



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.

CONTENTS

TACD and TAED Release Annual Reports Criticizing U.S. and EU Governments	1
Transatlantic Business Dialogue Mid-Year Report	3
USDA Releases Report Criticizing FSIS Process for Determining Equivalence.....	4
Supreme Court Strikes Down Massachusetts Burma Law.....	6
Federal Register Alerts.....	8
Meetings/Events.....	18

Topic: *Transatlantic Consumer Dialogues Release Annual Reports, Slam Governments for Lack of Responsiveness*

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The Transatlantic Consumer Dialogue (TACD) and the Transatlantic Environmental Dialogue (TAED) each recently released their annual reports. The common theme was criticism of the U.S. government for systematically ignoring consumer and environmental recommendations on trade issues. The TACD was established in 1998 and the TAED in 1999. Both groups provide a public interest perspective in U.S.-European Union (EU) bilateral trade negotiations and balance a dialogue heavily influenced by the Transatlantic Business Dialogue (TABD).

The TABD was established in 1995 at the urging of then U.S. Commerce Secretary Ron Brown. TABD is comprised of U.S. and EU business interests who meet to

develop transatlantic trade-related demands of the U.S. and EU governments. The U.S. government has developed an interagency process simply to respond to TABD demands and these demands are frequently implemented.

The TACD is made up of 65 leading consumer groups on both sides of the Atlantic. On May 31, 2000, the TACD released its Annual Report measuring the governments' progress on implementing 22 recommendations issued by the TACD a year before. The report did not score the government's progress, but indicated little progress on any issue. "The U.S. government has shown the most enthusiasm for the core issue of transparency, yet even while they were promoting transparency in the WTO, [the U.S.

government] refused to give consumer advocates in Seattle access to key position papers,” said Niel Ritchie, U.S. chair of the TACD Trade Committee. Rhoda Karpatkin, President of Consumers Union, said the report demonstrated a “very poor record” and that “swift action to reverse this trend” is needed.¹

Similarly, the TAED brings environmental organizations together to make policy recommendations on environmental and trade issues to the governments. The May 2000 *TAED Report Card on US and EU Responses to Environment and Trade Issues* evaluates U.S. and EU responses to 16 recommendations issued by the TAED and gives both governments “D” averages for their responses. The TAED slams the U.S. government for “total failure to act or failure to act appropriately” on a wide variety of issues including: protecting Multilateral Environmental Agreements (MEAs) from challenge under the WTO, and adopting a normative rule on the Precautionary Principle.²

MEAs are the embodiment of global progress toward, and commitment to, the preservation of the environment. Yet many WTO rules explicitly contradict MEAs, including those in effect long before the WTO’s formation. As a matter of international law, the WTO automatically supercedes MEAs signed before the WTO’s formation. WTO negotiators refused to include language in the WTO to make MEAs and their domestic enforcement immune to WTO challenge.

Evaluating “the EU/US efforts to protect trade measures devised and applied in the context of Multilateral Environmental Agreements (MEAs) from challenge under WTO and other trade agreements,” the *TAED Report Card* gives the U.S. government an “F+” grade for failing “to push for clarity within WTO rules or to ratify several important MEAs” and pushing for a “savings clause in [the] Biosafety Protocol, to preserve WTO rights and obligations.”³ The Biosafety Protocol, agreed to by 131 nations on January 29, 2000, establishes rules for trade in genetically-modified organisms (GMOs). The “savings clause” language pushed by the U.S. government may subject the Biosafety Protocol to WTO rules. For taking a “relatively progressive position on this issue and develop[ing] a decent proposal for Seattle regarding deference to MEAs” the EU receives a “C” grade on this issue.⁴

The *TAED Report Card* also scores EU/U.S. “support for the adoption of a normative rule on the

precautionary principle to be applied in WTO decisions and proceedings, including in particular, in the Sanitary and Phytosanitary (SPS) Agreement.” The Precautionary Principle holds that nations should take protective action when faced with uncertain risks or inconclusive scientific knowledge and encourages regulators to err on the side of safety when faced with uncertain scientific evidence or great potential risks to public health or safety. The SPS Agreement is the WTO agreement governing how nations can set their domestic food safety standards.

The U.S. government receives an “F” grade for refusing to “acknowledge need for a ‘principle’” and opposing a discussion of the Precautionary Principle at the Codex Alimentarius Commission and in the Biosafety Protocol.⁵ Codex is the international standard-setting body empowered by the WTO to set presumptively WTO-legal food safety standards. While the U.S. government claims that all its domestic health, safety, and environmental regulations are based on precaution, the TAED states that the U.S. “allows risk assessment to undermine precaution [and] regards the principle as a cover for protectionism.”⁶ The EU is given a “C+” because it issued a Communication from the European Commission on the Precautionary Principle, which defines the Precautionary Principle and outlines the circumstances in which the EU will employ it. The EU also scored higher for taking a “pro-active role concerning GMOs and hormone-treated beef.”⁷

The lack of progress on TACD/TAED recommendations stands in sharp contrast to the relationship between the TABD and the U.S. government. In a 1998 speech at the TABD conference in Charlotte, North Carolina, Vice President Al Gore stated, “[O]f the 129 recommendations TABD has made in the past three years, over 50 percent have been implemented into law. I wish we had the same level of success with Congress!”⁸

In a more recent slap in the face of the consumer and environment dialogues, the U.S. government also ignored the recent unanimous TACD and TAED recommendation for a consumer and environmental representative to a new high-level U.S.-EU Biotechnology Consultative Forum. Establishment of this group was a TABD recommendation aimed at breaking the U.S.-EU stalemate on the issue of genetically-modified (GM) food. The U.S. insists GM foods should be treated the same as other foods and, as recently as June 2000, threatened the EU with a WTO challenge to the

EU's GM food regulations.

According to the U.S. announcement on June 7, 2000, the new forum "will take into account such factors as the food-security needs of developing countries, food safety, health, economic development and the environment."⁹ The forum "includes a carefully selected group of eminent scientists, ethicists, environmentalists, farmers, businessmen, consumer representatives and development experts."¹⁰ However, after soliciting a recommendation from the TACD and TAED, who unanimously chose Consumers Union as the best representative of a growing U.S. consumer consensus on the issues, the U.S. government decided to ignore both dialogues' recommendation and instead selected a former Monsanto lobbyist to the U.S. "consumer" seat in the new

forum. A group of consumer and environmental organizations, including Public Citizen, Sierra Club, Institute for Agriculture and Trade Policy, Friends of the Earth, Greenpeace, and Center for Food Safety, sent a strongly-worded protest letter to the Clinton Administration opposing the candidate and demanding her replacement. The Administration has ignored these demands. In contrast, the EU accepted both the TACD and TAED European nominees to the forum, naming two individuals selected by the European consumer and environmental groups to represent their interests.

The full TACD Annual Report and the TAED Report Card can be found on the Internet at the addresses above.

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

Contact: Lisa Schroeter, TABD US Director, 1401 I Street, NW, Suite 600, Washington, DC 20005; Tel: 202-336-7485. The complete report is available at www.tabd.com/index1.html

On May 23, 2000, the Transatlantic Business Dialogue (TABD), a coalition of U.S. and European business interests created by the U.S. and European Union (EU) governments in 1995, released its Mid-Year Report. The report contains TABD's analysis of the progress the U.S. and EU governments have made on past TABD recommendations for deregulation, harmonization, and greater economic integration. The Mid-Year Report is TABD's scorecard on government implementation of its requested policy changes and a list of future demands.

TABD has been criticized as a circumvention of the normal U.S. policy-making process, which requires openness and public input. TABD provides industry representatives contact with high-level U.S. and EU government officials, who are committed to considering each item the industry coalition presents. Indeed, in the U.S. an interagency process, chaired by the Commerce Department, has been developed simply to respond to TABD demands.

The Mid-Year Report's overarching themes of deregulation and harmonization are succinctly summarized in two sentences in the report's Chapeau: "The new obstacles to trade are now **domestic regulations**;" and "The TABD's ultimate objective is '**approved once, accepted everywhere**.'"¹¹ The report proposes harmonization and deregulation in dozens of areas, including: labeling, pharmaceuticals, medical devices, taxation, product and services liability, cosmetics, genetically-modified foods, cellular phones, dietary supplements, chemicals, and climate change. A summary of TABD's recommendations in some of these areas follows.

"**Approved Once, Accepted Everywhere**" - TABD is developing regulatory strategies to link "harmful regulatory

barriers with instruments for removing them" and to "set the right priorities for regulatory cooperation and reform"¹² TABD recommends that the U.S. and EU governments:

- < harmonize and recognize the "functional equivalence" of U.S. and EU regulations and standards;
- < harmonize and recognize each other's conformity assessment systems; and
- < delegate inspection and approval currently performed by regulatory bodies to third party or in-house corporate laboratories.¹³

Under the notion of "functional equivalence" promoted by TABD, significantly different -- and possibly less protective-- regulatory systems and standards in other nations would be declared "equivalent" to domestic regulatory systems. Once a foreign system is declared equivalent it must be treated as if it were a domestic system even if it differs from the domestic system in significant ways.

"Conformity assessment" means verification by a country that a product meets a required standard. Thus conformity assessment systems include product testing, quality systems audits, and the reporting required from such testing or audits. If the U.S. and EU implement TABD's recommendation and recognize each other's conformity assessment standards as "functionally equivalent," U.S. and European products will need the approval of only one of the U.S. or EU regulatory systems to be eligible for sale in both markets. Furthermore, if the U.S. and EU follow TABD's suggestion and delegate approval to third party or supplier's

laboratories, private companies, instead of government inspectors, will conduct product testing and perform quality systems audits.

Genetically-Modified Foods - TABD calls this “agri-biotech.” TABD demands “a transparent and predictable science-based approval system [for genetically-modified foods] on both sides of the Atlantic.”¹⁴ The current EU system has resulted in a freeze on approvals of genetically-modified seeds and foods given a lack of scientific evidence of the safety of such products. TABD also recommends an “early warning system” to notify industry of new regulatory requirements for approvals of genetically-modified products. TABD’s long-term objective is a centralized approval procedure for such products.

Cellular Phones - TABD notes that in both the U.S. and Europe, “there are public concerns about potential adverse health effects caused by the EMF [electromagnetic fields] exposure from mobile phones and their base stations.”¹⁵ The report states that such concerns may reduce the public acceptance of mobile phones and similar devices, with negative implications for trade. Rather than recommending ways to reduce exposure to EMF, however, TABD calls for activities “to inform the public and thereby reduce the concerns and the trade risks.”¹⁶

TABD notes that the U.S. Federal Communications Commission (FCC) has set standards for EMF exposure that provide more consumer protection than the standards set by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and that EU member nations are free to adopt EMF standards that provide more consumer protection

than the ICNIRP standards. TABD suggests that these differing standards and regulations “may be a potential trade barrier.”¹⁷ To avoid such a “trade risk,” TABD recommends that all national EMF regulations be harmonized with the ICNIRP standards. This would result in downward harmonization of both U.S. standards and the standards in EU countries with more stringent standards than ICNIRP.

Product and Services Liability - TABD calls the U.S. product and services liability system “a serious impediment to transatlantic trade and investment,” and recommends “reform” of the system at the federal and state level.¹⁸ TABD wants limits on punitive damages; the elimination of joint and several liability, which holds joint defendants individually liable for the entire amount of a judgment; the elimination of strict liability, which holds a defendant liable for damages caused by certain activities without proof of negligence; the establishment of statutes of limitation, which force plaintiffs to sue within a set period of time; and the availability of affirmative defenses, which can be used to dismiss a lawsuit on legal grounds even if the plaintiff’s complaint is true.

The TABD Mid-Year report includes further recommendations for harmonization in the areas of labeling, aerospace, chemicals, cosmetics, dietary supplements, fasteners, medical devices, pharmaceuticals, recreational marine craft, refrigerants and telecommunications services. For a complete account of TABD’s activities and recommendations, see the complete 2000 Mid Year Report, available on the Internet at the address listed above.

FOOD SAFETY

Topic: *USDA Releases Report Criticizing FSIS Process for Determining Equivalence*

Contact: The complete report, which also covers FSIS’ HACCP system, pathogen testing program, and compliance activities, is available at www.usda.gov/oig/audit/rpt/full_fsis.pdf

On June 21, 2000, the U.S. Department of Agriculture’s (USDA) Office of Inspector General (OIG) released an extensive report highly critical of the Food Safety and Inspection Service (FSIS) for its implementation of international equivalency determinations, the Hazard Analysis and Critical Control Point (HACCP) system, pathogen testing program, and compliance activities.¹⁹ This article focuses on the section of the report devoted to FSIS’ equivalency determinations.²⁰

World Trade Organization (WTO) rules require the U.S. to make “equivalence determinations.”²¹ Under the

WTO’s notion of “equivalence,” significantly different - and possibly less protective - regulatory systems and standards in other countries can be declared “equivalent” to U.S. regulatory systems and standards. Once a foreign system is declared “equivalent,” it must be treated as if it were a U.S. system, even if it differs in significant ways. Equivalency decisions are designed to allow foreign goods produced under “equivalent” systems free passage into the U.S. market.

Although WTO rules mandate equivalence determinations, they provide for only subjective comparisons

without establishing clear procedural guidelines or factors to be considered when determining equivalency. The FSIS has laid out some criteria for determining equivalency, but the criteria lack specificity.²² As a result, the FSIS declared a highly privatized and controversial Australian meat inspection system equivalent to the U.S. system even though the Australian program turned over a significant portion of government inspectors' duties to company employees.²³ The relevant U.S. law, the Wholesome Meat Act, requires beef and other meat from animals to be examined by federal inspectors for safety.²⁴

Nevertheless, at the time of the OIG report FSIS was treating the meat and/or poultry inspection systems of 36 other countries as equivalent to the FSIS system, and thus eligible to ship meat and/or poultry to the U.S. market. These countries are: Argentina, Australia, Austria, Belgium, Brazil, Canada, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, Finland, France, Germany, Guatemala, Honduras, Hong Kong, Hungary, Iceland, Israel, Republic of Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Northern Ireland, Poland, Romania, Slovenia, Spain, Sweden, Switzerland, United Kingdom, and Uruguay.²⁵

The OIG was highly critical of the FSIS' lack of criteria and controls for determining equivalence:

Detailed control process and procedures for determining the equivalency or the continuing eligibility of foreign inspection programs to export meat and poultry products to the United States were not adequately developed, were not incorporated in formal agency procedures for distribution to responsible personnel, or were not functioning as required by regulation. Responsibilities were also not well defined, resulting in unclear lines of authority, minimal supervisory oversight, and training goals that has not been achieved. The absence of a strong internal control structure does not provide reasonable assurance that objectives of the import inspection program are being achieved.²⁶

Second, the OIG noted that each foreign country must certify annually that each of its establishments that export meat and poultry products to the U.S. continue to comply with U.S. standards. The OIG found, "FSIS did not enforce this requirement and 19 countries were allowed to continue to export to the United States, even though they had not certified their establishments as meeting U.S. standards during 1999."²⁷

Third, the OIG report stated that foreign countries must maintain residue control standards equivalent to U.S. standards to identify the use of residues that have been classified as potential contaminants. The OIG found: "As of April 29, 1999, 15 of 36 countries that were certified to ship meat and poultry products to the United States had not submitted their 1999 residue test plans."²⁸

Fourth, the OIG noted that the FSIS maintains a computerized reinspection system that tells FSIS inspectors whether a particular foreign establishment is eligible to ship meat or poultry products to the U.S. When a foreign establishment is declared ineligible to export meat or poultry products to the U.S., the FSIS must update this system in a timely manner to prevent products from decertified establishments from reaching the U.S. market. The OIG found: "When FSIS or foreign inspectors declared an establishment ineligible to export product to the United States, FSIS did not always timely update its reinspection system with this information. **As a result, seven establishments from four foreign countries shipped over 4 million pounds of meat and poultry products and presented them for reinspection although they were delisted by their foreign inspection systems.**"²⁹

The OIG also "could not determine whether FSIS timely updated its reinspection system with critical laboratory results of microbiological tests."³⁰ Such tests are used to determine if meat and poultry products should be allowed to enter the U.S., how products should be sampled at ports of entry, and what microbiological tests should be performed.

Finally, the OIG discovered several significant problems with the FSIS' analysis of foreign food safety systems:

FSIS cannot demonstrate that it judged the foreign food safety systems of current trading partners according to U.S. standards. . . . Control procedures for equivalency determinations were not developed or adequately documented, technical subject-matter experts were not always involved in the process, and specific areas of foreign inspection systems have not yet been reviewed to verify that they are equivalent to U.S. standards. FSIS' country files did not contain sufficient evidence of FSIS' analysis of the information the country governments submitted to document their inspection systems. Moreover, FSIS granted equivalency status to six countries before it performed onsite equivalency verification reviews, and the onsite reviews that were performed were

not adequately documented to support what was reviewed and what deficiencies were found. . . . We concluded that inadequate planning for the transition to the new organization structure, as well as inadequate management oversight of the operational changes to the import inspection processes, contributed to the breakdown in controls that were designed to ensure the safety and wholesomeness of imported products entering the United States.³¹

To resolve these problems, the OIG made 35 recommendations, several of which go to the heart of consumer groups' years of criticism of the equivalence determination process. For instance, the OIG recommended "that FSIS develop and implement formal procedures, approved by FSIS management, for all aspects of its import inspection program, most specifically those related to (1) making equivalency determinations based on an evaluation of each foreign country's food safety regulatory system, as appropriate, (2) its enforcement of sanitary measures, and (3) entering country eligibility information into FSIS' reinspection system;" and "that FSIS enforce the regulatory requirements for countries to submit their residue test plans and test results and establishment certifications by foreign inspection systems."³²

The OIG also recommended "that FSIS conduct an assessment of the current organizational structure, clarify roles and responsibilities, and establish a system of management and operating control objectives and processes to ensure the safety and wholesomeness of imported meat and poultry products."³³

Regarding equivalency determinations, the OIG recommended that FSIS "establish a time-phased plan to complete each determination and ensure that technical subject-matter experts are involved, as appropriate, in determinations; the determinations are documented; and onsite verification reviews are conducted prior to granting equivalency status. For current trading partners, FSIS needs to develop and implement a policy for onsite verifications of changes in the requirements for foreign systems and ensure that onsite audits are conducted annually."³⁴

The FSIS accepted 33 of the OIG's 35 recommendations. However, the FSIS denied that any material management control weaknesses existed in its import inspection program and claimed that management oversight of import inspection operations was adequate. The OIG noted that under Departmental Regulation 1720-1, the FSIS has six months (until December 21, 2000) to reach management decisions on all the OIG recommendations.

The full OIG report is available at the Internet address listed above.

HUMAN RIGHTS

Topic: *Supreme Court Strikes Down Massachusetts Burma Law*

Contact: Simon Billenness, Trillium Asset Management, 711 Atlantic Avenue, Boston, MA 02111 (617) 423-6655. Mr. Billenness coordinated the amicus briefs in defense of the Massachusetts law.

On June 19, 2000, the U.S. Supreme Court unanimously struck down a Massachusetts state law which effectively prohibited Massachusetts government offices and agencies from purchasing goods or services from companies doing business in the country of Burma (now known as Myanmar).³⁵ The Court held that under the Constitution's Supremacy Clause, a federal law sanctioning Burma preempted the Massachusetts law.³⁶

The ruling was based on significantly narrower grounds than the arguments made by the corporate coalition challenging the law, who sought a ban on all social or human rights links to sub-federal procurement policies. However, the ruling undermines the practice of using local procurement to further the policy interests of tax payers employed by

many state and local governments.

The Massachusetts legislature passed the Burma law, which added a ten percent surcharge on bids for state contracts from companies with investments in Burma, in 1996. The law was modeled on the anti-apartheid selective purchasing laws adopted by 25 states and 164 local governments in the 1980s. In fact, Massachusetts State Representative Byron Rushing, who introduced the Massachusetts Burma law, has said that he copied the Massachusetts anti-apartheid law word-for-word, merely exchanging the word "Burma" for "South Africa." Anti-apartheid laws creating economic leverage for change, such as the one adopted by Massachusetts, were widely credited for helping to end apartheid in South Africa. There are 31

state and local Burma laws similar to the Massachusetts law.

These laws were passed at the request of Burmese democracy activists to protest the Burmese military government's violent and oppressive tactics. In 1988, the Burmese military violently repressed a popular revolt against military rule. In 1990, the military dictatorship overturned a democratic election won by the National League for Democracy, which is led by Aung San Suu Kyi, who later was awarded the Nobel Peace Prize.³⁷ Gare Smith, the State Department's acting Assistant Secretary for Democracy, Human Rights and Labor, citing the Burmese government's corruption, torture of political prisoners, and forced labor, stated, "Burma is a textbook case of a country gone bad."³⁸

In September, 1996, three months after the Massachusetts law was enacted, the U.S. Congress passed a law imposing sanctions on Burma.³⁹ The federal law has three substantive parts. First, it imposes three sanctions on Burma. It prohibits all aid to Burma's government except for humanitarian aid, counter-narcotics efforts, and promotion of human rights and democracy.⁴⁰ It instructs U.S. representatives to international financial institutions to vote against aid to Burma,⁴¹ and it prohibits the issuance of entry visas to Burmese government officials unless required by treaty or for United Nations staff.⁴² Second, the federal law authorizes the President to prohibit U.S. companies from "new investment" in Burma.⁴³ Finally, the federal law directs the President to work to "bring democracy to and improve human rights practices and the quality of life in Burma."⁴⁴

On May 27, 1997, President Clinton issued the Burma Executive Order, which certified that the Burmese government had "committed large-scale repression of the democratic opposition in Burma" and that the Burmese government's actions constituted "an unusual and extraordinary threat to the national security and foreign policy of the United States."⁴⁵ The Executive Order banned new investment in Burma by U.S. companies, but grandfathered in previous investments. Thus, U.S. companies that already had invested in Burma did not have to withdraw their money.

In October 1998, the European Union (EU) and Japan filed a case challenging the Massachusetts Burma law in the World Trade Organization (WTO).⁴⁶ The EU and Japan complained that the law violated the WTO's Agreement on Government Procurement. Under WTO procedures, Massachusetts state officials would have had no role in the defense of their law; rather, the U.S. Trade Representative would have exclusive authority to defend the law at the WTO. However, the EU and Japan suspended the WTO case when the National Foreign Trade Council (NFTC), a U.S. association of corporations engaging in foreign trade, sued the state of Massachusetts in the U.S. District Court for the

District of Massachusetts to have the law overturned.⁴⁷

The NFTC argued that the Massachusetts law "unconstitutionally infringed on the federal foreign affairs power, violated the Foreign Commerce Clause, and was preempted by the federal Act."⁴⁸ The District Court permanently enjoined enforcement of the state law, ruling that it "unconstitutionally impinge[d] on the federal government's exclusive authority to regulate foreign affairs."⁴⁹ Massachusetts appealed, but the U.S. Court of Appeals for the First Circuit affirmed the District Court's decision, holding that the law unconstitutionally interfered with the foreign affairs power of the federal government, violated the Constitution's Foreign Commerce Clause, and was preempted by the federal Burma law.⁵⁰

Massachusetts appealed to the Supreme Court. Seventy-eight Members of Congress, 38 state and local governments, all eight major state and local government associations, and 66 non-profit organizations filed *amicus curiae* ("friend of the court") briefs supporting the Massachusetts law.⁵¹ Nonetheless, the Supreme Court affirmed the lower courts' decisions, although on narrower grounds, simply ruling that under the Constitution's Supremacy Clause the law was preempted by the federal Burma statute.

The Supreme Court's ruling was very narrow. It held that a state or local selective purchasing law sanctioning a nation is preempted only when Congress has passed a corresponding law sanctioning that nation, and the two laws differ. This leaves the door open for state and local governments to pass several other types of laws.

For example, state and local governments could enact general laws to avoid purchasing goods and services from companies that violate human rights or labor standards as long as the laws do not apply specifically to companies doing business in a country where Congress has adopted federal sanctions.⁵² State and local governments also could require companies to disclose whether they do business in Burma as a condition for selling goods or services to the government. Furthermore, states and cities could divest their holdings in companies that do business in Burma. Thus, the Supreme Court decision does not rob state and local governments of all their options regarding the use of government procurement to discourage companies from doing business with violent, repressive regimes.

The U.S. Supreme Court ruling is more permissive of human rights links to procurement decisions than the relevant WTO rules. The WTO Agreement on Government Procurement forbids consideration of any non-commercial factors in governments', even sub-federal governments', procurement decisions.

FEDERAL REGISTER ALERTS

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Topic: *Sea Turtle Protections/Shrimp Imports*

Action: Notice of Certification of 41 Countries as Complying with Endangered Species Act

Venue: Bureau of Oceans and International Environmental and Scientific Affairs, Department of State

FR Cite: *65 Federal Register 25785* (May 3, 2000)

Deadline: The certifications take effect May 3, 2000

Contact: For more information, David Hogan, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, Washington, DC 20520-7818; Tel: (202) 647-2335.

On April 25, 2000, the U.S. State Department certified that 16 nations⁵³ have adopted programs for reducing sea turtle deaths caused by shrimp fishing nets which are "comparable" to the U.S. program. U.S. rules require shrimp fishers operating in waters inhabited by sea turtles to install turtle excluder devices (TEDs) - inexpensive trapdoors which allow sea turtles to escape the nets - in all their fishing nets.⁵⁴ The State Department also certified that the shrimp fishing environments in 25 other nations⁵⁵ do not pose a threat to sea turtles. Consequently, these 41 nations can export shrimp to the U.S.

Under Section 609 of Public Law 101-162, the State Department is required to certify to Congress by May 1 of each year either: (1) that a foreign nation has adopted a program regulating the incidental capture of sea turtles in its commercial shrimp fishery which is "comparable" to the U.S. program and has an incidental kill rate "comparable" to that of the U.S.; or (2) that the shrimp fishing environment in a nation does not pose a threat to sea turtles.⁵⁶ Any nation that does not receive such certification is prohibited from exporting shrimp to the U.S.

The State Department published its guidelines for determining certification in the *Federal Register* on July 8, 1999.⁵⁷ The State Department stated that it "is presently aware of no measure or series of measures that can minimize the capture and drowning of sea turtles in such nets that is comparable in effectiveness to the required use of TEDs."⁵⁸ Thus, the 16 nations certified as having programs "comparable" to the U.S. in fact require the use of TEDs.

However, the State Department also will certify a nation with a different sea turtle protection program as having a "comparable" program if the nation demonstrates - based on empirical data supported by objective scientific

studies - that its program is as effective as the U.S. TEDs program. To date, no nation has implemented such a program.

The State Department was forced to add the certification provision by a 1998 World Trade Organization (WTO) Appellate Body decision. Previously, the State Department prohibited shrimp imports from nations unless they required their shrimp fishers to use TEDs.

Four nations - India, Pakistan, Thailand, and Malaysia - challenged the TED requirement at the WTO, and on October 12, 1999, the WTO Appellate Body ruled this requirement amounted to "arbitrary and unjustifiable discrimination."⁵⁹ The U.S. argued that it required TEDs because the use of TEDs had proved to be the most cost-effective means of protecting sea turtles. The Appellate Body rejected this sort of regulatory discretion, noting that the U.S. required "other WTO Members to adopt a regulatory program that is not merely *comparable*, but rather *essentially the same*, as that applied to the United States shrimp trawl vessels."⁶⁰ The Appellate Body held, "It is not acceptable, in international trade relations, for one WTO Member to use an economic embargo to *require* other Members to adopt essentially the same comprehensive regulatory program, to achieve a certain policy goal. . . ."⁶¹ The Clinton Administration labeled this WTO ruling a victory, even though the WTO ordered the U.S. to change its policy. The WTO Appellate Body announced that the U.S. is able to pursue its goal of protecting sea turtles, but the ruling severely limited the possibility of the enforcement of policies designed to obtain that goal. The U.S. State Department changed the U.S. regulations to allow shrimp imports from nations with different but "comparable" sea turtle protection programs.

Topic: *Imports of Tuna from Mexico*
Action: Removal of Embargo
Venue: National Marine Fisheries Service, National Oceanic and Atmospheric Administration
FR Cite: *65 Federal Register 26585* (May 8, 2000)
Deadline: The removal of the embargo is effective April 12, 2000 - March 31, 2001
Contact: Regional Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213; Tel: (562) 980-4000; Fax: (562) 980-4018.

On April 12, 2000, the National Marine Fisheries Service (NMFS), part of the National Oceanic and Atmospheric Administration (NOAA), lifted an embargo on the importation of tuna from Mexico. This dramatic policy reversal, once again permitting sale of tuna caught using a long-banned method involving circling dolphins with huge nets, is the result of the U.S. losing trade challenges brought against U.S. dolphin protection laws.

The move permits imports of yellowfin tuna and tuna products harvested by Mexican purse seine vessels in the Eastern Tropical Pacific Ocean (ETP) to enter the U.S. for the first time in twenty years. The history of the ban on imports of tuna from Mexico spans several decades and includes a landmark 1991 General Agreement on Tariffs and Trade (GATT) ruling dubbed *GATTzilla v. Flipper* by environmentalists.

In 1959, fishermen in the 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.⁶²

In 1972, Congress passed the Marine Mammal Protection Act (MMPA),⁶³ which prohibited U.S. tuna fishermen from using fishing methods that resulted in dolphin deaths. In 1988, Congress passed amendments to the MMPA banning the sale of any tuna caught in a manner harmful to dolphins, thus excluding 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.⁶⁴ As a result of the MMPA, dolphin deaths in the ETP dropped dramatically - from 423,678 deaths per year in 1972 to 15,550 per year in 1992.⁶⁵

In 1991, Mexico successfully challenged the provisions of the MMPA excluding tuna from the U.S. market

if it was caught using purse seine nets in a GATT case.⁶⁶ In 1994 the European Community followed on the 1991 ruling against the U.S. dolphin law by challenging U.S. embargoes on countries processing tuna caught by other nations' fleets in violations of the MMPA.⁶⁷ 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.⁶⁸

In contrast to current World Trade Organization (WTO) rules, previous 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 could 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 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."⁶⁹

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).⁷⁰ The bill, sponsored by key anti-environment House and Senate members and opposed vehemently by the MMPA's original sponsors, amended the MMPA to allow tuna imports from countries that permit their fishermen to use purse seine nets under certain conditions - *i.e.* the country sends the Secretary of State a formal communication in which the

country commits to requiring an observer on each large ship engaging in purse seine fishing for yellowfin tuna in the ETP, or significantly reduces the dolphin mortality resulting from purse seine fishing.⁷¹ The IDCPC requires the NMFS to certify that a nation is meeting these conditions before imports of tuna from that nation are permitted into the U.S.

The NMFS has affirmed that Mexico has met the necessary conditions, and thus will allow imports of tuna caught by Mexican purse seine vessels to enter the U.S.

This finding removing the embargo on Mexican tuna is effective for one year (April 12, 2000 - March 31, 2001). The NMFS will determine whether Mexico is meeting the requirements of the IDCPC on an annual basis.

In a related development, on April 11, 2000, a U.S. federal court rejected the Department of Commerce's attempt to weaken standards on "dolphin safe" labeling for tuna.⁷² For a full description of this case, see the March/April edition of *Harmonization Alert*.

Topic: *Food Safety: Industry Petition on HACCP Inspection*

Action: Request for comments on industry petition

Venue: Food Safety and Inspection Service

FR Cite: 65 *Federal Register* 30952 (May 15, 2000)

Deadline: Comments are due July 14, 2000

Contact: For more information, Philip Derfler, Deputy Administrator, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, at (202) 720-2709. Send comments in triplicate to USDA, FSIS Docket Room, Docket No. 00-014N, Room 102 Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700.

The Food Safety and Inspection Service (FSIS) is requesting public comment on an industry petition that asks FSIS to amend sections of the Hazard Analysis and Critical Control Point (HACCP) inspection regulations. The petition was submitted by a group of meat and poultry trade associations, including the American Meat Institute, American Association of Meat Processors, National Chicken Council, National Food Processors Association, National Meat Association, National Turkey Federation, and North American Meat Processors.

The FSIS issued final HACCP regulations on July 25, 1996.⁷³ HACCP essentially transfers to meat establishment employees many of the responsibilities traditionally handled by government inspectors. The FSIS has been exporting its HACCP model worldwide by requiring countries that wish to export meat and poultry to the U.S. to adopt HACCP or equivalent inspection regulations.

In its petition, industry claims that FSIS interprets HACCP rules too narrowly and ignores the "commonsense approach needed to make HACCP successful." Specifically, industry requests FSIS to recognize other components of a HACCP system, like good manufacturing practice (GMP) programs, as addressing food safety concerns. Industry also recommends that FSIS change its definitions of several terms, including "food safety hazard," "hazard analysis," "severity," and "shipped." Finally, industry asks FSIS to amend its rules to provide that a HACCP system may be

found inadequate only when adulterated product is "shipped." Currently, FSIS rules provide that a HACCP system may be found inadequate when adulterated product is "produced" or "shipped."⁷⁴ The industry petition is reproduced in full in the *Federal Register* notice.

FSIS seeks public comment on the industry petition. Specifically, FSIS asks: (1) Would amending HACCP regulations in the manner suggested in the industry petition result in rules that provide the level of public health protection required by the Federal Meat Inspection Act and Poultry Products Inspection Act?; (2) Should FSIS consider regulatory modifications acknowledging other components of a HACCP system?; (3) What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?; and (4) Should the amendments suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and by other countries?

Consumer advocates have called on the FSIS to suspend consideration of the industry proposal in light of recent developments impacting HACCP rules. Most importantly, on June 30, 2000, the U.S. Court of Appeals for the District of Columbia struck down the HACCP Inspection Models Project ("HIMP"), which delegates the task of separating normal from abnormal carcasses and parts to industry employees, as violative of the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA).⁷⁵ The American Federation of Government

Employees, a union representing meat inspectors, had challenged HIMP, claiming the FMIA and PPIA explicitly required government inspectors, not company employees, to perform post-mortem inspections of each beef, poultry, and pork carcass.

The district court sided with the FSIS, holding that the inspection statutes permitted government inspectors to oversee company employees while the company employees

performed inspections. However, the appeals court overturned this decision, ruling that, under HIMP, "To the extent that federal employees are doing any systematic inspecting . . . they are inspecting people not carcasses. Delegating the task of inspecting carcasses to plant employees violates the clear mandates of the FMIA and PPIA."⁷⁶

Topic: *Harmonization of Auto Safety Standards on Side Impact Protection*
Action: Denial in part, grant in part of petition for rulemaking
Venue: National Highway Traffic Safety Administration
FR Cite: 65 *Federal Register* 33508 (May 24, 2000)
Contact: For legal issues, Deirdre Fujita, Office of Chief Counsel, (202) 266-2992. For non-legal issues, Dr. William Fan, Office of Crashworthiness Standards, Light Duty Vehicle Division, (202) 366-4922.

The National Highway Traffic Safety Administration (NHTSA) denied in part and granted in part a petition for rulemaking submitted by the Association of International Automobile Manufacturers, the Insurance Institute for Highway Safety, and the American Automobile Manufacturers Association. The petition requested that NHTSA determine that European regulation on side impact requirements is "functionally equivalent" to the U.S. side impact standard. NHTSA denied this aspect of the petition.

The petition also requested that NHTSA consider replacing the side impact test dummy (SID) specified in the U.S. regulation with a different version of the dummy specified in the European regulation (EuroSID). NHTSA granted this part of the petition, and will open a rulemaking proceeding to consider replacing the U.S. SID with the EuroSID.

The 1996 Department of Transportation and Related Agencies Appropriations Act directed NHTSA to study the differences between the U.S. and European side impact regulations and develop a plan for harmonizing these regulations. Consequently, in 1997 NHTSA tested eight vehicles that were certified to the U.S. standard using the procedures and criteria of the European standard. The results indicated that the ranking of the eight vehicles, according to their relative performance, was different when tested under the European standard. Thus, NHTSA could not conclude from this test whether vehicles designed to meet the European standard would meet the U.S. standard.

Furthermore, the European regulation allows for side impact testing with a "moving deformable barrier" - the frame slammed into vehicles to simulate crashes - that is significantly smaller than the U.S. barrier. The European

barrier is seven inches narrower and almost 1,000 pounds lighter than the U.S. barrier. NHTSA concluded that the European barrier is less representative of the side impact crash environment in the U.S. than the current U.S. barrier due to the increased U.S. market share of wider, heavier vehicles such as trucks, vans, and sport utility vehicles. In fact, NHTSA stated, "Instead of adopting the smaller [European] barrier, NHTSA plans to consider adopting a more representative [i.e. larger and heavier] barrier than the current barrier used in" the U.S. standard."⁷⁷

Based on the NHTSA test and the differences in the European MDB, NHTSA determined that the European side impact regulation is not functionally equivalent to the U.S. regulation, and thus denied that part of the petition.

However, NHTSA said it would consider the request that NHTSA replace the U.S. SID with an enhanced side impact dummy. NHTSA is not adopting the EuroSID because it is not "biofidelic" - or lifelike - enough. NHTSA stated: "A test dummy that is not biofidelic is unsuitable as a compliance test device. The less biofidelic a test device is, the less likely its results are reasonable and useful as a test measure of the protection a vehicle provides to a real occupant. A test dummy that is not representative of a human could lead to vehicle designs that provide little or no benefit to real occupants."⁷⁸

NHTSA stated that if the EuroSID's biofidelity problems can be solved, the agency will consider adopting it. Thus, NHTSA's first step will be working with European regulators to resolve these problems. Only then will NHTSA consider issuing a proposed rule to replace the U.S. SID with the improved EuroSID.

Topic: *Irradiation of Imported Fruits and Vegetables*
Action: Proposed rule
Venue: Animal and Plant Health Inspection Service
FR Cite: 65 *Federal Register* 34113 (May 26, 2000)
Deadline: Comments must be received by July 25, 2000
Contact: For general program and phytosanitary issues, Donna L. West, Import Specialist, Phytosanitary Issues Management, (301) 734-6799. For technical irradiation issues, Dr. Arnold Foudin, Assistant Director, Scientific Services, (301) 734-7710. Submit comments and three copies to Docket No. 98-030-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Animal and Plant Health Inspection Service (APHIS), a division of the U.S. Department of Agriculture (USDA), is proposing regulations allowing the use of irradiation to treat imported fruits and vegetables. APHIS believes irradiation will prevent exotic plant pests, such as fruit flies and the mango seed weevil, from being introduced into the U.S.

In the proposed rule, APHIS proposes the doses of radiation for imported fruits and vegetables to prevent the emergence of living adult forms of eleven species of fruit fly and one species of seed weevil. APHIS also proposes changes in the Code of Federal Regulations to authorize the importation of foods irradiated in accordance with the proposed rule's provisions, and requirements for the facilities performing the irradiation.

The proposed rule requires the pallets or cartons in which irradiated fruits and vegetables are shipped to be labeled as irradiated, but does not require the individual fruits and vegetables to be labeled at the retail level. Thus, consumers will not know whether the fruits and vegetables

they buy have been irradiated.

APHIS notes that 38 countries have approved the use of irradiation to control plant pests, as well as the World Health Organization, the International Plant Protection Convention, and the North American Plant Protection Organization. However, U.S. consumer organizations have questioned the safety of food irradiation.

For example, Public Citizen's Critical Mass Energy and Environment Program, which has systematically researched the studies upon which the Food and Drug Administration and USDA based their approval of food irradiation, lists several problems with irradiation, including: (1) irradiated food has caused health problems in laboratory animals, including kidney damage, tumors, and immune and reproductive system problems; (2) irradiation destroys vitamins, nutrients, and essential fatty acids in foods; (3) irradiation can lead to the formation of carcinogens and other toxic chemicals, such as benzene, octane, and formaldehyde; and (4) irradiation kills beneficial microorganisms, such as the yeasts and molds that help keep botulism at bay.

Topic: *International Standard-Setting Activities of the FSIS*
Action: Annual notice of FSIS activity in the Codex Alimentarius Commission
Venue: Food Safety and Inspection Service
FR Cite: 65 *Federal Register* 34637 (May 31, 2000)
Deadline: Comments may be submitted at any time.
Contact: F. Edward Scarbrough, U.S. Manager for Codex, USDA, (202) 205-7760. Submit comments to FSIS Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, Washington, DC 20250-3700.

The Food Safety and Inspection Service (FSIS) released a notice informing the public of the agency's sanitary and phytosanitary standard-setting activities in the Codex Alimentarius Commission. Codex is the international

standards-developing body empowered by the World Trade Organization (WTO) to set presumptively WTO-legal food safety standards. WTO Members are required to base their food safety standards (including regulations on inspection,

labeling, pesticide tolerances, genetically-modified foods, and risk assessment) on Codex standards. Thus, the standards set by Codex influence food safety regulations worldwide.

The annual notice, required by the Uruguay Round Agreements Act which established the World Trade Organization,⁷⁹ describes the standard-setting activities of each of Codex's approximately two dozen committees and lists a USDA contact person for each committee. To review specific activity in areas of interest to you, please examine the complete *Federal Register* notice, available at Public Citizen or on the Internet at the National Archives and Records Administration web site.⁸⁰

Codex Committees include: (1) Residues of Veterinary Drugs in Foods - which sets Maximum Residue

Limits for veterinary drugs in foods; (2) Food Additives and Contaminants - which sets maximum levels for additives, contaminants, and toxicants in foods, including irradiation; (3) Pesticide Residues - which sets maximum limits for pesticide residues in foods; (4) Food Import and Export Inspection and Certification Systems - which sets guidelines for WTO Members to follow when determining whether foreign nations' food inspection systems are "equivalent" to their own system; (5) General Principles - which deals with procedural and general matters; (6) Food Labeling - which develops guidelines for food labels; (7) Fresh Fruits and Vegetables; (8) Milk and Milk Products; (9) Fish and Fishery Products; and (10) the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology - which develops standards on genetically-modified foods.

Topic: *Harmonization of Fire Protection Requirements on Transport Airplanes*
Action: Proposed Rule
Venue: Federal Aviation Administration
FR Cite: 65 *Federal Register* 36977 (June 12, 2000)
Deadline: Comments are due by August 11, 2000
Contact: Michael K. McRae, Propulsion/Mechanical Systems Branch, ANM-112, Transport Airplane Directorate, Aircraft Certification Service, FAA, Northwest Mountain Region, 1601 Lind Ave. SW, Renton, WA 98055-4056; Tel: (425) 227-2133; Fax: (425) 227-1320; E-mail: mike.mcrae@faa.gov. Submit 2 copies of comments, identifying docket number FAA-2000-7471, to Dockets Management System, U.S. Department of Transportation Dockets, Room Plaza 401, 400 Seventh St. SW, Washington, DC 20590-0001.

The Federal Aviation Administration (FAA) is proposing to amend the standards for transport (passenger or cargo) airplanes to establish a new requirement for fire protection of powerplant installations. If adopted, this current proposal on fire protection of airplanes' powerplant installations would require all components (including ducts) within a designated fire zone to be fireproof if, when exposed to or damaged by fire, they could result in fire spreading to other regions of the airplane or cause unintentional operation of or inability to operate essential services or equipment. The FAA stated that the proposal would not add any new or different objectives to the current FAA regulations. Rather, it would "clarify and codify the way that the FAA traditionally has applied the related rules."⁸¹

This proposed rule is a result of the FAA's efforts to harmonize U.S. aviation regulations with European regulations. The FAA and the EU's Joint Aviation Authorities (JAA) began their effort to harmonize their respective aviation standards in 1988. Their stated goal is to ensure that: (1) standards do not require domestic and

foreign parties to manufacture or operate to different standards; and (2) the standards adopted are mutually acceptable to the FAA and the foreign aviation regulators. Ensuring the safety of airline passengers is not listed as a goal of these international harmonization efforts.

Recently aviation industry representatives - including the Aerospace Industries Association of America (AIA), General Aviation Manufacturers Association (GAMA), and European Association of Aerospace Industries (AECMA) - proposed a process for accelerating harmonization. The representatives recommended that the FAA and JAA harmonize their standards by adopting the more "stringent" of the two standards, with "stringent" meaning the relative higher level of safety or greater applicability to modern technology.

In response to this recommendation, the FAA and JAA agreed in March 1999 to a "Fast Track Harmonization Program" aimed at expediting the rulemaking process for the 42 standards currently tasked for harmonization and 80 additional standards. The FAA initiated the Fast Track

program on November 26, 1999,⁸² by requesting the U.S. Aviation Rulemaking Advisory Committee (ARAC) to: (1) review a list of U.S. and European standards identified by industry, the FAA, and the JAA as having differences that should be harmonized to establish one set of standards that represent the highest level of safety; (2) identify changes to the standards necessary for harmonization; and (3) submit to the FAA a technical report on each standard and recommend what the requirements of the harmonized standard should be. The FAA then considers the ARAC recommendations and initiates rulemaking based on those recommendations.

The FAA created the ARAC in 1991 to provide advice and recommendations regarding all of the FAA's safety-related rulemaking activities.⁸³ In 1992, the FAA assigned its entire harmonization effort to the ARAC.

Yet, the ARAC is riddled with problems. For example, few public interest organizations actively participate in ARAC. The committee is dominated by industry representatives and trade associations, including Airbus

Industrie, Airline Suppliers Association, Association of European Airlines, and Boeing Commercial Airplane Group.

Moreover, one public interest organization that actively participates in the ARAC steering committee and various working groups - the Aviation Consumer Action Project (ACAP) - may no longer be able to do so as a result of recent FAA actions. First, the FAA moved three out of four meetings of key ARAC issues groups to Seattle, Washington, making it difficult for public interest organizations to attend. Second, one issues group recently did away with proxy voting for committee members and the FAA is considering further restricting proxy voting. Third, the FAA stopped reimbursing ACAP for its travel expenses. This combination of factors means that the one active public interest representative with interest and expertise in airline safety may no longer be able to track or vote on important harmonization activities in this critical area of public concern.⁸⁴

Topic: *Genetically-Modified Plants*
Action: Notice of request for an exemption from the requirement of a tolerance
Venue: Environmental Protection Agency
FR Cite: 65 *Federal Register* 37545 (June 15, 2000)
Deadline: Comments must be received by July 17, 2000
Contact: Mike Mendelsohn, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA at Tel: (703) 308-8715; E-mail: mendelsohn.mike@epa.gov. Submit comments, identifying docket number PF-944, 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) has received a petition proposing the establishment of an exemption from the requirement of a tolerance for the plant pesticide *Bacillus thuringiensis* (*Bt*) Cry1F and the genetic material necessary for its production in plants in or on all food commodities. U.S. law requires pesticide manufacturers to petition the EPA to establish tolerances for plant pesticides or to permit an exemption from the tolerance requirement. The petition was submitted by Mycogen Seeds, a subsidiary of Dow AgroSciences.

Although the petition requests an exemption for the Cry1F pesticide in or on **all** food commodities, it relies solely on scientific evidence from testing of Mycogen Brand Bt Cry1F Insect Resistant Corn. This corn has been genetically-modified with a gene from the bacterium *Bt* to make the plant's cells continuously produce a natural endotoxin that is toxic to all insects. The *Bt* endotoxin is widely used by

organic and conventional (mostly family) farmers because it is a relatively harmless, natural pesticide. Corporations have produced *Bt* corn, cotton, potatoes, rice, and tomatoes, and they boast that such crops are environmentally sound because they require fewer pesticide treatments.

However, plants that constantly produce the *Bt* endotoxin speed up the spread of *Bt* resistance among pests that feed on those plants. University of North Carolina scientists have discovered *Bt*-resistance genes in populations of moths that feed on corn genetically-engineered to produce the *Bt* endotoxin.⁸⁵ If pests become resistant to *Bt*, organic and family farmers will have to turn to more toxic pesticides, undermining their farming methods.

Furthermore, *Bt* crops also may be toxic to harmless and beneficial insects, such as green lacewings and springtails, thereby reducing insect diversity.⁸⁶ Reductions in insect populations could harm the species that depend on

insects for food, including such birds as the corn bunting, partridge, and skylark. Researchers funded by the British government found that plants genetically engineered to resist aphids had serious effects on the fertility and life-span of ladybirds that fed on aphids.⁸⁷

This notice essentially serves as the EPA's version of a proposed rule. After reviewing comments received in response to this notice, the agency's next step will be to issue a final rule.

Topic: *Genetically-Engineered Potatoes*
Action: Notice of determination of non-regulated status
Venue: Animal and Plant Health Inspection Service
FR Cite: 65 *Federal Register* 37516 (June 15, 2000)
Deadline: The decision is effective July 17, 2000
Contact: Dr. James White, Biotechnology Assessments Section, Permits and Risk Assessments, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; Tel: (301) 734-5940.

The Animal and Plant Health Inspection Service (APHIS) is advising the public of the agency's decision to extend to an additional potato line (the "NewLeaf" potato) APHIS's determination that potatoes which have been genetically engineered for insect and virus resistance are no longer considered "regulated articles." As a result, APHIS regulations pertaining to field testing, importation, and interstate movement will no longer apply to the NewLeaf potato.

The NewLeaf potato has been genetically engineered for resistance to the Colorado potato beetle and potato leaf roll virus. Monsanto applied for a determination of non-regulated status regarding the NewLeaf potato on June 22, 1999, and on March 6, 2000, APHIS published a notice in the *Federal Register* requesting public comment on the petition.⁸⁸ APHIS received ten comments, six in favor of granting non-regulated status to the NewLeaf potato, and four against. The commenters opposed to deregulating the NewLeaf potato expressed concern that insufficient safety

testing had been performed on potential problems such as genetic drift (when the resistance genes from the potato plant are transferred to nearby weeds or traditional crops), the development of insect resistance, effects on beneficial organisms, and the potential for the development of novel plant viruses.

However, APHIS, after reviewing data submitted by Monsanto and other scientific data, found that the NewLeaf potato will have no significant impact on the environment. APHIS determined that the NewLeaf potato: "(1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than similar pest-resistant potatoes developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or unprocessed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture."⁸⁹

Topic: *U.S.-Jordan Free Trade Agreement*
Action: Notice and request for comments
Venue: U.S. Trade Representative
FR Cite: 65 *Federal Register* 37594 (June 15, 2000)
Deadline: Comments are due by noon, July 17, 2000
Contact: For procedural questions, Gloria Blue, Executive Secretary, Trade Policy Staff Committee, U.S. Trade Representative, 600 17th St., NW, Washington, DC 20508; Tel: (202) 395-3475. For all other questions regarding the negotiations, Adam Shub, Director for Middle Eastern Affairs, USTR, (202) 395-3320. Submit 20 copies of comments to Gloria Blue at the above address.

On June 6, 2000, President Clinton and Jordan's King Abdullah II agreed to negotiate a bilateral free trade agreement. The U.S. Trade Representative (USTR) intends to negotiate the free trade agreement, which will "eliminate duties and commercial barriers to bilateral trade in U.S.-Jordanian-origin goods and . . . address trade in services, trade-related aspects of intellectual property rights, trade-related environmental and labor matters, and other issues."⁹⁰

The pact is to be modeled on the 1985 U.S.-Israel Free Trade Agreement, a five-page agreement focusing on tariff cuts and government procurement. The Jordanian government has signaled interest in including labor and environmental provisions in the new agreement. Thus, Congressional and non-governmental organization (NGO) critics of the North American Free Trade Agreement (NAFTA) are awaiting the outcome of the talks before commenting on the proposal.

USTR invites comments on: (1) general and commodity-specific negotiating objectives for the agreement; (2) economic costs and benefit to U.S. producers and

consumers of removal of tariffs and non-tariff barriers to U.S.-Jordan trade; (3) treatment of specific goods under the agreement; (4) adequacy of existing customs measures to ensure Jordanian origin of imported goods; (5) proposals for service sectors to be addressed in the agreement, existing barriers to trade in those sectors, and economic costs and benefits of removing such barriers; (6) relevant trade-related intellectual property rights issues that should be addressed; (7) relevant trade-related environmental and labor issues that should be addressed; and possible environmental effects of the agreement. The USTR will perform an environmental assessment of the proposed agreement. See the November/December, 1999 issue of *Harmonization Alert* for more information on the USTR's proposed procedures for reviewing the environmental impacts of trade agreements.

The agreement will be negotiated and presented to Congress for approval outside of the Fast Track system, which expired in 1995 after being used for five trade agreements in its twenty-year existence.

Topic:	<i>APHIS Allows Imports of Grapefruit, Lemons, and Oranges from Argentina</i>
Action:	Final rule
Venue:	Animal and Plant Health Inspection Service
FR Cite:	65 <i>Federal Register</i> 37608 (June 15, 2000)
Deadline:	The rule is effective June 15, 2000
Contact:	Wayne D. Burnett, Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Rd. Unit 140, Riverdale, MD 20737-1236; Tel: (301) 734-6799.

The Animal and Plant Health Inspection Service (APHIS) is amending the citrus fruit regulations by designating a citrus-growing area within Argentina as free from citrus canker, a disease of citrus trees characterized by spongy eruptions on leaves and fruit. APHIS is also amending the regulations to allow the importation of grapefruit, lemons, and oranges from this area under conditions designed to prevent the introduction into the U.S. of plant pests and two other citrus diseases: sweet orange scab, a disease characterized by crust-like lesions on fruit, and citrus black spot, a disease characterized by black spots on fruit and leaves, twig lesions, defoliation, and rotting.

APHIS plans on limiting the distribution of Argentine citrus by implementing a three-stage distribution phase-in. In Stage One (during the 2000 and 2001 shipping seasons), APHIS will allow imports of Argentine citrus into 34 states in the continental U.S. that are neither commercial citrus-producing states nor states that border commercial citrus-producing states. In Stage Two (the 2002 and 2003 seasons), APHIS will allow imports of Argentine citrus into

all states in the continental U.S. except for the five commercial citrus-producing states (Arizona, California, Florida, Louisiana, and Texas). In Stage Three (beginning the 2004 season), APHIS will allow imports of Argentine citrus into all states in the continental U.S.

To monitor this phase-in plan, the final rule requires the boxes in which Argentine citrus is packed to be marked with the registration number of the grove that produced the fruit and a statement indicating that the fruit may not be distributed in Hawaii, Guam, the Northern Mariana Islands, Puerto Rico, the U.S. Virgin Islands, or any prohibited state under the limited distribution plan. The rule also requires each fruit to be individually labeled with a sticker identifying packing house in which they were packed.

APHIS also will monitor Argentine citrus producers by: (1) inspecting groves following the removal of leaves and other litter; (2) reviewing the timing and application of fungicidal sprays; (3) accompanying Argentine inspectors as they conduct pre-harvest grove inspections and collect

samples of fruit for laboratory examination; (4) reviewing the procedures for and results laboratory tests; (5) observing the harvesting of fruit, its transport to packing houses, and the entry control systems in place at the packing houses; and (5) ensuring that the required handling, treatment, inspection, identification, and packing requirements of the rule are being observed in the packing houses.

APHIS estimates that imports of Argentine lemons

will force the price of lemons in the U.S. down by as much as 19 percent, costing U.S. lemon producers between \$21.35 million and \$36.96 million each year, but saving U.S. consumers \$21.74 million to \$38.83 million each year. APHIS estimates that imports of Argentine oranges and grapefruits will have minimal impacts on the U.S. prices of those fruits. APHIS concludes, "In all cases, consumer gains are equal to or slightly outweigh grower losses."⁹¹

Topic: *FTAA Committee on the Participation of Civil Society*

Action: Notice and request for comments

Venue: U.S. Trade Representative

FR Cite: *65 Federal Register* 38872 (June 22, 2000)

Deadline: Comments are due by September 30, 2000

Contact: USTR Office of Western Hemisphere Affairs at (202) 395-5190. In order to be considered, comments must identify the person(s) and/or organization(s), with their address(es), that is/are commenting; refer to the trade matters related to the FTAA process, using the Ministerial Declarations of San Jose and Toronto as the frame of reference; be prefaced by the information requested in the cover sheet available on the FTAA web site (www.ftaa-alca.org); include an executive summary of no more than two pages; and be sent directly to the Chair of the Committee of Government Representatives on the Participation of Civil Society, c/o Tripartite Committee (Ref. Civil Society), Economic Commission for Latin America and the Caribbean (ECLAC), 1825 K St., NW, Ste. 1120, Washington, DC 20006; Fax: (202) 296-0826; E-mail: socs@eclac.org.

The Committee of Government Representatives on the Participation of Civil Society, established by the 34 countries participating in the Free Trade Area of the Americas (FTAA) negotiations, invites public comment on trade matters related to the FTAA process. If adopted, the FTAA would create a free trade zone, similar to the North American Free Trade Agreement (NAFTA), spanning all of North and South America.

The Committee was established as a consolation to consumer and environmental non-governmental organizations (NGOs) after FTAA negotiators refused to open the actual negotiation process to public participation and refused to include environmental, health, democracy, and human and labor rights provisions as FTAA negotiating topics. Previous NGO comments to the Committee have not been responded to, leaving some to question if they are even reviewed, much less connected in any way to the actual negotiations.

On December 11, 1994, President Clinton and 33 other leaders in the Western Hemisphere met in Miami, Florida for the first Summit of the Americas. The leaders agreed to conclude FTAA negotiations by 2005 and announced a Plan of Action, which focuses on: tariffs and

non-tariff barriers affecting trade in goods and services, agriculture, subsidies, investment, intellectual property rights, government procurement, technical barriers to trade, safeguards, rules of origin, antidumping and countervailing duties, sanitary and phytosanitary standards and procedures, dispute resolution, and competition policy.

These are all areas covered by World Trade Organization (WTO) agreements. In fact, the Plan of Action specifically mentions the WTO: "Free trade and increased economic integration are key factors for sustainable development. This will be furthered as we strive to make our trade liberalization and environmental policies mutually supportive, taking into account efforts undertaken by the GATT/WTO and other international organizations."⁹²

On March 19, 1998, 34 Western Hemisphere trade ministers met in San Jose, Costa Rica for a FTAA ministerial. The ministers established nine working groups responsible for the following areas under negotiation: (1) market access; (2) investment; (3) services; (4) government procurement; (5) dispute settlement; (6) agriculture; (7) intellectual property rights; (8) subsidies, antidumping, and countervailing duties; and (9) competition policy. The ministers also created three non-negotiating committees: (1) the Consultative Group on

Smaller Economies; (2) Committee of Government Representatives on the Participation of Civil Society; and (3) Joint Government-Private Sector Committee of Experts on Electronic Commerce.

The Committee on the Participation of Civil Society's mandate requires it to receive, analyze, and report on the full range of comments from non-governmental organizations (NGOs) in the hemisphere. Thus, the Committee is soliciting NGO comments on the FTAA process. According to the notice, "The U.S. Government

encourages the widest participation in this public comment process and will ensure that U.S. negotiators review all submissions for consideration in the ongoing FTAA negotiations."⁹³

The Committee will use the comments it receives as the basis for its report to the FTAA trade ministers. In the U.S. and throughout the hemisphere, NGOs are divided as to the effectiveness of using resources to participate in the Committee process.

- Topic:** *Environmental Review of U.S.-Jordan Free Trade Agreement*
- Action:** Notice and request for comments
- Venue:** Trade Policy Staff Committee, U.S. Trade Representative
- FR Cite:** *65 Federal Register* 39976 (June 28, 2000)
- Deadline:** Comments are due by July 17, 2000
- Contact:** For procedural questions, Gloria Blue, Executive Secretary, U.S. Trade Representative, 600 17th St., NW, Washington, DC 20508, Tel: (202) 395-3475. All other questions, Mary Latimer, Deputy Assistant U.S. Trade Representative for Environment and Natural Resources, (202) 395-7230; or Adam Shub, Director for Middle Eastern Affairs, (202) 395-3320. Submit 20 copies of comments to Gloria Blue at the above address.

The U.S. Trade Representative's Trade Policy Staff Committee (TPSC) is initiating an environmental review of the U.S.-Jordan free trade agreement currently under negotiation. For more information about this agreement, see the related article above. The TPSC is requesting comment on what should be included in the scope of the review, including the agreement's potential environmental effects and potential implications for U.S. environmental laws and regulations.

The Clinton Administration systematically has refused to apply the National Environmental Policy Act (NEPA), which requires environmental impact statements for

all major federal actions, to trade negotiations. Instead the Office of the U.S. Trade Representative has done a series of highly-politicized internal reviews which do not meet NEPA's requirements regarding public participation, scope, or timing. Jordan has indicated that it plans to perform its own environmental review of the agreement.

See the November/December, 1999 issue of *Harmonization Alert* for an article critiquing the USTR's process for reviewing the environmental impacts of trade agreements.

MEETINGS/EVENTS

- Event:** *Public Meeting on the Future of the ICH*
- Date:** May 16, 2000
- Location:** Center for Drug Evaluation and Research, Advisory Committee Conference Room, 5630 Fishers Lane, Room 1066, Rockville, MD 20857
- FR Cite:** *65 Federal Register* 25938 (May 4, 2000)

Contact: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; Tel: (301) 827-7001; Fax: (301) 827-6801; E-mail: Topperk@cder.fda.gov. Submit comments to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

On May 16, 2000, the Food and Drug Administration (FDA) held a public meeting on the future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). The FDA solicited public input on the future of the ICH to prepare for the July 2000 ICH Steering Committee meeting in Brussels, Belgium, where the ICH's future will be discussed.

The ICH was created by regulatory authorities in the U.S., European Union (EU), and Japan to develop harmonization initiatives with input from regulatory and industry representatives. Public-interest and consumer groups are excluded. The ICH is concerned with the harmonization of technical requirements for the registration of pharmaceuticals among the U.S., EU, and Japan.

Dr. Peter Lurie of Public Citizen's Health Research Group and Mary Bottari of Public Citizen's Global Trade Watch addressed a May 16, 2000 FDA meeting on the future of ICH. Lurie said that the underlying issue was who controlled the agenda of ICH. As long as it was controlled by the regulatory agencies and the industry, the concerns of consumers were likely to get short shrift.

Most of the efforts to date had addressed approaches to making the drug approval process quicker or otherwise easier for industry. But other issues of concern to the consumer were excluded: marketing and advertising, labeling, patient information, postmarketing surveillance, openness, access to records, etc. He noted that no consumer group had ever addressed the full ICH group.

Moreover, Public Citizen is concerned that the harmonization process may result in lower standards than those currently operating in the U.S. Dr. Lurie cited the already-approved switch from requiring carcinogenicity testing in two species to only requiring it in one, as is the EU practice, in order to secure FDA approval of a new drug. In addition, the draft ICH guidance on control groups in clinical trials would expand the use of placebos in studies of some serious conditions for which effective therapy exists, raising serious ethical problems.

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 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.

Issues discussed at the May 16 meeting included the FDA's future participation in the ICH and global cooperation. More information on the ICH is available on the Internet at www.ifpma.org/ich1.html.

Event: *Public Meetings: International Standards on the Transport of Dangerous Goods*

Dates: June 21, 2000, 10 a.m.-1 p.m.; and July 19, 2000, 10 a.m.-1 p.m.

Location: Both meetings will be held in Room 6244-6248 of the Department of Transportation Headquarters, Nassif Building, 400 Seventh St., SW, Washington, DC 20590

FR Cite: 65 *Federal Register* 33881 (May 25, 2000)

Contact: Frits Wybenga, International Standards Coordinator, or Bob Richard, Assistant International Standards Coordinator, Office of Hazardous Materials Safety, Department of Transportation, (202) 366-0656.

The Department of Transportation's Research and Special Programs Administration (RSPA) is holding public meetings in preparation for and to report the results of the

Eighteenth Session of the United Nation's Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCOE), which will be held July 3-13, 2000, in Geneva, Switzerland.

Topics to be discussed in the public meetings include: global harmonization of classification criteria; reformatting the UN Recommendations into a model rule; criteria for environmentally hazardous substances; harmonized requirements for compress gas cylinders; classification of individual substances; requirements for bulk and non-bulk packaging used to transport hazardous materials; and hazard communication requirements, including harmonized shipping paper requirements.

Copies of documents for the UNSCOE meeting may be obtained on the United Nations Transport Division's web site at www.unece.org/trans/main/dgdb/dgsubc/dgscmm.html. Information concerning UN dangerous goods meetings may be obtained at www.unece.org/trans/danger/meetings.htm#ST/SG. Other information is available at the RSPA's Hazardous Materials Safety web site at <http://hazmat.dot.gov/intstandards.htm>.

Event: *ARAC Public Meeting on Emergency Evacuation Issues*
Date: June 29, 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* 37448 (June 14, 2000)
Contact: Effie M. Upshaw, Office of Rulemaking, ARM-209, Federal Aviation Administration, 800 Independence Ave., SW, Washington, DC 20591; Tel: (202) 267-7626; Fax: (202) 267-5075; E-mail: effie.upshaw@faa.gov.

The Federal Aviation Administration's (FAA) Aviation Rulemaking Advisory Committee (ARAC) held a public meeting to discuss emergency evacuation issues. The agenda included reports from the FAA; the Joint Aviation Authorities (the European aviation regulatory body); the

Cabin Safety Harmonization Working Group; and the Performance Standards Working Group; and a proposal for the emergency evacuation charter update. For more information about the ARAC, see the article on ARAC in the Federal Register Alerts section above.

Event: *ARAC Public Meeting on Transport Airplane and Engine Issues*
Date: June 27-28, 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* 37449 (June 14, 2000)
Contact: Effie M. Upshaw, contact information above.

The Federal Aviation Administration's (FAA) Aviation Rulemaking Advisory Committee (ARAC) held a public meeting to discuss transport airplane and engine issues. The agenda included reports from the FAA; Joint Aviation Authorities (the European aviation regulatory body); Transport Canada; Harmonization Management Team; Engine Harmonization Working Group (HWG); Avionics Systems HWG; Flight Guidance System HWG; Systems Design and Analysis HWG; Ice Protection HWG; Powerplant Installation HWG; Seat Test HWG; Design for Security HWG; Braking System HWG; General Structures HWG; Airworthiness Assurance HWG; Flight Test HWG;

Electromagnetic Effects HWG; Loads and Dynamics HWG; Flight Controls HWG; Mechanical Systems HWG; and Electrical Systems HWG.

Nine of the HWGs - Avionics Systems, Flight Guidance System, Powerplant Installation, General Structures, Flight Test, Loads and Dynamics, Flight Controls, Mechanical Systems, and Electrical Systems - requested approval of technical reports drafted under the "Fast Track" harmonization process. For more information on this process and the ARAC, see the article on ARAC in the Federal Register Alerts section above.

NOTES

1. TACD "US and EU Consumer Groups Call For Swift Action to Balance Trade Dialogue: Business Demands Become Law, Consumer Demands Languish," Press Release, May 30, 2000.
2. TAED "TAED Report Card on US and EU Responses to Environment and Trade Issues," Explanation of Scorecard, May 2000, available at http://www.tiesweb.org/taed/new/scorecard_explanation.htm.
3. *Id.*
4. *Id.*
5. *Id.*
6. *Id.*
7. *Id.*
8. Al Gore, Speech to the TABD Charlotte Conference, Nov. 6, 1998.
9. U.S. Department of State, "U.S. and EU Establish Biotechnology Consultative Forum," Media Note, Jun. 7, 2000.
10. *Id.*
11. TABD, "2000 Mid Year Report," May 23, 2000, at 3 (emphasis original).
12. *Id.* at 6.
13. *Id.* at 6-7.
14. *Id.* at 17.
15. *Id.* at 25.
16. *Id.*
17. *Id.*
18. *Id.* at 55.
19. U.S. Department of Agriculture, Office of Inspector General, "Food Safety and Inspection Service: HACCP Implementation, Pathogen Testing Program, Foreign Country Equivalency, Compliance Activities," Reports Nos. 24001-3-At, 24601-1-Ch, 24099-3-Hy, and 24601-4-At (Jun. 2000).
20. U.S. Department of Agriculture, Office of Inspector General, "Food Safety and Inspection Service: Imported Meat and Poultry Inspection Process Phase 1," Report No. 24099-3-Hy (Jun. 2000).
21. World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures, Art. 4.
22. *See* Food Safety and Inspection Service, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," Mar. 12, 1999. The FSIS made the procedures outlined in this document a final rule, and official U.S. policy, on December 17, 1999. 64 Fed. Reg. 70690.

23. 64 Fed. Reg. 30299 (Jun. 7, 1999).
24. 21 U.S.C. § 601, *et seq.*
25. Food Safety and Inspection Service, "Equivalence Evaluation of Pathogen Reduction and HACCP Requirements," Dec. 14, 1999, on file with Public Citizen.
26. USDA, OIG, "Food Safety and Inspection Service: Imported Meat and Poultry Inspection Process Phase 1," Report No. 24099-3-Hy (Jun. 2000), at Sec. III, p. ii.
27. *Id.*
28. *Id.* at Sec. III, p. iii.
29. *Id.* (emphasis added).
30. *Id.*
31. *Id.* at Sec. III, pp. iii-iv.
32. *Id.*
33. *Id.* at Sec. III, p. iv.
34. *Id.*
35. "An Act Regulating State Contracts with Companies Doing Business with or in Burma (Myanmar)," 1996 Mass. Acts 239, ch. 130 (codified at Mass. Gen. Laws §§ 7:22G-7:22M).
36. Crosby, *et al.* v. National Foreign Trade Council, U.S. Sup. Ct., No. 99-474, Jun. 19, 2000.
37. Gaedig Bonabesse, "Sanctions on Burma deemed effective," *The Washington Times*, Sep. 28, 1998.
38. *Id.*
39. Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1997, § 570, 110 Stat. 3009.
40. *Id.* at § 570(a)(1).
41. *Id.* at § 570(a)(2).
42. *Id.* at § 570(a)(3).
43. *Id.* at § 570(b).
44. *Id.* at § 570(c).
45. Exec. Order No. 13047 (May 20, 1997).
46. "WTO to decide case against Myanmar curbs," *The Journal of Commerce*, Oct. 22, 1998.
47. "EU suspends Massachusetts case," *The Washington Times*, Feb. 9, 1999.
48. Crosby *et al.* v. National Foreign Trade Council, U.S. Sup. Ct., No. 99-474, Jun. 19, 2000, sec. II.

49. National Foreign Trade Council v. Baker, 26 F. Supp. 2d 287, 291 (Mass. 1998).
50. National Foreign Trade Council v. Natsios, 181 F.3d 38, 45 (CA1 1999).
51. Robert Stumberg, "No Business in Burma," *Legal Times*, Mar. 20, 2000.
52. Robert Stumberg and Matthew Porterfield, "Preliminary Analysis of Supreme Court Decision: Impact on Options for Free-Burma Legislation," Harrison Institute for Public Law, Georgetown University Law Center, Jun. 20, 2000.
53. Belize, Columbia, Costa Rica, Ecuador, El Salvador, Guatemala, Guyana, Indonesia, Mexico, Nicaragua, Nigeria, Panama, Suriname, Thailand, Trinidad and Tobago, and Venezuela. Honduras, which was certified in 1998, had its certification revoked after failing to demonstrate that it was adequately enforcing its regulations requiring the use of TEDs.
54. *See* 50 C.F.R. §§ 227.17 and 227.72(e).
55. The State Department found that sixteen of these nations - Argentina, Belgium, Canada, Chile, Denmark, Finland, Germany, Iceland, Ireland, the Netherlands, New Zealand, Norway, Russia, Sweden, the United Kingdom, and Uruguay - have shrimping grounds only in cold waters where the risk of taking sea turtles is negligible. The other nine nations - the Bahamas, China, the Dominican Republic, Fiji, Haiti, Jamaica, Oman, Peru, and Sri Lanka - harvest shrimp only with small boats with crews of less than five that use manual rather than mechanical means to retrieve nets, or catch shrimp using other methods that do not threaten sea turtles.
56. Pub. L. 101-162 § 609 (1990).
57. 64 Fed. Reg. 36946 (Jul. 8, 1999).
58. *Id.* at 36950.
59. WTO, "United States - Import Prohibition of Certain Shrimp and Shrimp Products," Report of the Appellate Body (WT/DS58/AB/R), Oct. 12, 1998, at 76.
60. *Id.* at 64 (emphasis original).
61. *Id.* at 65 (emphasis original).
62. Earth Island Institute v. Brown, 865 F. Supp. 1364, 1366 (N.D. Cal. 1994).
63. 16 U.S.C. § 1361.
64. *See* 42 Fed. Reg. 64548-60 (1977).
65. Administrative Record, Tab 50 at 1590.
66. GATT, United States - Restrictions on Imports of Tuna (DS21/R), Report of the Panel, Sep. 3, 1991.
67. GATT, United States - Restrictions on Imports of Tuna (DS29/R), Report of the Panel, Jun. 1994.
68. *See* GATT, Findings on U.S. Tuna Ban, Report of Dispute Panel, Aug. 16, 1991, at Paras. 5.24-5.29.
69. "Clinton Pledges Early, Renewed Effort to Pass Tuna-Dolphin Bill," *Inside U.S. Trade*, Oct. 1996.
70. 16 U.S.C. § 1414 (amending the MMPA).

71. *Id.* at § 1415(a).
72. David R. Brower, *et al.* v. William Daley, *et al.*, U.S. Dist. Ct. for the N.D. of Cal., Case No. C99-3892 TEH, Apr. 11, 2000.
73. 61 Fed. Reg. 38806 (Jul. 25, 1996).
74. 9 C.F.R. § 417.6(e).
75. American Federation of Government Employees, *et al.* v. Daniel R. Glickman, Secretary of the U.S. Department of Agriculture, *et al.*, U.S. Ct. of App. for the Dist. of Columbia, 98cv00893, Jun. 30, 2000.
76. *Id.*
77. 65 Fed. Reg. 33512 (May 24, 2000).
78. *Id.* at 33511.
79. Pub. L. 103-465, 108 Stat. 4809.
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81. 65 Fed. Reg. at 36981 (Jun. 12, 2000).
82. 64 Fed. Reg. 66522 (Nov. 26, 1999).
83. 56 Fed. Reg. 2190 (Jan. 22, 1991).
84. *See* Aviation Consumer Action Project, Letter to Honorable Jane Garvey, May 10, 2000, on file with Public Citizen.
85. *See* F. Gould, A. Anderson, A. Jones, D. Sumerford, D.G. Heckel, J. Lopez, S. Micinski, R. Leonard, and M. Laser, 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.
86. *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.
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89. 65 Fed. Reg. at 37517 (Jun. 15, 2000).
90. 65 Fed. Reg. at 37594-95 (Jun. 15, 2000).
91. 65 Fed. Reg. at 37666 (Jun. 15, 2000).
92. 65 Fed. Reg. at 38872 (Jun. 22, 2000).
93. *Id.*