eastern spinner dolphin population had remained the same or declined slightly.[19] NMFS also found that chase and encirclement is a plausible cause of stress in dolphins that could depress population growth. Thus, the NMFS concluded that "the information suggests but by no means conclusively that the fishery has been the source of significant adverse impact on these two [dolphin] populations."[20]

However the Secretary of Commerce determined "that there [was] insufficient evidence that chase and encirclement by the tuna purse seine fishery 'is having a significant adverse impact' on depleted dolphin stocks in the ETP."[21] Consequently, the dolphin safe tuna label regulations were changed on February 2, 2000, to allow tuna caught with purse seine nets to carry the dolphin safe label as long as the monitor on a tuna fishing vessel did not observe dolphins being killed or seriously injured during the netting.[22]

Soon after, the Earth Island Institute, the Humane Society of the U.S., and other organizations and individuals filed a law suit against the Secretary, arguing that the new regulations were not supportable given the underlying legislation. On April 11, 2000, the U.S. District Court held that the Secretary had not conducted sufficient research as mandated by the IDCPA.[23] That Court also found that the stress literature "demonstrated that it was likely that dolphins experience a multitude of harmful stress effects from the chase and capture process, and that it was scientifically plausible that such effects could be causing population level effects."[24] Thus, the Court held that the Secretary's decision to change the dolphin safe label standards "flies in the face of Congress' manifest intent"[25] and set aside the Secretary's finding until the NMFS conducts the Congressionally-mandated stress research studies.

COSMETICS

Topic: *CHIC - The FDA Considers Forming a New Cosmetics Harmonization Body*

Contact: John Bailey, Director of the Office Cosmetics and Colors, CFSAN, FDA, 200 C St., SW (HFS-100), Washington, DC 20204; Tel: 202-205-4530; E-mail: jbailey@bangate.fda.gov.

The Food and Drug Administration (FDA) is pursuing a plan to set up a new international harmonization institution for cosmetics which it has tentatively named CHIC (Cosmetic Harmonization and International Cooperation). According to the record of the first meeting to discuss CHIC, regulators on both sides of the Atlantic want to form CHIC, in part, to keep cosmetics harmonization out of the International Organization for Standardization (ISO), a solely private sector international standard-setting institution.[26]

The FDA is contemplating entering into a "Memorandum of Cooperation" with Japan, Canada, and the European Union (EU) on the goals and priorities for CHIC. According to the memorandum, the purpose of CHIC is to facilitate:

- the exchange of information about regulatory systems, including legislation, regulations, proposed amendments, guidelines, enforcement decisions and recalls;
- the exchange of information at the earliest feasible stages of investigations into the safety of products; communication on the chemical and microbiological safety of cosmetics;
- and communication on the development of research and monitoring protocols and projects.

This cooperation is intended to result in the harmonization of regulatory requirements between the nations, a common approach in determining compliance with these harmonized requirements, and increased efforts to achieve a common position with other international organizations.[27]

CHIC had its initial meeting in Brussels in April of 1999. Regulators from both sides of the Atlantic met for two days to discuss issues including basic safety substantiation, the exchange of data and scientific reviews, the development of a rapid alert system, sun screens and ultra violet filters (more below on sun screens), labeling requirements and the new EU directive on animal testing.[28]

After two days of meetings between the regulators, the door was opened to industry participation. On the invitation list was the U.S.-based Cosmetics Toiletry and Fragrance Association (CTFA), which is comprised of large domestic and multinational companies such as Proctor and Gambel, Almay, Elizabeth Arden, Clinique, and Colgate. Also present were representatives from the European Cosmetic, Toiletry and Perfumery Association (COLIPA), which includes companies like Gillette, L'Oreal, Avon, L'Ancome,

and Johnson & Johnson of Germany.

The record of the April 1999 meeting includes a discussion between regulators and industry about the need to include consumers and consumer representatives in the discussion. U.S. federal regulators asked industry representatives if they were including consumers in industry discussions of harmonization initiatives. The industry representatives responded by saying that this responsibility rested with the regulators. The conversation was concluded with the assurance that "the needs of consumers were amongst the highest priority of all parties."[29] Despite this, no consumer representatives were present at the April meeting.

Not surprisingly, given the absence of consumer representatives, the tentative agenda for CHIC reflects industry demands. Industry has a variety of plans for new harmonization proposals. For example, the cosmetic industry wants to replace the U.S. common-language labeling system for certain cosmetic ingredients, now required by the Fair Packaging and Labeling Act, with a new EU system for labeling in Latin. If this proposal were adopted, instead of reading "peach" as the key ingredient in a cosmetic, consumers, many of whom may suffer from serious allergies, would read the Latin "*persicum.*"

U.S. industry also wants to adopt the EU definition of "cosmetic." The primary goal of this proposal is to switch some products the U.S. regulates as drugs into the less-regulated EU "cosmetics" category, with sun screens being a top target. Sun screens are regulated as an OTC (over-the-counter drug) in the U.S., but as cosmetics in the EU which does not have a similar over-the-counter category.[30] U.S. companies also want to adopt the EU system of color additives. The EU has approved a longer list of additives, including many color additives banned in the U.S.

To date, no information about this nascent harmonization effort has been posted in the *Federal Register*. The next meeting of CHIC was scheduled for May 8-10, 2000 in Washington, D.C. The draft agenda for the meeting included open and closed portions and discussion topics included animal testing, ingredient nomenclature, color additives, sun screens, over-the-counter drug labeling requirements in the U.S., cosmetic product/ingredient safety substantiation guidelines, fragrance allergens in the EU, alert systems and future scientific administrative collaboration.[31]

U.S. regulations concerning OTC drugs and pre-market approval for color additives provide a higher level of consumer protection than similar regulations in other nations. However, in other areas, the EU has more rigorous regulations. EU member states now keep company dossiers containing a large amount of information about the safety and efficacy of each cosmetic product, and require labeling which includes expiration dates, function of the ingredients, precautions, and batch numbers.

It appears that cosmetic companies on both sides of the Atlantic are seeking to have the least restrictive standards between the nations become the internationally-harmonized CHIC standards. Whether or not interested consumers will be able to turn the conversation around to push for the upward harmonization of cosmetics regulations worldwide remains to be seen.

FOOD SAFETY

Topic: *U.S. Codex Committee on General Principles Meeting: Precautionary Principle*

Contact: Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Ave., SW, Washington, DC 20250-3700; Tel: 202-205-7760; Fax: 202-720-3157.

On March 22, 2000, the U.S. Delegation to the Codex Committee on General Principles (CCGP) held a public meeting to discuss the Precautionary Principle and the use of precaution in the U.S. food safety system in preparation for the April 10-14, 2000 meeting of the full CCGP in Paris. The CCGP sets the general rules and policies followed by each Codex Committee, and it is here that the most politically-charged issues, such as the Precautionary Principle, are considered. The Codex Alimentarius Commission is the international standard-setting body empowered by the World Trade Organization (WTO) to set presumptively WTO-legal food safety standards.

The Precautionary Principle encourages regulators to err on the side of safety when faced with uncertain scientific evidence or great potential risks to public health or safety. This principle has been undercut in recent WTO dispute panel rulings, such as the U.S. case against the European Union (EU) ban on the sale of meat from animals given artificial growth hormones.

At the March meeting, U.S. government officials first discussed the European Commission's (EC) White Paper on the Precautionary Principle.[32] In the White Paper, the EC establishes its approach to using the Precautionary Principle and guidelines for applying it.

The use of the Precautionary Principle is a highly controversial issue between the U.S. and the EC. The EC favors explicitly adding the Precautionary Principle to Codex rules. The U.S. argues that countries will use the Principle to restrict food imports based on non-scientific factors, and the U.S. prefers a "precautionary approach," which U.S. officials claim is already built into both U.S. and Codex risk assessment procedures.

This disagreement is heating up in the context of the continuing U.S.-EC fight over genetically-modified (GM) foods. European consumers have largely rejected GM foods because of their unknown effects on human health and the environment. Thus, EC regulators have relied on the Precautionary Principle to halt approvals of such seeds in the EU and sales - including of imports - of GM foods. Since the U.S. is the leading producer of GM foods, U.S. officials have protested these restrictions, claiming they are based solely on political factors.

The EC White Paper begins by defining the Principle: "Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty."[33] The Paper continues: "Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an 'acceptable' level of risk for society is an eminently *political* responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. There, all these factors have to be taken into consideration."[34]

Then the Paper sets guidelines for invoking the Precautionary Principle. It states that laws and regulations based on the Precautionary Principle should be:

- *proportional* to the chosen level of protection;
- *non-discriminatory* in their application;
- *consistent* with similar measures already taken;
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis);
- *subject to review*, in the light of new scientific data; and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.[35]

The White Paper goes to great length to explain the EC's policy with regard to invoking the Precautionary Principle. However, at the March 22 meeting, the U.S. released a Conference Room Document outlining twenty-seven "Points of Concern" with the EC White Paper.[36] A Conference Room Document is a paper that outlines U.S. policy on a specific issue. Such papers are prepared by U.S. government officials for use in international bodies such as Codex. Following is a brief summary of some of the concerns listed in the U.S. Conference Room Document.

First, the U.S. claims that the White Paper does not sufficiently define the Precautionary Principle. Second, the U.S. complains that applying one Precautionary Principle to a broad range of areas - including food safety, environment, and human, animal, and plant health - will be difficult. Third, the U.S. finds fault with the White Paper's statement that the decision to exercise precaution in the face of uncertain risk is a "political decision." The U.S. believes this decision should be based on science. Despite the Paper's avowal to "avoid unwarranted recourse to the precautionary principle as a disguised form of protectionism,"[37] the U.S. government stated that the EC may use the Precautionary Principle to make arbitrary decisions on food and product safety regulations.

The second item on the meeting's agenda was a discussion of the U.S. paper describing the U.S. food safety system and the use of precaution in U.S. risk analysis.[38] In fact, the paper contains a 55-page annex entitled "Precaution in U.S. Food Safety Decisionmaking." It gives several examples in which U.S. regulators have employed a precautionary "approach" in controlling certain risks. For example, the U.S. prohibits the feeding of certain animal proteins to ruminants to prevent the introduction of bovine spongiform encephalopathy (BSE) into the U.S. Another example of the U.S. precautionary approach is the pre-market approval procedure for food additives, animal drugs, and pesticides. These products are not allowed on the U.S. market until producers prove them to be safe.[39]

Discussions of the Precautionary Principle and the U.S. precautionary approach are taking place in venues other than the Codex and WTO. For example, the U.S. paper describing the U.S. food safety system was developed for the Organization for Economic Cooperation and Development's (OECD) Ad Hoc Working Group on Food Safety. The OECD also has a Working Group on the Harmonization of Regulatory Oversight in Biotechnology and a Task Force on Novel Foods and Feed developing reports on precaution. In addition, a Conference on Biotechnology in Edinburgh, Scotland, is working on a report on precaution.

Finally, at the meeting, several groups, including the Institute for Agriculture and Trade Policy (IATP), Sierra Club, and Public Citizen, released a letter to Tom Billy, Administrator of the Food Safety and Inspection Service and Chair of the Codex Alimentarius Commission.[40] The letter, signed by over 200 organizations and individuals worldwide, directed Mr. Billy's attention to several mis-characterizations of the Cartagena Biosafety Protocol,[41] which was signed on January 29, 2000, by representatives from 131 nations and is contained in a Codex document[42] which the U.S. helped to prepare.

For example, the Codex document states that the

Biosafety Protocol is based on a "precautionary approach." However, the Protocol negotiations specifically rejected that formulation. The substantive text of the Protocol (in Articles 10.6 and 11.8) explicitly operationalizes the Precautionary Principle. The Codex document also states, "Risk assessments shall be carried out in a scientifically sound manner taking into account risks to human health." However the Codex document excludes the language in the Protocol by allowing countries to consider socio-economic effects in decision-making.

After all of this hair-splitting over the definition of the Precautionary Principle, the U.S. reportedly supported language that introduces the Precautionary Principle into a Codex agreement at the April 10-14, 2000 meeting of the full CCGP in Paris.[43] The agreed-upon language states that "when relevant scientific evidence is insufficient to objectively and robustly assess risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on human health may occur, the nature and extent of which are difficult to evaluate, precautionary measures may be taken by risk managers in the interim to apply precaution to protect the health of consumers without awaiting additional scientific data and a full risk assessment. . . ."[44]

A footnote to this text states that some countries refer to this concept as the "Precautionary Principle." Industry groups vigorously objected to this footnote, claiming it would enshrine the text as a definition of the Precautionary Principle.[45] Industry groups are concerned that if Codex adopts this language, it could be used in a WTO dispute to interpret the WTO's Sanitary and Phytosanitary Agreement's rules requiring countries to base their food safety standards on "sound science."[46]

However, Catherine Woteki, head of the U.S. Codex delegation, stated, "The United States has not endorsed the 'Precautionary Principle' in any way."[47] Woteki continued, "There are countries that use what they call the 'Precautionary Principle' domestically, and it is in the interest of the United States to ensure that is only used in clearly defined, limited instances."[48]

Nevertheless, both industry officials and allied Members of Congress criticized the U.S. government's performance at the meeting. For instance, on April 19, 2000, Senator John Ashcroft (R-MO) wrote a letter to Secretary of State Madeleine Albright, Secretary of Commerce William Daley, Secretary of Agriculture Dan Glickman, and U.S. Trade Representative Charlene Barshefsky accusing them of failing to defend U.S. industry interests by allowing the Precautionary Principle to be introduced into a Codex agreement.[49]

The controversial language is set to be considered by the CCGP at a later date. Meanwhile, the CCGP established a group, which, unfortunately, is closed to the public, to discuss the issue via e-mail.

FEDERAL REGISTER ALERTS

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Topic: *VICH Final Guidance on Stability Testing for Medicated Premixes*

Action: Notice of availability

Venue: Food and Drug Administration

FR Cite: 65 *Federal Register* 13785 (March 14, 2000)

Deadline: Written comments may be submitted at any time

Contact: For more information on VICH, Sharon R. Thompson, Center for Veterinary Medicine (HFV-3), FDA, Tel: 301-594-1798; or Robert C. Livingston, Tel: 301-594-5903. For information on the guidance, William G. Marnane, Tel: 301-827-6966. Copies of the guidance are available at www.fda.gov/cvm/fda/mappgs/vich.html. Submit comments to the Policy and Regulations Team (HFV-6), CVM, FDA, 7500 Standish Pl., Rockville, MD 20855.

The Food and Drug Administration (FDA) released a final guidance for industry entitled "Stability Testing for Medicated Premixes." The guidance is an annex to a related guidance entitled "Stability Testing of New Veterinary Drug

Substances and Medicinal Products." The annex addresses the recommendations for stability testing of veterinary medicinal Type A medicated articles (referred to as "medicated premix drug products") intended for submission for approval to the European Union (EU), U.S., and Japan.

The guidance was developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH meetings are held under the auspices of the Office International des Epizooties (OIE). The VICH develops harmonized technical requirements for the approval of veterinary pharmaceutical products in the EU, U.S., and Japan. It includes input from regulatory and industry, but not consumer representatives.

The OIE, headquartered in Paris, France, is an intergovernmental organization that bills itself as the "World Organization for Animal Health." It was created January 25, 1924, and currently comprises 155 member nations. Its missions include the harmonization of regulations governing trade in animals and animal products among its member nations. The OIE has several working groups and commissions, including one on biotechnology and one on international animal health code standards. OIE Delegates are drawn from government agencies that regulate animal health. The OIE has "permanent working relations" with over 20 other international organizations, including the World Trade Organization.[50]

The guidance addresses the generation of acceptable stability information for submission in new animal drug applications for Type A medicated articles containing new molecular entities. It will be implemented in May, 2000.

According to the FDA, the guidance represents the FDA's current thinking on acceptable stability testing of Type A medicated articles. It does not create or confer any rights for or on any person and will not operate to bind the FDA or the public.

Topic: *EPA's Process for Public Participation in Pesticide Tolerance Reassessments*

Action: Notice

Venue: Environmental Protection Agency

FR Cite: 65 *Federal Register* 14200 (March 15, 2000)

Deadline: Comments must be received by April 14, 2000

Contact: Karen Angulo, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, EPA; Tel: 703-308-8004; E-mail: angulo.karen@epa.gov. Submit comments, with docket control number OPP-00645 identified on the first page, to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), OPP, EPA, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460.

The Environmental Protection Agency (EPA) is proposing a public participation process for pesticide tolerance reassessment and re-registration. This proposal is in response to a joint initiative with the U.S. Department of Agriculture (USDA) to increase transparency and stakeholder involvement in the development of pesticide risk assessments and risk management documents and decisions. Since 1998, EPA has been using a Pilot Public Participation Process for tolerance reassessment and re-registration which was developed in consultation with the Tolerance Reassessment Advisory Committee (TRAC). EPA is requesting public comment on this process and will consider any comments before adopting it or some other process as the final process used for tolerance reassessment and re-registration of all pesticides.

The EPA's procedure for involving the public in tolerance reassessment and re-registration is of interest to anyone interested in pesticide harmonization issues in the EPA. The EPA is currently involved in the harmonization of pesticide standards in two venues. The NAFTA Technical Working Group on Pesticides is charged with creating a process for establishing North American Maximum Residue Limits (MRLs) or tolerances for pesticide residues on foods. It was also recently announced that the EPA will soon be working with the EU on creating harmonized standards for the testing of new pesticides.[51]

The Pilot Public Participation Process EPA has been using for organophosphate pesticides consists of six phases:

Phase 1 - Registrant "Error Only" Review (takes 30 days): EPA sends its preliminary human health and ecological risk assessments to the registrant of the pesticide and the USDA for a 30-day error correction review. EPA asks the registrant and the USDA to identify any computational or other errors that EPA has made in developing its preliminary assessment of the pesticide's risks.

Phase 2 - EPA Considers Registrant's Error Comments (up to 30 days): EPA summarizes and considers comments from the registrant and the USDA. EPA incorporates their comments or makes changes in the preliminary risk assessments to correct any errors identified.

By the end of this phase, EPA opens a public docket for the pesticide.

Phase 3 - Public Comment on Preliminary Risk Assessments (60 days): EPA publishes a *Federal Register* Notice of Availability announcing its preliminary risk assessments and opening a 60-day public review and comment period. Registrants, grower groups, other stakeholders, and the public are encouraged to submit data and other information to refine EPA's preliminary risk assessments. They also may begin submitting risk management proposals to address any risk concerns identified in the docket. EPA may meet with registrants and other stakeholders to discuss risk related data, use information, and risk assessment/risk management alternatives.

Phase 4 - EPA Revises Risk Assessments (up to 90 days): EPA summarizes and considers comments, data, and risk mitigation proposals during Phase 3. EPA develops the revised risk assessments and sends them to USDA for review. EPA and USDA may host public meetings to share the revised risk assessments with interested stakeholders and discuss risk management ideas.

Phase 5 - EPA Solicits Risk Management Ideas (60 days): EPA releases the revised risk assessments to the public. EPA publishes a *Federal Register* Notice of Availability opening a 60-day public consultation period during which risk management proposals are solicited. Registrants, grower groups, other stakeholders, and the public are encouraged to participate and submit their risk management proposals. EPA and USDA may meet with stakeholders to discuss risk management alternatives and strategies. Meeting minutes will be included in the public docket.

Phase 6 - EPA Develops Risk Management Strategies (up to 60 days): EPA considers all risk management proposals received. With input from USDA, EPA develops risk management strategies that ultimately will contribute to EPA's risk management decisions for this and other pesticides.

It is at Phase 6 that EPA is required to consider Codex tolerances. The Food Quality Protection Act (FQPA) of 1996 requires EPA to consider Codex tolerances. If EPA decides not to adopt a Codex tolerance, the agency must publish in the *Federal Register* a written explanation detailing its reasons for not adopting the Codex tolerance and allowing the public to comment on this decision.[52]

EPA reports that to date this public participation process has been a success. It has provided EPA and USDA a "great deal of information for use in refining the risk assessments and in developing risk management options." In addition, "[s]takeholder participation has risen substantially." In fact, according to EPA, "[c]omments received during the public comment period on the preliminary risk assessments (Phase 3) substantially affected approximately one-third of the organophosphate preliminary risk assessments."

EPA's new proposed public participation process consists of the same six phases, but also enhances public participation at stages. For example, EPA is proposing a "Pre-Phase 1 - Public Engagement" step in which EPA, in conjunction with USDA and the Food and Drug Administration (FDA), would organize meetings with stakeholders to discuss pesticide use and usage, and inform the public in advance about pesticides that are scheduled for the public participation process.

Until the notice and comment period for the new public participation process is complete and the new process is finalized, EPA will continue to use the Pilot Public Participation Process when reviewing pesticides.

Topic: *USTR Seeks Comment on U.S. Objectives for Agriculture and Services at WTO*

Action: Notice and request for comments

Venue: U.S. Trade Representative, Trade Policy Staff Committee

FR Cite: 65 *Federal Register* 16450 (March 28, 2000)

Deadline: Comments are due by noon, May 12, 2000

Contact: For agriculture, Steve Neff, Office of Agricultural Affairs, 202-395-6127; for services, Peter Collins, Office of Services, Investment and Intellectual Property, 202-395-7271; for non-agricultural market access, Barbara Chattin, Office of WTO and Multilateral Affairs 202-395-5097; for procedural questions, Gloria Blue, Trade Policy Staff Committee, 202-395-3475. Submit 20 copies of written comments to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the U.S. Trade Representative, Room 122, 600 17th St., NW, Washington, DC 20508.

The Trade Policy Staff Committee (TPSC) of the Office of the United States Trade Representative (USTR) is

requesting public comments on general U.S. negotiating objectives as well as country and item-specific export priorities for agriculture and services. The TPSC also seeks comment on country-specific export priorities for tariffs and non-tariff measures for non-agricultural products. The Executive Branch will consider comments when formulating U.S. positions and objectives for U.S. participation in the mandated WTO negotiations on agriculture and services, and on market access for non-agricultural products should WTO Members agree to launch negotiations in this area. The TPSC is a federal interagency group, composed of 17 federal agencies and offices but administered and chaired by the USTR, which develops and coordinates U.S. Government positions on international trade and trade-related investment.

The WTO Agreement on Agriculture (AOA) and the General Agreement on Trade in Services (GATS), agreed to as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) that concluded in 1993, include a built-in agenda of further negotiations on agriculture and services to begin in the year 2000. After the events surrounding the Seattle WTO Ministerial, those negotiations have gotten off to a slow start.

For agriculture, topics on which input on negotiating objectives are requested include reforms in market access, domestic support (i.e. subsidies), export competition, and biotechnology. For services, topics include removal or reduction of barriers to U.S. services exports under existing GATS rules, establishment of new rules to ensure market access, and clarification of sectoral definitions in the GATS. Service sectors under consideration in the negotiations include: business services (e.g. accounting, advertising, and medical), communication, construction and engineering, distribution, educational, environmental, energy, financial (e.g. banking and insurance), health-related, tourism, recreational, and transport.

Comments should clearly state the objectives and provide detailed information supporting them. Submissions should indicate the general topic (i.e. agriculture, services, or non-agricultural products).

Topic: *FAA Assigns Harmonization Tasks to Aviation Rulemaking Advisory Committee*
Action: Notice of new task assignments
Venue: Federal Aviation Administration
FR Cite: 65 *Federal Register* 17936 (April 5, 2000)
Contact: Mark Schilling, Rotorcraft Standards Staff (ASW-119), FAA, 2601 Meacham Blvd., Fort Worth TX 76137-4298; Tel: 817-222-5110; Fax: 817-222-5961; E-mail: Mark.R.Schilling@faa.gov

The Federal Aviation Administration (FAA) has assigned two new tasks to the Aviation Rulemaking Advisory Committee (ARAC). FAA established ARAC to provide advice and recommendations to the FAA Administrator on FAA's rulemaking activities with respect to aviation-related issues, including advice on the FAA's commitment to harmonize U.S. aviation regulations and practices with its European and Canadian trading partners.

FAA has asked ARAC to provide advice and recommendations on the following harmonization tasks: (1) Damage Tolerance and Fatigue Evaluation of Metallic Rotorcraft Structure, and (2) Damage Tolerance and Fatigue Evaluation of Composite Rotorcraft Structure. These two tasks are highly technical, and *Harmonization Alert* directs interested readers to the full Federal Register notice, cited above, for full information on the tasks' scope and specifics.

Topic: *Downward Harmonization of EPA Pesticide Tolerances*
Action: Notice
Venue: Environmental Protection Agency (EPA)
FR Cite: 65 *Federal Register* 18328 (April 7, 2000)
Deadline: Comments must be received by May 8, 2000

Contact: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460; Tel: 703-308-9423; E-mail harris.thomas@epa.gov. Submit comments (Docket No. PF-930) to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460.

After receiving a petition from Novartis Crop Protection, Inc., the Environmental Protection Agency (EPA) is proposing to amend its tolerances for the pesticide "abamectin" (or "avermectin") to harmonize them with Codex tolerances. EPA originally set avermectin tolerances for tomatoes and bell peppers at .01 parts per million (ppm) and for head lettuce and celery at .05 ppm.[53] However, on September 7, 1999, EPA doubled its avermectin tolerance for all peppers to .02 ppm in order to harmonize with the Codex tolerance.[54] Now, based on information submitted by Novartis, EPA is proposing to lump tomatoes, peppers, and other "fruiting" vegetables into one category with a tolerance of .02 ppm, and head lettuce, celery, and other "leafy" vegetables into one category with a tolerance of .10 ppm. This will effectively double EPA's current tolerances for tomatoes, head lettuce, and celery.

Topic: *USTR and Department of Commerce Seek Public Comment on Procedures for Obtaining Trade Policy Advice from Non-governmental Organizations*

Action: Request for public comment

Venue: Office of the U.S. Trade Representative and Department of Commerce

FR Cite: 65 *Federal Register* 19423 (April 11, 2000)

Deadline: Written comments are due by July 10, 2000

Contact: For more information, Pate Felts, Assistant USTR for Intergovernmental Affairs and Public Liaison, 202-395-6120; or Patrick Morris, Director of the Office of Export Promotion Coordination, Department of Commerce , 202-482-4501. Submit 20 typed copies of comments to Gloria Blue, Office of the U.S. Trade Representative, Room 122, 600 17th St., NW, Washington, DC 20508.

The U.S. Trade Representative (USTR) and the Department of Commerce have announced a joint initiative which, they say, is targeted toward enhancing opportunities for non-governmental organizations (NGOs) to provide their views to the Clinton administration on key trade issues. As part of the initiative, USTR and Commerce request public comment and suggestions on ways to strengthen channels of communication between NGOs and the administration on trade policy issues.

Congress and the administration have established a variety of advisory committees from which the Executive Branch obtains advice on trade policy issues. U.S. law establishes a three-tier trade policy advisory committee system: one committee addresses overall policy advice, others provide advice on more specific policy issues, and others cover sectoral, technical, or functional issues.[55]

The Administration is seeking trade policy advice from environmental, labor, consumer, and other groups through three advisory committees: the Advisory Committee for Trade Policy and Negotiations (ACTPN), Trade and Environment Policy Advisory Committee (TEPAC), and Labor Advisory Committee (LAC). The ACTPN provides the President and USTR with broad advice on trade issues and is comprised of chief executive officers of agriculture, consumer, environment, industry, and labor groups. The TEPAC addresses trade and environment issues and is made up of representatives of agriculture, consumer, environmental, industry, and labor groups, and non-federal governments. The LAC provides advice on labor and trade issues and is composed of labor union representatives.

The ACTPN has been the subject of controversy. On February 24, 2000, the only three labor representatives on ACTPN - John J. Sweeney, president of the AFL-CIO; Jay Mazur, president of UNITE; and Lenore Miller, head of the Retail, Wholesale, and Department Store Union - resigned from the ACTPN in protest. ACTPN's chair had decreed that the committee would limit its focus to the issue of granting China permanent normal trade relations (PNTR), a proposal American unions vehemently oppose.

Labor, consumer, and environmental groups are taking the Clinton Administration's new "initiative" with a grain of salt. On November 9, 1999, a federal district judge

ordered the USTR to include at least one environmentalist on each of two committees that advise the Clinton administration on timber-trade policy.[56] Previously the membership of the paper and wood products committee was limited to representatives of the timber industry. Environmentalists hailed this ruling as a major victory. However, the Clinton administration is appealing the decision. In fact, during the same week President Clinton gave a major policy speech on opening the trade policy-making process to new NGO "voices," the Administration announced it would appeal this decision.

Topic: *ICH Guidance on Clinical Investigation of Medicinal Products in Pediatrics*

Action: Notice of availability

Venue: Food and Drug Administration

FR Cite: 65 *Federal Register* 19777 (April 12, 2000)

Deadline: Written comments are due by May 30, 2000

Contact: For more information on the guidance, M. Dianne Murphy, Center for Drug Evaluation and Research (HFD-2), FDA, 5600 Fishers Lane, Rockville, MD 20857. For more information on the ICH, Janet J. Showalter, Office of Health Affairs (HFY-20), FDA, 301-827-0864. Submit comments to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch, 301-827-4573, or at www.fda.gov/cder/guidance/index.htm.

The Food and Drug Administration (FDA) is publishing a draft guidance entitled "E11: Clinical Investigation of Medicinal Products in the Pediatric Population," prepared by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance sets forth critical issues in pediatric drug development and approaches to the safe, efficient, and ethical study of medicinal products in the pediatric population. The draft guidance is intended to encourage and facilitate the timely development of pediatric medicinal products internationally.

The ICH was created by industry and regulatory authorities in the U.S., European Union, and Japan to harmonize technical requirements for the production and registration of pharmaceuticals among the U.S., EU, and Japan. The six ICH sponsors are the European Commission, Japanese Ministry of Health and Welfare, U.S. Centers for Drug and Biologics Evaluation and Research, European Federation of Pharmaceutical Industries Association, Japanese Pharmaceutical Manufacturers Association, and Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of ICH documents, is provided by the International Federation of Pharmaceutical Manufacturers Association (IFPMA). The ICH Steering Committee includes representatives from each of the six ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Canadian Therapeutics Products Programme, and European Free Trade Area. There are no representatives from consumer organizations.

In fact, consumer and public health groups have no formal role in the ICH. They cannot sit on the ICH Steering Committee and are rarely given an opportunity to address the full ICH at its annual meeting or individual ICH committees working on standards.

The draft guidance addresses the following clinical study issues: (1) considerations when initiating a pediatric program for a medicinal product; (2) timing of initiation of pediatric studies during medicinal product development; (3) types of studies; (4) age categories for studies; and (5) ethics of pediatric clinical investigation. The FDA states, "This draft guidance represents the agency's current thinking on clinical investigation of medicinal products in the pediatric population. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public."

Topic: *Membership on the National Advisory Committee on Meat and Poultry Inspection*

Action: Notice of solicitation for nominations

Venue: Food Safety and Inspection Service

FR Cite: 65 *Federal Register* 20129 (April 14, 2000)

Deadline: Nomination packages must be postmarked by June 30, 2000

Contact: For more information, Michael Micchelli, Evaluation and Analysis Division, FSIS, Rm. 3833, South Agriculture Bldg., 1400 Independence Ave., SW, Washington, DC 20250-3700; Tel: 202-720-6269; Fax: 202-690-1030; E-mail: michael.micchelli@usda.gov. Send nominations to Margaret Glavin, Associate Administrator, FSIS, USDA, Rm. 331-E, Whitten Bldg., 1400 Independence Ave., SW, Washington, DC 20250-3700.

The U.S. Department of Agriculture (USDA) is soliciting nominations for membership on the National Advisory Committee on Meat and Poultry Inspection (NACMPI). The NACMPI provides advice and recommendations to the Secretary of Agriculture on the USDA's meat and poultry inspection programs. The NACMPI has three subcommittees - on Inspection Methods; Intergovernmental Roles; and Hazard Analysis and Critical Control Points (HACCP) Systems - that consider specific issues and make recommendations to the full Committee. The full Committee then makes recommendations to the Secretary of Agriculture.

The USDA's HACCP model shifts to industry employees many of the responsibilities traditionally undertaken by government inspectors. HACCP also focuses on the areas of the meat or poultry plant where the plant's management believes meat and poultry are most likely to become contaminated rather than inspection of each individual meat or poultry carcass. The USDA is exporting its HACCP model to other nations through WTO-mandated equivalence determinations. The NACMPI is one avenue for consumers to have a voice in USDA policy.

The Secretary of Agriculture makes appointments to the NACMPI. Nominees initially will serve two-year terms, but no member may serve for more than three consecutive terms. The NACMPI's duties are solely advisory. Members meet annually, and the USDA reimburses them for travel expenses.

The nomination package should include the following information: (1) a brief summary of no more than two pages explaining the nominee's suitability to serve on the NACMPI, and (2) a resume or *curriculum vitae*.

The current members of NACMPI are: Magdi Abadir, Cuisine Solutions; Terry Burkhardt, Wisconsin Bureau of Meat Safety and Inspection; Dr. James Denton, University of Arkansas; Caroline Smith-DeWaal, Center for Science in the Public Interest; Nancy Donley, Safe Tables Our Priority; Carol Tucker Foreman, Consumer Federation of America; Dr. Cheryl Hall, Zacky Farms, Inc.; Kathleen Hanigan, Farmland Foods; Dr. Lee C. Jan, Texas Department of Health; Alice Johnson, National Turkey Federation; Dr. Collette Schultz Kaster, Premium Standard Farms; Dr. Daniel E. LaFontaine, South Carolina Meat-Poultry Inspection Department; Michael Mamminga, Iowa Department of Agriculture; Dr. Dale Morse, New York Office of Public Health; Rosemary Mucklow, National Meat Association; Donna Richardson, Howard University Cancer Center; and Gary Weber, National Cattlemen's Beef Association.

Topic: *EPA's Procedural Regulations for Pesticide Registration Review*

Action: Advanced Notice of Proposed Rulemaking

Venue: Environmental Protection Agency (EPA)

FR Cite: 65 *Federal Register* 24586 (April 26, 2000)

Deadline: Comments must be received by June 26, 2000

Contact: Vivian Prunier, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460; Tel: 703-308-9341; E-mail: prunier.vivian@epa.gov; Fax: 703-305-5884. Submit comments to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460.

The Environmental Protection Agency (EPA) is proposing to establish procedural regulations for conducting reviews of pesticide registrations in order to comply with the Food Quality Protection Act of 1996, which mandates such periodic reviews. EPA is proposing to review pesticide registrations every 15 years.

EPA plans to: (1) review first those pesticides which EPA believes will produce the greatest human health and environmental benefits; (2) establish methods for ensuring it has all necessary data to make regulatory decisions; (3) standardize data submission by adopting guidance for data submitters, such as the guidance developed by the Organization for Economic Cooperation and Development (OECD); (4) review related pesticides simultaneously; (5)

tailor the level and nature of the review to the specific facts and concerns of each case; (6) build on the results of prior review efforts; (7) adopt or use state and foreign governments' reviews of pesticide studies, including through the North American Free Trade Agreement (NAFTA) and OECD; (8) standardize its approach to documenting data reviews by adapting OECD guidelines; and (9) seek stakeholder views and input through an open process.

With several of these plans, specifically numbers (3), (6), (7), and (8), EPA appears to be harmonizing its procedures with international procedures and attempting to use studies done by foreign governments rather than relying on its own studies. This has implications for the U.S. democratic rulemaking process because consumer and environmental groups are not represented at the OECD or under NAFTA and have no opportunity to comment on procedural proposals or pesticide studies published under their auspices.

The OECD, for example, is comprised of the 29 richest nations. Ambassadors and ministers from these nations' governments regularly meet - with little consumer or environmental representation - to harmonize laws and regulations governing myriad issues, including biotechnology, electronic commerce, food safety, taxation, transportation, health, and the environment.

MEETINGS/EVENTS

Event: *Meeting on HACCP-Based Inspection Models Project (HIMP)*

Date: March 30, 2000, 9 a.m.-3 p.m.

Location: Holiday Inn Rosslyn at Key Bridge, 1900 North Fort Myer Dr., Arlington, VA 22209, 703-807-2000

FR Cite: 65 *Federal Register* 14939 (March 20, 2000)

Contact: Ron Niemeyer, FSIS Planning Staff, Tel: 202-501-7247; Fax: 202-501-7642; E-mail: ron.niemeyer@usda.gov.

The Food Safety and Inspection Service (FSIS) held a public meeting to discuss its Hazard Analysis and Critical Control Points (HACCP) based Inspection Models Project (HIMP) for slaughter plants. The purpose of the meeting was to present new inspection procedures and performance standards that the FSIS is developing through the project for plants that slaughter young chickens. The FSIS also described the rulemaking process it intends to follow to implement these new inspection procedures and performance standards for all young chicken slaughter plants under federal inspection, should the data developed in the project support such an action.

HACCP is a regulatory model that turns over a large number of duties from federal inspectors to industry employees. HIMP continues in HACCP's path and turns over the ante and post mortem examination of animals for disease and contamination from federal inspectors to company employees.

Recently, a HIMP pilot-project at the Gold Kist Plant in Guntersville, Alabama came under scrutiny when federal inspectors reported to the press that diseased chicken "was moving unhindered down the processing line" where it was eventually turned into chicken nuggets or other processed chicken products sold for school lunch programs.[57] Inspectors estimated that the amount of diseased product leaving the plant had increased 50 percent due to the pilot-project.

"Before the USDA extends the HIMP model to all plants nation-wide they need to ensure any new inspection techniques adopted by FSIS are effective in guaranteeing that plants are living up to their responsibility to produce clean, safe and wholesome product," said Felicia Nestor of the Government Accountability Project.

FSIS designed HIMP to help define the respective responsibilities of FSIS and the regulated industry in slaughter establishments operating under HACCP systems and to develop new approaches to inspection in plants slaughtering young, healthy, and uniform animals. HACCP requires slaughter establishments to designate the points in their establishments where microbiological contamination (e.g. from salmonella, *E. coli*) is most likely to occur and develop a plan to prevent such contamination. It also shifts FSIS's inspection procedures from sensory to scientific testing. FSIS inspectors test samples of raw meat and poultry for microbiological contamination, and slaughter establishments are required to meet performance standards for certain contaminants.

At the meeting, FSIS presented performance standards for food safety and non-food safety concerns in HIMP young chicken plants. The standards were drawn from the baseline data collection results and will provide the terms by which HIMP young chicken plants will be measured. FSIS

is designing new inspection procedures to verify that establishments are meeting these standards.

Event: *Public Meeting of the National Advisory Committee for the North American Agreement on Labor Cooperation*

Date: April 20, 2000, 1-3 p.m.

Location: U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, Conference Room B at C-5515

FR Cite: 65 *Federal Register* 17311 (March 31, 2000)

Contact: Lewis Karesh, U.S. National Administrative Office, Bureau of International Labor Affairs, Department of Labor, 200 Constitution Ave., NW, Room C-4327, Washington, DC 20210, 202-501-6653.

The U.S. National Administrative Office (NAO) held a public meeting of the National Advisory Committee for the North American Agreement on Labor Cooperation (NAALC). The Committee was established to provide advice to the U.S. Department of Labor on issues pertaining to the implementation and further elaboration of the NAALC, the labor side agreement to the North American Free Trade Agreement (NAFTA). The Committee is comprised of twelve representatives drawn from labor organizations, business and industry, educational institutions, and the general public.

The NAALC requires each NAFTA country to establish a NAO at the federal government level. The NAO serves as a U.S. point of contact with respect to the NAALC, provides information about U.S. labor law matters, and receives and reviews submissions from the public regarding labor law matters in Mexico and Canada.[58]

Event: *Public Meeting of the U.S. Codex Committee on Food Labeling*

Date: April 17, 2000, 1-4 p.m.

Location: Room 1409, Federal Office Building 8, 200 C St., SW, Washington, DC

FR Cite: 65 *Federal Register* 17623 (April 4, 2000)

Contact: Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue, SW, Washington, DC 20250; Tel: 202-205-7760; Fax: 202-720-3157.

The Office of the Under Secretary for Food Safety and the Food and Drug Administration (FDA) held a public meeting to provide information and receive public comment on agenda items that will be discussed at the Twenty-eighth Session of the Codex Committee on Food Labeling (CCFL), which will be held in Ottawa, Canada, May 9-12, 2000. The Codex Alimentarius Commission (Codex) is the international body empowered by the WTO's Agreement on Sanitary and Phytosanitary Measures to set presumptively WTO-legal food safety standards.

Issues for the April 17 meeting included: (1) draft guidelines for the production, processing, labeling, and marketing of organically produced foods; (2) recommendations for the labeling of foods obtained through biotechnology; (3) guidelines on nutrition labeling; (4) recommendations for the use of health claims; (5) guidelines for the use of the term "vegetarian;" and (6) labeling of prepackaged foods.

Event: *Public Meeting on International Harmonization of Chemical Hazard Classification and Labeling*

Date: April 27, 2000, 10 a.m.-noon

Location: Room 311, U.S. Environmental Protection Agency, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, VA

FR Cite: 65 *Federal Register* 19036 (April 10, 2000)

Contact: Marie Ricciardone, U.S. Department of State, Office of Environmental Policy (OES/ENV), Room 4325, 2201 C St., NW, Washington, DC 20520; Tel: 202-647-9799; Fax: 202-647-5947; E-mail: RicciardoneMD@state.gov

The U.S. government, through an interagency working group, is preparing for a series of international meetings to further develop a harmonized system of chemical hazard classification and labeling, an effort referred to as the "globally harmonized system" (GHS). Several agencies participate in the interagency working group, including: the Department of State, Environmental Protection Agency (EPA), Department of Transportation (DOT), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), Department of Commerce, Department of Agriculture (USDA), and U.S. Trade Representative (USTR).

On April 3, 1997, the State Department published Public Notice 2526 in the *Federal Register* detailing the interagency working group and its work with international organizations and other nations to harmonize regulatory requirements for chemical safety and health information.[59] U.S. laws and regulations potentially affected by these harmonization efforts include worker, consumer, and environmental protections and transportation of hazardous materials rules. More specifically, potentially-affected rules include provisions for classifying chemicals regarding their hazards, the preparation and dissemination of information about hazardous chemicals, the appropriate safe handling procedures for hazardous chemicals, and rules for labels, placards, material safety data sheets, and other written materials.

According to the State Department, "Harmonization of such requirements internationally has been a long-term goal for the United States Government."[60] The U.S. initiated this process domestically through a 1984 interagency policy on chemical labeling trade issues and internationally through a series of agreement with other countries in conjunction with the United Nations Conference on Environment and Development (UNCED) in 1992. The UNCED objective is: "A globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000."[61]

The Department of State held a public meeting to review the progress since the last public meeting on October 6, 1999, and to discuss the issues likely to arise in upcoming international meetings. GHS activities include: (1) Fourth Meeting of the Inter-Organization Program for the Sound Management of Chemicals (IOMC)/International Labor Organization (ILO) Working Group on Hazard Communication, November 1-4, 1999; (2) Fifteenth Consultation of the IOMC Coordinating Group for the Harmonization of Chemical Classification Systems, November 5, 1999; (3) Fifth Meeting of the Organization for Economic Cooperation and Development (OECD) Expert Group on Classification Criteria for Chemical Mixtures, November 8-9, 1999; (4) Seventeenth Session of the UN Subcommittee of Experts on the Transport of Dangerous Goods, December 6-16, 1999; (5) Fifth Meeting of the Expert Group on Aquatic Environmental Hazards, February 14-15, 2000; (6) Third Meeting of the OECD Ad Hoc Expert Group on Target Organ/Systemic Toxicity of the Task Force on Harmonization of Classification and Labeling, February 16-17, 2000; and (7) Ninth Meeting of the OECD Task Force on Harmonization of Classification and Labeling, February 17-18, 2000.

Members of the interagency working group also gave an overview of the U.S. preparations for upcoming international meetings, including: (1) Fifth Meeting of the IOMC/ILO Working Group of Hazard Communication, May 22-25, 2000; (2) Sixteenth Consultation of the IOMC Coordinating Group for the Harmonization of Chemical Classification Systems, May 26, 2000; (3) Sixth Meeting of the OECD Expert Group on Classification Criteria for Chemical Mixtures, May 29-31, 2000; and (4) Eighteenth Session of the UN Subcommittee on Experts on the Transport of Dangerous Goods, July 3-13, 2000.

Event: *Public Meeting of the Advisory Committee on International Economic Policy*

Date: June 13, 2000, 9 a.m.-1 p.m.

Location: Room 1107, U.S. Department of State, 2201 C St., NW, Washington, DC 20520

FR Cite: 65 *Federal Register* 19805 (April 12, 2000)

Contact: Carol Thompson, ACIEP Secretariat, Department of State, Bureau of Economic and Business Affairs, Room 3638, Main State, Washington, DC 20520; E-mail: thompsonce@state.gov

The Advisory Committee on International Economic Policy (ACIEP) is holding a public meeting to discuss the following topics: U.S.-European Union Summit Issues, G-8 Summit Preview, Sanctions, Biotechnology, China-WTO Accession, and other current foreign policy issues. The ACIEP, based in the U.S. Department of State, serves the U.S. government as an advisor on issues and problems in international economic policy. The ACIEP's objective is to provide expertise and insight otherwise unavailable in the U.S. government.

Interested parties may attend the meeting, but admittance to the Department of State building is by means of a pre-arranged clearance list. To be placed on this list, you must fax your name, title, company or other affiliation, social security number, birth date, and citizenship to the ACIEP Executive Secretariat (Attention: Carol Thompson) at 202-647-5936 by June 6, 2000. The meeting will be hosted by Committee Chairman R. Michael Gadbaw and Under Secretary of State for Economic, Business, and Agricultural Affairs Alan P. Larson.

The ACIEP is creating a working group comprised of approximately twenty experts in fields such as science, academia, agriculture, consumer interests, environment, and industry to examine issues regarding new agricultural technologies, including biotechnology. This group will generate recommendations on international aspects of new agricultural technologies and will report back to the full ACIEP. Those interested in participating in the working group should send a resume by April 28, 2000, to Agricultural Office, Attention: S. Kenny, Department of State, 2201 C Street, NW, Room 3526, Washington, DC 20520.

Event: *Public Meeting: National Advisory Committee on Meat and Poultry Inspection*

Date: The full Committee will meet May 16-17, 2000, 8:30 a.m.-5:30 p.m. The Subcommittees will meet May 16, 2000, 7-9 p.m.

Location: Quality Hotel & Suites, Courthouse Plaza, 1200 North Courthouse Rd., Arlington, VA 22201; 703-524-4000. The full Committee will meet in the Jefferson Room. The Subcommittees will meet in the Kennedy, Roosevelt, and Lincoln Rooms

FR Cite: 65 *Federal Register* 20130 (April 14, 2000)

Contact: For more information, Michael N. Micchelli, Tel: 202-720-6269; Fax: 202-720-2345; E-mail: michael.micchelli@usda.gov. An agenda is available at www.fsis.usda.gov/OPPDE/nacmpi. Submit 3 copies of written comments to the FSIS Docket Clerk, USDA, Docket #00-008N, Room 102 Cotton Annex, 300 12th St., SW, Washington, DC 20250-3700 or by fax to 202-205-0381.

The National Advisory Committee on Meat and Poultry Inspection (NACMPI) will host a public meeting to discuss four issues: (1) the requested changes to the Food Safety and Inspection Service's (FSIS) Hazard Analysis and Critical Control Point (HACCP) regulations - via an industry petition; (2) the extension of the USDA's meat and poultry inspection program to additional species (including the use of nitrates in non-amenable species); (3) *E. coli* developments; and (4) Listeria developments. NACMPI's three subcommittees also will meet to continue working on issues discussed during the full Committee meeting.

NACMPI provides advice and recommendations to the Secretary of Agriculture pertaining to federal and state meat and poultry inspection programs. The FSIS Administrator (Tom Billy) is the chairperson of the Committee, and the Members of the Committee are drawn from representatives of consumer groups; producers, processors, and marketers from the meat and poultry industry; and state government officials. For a complete list of current members, see the Federal Register notice above.

NOTES

1. David R. Brower, *et al.* v. William Daley, *et al.*, U.S. District Court for the Northern District of California, Case No. C99-3892 TEH, Apr. 11, 2000.

2. *Id.* at 29.

3. Harriet Chiang, "Judge Says Tuna Must Remain 'Dolphin Safe': Ruling in S.F. Blocks Attempt by White House to Lower Standard," *San Francisco Chronicle*, Apr. 12, 2000.

4. Dolphin Protection Consumer Information Act, 16 U.S.C. § 1385 (1990).

5. Sen. Barbara Boxer, "Boxer Praises Court Decision to Protect Dolphin," *News Release*, Apr. 11, 2000.

6. Earth Island Institute v. Brown, 865 F. Supp. 1364, 1366 (N.D. Cal. 1994).

7. 16 U.S.C. § 1361.

8. *See* 42 Fed. Reg. 64548-60 (1977).

9. *See* 16 U.S.C. § 1385.

10. Administrative Record, Tab 50 at 1590.

11. GATT, United States - Restrictions on Imports of Tuna (DS21/R), Report of the Panel, Sep. 3, 1991.

12. GATT, United States - Restrictions on Imports of Tuna (DS29/R), Report of the Panel, Jun. 1994.

13. *See* GATT, Findings on U.S. Tuna Ban, Report of Dispute Panel, Aug. 16, 1991, at Paras. 5.24-5.29.

14. "Clinton Pledges Early, Renewed Effort to Pass Tuna-Dolphin Bill," *Inside U .S. Trade*, Oct. 1996.

15. 16 U.S.C. § 1414 (amending the MMPA).

16. *Id.* at § 1414(a).

17. 16 U.S.C. § 1385(d)(2)(B).

18. Report to Congress, in the Administrative Record, *supra* note 10, Tab 73 at 2136 (hereinafter "Report").

19. Report at 2155-57.

20. *Id.* at 2160.

21. 64 Fed. Reg. 24590 (Apr. 29, 1999).

22. *See* 65 Fed. Reg. 30 (Jan. 3, 2000).

23. The Act required the Secretary to conduct three stress-related projects (a necropsy study, a chase-recapture experiment, and a review of historical and demographic data) before making his initial determination. However, the NMFS Report was based solely on a review of stress literature. The necropsy study and chase-recapture experiments were not completed.

24. Brower v. Daley, *supra* note 1, at 25.

25. *Id.* at 28.

26. European Commission, DG III/E/3, "Cosmetic Products: Record of the Meeting, Cosmetics Harmonization and International Cooperation" (99/III/COS/53) Brussels, April 9, 2000, at 6, on file with Public Citizen.

27. Memorandum of Cooperation Between the Commission for European Communities, Directorate General III, the Ministry of Health and Welfare of Japan, and the Food and Drug Administration, Department of Health and Human Services of the United States of America Regarding Cosmetics Harmonization International Cooperation, on file with Public Citizen.

28. European Commission, DG III/E/3, "Cosmetic Products: Record of the Meeting, Cosmetics Harmonization and International Cooperation" (99/III/COS/52) Brussels, April 7-8, 2000, on file with Public Citizen.

29. *Id.* at 4.

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