



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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NORTH AMERICAN FREE TRADE AGREEMENT

Topic: *Sanitary and Phytosanitary (Food Safety and Animal/Plant Health) Provisions*

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The North American Free Trade Agreement's (NAFTA) Chapter Seven, covering Sanitary and Phytosanitary (SPS) Measures, establishes rules NAFTA member nations must follow when setting food-related policies concerning human, animal, or plant life or health.¹ This includes food safety standards, such as pesticide residue levels and meat inspection rules; some environmental policies; and policies regarding animal and plant health, such as those preventing invasive species to preserve biodiversity.

NAFTA's SPS chapter has several provisions requiring harmonization. For example, Article 713 requires a member nation to base its policies governing the protection

of human, animal, and plant life and health on international standards, "with the objective, among others, of making its sanitary and phytosanitary measures equivalent or, where appropriate, identical to those of the other Parties."² In fact, each member nation must participate in international standardizing organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the International Plant Protection Convention.³

If a member nation's policies conform to international standards, they are presumed to be consistent with the rest of the SPS chapter.⁴ If a member nation's policies provide a "different" level of protection for human,

animal, or plant life or health than international standards, they “shall not for that reason alone be presumed to be inconsistent with this Section.”⁵ In addition, the SPS chapter states that a member nation’s obligation to base its policies on international standards does not prevent it “from adopting, maintaining or applying, **in accordance with the other provisions of this Section**, a sanitary or phytosanitary measure that is more stringent than the relevant international standard.”⁶

While these provisions may seem to give member nations some leeway to set standards that provide more protection than international standards, member nations are still bound by the rules in the remainder of the SPS section, including those requiring member nations to base their standards on a risk assessment and scientific evidence and to minimize their standards’ effects on trade. Thus, a member nation attempting to promulgate or maintain food safety regulations that are more stringent than international regulations bears the burden of proving that its regulations have a scientific basis. A member nation with food safety regulations that are less stringent than international regulations need do nothing.

Article 715 allows member nations to establish their “appropriate levels of protection” in protecting human, animal, or plant life or health, but only under certain conditions.⁷ For instance, Member nations must perform risk assessments before establishing their level of protection and “take into account the objective of minimizing negative trade effects.”⁸

When conducting a risk assessment to justify more protective food safety standards, a member nation must take into account relevant risk assessment techniques developed by international or North American standardizing organizations; scientific evidence; processes and production methods; and inspection, sampling, and testing methods.⁹ Furthermore, when assessing risks from and setting policies regarding the introduction or spread of animal or plant pests or diseases, a member nation also must take into account certain economic factors, including the cost-effectiveness of

alternative approaches to preventing such risks.¹⁰

The SPS chapter also requires harmonization by obligating member nations to “pursue equivalence of their respective sanitary and phytosanitary measures.”¹¹ Under Article 714, each importing member nation must treat an exporting member nation’s standards as equivalent to its own, even when the standards are different, when the exporting nation provides scientific evidence or other information that demonstrates that the exporting nation’s standards achieve the importing nation’s appropriate level of protection.¹² An importing nation may determine that an exporting nation’s standards are not equivalent only when it has a scientific basis.¹³

Under NAFTA’s notion of equivalence, substantially different - and possibly less protective - standards in other nations can be declared “equivalent” to domestic standards. Once a foreign standard is declared “equivalent,” it must be treated as if it were a domestic standard, even if it differs in significant ways. Equivalence determinations are designed to allow foreign goods produced under “equivalent” standards free passage into the U.S. market.

While NAFTA rules mandate equivalence determinations, they do not provide procedural guidelines or factors to consider. The absence of such guidelines and factors may result in subjective comparisons, making it difficult, if not impossible, to understand *how* nations, including the U.S., will fulfill the requirement to determine whether the standards of other nations are “equivalent” to their own.

To date, this publication knows of no cases filed under the NAFTA SPS chapter. This may be because the U.S., Mexico, and Canada are members of the World Trade Organization (WTO), and the WTO’s Agreement on the Application of Sanitary and Phytosanitary Measures is even more restrictive than its NAFTA counterpart. For a full account of the WTO’s SPS Agreement, see the March 1999 edition of *Harmonization Alert*.

Topic: *NAFTA Technical Barriers to Trade Chapter*

Contact: Suzanne Troje, Director, Technical Barriers to Trade, Office of the U.S. Trade Representative, 600 17th St., NW, Washington, DC 20508; Tel: 202-395-3063; E-mail: stroje@ustr.gov.

Harmonization Alert is a 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 the *Alert’s* listings are available through the harmonization clearing house. If you have information on harmonization-related issues, clearing house requests, or would like to subscribe, please contact Dion Casey at abailey@citizen.org or Mary Bottari at mbottari@citizen.org, or call (202) 546-4996. *Harmonization Alert* is available free of charge by mail, list serve, and on the Internet at www.harmonizationalert.org. Public Citizen’s Harmonization Project is supported by grants from the Ford Foundation, the National Association for Public Interest Law, and the Cummings Foundation.

The North American Free Trade Agreement's (NAFTA) Chapter Nine, covering Technical Barriers to Trade (TBT), sets the rules member nations must follow when establishing standards, technical regulations, and conformity assessment rules on most non-food matters.¹⁴ Its provisions apply to all standards-related measures, except for sanitary and phytosanitary (SPS) measures, "that may, directly or indirectly, affect trade in goods or services" between member nations.¹⁵ The overarching goal of the TBT chapter is to make national standards uniform worldwide and to make member nations' standards-setting processes transparent, albeit to other member nations, not to consumer and environmental groups.

The NAFTA TBT chapter contains several provisions requiring a member nation that proposes to adopt or modify a technical regulation to notify other member nations. For example, a member nation must publish a notice and notify in writing the other member nations at least 60 days before adopting or modifying a technical regulation.¹⁶ In addition, in its notice a member nation must "identify any provision that deviates in substance from relevant international standards," thus highlighting standards vulnerable to challenge.¹⁷ Member nations also must maintain "inquiry points" to answer questions and provide documents regarding "any standards-related measure proposed, adopted or maintained in its territory at the federal, state or provincial government level."¹⁸

The NAFTA TBT chapter requires member nations' federal governments to ensure that all sub-federal governments, which in the U.S. includes state, county, and municipal governments, in their territories conform to the TBT chapter's provisions.¹⁹ Thus, state and local governments in the U.S., Canada, and Mexico must abide by the TBT chapter's rules when passing the myriad local standards that may affect trade in goods or services.

When state and local standards mirror corresponding federal or international standards, there is no potential TBT problem. However, if a state or local government passes a standard that provides more consumer or environmental protection than the relevant federal or international standard, that standard may be challenged as a barrier to trade by another NAFTA nation.

The NAFTA TBT chapter specifies what are legitimate objectives member nations may pursue in making NAFTA-legal domestic policies. The text allows a member nation to, in pursuit of "its legitimate objectives of safety or the protection of human, animal or plant life or health, the environment or consumers, establish the levels of protection that it considers appropriate **in accordance with Article 907(2)**."²⁰ Article 907(2) prohibits a member nation from making:

arbitrary or unjustifiable distinctions between similar goods or services in the level of protection it considers

appropriate, where the distinctions: (a) result in arbitrary or unjustifiable discrimination against goods or service providers of another party; (b) constitute a disguised restriction on trade between the Parties; or (c) discriminate between similar goods or services for the same use under the same conditions that pose the same level of risk and provide similar benefits.²¹

These provisions have caused environmental and consumer groups considerable concern because they empower closed NAFTA tribunals with enormous discretion in deciding whether governments' choices in setting different levels of protection for related matters are permissible. The use of the term "similar" rather than the term "identical" means this provision goes beyond a basic non-discrimination requirement (that foreign and domestic goods be treated the same) and encroaches on subjective policy judgments. For instance, a panel would decide if a government's choice to require different levels of safety protection for similar products (e.g. a gas stove versus an electric stove, or a halogen light versus a filament bulb) is NAFTA-legal.

The specific NAFTA provisions mandating TBT standards harmonization require member nations to base their standards on "relevant international standards or international standards whose completion is imminent."²² The only exception to the rule is if such standards would not be appropriate "because of fundamental climatic, geographical, technological or infrastructural factors, scientific justification or the level of protection that the Party considers appropriate."²³ If a member nation's standards conform to international standards, they are presumed to be consistent with the rest of the chapter.²⁴

As with the NAFTA SPS section, the NAFTA TBT chapter mandates equivalence determinations for technical regulations and conformity assessment procedures.²⁵ "Conformity assessment" means verification by a nation that a product meets a required standard. Thus conformity assessment procedures include product testing, quality systems audits, and the reporting required from such testing or audits.

However, the NAFTA TBT chapter goes further than the SPS section by requiring member nations "to make compatible their respective standards-related measures, so as to facilitate trade in a good or service."²⁶ Furthermore, the TBT's provisions require member nations promote the compatibility of its specific standards and conformity assessment procedures with those maintained in other member nations.²⁷

The NAFTA TBT chapter also prohibits member nations from adopting or maintaining measures that create "unnecessary obstacles to trade."²⁸ The only exception is if the "demonstrable purpose of the measure is to achieve a

legitimate objective; and the measure does not operate to exclude the goods of another Party that meet that legitimate objective.”²⁹ This places the burden of proving that a standard has a legitimate objective on the nation whose standard is being challenged. However, the NAFTA TBT chapter provides no definition of what a “legitimate” objective is. Thus, a NAFTA tribunal will make that decision

with no guidance from the NAFTA agreement itself.

The NAFTA TBT chapter is strikingly similar to the WTO’s Agreement on Technical Barriers to Trade. In fact, the NAFTA TBT chapter affirms member nations’ rights and obligations under the WTO TBT Agreement.³⁰ For a complete description of the WTO TBT Agreement, see the March 1999 edition of *Harmonization Alert*.

Topic: *The Globally Harmonized System for Chemical Classification and Labeling*

Contact: Jennifer Silk, Director, Office of Technical Programs and Coordination Activities, Occupational Safety and Health Administration, Room N3655, 200 Constitution Avenue, NW, Washington, D.C. 20210; Tel: 202-693-2110.

The Organization for Economic Cooperation and Development (OECD), the International Labor Organization (ILO), the United Nations (U.N.) and no less than ten U.S. federal agencies have been involved in a decade-long effort to create a Globally Harmonized System (GHS) for chemical classification and labeling.³¹ The definition of “chemicals” for this harmonization process includes pesticides, pharmaceuticals and consumer products. The massive international effort will result in a system that will have a profound effect on U.S. regulations regarding worker, consumer and environmental protections, the transportation of hazardous materials, and community-right-to-know laws.

How a chemical is classified has significant consequences down the line for workers and communities who need to be knowledgeable about the hazards posed by the materials they are working with or that are being stored or disposed of in their communities. Chemical classification has been described as a “gateway through which all chemicals have to pass in order to generate information to be disclosed in some way to the public” and as “key to right to know.”³² The categorization of a chemical determines its level of restriction, worker safety requirements, and community right-to-know requirements.

A variety of international agencies have a piece of the GHS pie. The OECD has primary responsibility for classifying acute health hazards (such as irritation, sensitization and acute toxicity), chronic health hazards (such as carcinogenicity and reproductive toxicity) and environmental hazards through a series of expert committees. The U.S. Environmental Protection Agency (EPA) is the lead U.S. agency in the OECD work.

The U.N. Committee on the Transport of Dangerous Goods, which already has a set of international rules governing the transportation of hazardous materials, is charged with harmonizing criteria for classification of physical hazards, including flammability and reactivity (explosive hazards). The U.S. Department of Transportation is the lead agency involved in the U.N. work. The ILO is responsible for hazard communication, including rules

regarding labeling and material safety data sheets. The Occupational Safety and Health Administration (OSHA) is the lead agency involved in the ILO effort.

Overall coordination of the entire harmonized system is provided by the Inter-organization Programme for the Sound Management of Chemicals (IOMC). The IOMC includes all of the international organizations that are involved in implementing mandates regarding chemical safety that were adopted during the 1992 United Nations Conference on Environment and Development (UNCED). The IOMC Coordinating Group on Harmonization of Chemical Classification systems coordinates the work related to the harmonization mandate, and includes representatives from the chemical classification and labeling systems of the U.S., European Union (EU), Canada, and U.N. transportation systems. U.S. OSHA currently chairs the IOMC. Once completed, the GHS is likely to be housed at the United Nations Economic and Social Council (U.N. ECOSOC) for implementation and updating of the system.

Mixtures: Currently, the hot topic of debate in the GHS is the classification of chemical mixtures. The U.S. and the EU handle the assessment of the health effects of untested mixtures in very different ways. In the U.S., the acute toxicity of a mixture is based on a percentage cut-off approach. If the mixture contains more than one percent of an ingredient that is itself acutely toxic, the mixture will be considered toxic as well. The EU uses a formula approach that adds the toxicity of the various ingredients. In this approach, the toxicity of “unknown” components is ignored, and thus assumed to be non-toxic for purposes of the calculations. This has the effect of diluting the toxicity of the known components, and is like to lead to fewer mixtures being considered acutely toxic.

In addition, in the EU, chemicals that make it into the most dangerous categories (i.e., class one carcinogens) face significant regulatory consequences downstream. For example, class one carcinogens are banned for certain uses. Thus the EU generally classifies fewer chemicals in these classes to limit the number subject to these types of

consequences. In the U.S., classifications are not automatically linked to such consequences, and thus tend to favor broader disclosure of information for protective purposes. The different handling of chemicals poses a variety of challenges for regulators working on harmonization. The resolution of this standoff will be closely monitored by concerned labor and consumer groups.

Proponents of the process argue that gains in efficiency and worker safety may accrue from a GHS on chemicals. Diligent union representatives have worked hard to monitor the negotiations and to promote upward harmonization. However, the current negotiations pose a variety of concerns.

First, many important battles have been fought in ten years of negotiations, and many more years of negotiations are still planned. By the time the GHS is implemented in the U.S. likely via half a dozen large Federal Register notices posted by the federal agencies involved, crucial issues will have been decided, including: the definition of "acute toxicity," rules governing mixtures and alloys, and whether worker-protective "hazard-based" labeling or "risk-based" labeling, which provides a lesser level of worker protection, will be used. The ability of any small group of public interest organizations or public health officials to impact those decisions so late in the game will be

minimal.

Second, once in place and adopted by many nations and thousands of manufacturers, the system will be extraordinarily difficult to modify. As currently constituted, it is not clear how the GHS will incorporate change as new science presents new evidence of hazard. In addition, the negotiators have yet to decide how to handle trade secret claims raising the fear that chemical suppliers will be able to claim business confidentiality and thus nullifying the information requirements at the core of the agreement.

Finally, labor representatives involved in the GHS lost a battle in their attempt to make the harmonization activity a binding international convention. This means that there will be no capacity to sanction countries for violating the standards or having a lower standards. However, the dispute resolution system of the World Trade Organization (WTO) will stand ready to enforce the GHS, as the presumptively WTO-legal international standard. Should any nation adopt worker safety protections that *exceed* those in the GHS, those protections could be subject to challenge as an unfair barrier to trade in the WTO. Thus, the harmonization of chemical classifications could be used to attack domestic laws providing greater health or environmental protection, but would set no floor for minimal conduct.

FEDERAL REGISTER ALERTS

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Topic: *Harmonization of Radioactive Material Packaging and Transportation Standards*
Action: Request for comments on issues paper
Venue: Nuclear Regulatory Commission
FR Cite: 65 *Federal Register* 44360 (July 17, 2000)
Deadline: Comments are due by September 30, 2000
Contact: For more information, Naiem S. Tanius, Office of Nuclear Material Safety and Safeguards, USNRC, Washington, DC 20555-0001; Tel: 301-415-6103; E-mail: nst@nrc.gov. Submit comments to Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attn: Rulemaking and Adjudications Staff

The Nuclear Regulatory Commission (NRC) is considering a rule that would change the NRC's regulations on the packaging and transporting of radioactive material to harmonize them with International Atomic Energy Agency (IAEA) standards. The IAEA was created in 1957 under the

auspices of the United Nations to foster scientific and technical cooperation in the nuclear field. It is comprised of 130 member nations, including the U.S., and is headquartered in Vienna, Austria.

The NRC is requesting public comment on a paper -

entitled "Issues Paper on Major Revision to 10 CFR Part 71: Compatibility with ST-1--the IAEA Transportation Safety Standards--and Other Transportation Safety Issues" - that discusses the major issues involved in such harmonization. The paper is included in the *Federal Register* notice.

More specifically, the NRC is soliciting public comment related to: (1) information on the costs and benefits resulting from such harmonization; (2) operational data on radiation exposure that might result from the proposed changes in the NRC regulations; (3) whether the factors presented in the issues paper are appropriate; and (4) whether other factors should be considered. The NRC intends to host three public meetings in August and

September, 2000, to discuss the issues raised in the issues paper and provide additional opportunities for the public to comment.

The IAEA revises its regulations on the transportation of radioactive material about every ten years to accommodate scientific and technical advances, and the NRC periodically updates its regulations to make them compatible with IAEA regulations. For example, in 1985 the IAEA revised its radioactive material transportation regulations, and the NRC correspondingly changed its regulations in 1995.³³ The most recent IAEA revision occurred in 1996, and the NRC is proposing these changes to harmonize its regulations with that update.

Topic: *Harmonization of Auto Regulations*
Action: Request for comments
Venue: National Highway Traffic Safety Administration
FR Cite: 65 *Federal Register* 44565 (July 18, 2000)
Deadline: Written comments must be received by September 1, 2000
Contact: For technical and policy issues, Julie Abraham, Director, Office of International Policy and Harmonization, NHTSA, 400 Seventh St., SW, Washington, DC 20590; Tel: 202-366-2114; Fax: 202-366-2559. For legal issues, Nancy Bell, Attorney-Advisor, Office of the Chief Counsel, NCC-20, NGTSA, 400 Seventh St., SW, Washington, DC 20590; Tel: 202-366-2992; Fax: 202-366-3820. Submit comments, identified with Docket No. NHTSA-00-7638, to Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590.

The National Highway Traffic Safety Administration (NHTSA), the agency responsible for promulgating auto safety regulations in the U.S., is seeking public comment on its preliminary recommendations for the first auto safety regulations to be considered for establishment under a new global auto standards agreement. That harmonization pact is called the 1998 United Nations Economic Commission for Europe (UN/ECE) Agreement Concerning the Establishment of Global and Technical Regulations for Wheeled Vehicles, Equipment and Parts Which Can Be Fitted and/or Be Used on Wheeled Vehicles (the "1998 Global Agreement").

The 1998 Global Agreement provides for the development of global technical regulations on auto safety, emissions, energy conservation, and theft prevention. The Agreement allows for the establishment of global technical regulations by either harmonizing existing national regulations or developing new regulations. According to NHTSA, "the Agreement explicitly recognizes the right of governments to adopt and maintain technical regulations that are more stringently protective of health and the environment than the global technical regulations."³⁴ The U.S. signed the Agreement on June 25, 1998, and it went into effect on August 25, 2000.

NHTSA is considering harmonizing the following

U.S. auto safety regulations with UN/ECE regulations:

Head restraints: NHTSA received a petition from the American Automobile Manufacturers Association (AAMA) and the Association of International Automobile Manufacturers (AIAM) requesting that NHTSA recognize the ECE head restraint as "functionally equivalent" to the NHTSA standard. NHTSA reviewed the Economic Commission for Europe (ECE) standard and believes it is more stringent in several respects. Thus, NHTSA intends to propose changing the U.S. standard to at least the level of the ECE standard.

Steering column movement: The ECE regulation limits both rearward and vertical movement of the steering column, while the U.S. regulation limits rearward movement only. Thus, NHTSA is considering adopting the ECE regulation.

Frontal offset crash test: This tests an automobile's performance in frontal crashes in which the impact is on one side of the automobile's front, rather than directly head-on. NHTSA currently performs only full frontal crash tests, but does not perform frontal offset crash tests. However, the ECE does, and NHTSA is studying the ECE tests and plans to propose a frontal offset crash test to supplement its full frontal crash test.

Crash test dummies: The largest dummy required by the ECE child restraint regulation is a 70-75 pound dummy (which represents ten-year-olds), while the largest dummy required by the U.S. child restraint regulation is 50 pounds (six-year-olds). NHTSA is considering adding the 70-75 pound dummy. NHTSA also is considering adding an updated version of the ECE side impact dummy (EuroSID-2) that measures the potential for injury to the same body parts measured by the U.S. dummy but also to parts (*i.e.*, head, upper neck, and abdomen) that the U.S. dummy does not measure.

Car tires: NHTSA received a petition from the Rubber Manufacturers Association and five other tire industry organizations requesting that NHTSA adopt a global tire standard agreed upon by the tire industry

worldwide. NHTSA considers tire harmonization a priority and is considering adopting the best practices in national tire standards from around the world.

Signal lamp visibility: NHTSA is seeking to harmonize the U.S. standard on lighting with the ECE standard. NHTSA has issued a notice of proposed rulemaking based on the ECE rules for signal lamp visibility.

NHTSA is also considering harmonizing regulations in several other areas, including: vehicle classification, upper interior impact protection, full frontal crash tests, lower anchors and tethers for children, door retention components, fuel system integrity, controls and displays, and area of windshield cleared by defrosters, defoggers, and windshield wipers.

Topic: *ICH Draft Guidance on Impurities in New Drug Products*
Action: Notice and request for comments
Venue: Food and Drug Administration
FR Cite: *65 Federal Register* 44791 (July 19, 2000)
Deadline: Comments must be received by September 18, 2000
Contact: For information on the ICH, Janet J. Showalter, Office of Health Affairs (HFY-20), FDA, 5600 Fishers Lane, Rockville, MD 20857; Tel: 301-827-0864. For information on the guidance, Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD-800), FDA, 5600 Fishers Lane, Rockville, MD 20857; Tel: 301-827-5169. Submit comments, on Docket No. 96D-0009, to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

The Food and Drug Administration (FDA) is publishing and soliciting public comment on a draft revised guidance entitled "Q3B(R) Impurities in New Drug Products," prepared by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to provide guidelines for registration and marketing applications on the content and qualification of impurities in new drug products produced from chemically synthesized new drug substances not previously registered in another nation.

The ICH was created by industry and regulatory authorities in the U.S., European Union (EU), 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 industry's international trade association. 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 FDA states, "This draft revised guidance represents the agency's current thinking on impurities in new drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public."³⁵

Topic: *ICH Draft Guidance on Impurities in New Drug Substances*
Action: Notice and request for comments
Venue: Food and Drug Administration
FR Cite: 65 *Federal Register* 45085 (July 20, 2000)
Deadline: Comments must be received by September 18, 2000
Contact: Janet J. Showalter or Charles P. Hoiberg, contact information above. Submit comments, on Docket No. 94D-0325, to the address above.

The Food and Drug Administration (FDA) is publishing and soliciting public comment on a draft revised guidance entitled "Q3A(R) Impurities in New Drug Substances," prepared by the ICH. The guidance updates, clarifies, and adds information to the 1996 guidance, and provides consistency with more recently published ICH guidances. The guidance is intended to provide guidelines

to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in another country. Drug substances are the active components in drug products. Drug products may be made up of one or more drug substances.

Topic: *Irradiation of Fresh Shell Eggs*
Action: Final rule
Venue: Food and Drug Administration
FR Cite: 65 *Federal Register* 45280 (July 21, 2000)
Deadline: The rule is effective July 21, 2000. Submit written objections and requests for a hearing by August 21, 2000
Contact: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS-206), FDA, 200 C St., SW, Washington, DC 20204; Tel: 202-418-3088. Submit written objections, on Docket No. 98F-0165, to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

The Food and Drug Administration (FDA) is amending its food additive regulations to allow for the use of ionizing radiation to reduce *Salmonella* in fresh shell eggs. In 1998, the FDA received a petition from Edward S. Josephson, of the University of Rhode Island's Food Science and Nutrition Research Center, requesting that the agency take this action. After reviewing the data and studies submitted by the petitioner and other information in its files, the FDA approved the petition and issued this final rule.

In response, Public Citizen immediately petitioned the FDA to delay implementing the final rule and hold a public hearing. "The FDA's decision is not only scientifically irresponsible, it is an insult to Americans who expect to wake up in the morning to a fresh, wholesome meal," said Wenonah Hauter, Director of Public Citizen's Critical Mass Energy and Environment Program.³⁶

In its petition, Public Citizen stated that food irradiation destroys nutrients, creates free radicals that make the human body more susceptible to cancer and diabetes, masks filthy food production and processing practices, and possibly forms carcinogens such as benzene and

formaldehyde in irradiated food. Lab animals fed irradiated food have suffered premature death, cancer, reproductive and immune problems, liver and kidney dysfunction, low birth weight, chromosomal damage, and nutritional muscular dystrophy.³⁷ Irradiated eggs are deficient in vitamin A and niacin.³⁸ In its petition, Public Citizen argued that FDA officials have ignored these problems, relying instead on questionable research - some of which has never been translated into English - that has obscured the well-documented hazards of exposing food to radiation.

Public Citizen noted that the petitioner, Mr. Josephson, oversaw the U.S. Army's food irradiation headquarters in Massachusetts during the 1960s and 1970s, when dozens of studies revealed serious health problems in lab animals that ate irradiated food.³⁹ At that time, the FDA prevented the Army from serving irradiated bacon to military personnel after the agency learned that lab animals fed irradiated food suffered, tumors, reproductive problems, cancer, and premature death.⁴⁰ Josephson's research on egg irradiation has been partially underwritten by MDS Nordion, an Ontario, Canada-based company that owns an irradiation

facility in Florida.⁴¹

Nevertheless, with this final rule, the FDA has approved egg irradiation as “safe.” The rule took effect July 21, 2000, so, despite the Public Citizen petition (which does

not delay implementation of the rule), egg producers can irradiate their eggs. While irradiated eggs must be labeled if they are on retail store shelves, they do not have to be labeled when sold in restaurants.

Topic: *Industry Petition on Hazard Analysis and Critical Control Point Inspection*
Action: Re-opening of comment period
Venue: Food Safety and Inspection Service
FR Cite: *65 Federal Register* 45749 (July 25, 2000)
Deadline: Comments must be received by September 12, 2000
Contact: Daniel L. Engeljohn, Director, Regulations Development and Analysis Division, FSIS, Washington, DC 20250-3700; Tel: 202-720-5627; Fax: 202-690-0486. Submit one original and two copies of comments to FSIS Docket Room, Docket # 00-014E, Room 102 Cotton Annex Bldg., 300 12th St., SW, Washington, DC 20250-3700.

The Food Safety and Inspection Service (FSIS) is re-opening the comment period on a notice published in the Federal Register on May 15, 2000.⁴² That notice solicited comment on a petition submitted by several industry trade associations requesting the FSIS to amend sections of its Hazard Analysis and Critical Control Point (HACCP) regulations governing meat and poultry inspection. For more

information on this industry petition seeking changes in the definitions of several terms, including “food safety hazard” and “hazard analysis,” see the Federal Register Alerts section of the May/June, 2000 issue of *Harmonization Alert*. The FSIS extended the comment period for an additional 60 days in response to a request from the National Advisory Committee on Meat and Poultry Inspection.

Topic: *ICH Draft Guidance on Good Manufacturing Practices for Active Pharmaceutical Ingredients*
Action: Notice and request for comments
Venue: Food and Drug Administration
FR Cite: *65 Federal Register* 46936 (August 1, 2000)
Deadline: Comments must be received by October 2, 2000
Contact: Joseph X. Phillips, Central Regional Office, U.S. Customhouse, 2d and Chestnut Sts., Room 900, Philadelphia, PA 19106; Tel: 215-597-0492; E-mail: Jphillip@ora.fda.gov; or Edwin Rivera, Center for Drug Evaluation and Research (HFD-320), FDA, 7520 Standish Pl., Rockville, MD 20855; Tel: 301-827-3031; E-mail: Rivera@cder.fda.gov. Submit comments, on Docket No. 00D-1418, to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

The Food and Drug Administration (FDA) is publishing and soliciting public comment on a draft revised guidance entitled “Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients,” prepared by the ICH. The guidance is intended to provide guidelines on current good manufacturing practices for manufacturing of

active pharmaceutical ingredients. The guidelines are intended to assist in the manufacture of active pharmaceutical ingredients that meet the standards for quality and purity they purport or are represented to possess.

Topic: *USTR Seeks Expert on Consumer Issues Related to Electronic Commerce for Work on Free Trade Area of the Americas Committee*

Action: Notice

Venue: U.S. Trade Representative

FR Cite: *65 Federal Register* 47818 (August 3, 2000)

Deadline: Written expressions of interest should be submitted by August 11, 2000

Contact: Regina Vargo, Deputy Assistant Secretary for the Western Hemisphere, U.S. Department of Commerce, 202-482-5324, or Regina_Vargo@ita.doc.gov

The U.S. Trade Representative (USTR) is seeking a private sector expert on consumer issues related to electronic commerce to participate in the work of the Free Trade Area of the Americas' (FTAA) Joint Government-Private Sector Experts Committee on Electronic Commerce (the "Joint Committee"). The Joint Committee was created in April 1998, at the Second Summit of the Americas in Santiago, Chile, where the leaders of 34 Western Hemisphere nations initiated negotiations to create the FTAA by 2005. It is comprised of government and private sector experts on electronic commerce who make recommendations to the trade ministers of the 34 nations on policies regarding electronic commerce.

The FTAA would create a free trade zone for most of the Western Hemisphere modeled on the North American Free Trade Agreement (NAFTA). In fact, if completed, the FTAA would expand NAFTA rules to almost all the nations of the Western Hemisphere.

At the Joint Committee's last meeting in January, 2000, Committee members included the following issues on their electronic commerce agenda: access and infrastructure, small and medium-size enterprises, authentication, online

payments, intellectual property, taxation, and consumer protection. The Joint Committee will make recommendations in these areas to trade ministers at the next FTAA Ministerial meeting in April 2001.

The notice says USTR is seeking to supplement U.S. private sector participation on the Joint Committee and to include expertise in consumer issues related to electronic commerce. Thus, the USTR is soliciting assistance in identifying U.S. private sector individuals with such expertise. Qualifications include: (1) demonstrated expertise in one or more aspects of electronic commerce and consumer protection; (2) an ability and willingness to broadly solicit views from and disseminate information to consumer groups; and (3) familiarity with U.S. and foreign trade and investment policies and obligations.

Persons wishing to make written submissions of interest should provide twenty copies to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the U.S. Trade Representative, Room 122, 600 17th Street, NW, Washington, DC 20508 by noon, August 11, 2000.

Topic: *ICH Guidance on Safety Pharmacology Studies for Human Pharmaceuticals*

Action: Notice and request for comments

Venue: Food and Drug Administration

FR Cite: *65 Federal Register* 48246 (August 7, 2000)

Deadline: Written comments must be received by September 6, 2000

Contact: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), FDA, 5600 Fishers Lane, Rockville, MD 20857; Tel: 301-594-5476. Submit written comments, on Docket No. 00D-1407, to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

The Food and Drug Administration (FDA) is publishing and soliciting public comment on a draft revised guidance entitled "S7 Safety Pharmacology Studies for Human Pharmaceuticals," prepared by the ICH. The guidance describes general principles and recommendations

for safety pharmacology evaluations. It is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and to avoid unnecessary use of animals and other resources.

Topic: *Genetically-Modified Corn and Cotton Registration Process*
Action: Notice of reassessment of registrations and public participation opportunity
Venue: Environmental Protection Agency
FR Cite: 65 *Federal Register* 48701 (August 9, 2000)
Deadline: EPA will provide notice of opportunities for public comment in the future.
Contact: Phil Hutton, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, EPA, 1200 Pennsylvania Ave., NW, Washington, DC 20460; Tel: 703-308-8260; Fax: 703-308-7026; E-mail: hutton.phil@epa.gov.

The Environmental Protection Agency (EPA) is conducting a "comprehensive reassessment" of the registrations for all existing corn and cotton plants that have been genetically modified (GM) to produce *Bacillus thuringiensis* (*Bt*), a naturally-occurring toxin used by many organic farmers. The EPA already has decided to extend the existing registrations for *Bt* corn and cotton until September 30, 2001. The notice sets forth the process the EPA intends to follow in deciding whether to renew registrations for *Bt* corn, cotton, and other plants.

Under the current registration system, the EPA requires the GM plant manufacturer to conduct studies on the GM plant's toxicity to mammals, non-target organisms (i.e. harmless insects such as butterflies), and beneficial species, and the fate of the pesticide in the environment.⁴³ The EPA also requires the manufacturer to develop insect resistance management plans to help control insect resistance to pesticides.⁴⁴ The EPA - based on the data supplied by the manufacturer, rather than independent studies - must determine that the plant pesticide is "fully protective of public health and the environment."⁴⁵ Then the agency registers the plant, and the manufacturer is free to sell the seeds to farmers.

Each cell of these GM corn and cotton plants continuously produces the *Bt* toxin. Thus farmers do not need to apply this pesticide as often. Corporations have engineered *Bt* potatoes, rice, and tomatoes, in addition to corn and cotton. However, critics have pointed out several potential problems with such GM plants.

For example, such GM plants may speed up the spread of *Bt* resistance among pests that feed on those plants. In fact, University of North Carolina scientists have discovered *Bt*-resistance genes in populations of moths that feed on *Bt* corn.⁴⁶ The *Bt* toxin is widely used by organic and conventional (mostly family) farmers because it is a relatively

harmless, natural pesticide. If insect pests become resistant to *Bt*, however, such farmers will have to turn to more toxic pesticides, undermining their farming methods and increasing environmental damage.

In addition, *Bt* crops may be toxic to harmless and beneficial insects, such as green lacewings, springtails, and monarch butterflies, thereby reducing insect diversity.⁴⁷ Reductions in insect populations could harm species that depend on insects for food, including such birds as the corn bunting, partridge, and skylark. Researchers funded by the British government have found that plants genetically engineered to resist aphids had serious effects on the fertility and life-span of ladybirds that fed on aphids.⁴⁸

Since 1995, the EPA has registered eleven *Bt* plants, including potatoes, cotton, and different types of corn. Before registering such plants, the EPA requires data on the characterization of the active toxic ingredients, the genetic material used to make the toxin in the plant, the donor organism and host plant, and studies on toxicity to mammals, non-target organisms and beneficial species, and the toxin's fate in the environment.⁴⁹ The EPA also requires insect resistance management plans. To control insect resistance, the EPA requires farmers growing *Bt* corn to plant an area of non-*Bt* corn equal to 20 percent of their acreage.⁵⁰

The EPA's proposed evaluation process consists of five phases: (1) completing comprehensive risk assessments currently under way; (2) soliciting scientific and public comment on the risk assessments by fall 2000; (3) incorporating comments from the EPA's Scientific Advisory Panel, the National Academy of Sciences, the public, and the Clinton administration by winter 2000; (4) revising risk assessments and proposing registration decisions by spring 2001; and (5) issuing final re-registration decisions by summer 2001. The EPA will undertake this process for each of the eleven *Bt* plants currently registered.

Topic: *U.S.-EU Transatlantic Economic Partnership Harmonizing Services Standards*
Action: Notice and request for comments on negotiating objectives
Venue: U.S. Trade Representative
FR Cite: 65 *Federal Register* 49623 (August 14, 2000)

Deadline: Comments must be received by September 11, 2000
Contact: Bernard Ascher (architectural and engineering services) or Ann Main (insurance or related services), Office of Services, Investment, and Intellectual Property, 202-395-4510. Submit 20 copies of comments to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the U.S. Trade Representative, 600 17th St., NW, Room 122, Washington, DC 20508.

The U.S. Trade Representative (USTR) is soliciting public comment on general U.S. negotiating objectives regarding the services trade component of the U.S.-European Union (EU) Transatlantic Economic Partnership (TEP). Under the TEP, the U.S. and EU have begun exploring the development of mutual recognition agreements (MRAs) and other regulatory cooperation models for insurance, architectural, and engineering services.

The TEP was created on May 18, 1998, with three goals: “(1) Negotiations to reduce barriers to bilateral trade in services, industrial goods, and agricultural products; (2) cooperative efforts in the World Trade Organization (WTO) and other international organizations to reduce or eliminate barriers that hinder international trade and capital flows and to address other related issues; (3) and efforts to enhance the transatlantic dialogue between business, non-governmental organizations, and governments on trade and investment matters.”⁵¹ The TEP will address trade barriers with particular focus on what the TEP dubs “unnecessary regulatory impediments” to transatlantic trade in such sectors as electronic commerce, services, agricultural products, and intellectual property rights.⁵² The TEP also intends to “advance shared labor and environmental values.”⁵³

The U.S. is seeking to negotiate MRAs governing the licensing of architects and engineers with EU member nations. An MRA is a negotiated, reciprocal agreement between nations which allows one nation to rely on the other’s “conformity assessment” system. “Conformity assessment” means verification by a nation that a product meets a required standard. Thus, conformity assessment systems include product testing, quality systems audits, and the reporting required from such testing and audits.

MRAs in the architectural and engineering services sector would allow architects and engineers licensed in one nation to be licensed or able to practice in another nation. U.S. officials currently are working with several national engineering and architectural organizations to develop negotiating approaches that could lead to the mutual recognition of U.S. and EU licensing standards.

The U.S. is also seeking MRAs governing insurance standards. U.S. officials are working with state insurance regulators to develop mutual recognition of U.S. and EU standards covering certain insurance sectors (including commercial lines, re-insurance, and agency/brokers) and private pension fund management.

Topic: *ICH Draft Guidance on Common Technical Document*

Action: Notice of public availability

Venue: Food and Drug Administration

FR Cite: *65 Federal Register* 51621 (August 24 2000)

Deadline: Comments on the draft guidance are due by September 30, 2000

Contact: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), FDA, 5600 Fishers Lane, Rockville, MD 20857; Tel: 301-594-5476. Submit written comments to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Copies of the guidance are available at www.fda.gov/cder/guidance/index.htm.

The Food and Drug Administration (FDA) is publishing a draft guidance, “M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use,” prepared by the ICH. The draft guidance details a harmonized format and content for new product applications (including applications for products derived from biotechnology) for submission to the regulatory bodies in the three ICH regions (the U.S.,

European Union, and Japan). This means pharmaceutical corporations will be able to submit the same application for approval of new pharmaceutical products to the regulatory authorities in the U.S., EU, and Japan, rather than having to submit three different applications. The draft guidance addresses the organization of information, not the content of the information, corporations must submit for new product approvals.

MEETINGS/EVENTS

Event: *Meeting of the Trade and Environment Policy Advisory Committee*
Date: July 6, 2000, 8:30 a.m.-noon
Location: Conference Rooms 1 and 2, USTR Annex Bldg., 1724 F St., NW, Washington, DC
FR Cite: 65 *Federal Register* 42418 (July 10, 2000)
Contact: Christina Sevilla, Office of the U.S. Trade Representative, 202-395-6120

On July 6, 2000, the Trade and Environment Policy Advisory Committee (TEPAC) held a meeting to review and discuss current issues which influence U.S. trade policy. Unfortunately, the notice of the meeting does not identify those issues. The "notice" also was published on July 10, 2000, four days after the meeting was held. That may not have mattered much, however, since the U.S. Trade Representative (USTR) closed the meeting for all but a half-hour because the agency "determined that this meeting [was]

concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any trade agreement and other matters arising in connection with the development, implementation and administration of the trade policy of the United States."⁵⁴ During that half-hour, individuals who are not members of TEPAC were only able to observe, not comment.

Event: *Hearings on Draft Guidelines for Environmental Reviews of Trade Agreements*
Dates: The public hearings will be held on August 2 and 3, 2000, starting at 9:00 a.m. both days
Location: The public hearings will be held at 1724 F St., NW, Washington, DC 20508.
FR Cite: 65 *Federal Register* 42743 (Jul. 11, 2000)
Deadline: Written comments are due by August 25, 2000.
Contact: For more information, U.S. Trade Representative, Environment and Natural Resources Section, at 202-395-7320. Submit 20 copies of comments to Gloria Blue, Attn: Draft Guidelines for Implementation of Executive Order 13141 - Environmental Review of Trade Agreements, Trade Policy Staff Committee, Office of the U.S. Trade Representative, Room 122, 600 Seventeenth St., NW, Washington, DC 20508.

On November 16, 1999, President Clinton issued Executive Order 13141, which mandates reviews of the environmental impacts of trade agreements.⁵⁵ Despite opposition from environmental groups, the Executive Order vests the U.S. Trade Representative (USTR) with the power to conduct these environmental reviews, rather than the Environmental Protection Agency (EPA). The USTR issued these draft guidelines to implement the Executive Order. The USTR will hold two public hearings to discuss the draft guidelines with interested parties and solicit public comment on them.

The Clinton Administration maintains its position that it is not required to issue environmental impact statements under the National Environmental Policy Act (NEPA) for trade agreements, a position it has held since Public Citizen, on behalf of Sierra Club and Friends of the Earth, sued to try to force the Administration to comply with NEPA and issue environmental impact statements for

NAFTA and the WTO. Thus, the "environmental reviews" this order requires do not comply with the comprehensive participatory, scop, timing, and other terms of NEPA. The Administration has been conducting such limited, politicized "environmental reviews" since NAFTA passed in 1993, although it refused to do even such a limited review of U.S. negotiating positions going into the Seattle WTO Ministerial in November 1999.

The Executive Order mandates environmental reviews for three types of trade agreements: (1) comprehensive multilateral trade rounds, (2) bilateral or plurilateral free trade agreements, and (3) major new trade liberalization agreements in natural resource sectors.⁵⁶ The Executive Order also allows the USTR to decide whether environmental reviews will be conducted for other types of trade agreements. The USTR's decision must be based on an analysis of the particular agreement, including an assessment of the significance of the reasonably foreseeable

environmental impacts. This assessment must include consideration of the following: “(a) the extent to which the agreement might affect environmentally sensitive resources and/or result in substantial changes in trade flows of products or services that could confer environmental harms or benefits; (b) the extent to which the agreement might affect U.S. environmental laws, regulations, policies, and/or international commitments; and (c) the magnitude and scope of reasonably foreseeable environmental impacts.”⁵⁷

However, the USTR guidelines state that when deciding whether to conduct an environmental review, the USTR may consider “operational constraints” such as “the negotiation timetable, the lack of available relevant data and analytical tools, and the relative priority among competing needs for environmental expertise in trade-related activities.”⁵⁸ In fact, the USTR declares, “The Executive Order anticipates that most sectoral liberalization agreements will not require an ER [environmental review] because it is expected that they are unlikely to result in significant impacts.”⁵⁹

If the USTR decides an trade agreement gets an environmental review, the agency will initiate the review with a notice in the *Federal Register*. The notice will solicit public comment on the scope of the review. The USTR will consider three types of information when determining the scope of the environmental review: “(a) the scope and objectives of the proposed trade agreement; (b) a realistic range of alternative approaches for accomplishing the broad objectives of the trade agreement; and (c) types of reasonably foreseeable environmental impacts.”⁶⁰

The USTR guidelines go into much greater detail in other areas, including the analysis of regulatory and economically-driven environmental impacts, public participation in and documentation of the environmental review process, and the process of ongoing environmental assessments. Interestingly, the USTR published notice of its intent to conduct an environmental review of the recently-

completed U.S.-Jordan Free Trade Agreement in the *Federal Register* on June 28, 2000, two weeks before it published these guidelines.⁶¹

Critics have noted several deficiencies in the Executive Order. First, it gives the USTR the discretion to “determine whether an environmental review of an agreement or category of agreements is warranted.”⁶² This prompted Carl Pope, Executive Director of the Sierra Club, to say, “Unfortunately, this review process also puts the fox in charge of the henhouse. Environmental officials - not the U.S. Trade Representative - should oversee the review process to make sure that future trade agreements protect our families’ health, safety and environment.”⁶³

In addition, the Executive Order does not require environmental reviews of “agreements reached in connection with enforcement and dispute resolution actions.”⁶⁴ This means that there is no requirement for an environmental review before the U.S. brings World Trade Organization (WTO) or North American Free Trade Agreement (NAFTA) challenges or threatens to bring such challenges against other countries. Similarly, if the U.S. is sued by another country in a WTO or NAFTA tribunal, and loses the case, there is no requirement for an environmental review before the U.S. decides how to handle the ruling, i.e. eliminate a U.S. environmental law or pay sanctions. Thus, for example, under the Executive Order, the USTR will not have to review the environmental impacts of the Shrimp-Turtle WTO case, which requires the U.S. to change aspects of its Endangered Species Act protecting endangered sea turtles, the U.S. lost in 1998.

Finally, as noted above, the Executive Order requires less than what U.S. law already mandates. The National Environmental Policy Act (NEPA) requires environmental impact statements for all major federal actions, but the Clinton-Gore Administration has repeatedly refused to comply with this law.⁶⁵

Event: *Meeting of the Advisory Committee on Agricultural Biotechnology*
Date: July 26, 2000, 8:30 a.m.-7:00 p.m. and July 27, 2000, 8:30 a.m. - 5:00 p.m.
Location: Empire Room, Omni Shoreham Hotel, 2500 Calvert St., NW, Washington, DC 20008
FR Cite: 65 *Federal Register* 44025 (July 17, 2000)
Contact: For more information, Michael Schechtman, Office of the Deputy Secretary, USDA, 202B Jamie L. Whitten Federal Bldg., 12th and Independence Ave., SW, Washington, DC 20250; Tel: 202-720-3817; Fax: 202-690-4265; E-mail: mschechtman@ars.usda.gov. To attend the meeting, you must register with Cindi White, Tel: 202-690-8647, Fax: 202-720-3191, E-mail: cwhite@ars.usda.gov, at least seven days before the meeting. You must provide your name, title, business affiliation, address, and phone and fax numbers. Submit written comments to Mr. Schechtman at the address above.

Committee on Agricultural Biotechnology (ACAB) was created on July 13, 1999 to provide the USDA with advice on agricultural biotechnology issues. The ACAB is composed of a cross-section of 38 individuals from government, academia, production agriculture, agribusiness, ethicists, environmental and consumer groups. There are, in addition, seven *ex officio* members from other Federal Departments and Agencies. Representatives with consumer and environmental perspectives include Carolyn Brickey of the National Campaign for Pesticide Policy Reform, Carol T. Foreman of Consumer Federation of America, and Michael K. Hansen of Consumer Policy Institute. More information on the ACAB, and a complete list of its membership, is available

at www.usda.gov/agencies/biotech/acab.html.

Issues discussed at the meeting included: (1) finalization of ACAB bylaws and operating procedures; (2) updates on recent issues, projects, and activities; (3) potential impacts of the licensing of USDA Control of Gene Expression patents; (4) collection and analysis of agricultural biotechnology statistics; (5) topics for potential consideration by the National Academy of Sciences' Standing Committee on Biotechnology, Food and Fiber Production, and the Environment; (6) biotechnology budget priorities; and (7) additional issues for future ACAB deliberations.

Event: *Meeting of the Aviation Rulemaking Advisory Committee's Executive Committee*
Date: August 8, 2000, 11:00 a.m.
Location: Federal Aviation Administration, 800 Independence Ave., SW, Room 1014, Washington, DC 20590
FR Cite: *65 Federal Register* 45125 (July 20, 2000)
Contact: Regina Jones, FAA, 800 Independence Ave., SW, Washington, DC 20591; Tel: 202-267-9822; Fax: 202-267-5075; E-mail: Regina.Jones@faa.gov

On August 8, 2000, the Aviation Rulemaking Advisory Committee's (ARAC) Executive Committee held a public meeting to discuss and receive public comment on its agenda, which included: new ARAC tasks, voting policy, meeting locations, and new ARAC members. Interested persons may submit written comments to the Executive Committee by providing 25 copies to the contact person listed above.

Mary Bottari from Public Citizen's Harmonization Project attended the public meeting to encourage the FAA to retain proxy voting. The FAA has recently moved some of its committee meetings to Seattle, Washington, to facilitate

industry involvement, but making it difficult for public interest representatives on key FAA harmonization committees to attend meetings. While not perfect, proxy voting is one mechanism that will enable public interest representatives to have substantive input into key decisions.

The Federal Aviation Administration (FAA) created the ARAC to provide advice and recommendations to the FAA Administrator on FAA's rulemaking activities with respect to aviation-related issues, including the FAA's commitment to harmonize U.S. aviation regulations with European and Canadian regulations.

Event: *ARAC Public Meeting on Rotorcraft Issues*
Date: August 8, 2000, 2:00 p.m.
Location: Helicopter Association International, 1635 Prince St., Alexandria, VA 22314; 703-682-4646
FR Cite: *65 Federal Register* 45817 (July 25, 2000)
Contact: Angela Anderson, Office of Rulemaking, ARM-200, FAA, 800 Independence Ave., SW, Washington, DC 20591; Tel: 202-267-9681

On August 8, 2000, the Aviation Rulemaking Advisory Committee (ARAC) held a public meeting to discuss and receive public comment on the following agenda: (1) damage tolerance and fatigue evaluation of composite rotorcraft structure; and (2) damage tolerance and fatigue evaluation of metallic rotorcraft structure. Interested persons

may submit comments by providing 16 copies to the contact person listed above.

The Federal Aviation Administration (FAA) created the ARAC to provide advice and recommendations to the FAA Administrator on FAA's rulemaking activities with respect to aviation-related issues, including the FAA's

commitment to harmonize U.S. aviation regulations with

European and Canadian regulations.

Event: *Public Meeting of the U.S. Codex Committee on Processed Fruits and Vegetables*
Date: August 10, 2000, 9:00 a.m. - 4:30 p.m.
Location: Room 0161, South Bldg., U.S. Department of Agriculture, 1400 Independence Ave., SW, Washington, DC
FR Cite: *65 Federal Register* 46145 (July 27, 2000)
Contact: Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Bldg., 1400 Independence Ave., SW, Washington, DC 20250; Tel: 202-205-7760; Fax: 202-720-3157. Documents referenced in this notice are available at www.fao.org/waicent/faoinfo/economic/esn/codex/ccpfv20/pf00--01e.htm. Submit one original and two copies of comments to the FSIS Docket Room, Docket No. 00-030N, USDA, FSIS, Room 102, Cotton Annex, 300 12th St., SW, Washington, DC 20250-3700.

On August 10, 2000, the Food Safety and Inspection Service (FSIS) and Agricultural Marketing Service (AMS) sponsored a public meeting to provide information and receive public comment on agenda items that will be discussed at the Twentieth Session of the Codex Committee on Processed Fruits and Vegetables (CCFV), which will be held September 11-15, 2000, in Washington, DC. The Codex Alimentarius Commission (Codex) is the international body empowered by the World Trade Organization's (WTO) Sanitary and Phytosanitary Agreement to set presumptively-WTO legal food safety standards. The CCFV sets global standards for various processed fruits and vegetables,

including dried, canned, and frozen fruits and vegetables, but not fruit and vegetable juices.

Issues discussed at the August 10 meeting included: (1) establishment of a priority list for the revision and standardization of processed fruits and vegetables; (2) draft revised standards for canned fruits, applesauce, and pears; (3) proposed draft guidelines for packing media for canned fruits and vegetables; (4) methods of analysis for processed fruits and vegetables; and (5) consideration of other standards. These issues will be taken up by the CCFV during its September 11-15, 2000 session.

Event: *ARAC Public Meeting on Air Carrier Operations*
Date: August 15, 2000, 2:00 p.m.
Location: Conference Rooms 8A and B, Federal Office Bldg. 10A, 800 Independence Ave., SW, Washington, DC 20591
FR Cite: *65 Federal Register* 47001 (Aug. 1, 2000)
Contact: Mark Lawyer, Office of Rulemaking, 800 Independence Ave., SW, Washington, DC 20591; Tel: 202-493-4531

On August 15, 2000, the Aviation Rulemaking Advisory Committee (ARAC) held a public meeting to discuss and receive public comment on a report from the Airplane Performance Working Group and a presentation from the Extended Range Operations of Airplanes Working Group. The Federal Aviation Administration (FAA) created

the ARAC to provide advice and recommendations to the FAA Administrator on FAA's rulemaking activities with respect to aviation-related issues, including the FAA's commitment to harmonize U.S. aviation regulations with European and Canadian regulations.

Event: *Codex Intergovernmental Task Force on Fruit and Vegetable Juices Meeting*
Date: September 7, 2000, 1:00-4:00 p.m.

Location: Room 1409, FDA Bldg., 200 C St., SW, Washington, DC 20204
FR Cite: 65 *Federal Register* 51283 (August 23, 2000)
Deadline: Comments may be submitted at any time.
Contact: Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, FSIS, Room 4861, South Bldg., 1400 Independence Ave., SW, Washington, DC 20250; Tel: 202-205-7760; Fax: 202-720-3157. Submit one original and two copies of written comments to FSIS Docket Room, Docket # 00-037N, USDA, FSIS, Room 102, Cotton Annex, 300 12th St., SW, Washington, DC 20250-3700. Documents related to this meeting will be available on the Internet at www.fao.org/waicent/faoinfo/economic/esn/codex/ccfvj01/fj00_01e.htm.

On September 7, 2000, the Office of the Undersecretary for Food Safety, the U.S. Department of Agriculture (USDA), and the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) will hold a public meeting to provide information and receive public comment on agenda items that will be discussed at the First Session of the Codex ad hoc Intergovernmental Task Force on Fruit and Vegetable Juices. That meeting will take place September 18-22, 2000, in Brasilia, Brazil.

The Codex Alimentarius Commission (Codex) is the international body empowered by the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures to set presumptively WTO-legal food safety standards.

Issues to be discussed at the September 7 meeting include: (1) proposed draft general standards for fruit juices and nectars; (2) proposed draft revised standards for vegetable juices; and (3) proposed draft guidelines for the labeling of mixed fruit juices and nectars.

Event: *ARAC Public Meeting on Transport Airplane and Engine Issues*
Date: September 12-13, 2000, beginning at 8:30 a.m.
Location: Boeing Commercial Airplane Group, 535 Garden Ave., N, Bldg. 10-16, Renton, WA
FR Cite: 65 *Federal Register* 51637 (August 24, 2000)
Contact: Effie M. Upshaw, Office of Rulemaking, ARM-209, FAA, 800 Independence Ave., SW, Washington, DC 20591; E-mail: effie.upshaw@faa.gov; Tel: 202-267-7626; Fax: 202-267-5075.

The Aviation Rulemaking Advisory Committee (ARAC) will hold a public meeting on September 12-13, 2000, to discuss transport airplane and engine issues. The agenda includes reports from the Engine, Human Factors, Avionics Systems, General Structures, Airworthiness Assurance, Seat

Test, Ice Protection, Powerplant Installation, Flight Guidance System, Systems Design and Analysis, Design for Security, Flight Test, Electromagnetic Effects, Loads and Dynamics, Flight Controls, Mechanical Systems, and Electrical Systems Harmonization Working Groups.

Event: *ARAC Public Meeting on Emergency Evacuation Issues*
Date: September 14, 2000, beginning at 8:30 a.m.
Location: Boeing Commercial Airplane Group, 535 Garden Ave., N, Bldg. 10-16, Renton, WA
FR Cite: 65 *Federal Register* 51637 (August 24, 2000)
Contact: Effie M. Upshaw, Office of Rulemaking, ARM-209, FAA, 800 Independence Ave., SW, Washington, DC 20591; E-mail: effie.upshaw@faa.gov; Tel: 202-267-7626; Fax: 202-267-5075.

The Aviation Rulemaking Advisory Committee (ARAC) will hold a public meeting on September 14, 2000, to discuss emergency evacuation issues. The agenda includes reports from the Federal Aviation Administration, the Joint

Aviation Authorities (the European aviation regulatory body), Cabin Safety Harmonization Working Group, and Performance Standards Working Group.

Event: *Annual Meeting of the NAFTA Land Transportation Standards Subcommittee*
Date: October 23-27, 2000
Location: Mansion Galindo Fiesta American Hotel, San Juan Del Rio, Queretaro, Mexico
FR Cite: 65 *Federal Register* 52156 (August 28, 2000)
Contact: Allen Wiener, U.S. Department of Transportation, OST/X-20, Room 10300, 400 Seventh St., SW, Washington, DC 20590; Tel: 202-366-2892; Fax: 202-366-7417.

On October 23-27, 2000, the North American Free Trade Agreement's (NAFTA) Land Transportation Standards Subcommittee (LTSS) will hold its seven annual plenary session and other related working group meetings. Only government officials from the U.S., Canada, and Mexico will be allowed to attend the plenary and working group meetings.

However, representatives of non-governmental organizations (NGOs) that work on land transportation issues are invited to participate in a "listening session" on October 23, 2000, and a briefing on October 27, 2000. NGO representatives will be permitted to make ten-minute oral presentations at the October 23 listening session. NGO

representatives who wish to make a presentation must notify Allen Wiener of the U.S. Department of Transportation and provide copies of their presentations in English and Spanish by October 10, 2000.

The NAFTA established the LTSS to harmonize the transportation regulatory regimes and specific transportation-related standards in the U.S., Canada, and Mexico. The following working groups will meet during the week of the plenary session at the same location: (1) Compliance and Driver and Vehicle Standards, (2) Vehicle Weights and Dimensions, (3) Hazardous Materials Transportation Standards, and (4) Traffic Control Devices.

NOTES

1. North American Free Trade Agreement, Chapter 7: Agriculture and Sanitary and Phytosanitary Measures, Section B, Articles 709-716.

2. *Id.* at Article 713.1.

3. *Id.* at Article 713.5.

4. *Id.* at Article 713.2.

5. *Id.*

6. *Id.* at Article 713.3 (emphasis added).

7. *Id.* at Article 712.2 (emphasis added).

8. *Id.* at Article 715.3.

9. *Id.* at Article 715.1.

10. *Id.* at Article 715.2.

11. *Id.* at Article 714.1.

12. *Id.* at Article 714.2(a).

13. *Id.* at Article 714.2(b).

14. North American Free Trade Agreement, Chapter Nine: Standards-Related Measures, Articles 901-910.
15. *Id.* at Article 901.1
16. *Id.* at Article 909.1(a).
17. *Id.* at Article 909.1(c).
18. *Id.* at Article 910.1(a).
19. *Id.* at Article 902.2.
20. *Id.* at Article 904.2 (emphasis added).
21. *Id.* at Article 907.2.
22. *Id.* at Article 905.1.
23. *Id.*
24. *Id.* at Article 905.2.
25. *Id.* at Article 906.4-7.
26. *Id.* at Article 906.2.
27. *Id.* at Article 906.3.
28. *Id.* at Article 904.4.
29. *Id.* at Article 904.4(a)-(b), emphasis added.
30. *Id.* at Article 903.
31. For the most thorough explanation of the GHS, see 62 Fed. Reg. 15951 (Apr. 3, 1997).
32. David Bennett, "Chemical Classification; Endangering the Right-to-Know," *New Solutions*, Vol. 7, No. 4, Summer 1997, at 74.
33. 60 Fed. Reg. 50248 (Sep. 28, 1995).
34. 65 Fed. Reg. 44565, 44566 (Jul. 18, 2000).
35. 65 Fed. Reg. 44791, 44792 (Jul. 19, 2000).
36. Public Citizen, "Radiation 'Treatment' of Eggs Will Deplete Vitamins, Disrupt Proteins, Mask Factory Farm Filth," News Release, Jul. 24, 2000.
37. See Tony Webb, Tim Lang, & Kathleen Tucker, *Food Irradiation: Who Wants It?* (1987).
38. See Memorandum from I. Chen, Food and Drug Administration, to W. Trotter, FDA, Mar. 31, 2000; see also Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, Apr. 11, 2000.
39. See Edward S. Josephson and Martin S. Peterson, eds., *Preservation of Food by Ionizing Radiation* (vol. 1, 1982; vols. 2 & 3, 1983).

40. See U.S. Government Accounting Office, *The Department of the Army's Food Irradiation Program - Is It Worth Continuing?*, PSAD-78-146, Sep. 29, 1978.

41. *Id.*

42. 65 Fed. Reg. 30952 (May 15, 2000).

43. 65 Fed. Reg. 48701, 48703 (Aug. 9, 2000).

44. *Id.*

45. *Id.*

46. F. Gould, *et al.*, Initial frequency of alleles for resistance to *Bacillus thuringiensis* toxins in field populations of *Heliothis virescens*, *Proceedings of the National Academy of Sciences, USA*, 94: 3519-3523.

47. See U.S. Consumer's Choice Council, Letter to the Honorable Frank Loy, Undersecretary for Global Affairs, U.S. Department of State, Feb. 9, 1999; *see also* John Barry, *et al.*, "Frankenstein Foods?," *Newsweek*, Sep. 13, 1999, 33-35.

48. James Meikle and Paul Brown, "Friend in Need. . . The Ladybird, an Agricultural Ally Whose Breeding Potential May Be Reduced by GM Crops," *Guardian* (London), Mar. 4, 1999.

49. 65 Fed. Reg. 48703 (Aug. 9, 2000).

50. Cat Lazaroff, "U.S. EPA Launches Comprehensive Review of BT Crops," *Environment News Service*, Aug. 10, 2000.

51. 63 Fed. Reg. 31546, 31546 (Jun. 9, 1998).

52. *Id.*

53. *Id.*

54. 65 Fed. Reg. 42418 (Jul. 10, 2000).

55. See 64 Fed. Reg. 63169 (Nov. 18, 1999). For more information on the Executive Order, *see* "White House Issues (Another) Order on Environmental Review of Trade Agreements" in the November/December, 1999 issue of *Harmonization Alert*.

56. 65 Fed. Reg. 42743, 42745 (Jul. 11, 2000).

57. *Id.* at 42746.

58. *Id.*

59. *Id.*

60. *Id.*

61. See 65 Fed. Reg. 39976 (Jun. 28, 2000).

62. White House, "Executive Order - Environmental Review of Trade Agreements," Nov. 16, 1999, at Section 4(c).

63. Sierra Club, "Statement of Sierra Club Executive Director Carl Pope on President Clinton's Executive Order on Trade and the Environment," Press Release, Nov. 16, 1999.

64. White House, "Executive Order - Environmental Review of Trade Agreements," Nov. 16, 1999, at Section 4(b).

65.42 U.S.C. § 4321.