



Vol. 1 No. 1

September 1998

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

CONTENTS

Transportation of Hazardous Materials	2
Cross-Border Trucking Under NAFTA	3
NAFTA Investor-State Provision, PCBs	4
Guatemalan Raspberries	5
Country-of-Origin Labeling Amendments	6
US - EU Mutual Recognition Agreement	7
WTO Ministerial Conference	8
Upcoming Meetings/Events	9
Agricultural and Food Standards	14

TRANSPORTATION

- Topic:** *Transportation of Hazardous Materials*
- Venue:** U.S. Department of Transportation, Research and Special Programs Administration (RSPA)
- ID:** Notice of Proposed Rulemaking - 63 Fed. Reg. 44311 (August 18, 1998)
- Deadline:** Comments on proposal due October 2, 1998. Comments must identify docket # - RSPA-98-4185 (HM-215c). Send 2 copies by mail to: Dockets Unit, U.S. Department of Transportation, Room PL 401, 400 Seventh St., S.W., Washington, D.C. 20590-0001; or by e-mail to: rules@rspa.dot.gov.
- Contacts:** Bob Richard, Assistant International Standards Coordinator, at (202) 366-0656; or Joan McIntyre, Office of Hazardous Materials Standards, at (202) 366-8553.

This proposed rule is an attempt to harmonize the current Hazardous Materials Regulations (HMR), which govern U.S. hazardous materials transporters, with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations). The UN Recommendations are used by many foreign countries, including Mexico and European nations, as a basis for their hazardous materials transportation regulations.

Currently the HMR requires a "POISON" label (incorporating a skull and crossbones) for any hazardous material posing a high or medium risk of toxicity. Any hazardous material posing a low risk of toxicity must be labeled with a "KEEP AWAY FROM FOOD" label (incorporating a stalk of wheat with an "X" through it). These requirements were based on past UN Recommendations.

However, in the eighth revised edition of the UN Recommendations, the UN Committee of Experts eliminated the "KEEP AWAY FROM FOOD" label because the experts felt it did not adequately communicate other hazards associated with lower-risk hazardous materials, such as risks from oral ingestion, dermal absorption, and inhalation. Thus, under the current UN Recommendations, **all** hazardous materials, regardless of their level of risk, must carry a "POISON" or "TOXIC" label. In addition, the vehicles transporting hazardous materials (e.g. rails cars, freight containers) must display "POISON" placards.

The U.S. Department of Transportation's

RSPA agrees with the UN Committee of Experts: "[T]he label fails to clearly convey a message of danger through direct oral ingestion. . . [and]. . .clearly fails to convey . . . skin absorption and inhalation hazards" associated with such materials' vapors, dusts, and mists.¹ The RSPA is proposing to adopt the UN Recommendations.

The RSPA received comments from chemical distributors and manufacturers, chemical trade associations, highway carriers, highway and rail carrier associations, and the Department of Energy, but none from consumer, labor, or health groups. Industry groups, including the American Trucking Associations, Inc., the Association of American Railroads, the Chemical Specialties Manufacturers Association, and a commenter described in the Federal Register notice as a "multinational chemical company," oppose the proposed rule, claiming that the "POISON" label overstates the hazards associated with lower-risk hazardous materials and that the proposed rule will result in increased costs, including higher motor carrier rates. In response to these comments, the RSPA proposed to allow the text "PG III" (short for Packing Group III materials, another phrase for lower-risk hazardous materials), on the "POISON" or "TOXIC" label, indicating the materials pose a lower risk of toxicity.²

This proposed rule could be the rare instance of upward harmonization of an existing U.S. regulation.

Topic: *Cross-Border Trucking Under NAFTA*
Venue: U.S. Department of Transportation (DOT)
Contacts: DOT's Office of International Transportation & Trade at (202) 366-2892; Tom Kozlowski, DOT's Office of Motor Carriers at (202) 366-4049; U.S. Trade Representative's Press Office at (202) 395-9501.

On September 22, 1998, Mexico formally requested a binding arbitration panel from the North American Free Trade Commission in an attempt to push the U.S. to open its border to Mexican trucks. This is the final step in the three-step dispute resolution process under NAFTA. The arbitration panel will hear both countries' cases and then make a decision. Either side may appeal the panel's decision, but it is otherwise binding on both countries. If the panel favors Mexico's position, Mexico can take retaliatory measures, such as raising tariffs, against U.S. imports.³

Currently, Mexican trucks are allowed to operate on U.S. roads for only a limited range in the border states. Under NAFTA, the U.S.-Mexico border was to be opened to international trucking on December 17, 1995. On that date, however, the U.S. Department of Transportation (DOT) denied access to the U.S. market to Mexican truckers because of safety concerns.⁴

These safety concerns have been well-documented. In Texas, trucks and their cargo can weigh no more than 80,000 pounds. In Mexico, trucks and their cargo can weigh up to 100,000 pounds, and that limit is enforced sporadically. Texas state inspectors have routinely found Mexican trucks on Texas highways weighing more than 120,000 pounds, and once discovered a Mexican truck weighing over 130,000 pounds.⁵

Texas Department of Public Safety (TDPS) officials have discovered these violations despite being able to inspect only one-fourth of one percent of all the trucks crossing the border. Almost one million Mexican trucks operated illegally in Texas in 1997, and eight to twelve million trucks per year could be crossing the U.S.-Mexico border by the year 2000. According to Texas officials, "At current rates, 69 percent - or a mind-numbing five to eight million of them - will have overweight loads, no insurance, faulty breaks, or some other serious problem."⁶

The problems associated with overweight trucks are serious. Studies show that an 80,000-pound

truck causes as much road damage as 9,600 cars. Overweight trucks also require more space to stop; under perfect conditions, an 80,000-pound truck traveling 55 mph takes 168 feet to come to a stop.⁷

Citizens for Reliable and Safe Highways (CRASH), a group that monitors traffic safety issues, has collected data showing that U.S. trucks average 4.5 years old, while Mexican trucks average 15 years old. In addition, U.S. trucks are required to have front brakes and Anti-Lock Braking Systems, while Mexican trucks are not required to have either.⁸

Such problems have led to a forced-out-of-service rate for Mexican trucks that is significantly higher than the rate for U.S. trucks. According to an April, 1997, report by the U.S. General Accounting Office (GAO), titled "Safety Concerns About Mexican Trucks Remain Even as Inspection Activity Increases," federal and state officials performed over 25,000 inspections of Mexican trucks in 1996. Each month an average of 45 percent of those trucks were ordered out of service due to serious safety violations, including unsafe loading and substandard tires. The forced out-of-service rate for U.S. trucks in 1995 was 28 percent.

The U.S. Department of Transportation argues that it has continued to refuse to open U.S. borders to Mexican trucks because of these safety concerns. Mexican officials call this refusal a continuing violation of NAFTA. They contend that "no safety issue is related to the U.S. obligation to allow entry of trucks into the United States."⁹ The two nations have been negotiating for nearly three years without coming to a resolution. Recently Mexican officials have stepped up their efforts to open the border. On July 24, 1998, Mexico requested a formal meeting of the Free Trade Commission, the second step in the NAFTA dispute resolution process. That meeting took place on August 19, 1998.¹⁰

Under NAFTA, no transcripts of NAFTA dispute-resolution meetings are made public, and public interest groups are not allowed to participate in these meetings. Even the binding arbitration panel is

closed to the public. The only document that may be made public is the panel's decision.

After the August 19th meeting, Mexican officials suggested that the two countries were close to settling the dispute. DOT officials recently indicated that Mexico is making progress in correcting the safety problems but expressed their continuing concern over

safety issues. In a telephone conversation on September 16th, an official from the DOT's Office of International Transportation and Trade, desiring to remain anonymous, said the two nations were not close to reaching an agreement because of the DOT's safety concerns.

TOXIC SUBSTANCES

Topic: *Hazardous Waste Company Uses NAFTA to Sue Canada Over PCB Ban*
Venue: NAFTA Dispute Tribunal

On July 22, 1998, S.D. Myers, an Ohio-based company hazardous waste treatment company, filed a "notice of intent" to seek compensation from the Canadian government under NAFTA §1110 (Expropriation and Compensation). This NAFTA provision can be enforced by private investors through direct suits in NAFTA tribunals against NAFTA nations. Among the new rights NAFTA established for foreign investors is a guarantee of compensation by NAFTA country governments for any government action "tantamount to" an "indirect expropriation." This provision has been criticized as establishing a broad regulatory takings mechanism.

S.D. Myers claims that Canada's 15-month ban in 1995 on the export to the U.S. of polychlorinated biphenyls (PCBs) waste cost it \$15 million and amounted to an expropriation of its business. The company is asking for \$6.3 million from the Canadian government. The Canadian government has 90 days (until October 22) to reach a settlement with S.D. Myers, or the case will go to a binding NAFTA arbitration panel which will determine whether the company is entitled to compensation from Canada.¹¹

Canada banned exports of PCBs, a hazardous coolant used in electricity transformers, in November, 1995, amid concerns that the PCBs were not being safely handled in the U.S. Fifteen months later, however, in February, 1997, the Canadian government rescinded the ban after being reassured about U.S. procedures. S.D. Myers is seeking \$6.3 million in compensation for the business it lost during the fifteen months the ban was in place. Canadian officials have stated that they will begin negotiating with S.D. Myers at the end of September.¹²

This is the second case in the last two months in which a U.S. corporation has sought compensation from the Canadian government under this NAFTA provision. The first such case was brought by Ethyl Corp., which sued Canada for \$250 million under the NAFTA investor-state provision over Canada's ban of imports of methylcyclopentadienyl manganese tricarbonyl (MMT), a gasoline additive. The Canadian Parliament, citing evidence that MMT posed health risks and clogged vehicles' catalytic converters, had passed legislation, effective June, 1997, banning interprovincial trade and import of MMT. Ethyl claimed the ban was an expropriation of its expected profits and its good reputation. As the Canadian government became aware it would lose the suit, it offered Ethyl a settlement, including: reversing the ban, publishing a statement declaring there was no evidence MMT posed a health or environmental risk, and paying Ethyl \$13 million in lost profits and legal fees.¹³ Ethyl accepted.

Environmental and public interest groups were outraged by this action, claiming that this NAFTA provision threatened a nation's sovereignty and ability to protect its citizens' health and environment.¹⁴ Both cases have proceeded under almost entirely in secret. NAFTA requires the proceedings of suits brought under the investor-state provision to be behind closed doors, with no public participation, despite the impact such suits might have on the public.¹⁵

A notice of intent was filed by S.D. Myers with the Canadian government on July 22, but was not revealed to the public until August 21, almost a month later, and then only through a leak.

Coming on the heels of the MMT case, the S.D. Myers case has environmentalists worried that a

new flood of cases aimed at health, safety, and environmental laws may be brought under the NAFTA investor-to-state provisions. “We are just seeing the tip

of the iceberg,” said one trade attorney, Howard Mann.¹⁶

FOOD

Topic: *Guatemalan Raspberry Imports*
Venue: Food and Drug Administration (FDA)

The FDA has decided to allow some Guatemalan farms to export raspberries to the U.S. beginning in September.¹⁷ This is an abrupt about-face for the FDA, which, only a few weeks earlier, had decided to prohibit all imports of Guatemalan raspberries this season after inspecting three Guatemalan raspberry farms at the end of June.¹⁸ All three farms failed safety inspections. FDA officials revisited several farms in July and found some to be in compliance with Guatemala’s “Model Plan of Excellence,” which the FDA helped develop.

The FDA has monitored Guatemalan raspberries since Cyclosporiasis outbreaks in North America in 1996 and 1997 caused by the imported fruit. Transmitted by a waterborne parasite found in developing countries, Cyclosporiasis causes an infection resulting in prolonged diarrhea, vomiting, chills, and significant weight loss. Before 1996, most Cyclosporiasis cases were reported by travelers returning from outside North America. In the summer of 1996, however, over 1,400 cases of Cyclosporiasis were reported by 20 U.S. states, the District of Columbia, and two Canadian provinces. Researchers investigating the outbreaks speculated that the number of actual cases was much larger because cases probably went unreported. Of the 1,465 reported cases, 22 people had to be hospitalized.

After investigators determined the cause of these infections to be Guatemalan raspberries, FDA officials inspected a number of Guatemalan farms and created three classifications for the farms based on the risk of Cyclosporiasis: high-risk, medium-risk, and low-risk. Only low-risk farms were allowed to export raspberries to the U.S. during the spring/early summer rainy season when the Cyclospora parasite is believed to be most infectious. Medium-risk farms were allowed to export raspberries to the U.S. before the onset of the rainy season. Exports from high-risk farms were banned.

This policy failed to protect against more outbreaks in 1997. In the first six months of 1997, 1,300 cases of Cyclosporiasis were reported in the U.S. and Canada. These cases were also associated with Guatemalan raspberries. The first reported cases stemmed from raspberries harvested in March, long before the rainy season, which began later than usual that year.

As a result of these infections, the FDA banned U.S. imports of fresh raspberries from all Guatemalan farms between March 15 and August 15 of 1998. This summer there were no reported cases of Cyclosporiasis in the U.S. Unfortunately for Canadian citizens, however, Canada did not ban imports of Guatemalan raspberries. As a result, 1998 was the third consecutive year that Cyclosporiasis outbreaks have been reported in Ontario. Over 300 people were stricken. Again investigators believe the cause of the outbreaks is Guatemalan raspberries.

After inspecting three Guatemalan raspberry farms in June, 1998, the FDA decided to prohibit imports of Guatemalan raspberries for the entire season. In several letters to Guatemalan officials, FDA officials outlined a number of conditions farms would have to meet before the FDA would allow them to export to the U.S. again, including installing biological filters for the water supply, employing a system of water tests, checking workers for diarrheal disease, and ensuring that raspberries would not be tampered with after leaving the farms.¹⁹ This deal, called the “Model Plan of Excellence,” reportedly drove about 125 high- and medium-risk Guatemalan farms out of business in 1998 because they could not comply with its requirements.²⁰

Two weeks later, however, the FDA determined that some Guatemalan farms had met the requirements of the Model Plan of Excellence and are acceptable for exporting raspberries to the U.S. These farms are preparing to export raspberries to the U.S. in

September.²¹ The FDA disregarded the continuing Cyclosporiasis outbreaks in Canada, even though the Canadian Food Inspection Agency was allowing only low-risk Guatemalan farms to export fresh raspberries to Canada at the time of the most recent outbreaks.

The FDA also ignored the difficulties in determining which raspberries were grown on which farms. According to officials from the Centers for Disease Control (CDC) which investigated the Cyclosporiasis outbreaks in the U.S., pinpointing the particular source farm for a Cyclosporiasis outbreak is difficult because numerous farms usually supply

raspberries to each shipment exported to the U.S. Furthermore, according to CDC Medical Epidemiologist Barbara Herwaldt, “[N]o one farm can account for an entire outbreak.”²² To get to the source of an outbreak, investigators must trace the raspberries from the consumer, to the store or restaurant, to the supplier, to the importer, to the exporter, and finally to the particular farm. Since the FDA is able to inspect only about 2% of imported food shipments, consumer groups have raised concerns about its capacity to monitor all Guatemalan raspberries to ensure that they were grown on acceptable farms.

Topic: *Country-of-Origin Labeling Amendments*
Venue: U.S. Congress
ID: Amendments to Senate Agriculture Appropriations Bill (S. 2159)
Contacts: Produce Amendment - Office of Sen. Bob Graham (D-Fla.) at (202) 224-3041;
 Meat Amendment - Office of Sen. Tim Johnson (D-S.Dak.) at (202) 224-5842.

On July 15, 1998, the U.S. Senate passed an amendment to the agriculture appropriations bill that would require U.S. retailers to inform customers of the country of origin of certain imported beef and lamb products. The Senate passed a similar amendment for all imported fresh fruits and vegetables on the following day. The Senate agriculture bill now goes to conference committee to be reconciled with the House bill, which does not contain any country-of-origin provisions.²³

The produce labeling amendment would require retailers to place country-of-origin information near displays of imported fresh produce, unless the produce is packaged, and the package label contains country-of-origin information. If a retailer fails to do so, it will be subject to a fine from the U.S. Department of Agriculture (USDA) of up to \$1,000 for the first day of the violation and \$250 for each subsequent day the violation continues. Food service businesses are exempted under the amendment.

The produce labeling amendment was introduced by Senator Bob Graham of Florida, where a similar state law has been in effect since 1979. A report by the Florida Department of Agriculture & Consumer Services noted that Florida’s country-of-origin statute “has proven to be a cost-effective, basic law providing beneficial information to all consumers.”²⁴ According to the report, most retailers

complied with the law simply by placing hand-lettered or permanent signs in retail bins containing imported fresh fruits or vegetables.

Retailers’ groups, including the Food Marketing Institute, an association representing supermarkets, oppose the amendment.

The meat labeling amendment would require the USDA to evaluate the costs to retailers and the benefits to consumers of providing country-of-origin labels within one year of the amendment’s enactment. Within 18 months of the amendment’s effective date, the USDA would have to enact regulations imposing the labeling requirements. Under the amendment, imported beef and lamb products must be labeled “Imported.” If a beef or lamb product contains both U.S. and imported meat, the label must identify the percentage of each.

Even before these amendments were approved, they had been threatened with possible NAFTA and WTO challenges.²⁵ Canadian officials claim that over \$2 billion (Canadian) in Canadian beef products might be affected by the meat labeling amendment, and that the amendment is inconsistent with NAFTA. They, along with officials from Mexico, have already requested formal NAFTA consultations with U.S. officials.²⁶ Mexican officials also have requested formal NAFTA consultations on the produce labeling amendment.²⁷

A confidential USDA memo, from Food Safety and Inspection Service Administrator Thomas J. Billy and Foreign Agriculture Service Administrator Lon S. Hatamiya to Undersecretary for Food Safety Catherine Woteki and Undersecretary for Farm and Agricultural Services August Schumacher, urged USDA officials to oppose the meat labeling amendment because it could open the U.S. to a WTO challenge for violating product marking rules.²⁸

U.S. industry and trade associations are using the specter of a WTO case to lobby against the amendments. The American Frozen Food Institute, in a July 24, 1998, letter to House Appropriations

Chairman Bob Livingston, cited possible violations of WTO rules as a reason to oppose the amendments.²⁹ The American Meat Institute argues that the meat labeling amendment is a non-tariff trade barrier.³⁰

In response to this pressure, the Senate removed both of the labeling amendments from the Agriculture Appropriations bill and replaced them with feasibility studies. The USDA will conduct a study of the meat labeling amendment, and the General Accounting Office (GAO) will conduct a study of the produce labeling amendment, to determine if they are “feasible.”

PHARMACEUTICALS

Topic: *US - EU Mutual Recognition Agreement (MRA)*
Venue: U.S. House of Representatives, Commerce Committee, Subcommittee on Oversight and Investigations
ID: Series of Hearings
Contacts: Office of the Subcommittee at (202) 225-2927/2125 or (202) 225-1919 (fax); Office of Rep. Joe Barton (Subcommittee Chairman) at (202) 225-2002; Office of Rep. Ron Klink (Ranking Member) at (202) 225-2565.

On October 2, 1998, the Commerce Committee’s Subcommittee on Oversight and Investigations held a hearing on the United States - European Union MRA on pharmaceuticals. Members of the Subcommittee who attended the hearing were Chairman Joe Barton (R-Tex.), Ranking Member Ron Klink (D-Penn.), Jim Greenwood (R-Penn.), Henry Waxman (D-Cal.), and Richard Burr (R-N.C.). Witnesses were Sharon Smith Holston, the Food and Drug Administration’s (FDA) Deputy Commissioner for External Affairs, Ralph Ives, the United States Trade Representative’s (USTR) Deputy Assistant Trade Representative for Europe and the Mediterranean, and Charles Ludolph, the Department of Commerce’s Deputy Assistant Secretary for Europe. This was the first of several hearings on this matter.

The U.S.-E.U. MRA consists of a general framework (“umbrella agreement”) and six sectoral annexes, which cover telecommunications, electromagnetic compatibility, electrical safety, recreational craft safety, medical devices, and pharmaceutical good manufacturing practices (GMPs).³¹ The agreement, signed in May, 1998, is set

to take effect on December 1, 1998. The October 2 hearing focused on the pharmaceutical GMP Annex, which covers human and animal drugs and certain biological products.³²

The purpose of the GMP Annex is to “govern the exchange . . . and normal endorsement . . . of official Good Manufacturing Practices (GMP) inspection reports after a [three-year] transitional period aimed at determination of the equivalence of the regulatory system of the Parties. . . .”³³ Essentially, the MRA would require the FDA to determine whether the regulatory and inspection systems of each of the 15 member nations of the European Union is “equivalent” to the FDA. Once the FDA finds a nation’s systems to be equivalent, drug manufacturers in that nation that have passed GMP inspection by that nation’s inspectors will be able to export drugs to the U.S. without having to submit them for re-inspection by the FDA.

The GMP Annex defines “equivalence” as “regulatory systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to

determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. ‘Equivalence’ does not require that the respective regulatory systems have identical procedures.”³⁴

The FDA’s definition of “equivalence” differs from the MRA’s definition. According to the FDA, “equivalence” means the FDA “has determined that another country’s regulatory system for GMPs (i.e., regulations, inspections procedures, and enforcement) provides at least the same level of consumer protection as FDA’s system.”³⁵ The FDA’s inability to agree with its European counterparts on definitions of terms was one of the problems noted by members of the Subcommittee. For example, Rep. Burr noted that the U.S. and the E.U. couldn’t even agree on the definition of GMPs. Thus, a nation may have laws and regulations on pharmaceuticals completely different from U.S. laws and regulations on pharmaceuticals and still be determined “equivalent” by the FDA.

The Subcommittee members cited numerous concerns with the MRA. Rep. Klink noted that the FDA would either need new funding or have to divert funds from other areas to be able to determine the equivalence of the statutory and regulatory systems of fifteen different countries with eleven different languages. Ms. Holston admitted that the FDA would be able to determine equivalence for only two or three countries in the three-year transition period.

Chairman Barton stated that E.U. nations that had not obtained equivalent status could just ship their pharmaceuticals to E.U. nations that had, and then those nations could ship those products to the U.S. He cited several past instances when the FDA had refused to allow pharmaceuticals from European drug manufacturers into the U.S. because of concerns about their manufacturing practices. Those manufacturers then simply shipped the products to E.U. nations.

Several Representatives expressed concern that the agreement on pharmaceuticals was included in the MRA only to get the Europeans to make concessions in the other five sectors. At one point, Rep. Greenwood suggested that the FDA agreed to the MRA so it would not endanger \$40 billion in trade

between the U.S. and the E.U. Rep. Klink stated that the FDA’s decision to sign the MRA was based on economics, not the health and safety of the U.S. public. Deputy Assistant Ives of the USTR said that the E.U., not the U.S., had raised the issue of pharmaceuticals in the MRA.

The Subcommittee members often referred to documents, including internal FDA memos and e-mail messages, to make their points. Rep. Greenwood read an e-mail message from Mike Dubinsky, an FDA official on the MRA negotiating team, to Walter Baxt, the Director of FDA’s Office of International Affairs, which stated that the MRA contained more cons than pros for the FDA and that the FDA should consider withdrawing from the MRA negotiations. Rep. Greenwood then noted that Mr. Dubinsky was no longer in the FDA’s employ. Ms. Holston claimed that all of Mr. Dubinsky’s concerns had been addressed, but could not point to any specific language in the MRA. Chairman Barton declared the record would be left open so the FDA could demonstrate precisely how Mr. Dubinsky’s concerns had been addressed by the MRA.

Rep. Klink read a long and detailed newspaper article about an Italian minister of health who for years took bribes in exchange for approving dangerous drugs and even HIV-tainted blood for sale in Italy and other E.U. nations. Rep. Klink then asked Ms. Holston how anyone could be sure such a situation would not be repeated with dangerous products being shipped to the U.S. She admitted the MRA contained no guarantees against fraud or bribery.

At the hearing’s conclusion, Chairman Barton apologized to Ms. Holston for the Subcommittee members’ harsh criticism of the FDA in this case. “But,” he stated, “you’re trying to defend something [the pharmaceutical MRA] that’s indefensible.” He used a poker analogy to describe the situation: “You don’t even have a pair of twos, and we’re all holding full houses and straight flushes.” Chairman Barton then stated that the witnesses had done nothing to assuage the concerns of the Subcommittee members and that the Subcommittee would hold further hearings on the MRA to give them the opportunity to do so.

WORLD TRADE ORGANIZATION

Topic: *WTO Ministerial Conference*

Harmonization Alert

September 1998

- Venue:** Office of the United States Trade Representative (USTR)
- Contact:** To submit written comments, send 20 copies to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the United States Trade Representative, Room 501, 600 17th Street, N.W., Washington, D.C., 20508. If you have procedural questions, contact Gloria Blue at (202) 395-3475. If you have general questions, contact the Office of WTO and Multilateral Affairs at (202) 395-6843. For more information on the WTO, see the USTR web site (www.ustr.gov) or the WTO web site (www.wto.org). The request for public comment was published at 63 Federal Register 44,500 on August 19, 1998.
- Subject:** U.S. positions on the agenda, scope, content, and timetables of the third Ministerial Conference of the World Trade Organization (WTO).
- Deadline:** October 16, 1998

At the second WTO Ministerial Conference, which was held in Geneva on May 18-20, 1998, WTO Members agreed on two Ministerial Declarations. The first instructed the WTO's General Council to prepare for negotiations on the WTO's "built-in" agenda for approval at the 1999 ministerial meeting, and the second prohibited WTO members from imposing customs duties on electronic commerce. The "built-in" WTO agenda is the result of compromise by the U.S. when it was unable to obtain certain elements of its liberalization agenda at the conclusion of the Uruguay Round. The left-over items - further agriculture liberalization, deeper intellectual property protections, and broader market access for services - were listed on a specific timeline for future negotiations.

The third WTO Ministerial Conference will take place in the U.S. in the fourth quarter of 1999. The Administration seeks opinions on possible issues for consideration, including subject matter and approaches to any new negotiations or future work in the WTO, such as improving consultations with non-governmental organizations.

In preparation for the General Council negotiations, the Trade Policy Staff Committee (TPSC) seeks public comment in the following seven areas: (1) Implementation of Existing Agreements and Work Programs; (2) Mandated Negotiations; (3) Reviews of Existing Agreements and Work Programs; (4) Singapore Ministerial Work Program; (5) Integration of Least-Developed Countries; (6) Other Trade Matters of Interest; and (7) Electronic Commerce. The notice states that the TPSC will develop U.S. positions on these matters based in part on the comments it receives. Comments should clearly state the presenter's position and cite specific information supporting that position.

Submitted comments, except for information deemed confidential, will be available for public review in the USTR Reading Room, Room 101, Office of the USTR, 600 17th Street, NW, Washington, DC. The Reading Room is open to the public from 9:30 a.m. to noon and from 1 p.m. to 4 p.m. Monday through Friday. To make an appointment to review the file, contact Brenda Webb at (202) 395-6186.

UPCOMING MEETINGS/EVENTS

- Event:** *Codex Regional Coordinating Committee for North America and the South-West Pacific (5th Session)*
- Dates:** October 6-9, 1998
- Location:** Seattle, Washington
- Contact:** U.S. Codex Office, Room 4861, South Building, Washington, D.C. 20250-3700; Tel.: (202) 205-7760; Fax: (202) 720-3157; E-mail: uscodex@usda.gov.

Event: *Multilateral Agreement on Investments (MAI) Hearings*
Dates: October 8-9 and 14-15, 1998
Location: Victoria, British Columbia
Contact: Margrete Strand-Rangnes (Public Citizen) at (202) 546-4996, or by e-mail at mstrand@citizen.org.

These are public hearings with members of the British Columbia Parliament on the MAI. Experts will testify on the MAI and its possible impacts on the Canadian environment and culture, and the regulatory ability of provincial, regional, local, and Indigenous governments. Members of the public are invited to

attend these hearings and ask questions and make comments. For those who are unable to attend, verbatim transcripts of the hearings will be available on the Internet at www.legis.gov.bc.ca/cmt. For more information on the MAI, see the MAI web page at www.mai.flora.org.

Event: *First Nations NAFTA International Summit & Trade Show*
Dates: October 17-19, 1998
Location: Calgary Convention Centre (Marriott Hotel), Calgary, Canada
Contacts: In Canada, Bruce Iron Shirt, Suite 310, 6940 Fisher Road, SE, Calgary, Alberta T2H 0W3; Tel.: (403) 258-1775; Fax: (403) 258-1811; e-mail: gsmith@mail1.treaty7.org; in the U.S., Deni Leonard, World Trade Centre, Suite 122, San Francisco, CA 94111; Tel.: (415) 288-8500; Fax: (415) 288-8510; E-mail: DLA1@aol.com.
Attndng: Jane Stewart, Canadian Minister of Indian Affairs; Bill Richardson, US Representative to the UN; Phil Fontaine, head of the Assembly of First Nations; Blaine Favel, Canada's world ambassador on Indigenous issues; Ron Allen, US National Congress of American Indians; Kevin Grover, head of the US Bureau of Indian Affairs; Nina Sibal, UNESCO; Simon Reisman, who negotiated NAFTA for former Canadian Prime Minister Brian Mulroney, and Canadian Indigenous band council representatives, including Chris Shade, Joe Norton, Marvin Mull, Willie Little Child, Deni Leonard, and Jessie Fisher.

Panels will discuss topics relating to trade between Canadian and American businesses and Indigenous peoples (First Nations). Issues will include creating an Indigenous trade group, overcoming possible barriers and opposition to trade, and addressing Indigenous peoples' labor, environmental, and sovereignty concerns with such trade. Kahn-Tineta Horn, President of the Canadian Alliance in Solidarity with the Native Peoples (CASNP) is concerned that this summit could result in a NAFTA-like trade deal for the Indigenous peoples of Canada, Mexico, the U.S., and Central and South America. Horn called this

summit "the latest maneuver to sell off [Indigenous peoples'] resources [including oil, gas, forestry, mining, fishery, agriculture, and cultural symbols] to benefit the multinational corporations who are behind this whole thing."

Horn also is worried about the lack of opposing viewpoints in this summit: "Dissenters, such as the Zapatistas, have not been invited to give their views on NAFTA which allows Canada, United States and Mexico and their business interests to overrule any U.S. and Canadian laws adopted by any state, tribe, band or local government if they interfere with

investments or sale of services or products by any multinational corporation.” Horn concludes that Indigenous people “should tell these corporate fronts

about the damage to workers, farmers and citizens by allowing cheap goods from undemocratic countries to come in. . . .”³⁶

- Event:** *International Citizens’ Summit Against the MAI (In Conjunction with MAI Negotiators)*
- Dates:** October 17-20, 1998
- Location:** Paris, France
- Contact:** Margrete Strand-Rangnes (Public Citizen) at (202) 546-4996, or by e-mail at mstrand@citizen.org.
- Speakers:** Include Maud Barlow, Council of Canadians; Luciana Castellina, REX Commission, and ex-Member of the Italian Parliament; Tony Clarke, Polaris Institute (Canada); Christian de Brie, Le Monde Diplomatique; Olivier Hodeoman, Corporate Europe Observatory; Martin Khor, Third World Network; Antonio Tujan, IBON Foundation (Phillipines); Lori Wallach, Public Citizen; and Mark Vallianatos, Friends of the Earth.

MAI negotiators, after a six-month hiatus, are meeting in Paris October 20-21 to continue negotiations on the MAI. Members of non-governmental organizations and activists will meet at the International Citizens’ Summit to discuss investment liberalization and its implications at the MAI and other targeted fora including the IMF, WTO,

and the Transatlantic Economic Partnership (TEP). Panel topics include globalization of poverty, destruction of cultural diversity, the hijacking of democracy, the globalitarian economy, the new media empires, privatization of social services, and threats to biological diversity and food security.

- Event:** *Transatlantic Environmental NGO Meeting*
- Dates:** October 22-23, 1998
- Location:** Brussels, Belgium
- Contact:** Lori Wallach at (202) 546-4996, or by e-mail at lwallach@citizen.org.

Representatives of European and American environmental non-governmental organizations will meet to discuss enhancing their transatlantic coordination, possible responses to the Transatlantic

Economic Partnership (TEP), and possible strategies for the upcoming EU-US summit, scheduled for December 15, 1998.

- Event:** *Codex Committee on Food Hygiene (31st Session)*
- Dates:** October 26-30, 1998
- Location:** Orlando, Florida

Contact: U.S. Codex Office, Room 4861, South Building, Washington, D.C. 20250-3700; Tel.: (202) 205-7760; Fax: (202) 720-3157; E-mail: uscodex@usda.gov.

Event: *Transatlantic Business Dialogue (TABD) Fourth Annual Conference (Closed to the Public)*

Dates: November 5-7, 1998

Location: Charlotte, North Carolina

Contacts: Selina Jackson (U.S./TABD) at (202) 293-7822, Stephen Johnston (EU/TABD) at (32) 2-231-1728, or Charlotte Myers Carolinas Partnership at (704) 347-8942. More information is available at the TABD web site (<http://www.tabd.com>) and the Carolinas Partnership web site (<http://www.charlotteregion.com>).

Co-chairs: Lodewijk de Vink, President and CEO of Warner-Lambert, and Jurgen Schrempp, CEO of Daimler-Benz.

The TABD is a coalition of U.S. and European business interests created by the U.S. and European governments in 1995. Its goal is to allow business interests to develop common positions on issues of interest. TABD has been criticized as a circumvention of the normal policy-making process with its openness and public input requirements. TABD recommendations - over 100 are expected from this conference - are received by Cabinet-level government officials. In the U.S., a separate interagency process has been developed to respond to TABD demands. TABD keeps a scorecard on government implementation of its requested policy changes.

Goals of TABD include reduction of barriers to trade between the U.S. and the EU, harmonization of American and European standards and certifications, equivalence determinations, and negotiation of so-

called Mutual Recognition Agreements (MRAs). These are bilateral agreements which require the U.S. and the EU to recognize each other's testing, inspection, and certification process. For example, if a product is tested and approved by the appropriate European regulatory body, U.S. must accept the product without having FDA or USDA test the product before it is imported into the U.S.

Top-level American and European business and government representatives, including representatives from the FCC, FDA, EPA, USTR, and Departments of Commerce and State, will attend this conference.

The conference is open to participants only, not the public or public interest groups. The press will not have access to the actual sessions, but there will be a press conference at the conclusion of the conference. This conference is closed to the public.

Event: *International Conference on Alternatives to Globalization*

Dates: November 7-9, 1998

Location: Development Academy of the Philippines, Tagaytay City, Philippines

Contacts: Conference Secretariat, International Conference on Alternatives to Globalization, IBON Foundation Inc., 3/F SCC Bldg. 4427 Int. Old Sta. Mesa, Manila 1008, Philippines; Phone: (063-2) 713-2737 / 713-2729; Fax: (063-2) 716-0108.

Speakers: Include Antonio Tujan, Jr., IBON Foundation, Inc., Philippines; Prof. Deepak

Nayyar, J. Nehru University, India; Martin Khor, Third World Network, Malaysia; Agnes Bertrand, ECOROPA, France; Bamrung Kayopha, Assembly for the Poor, Thailand; Andrew Rowell, International Society for Ecology and Culture, UK; Jason Fox, Maori Legal Service, New Zealand; Liza Masa, Gabriela, Philippines; Adelar Pizzeta, Movimento dos Trabalhadores Rurais sem Terra (MST), Brazil; Crispin Beltran, May First Movement, Philippines; Yash Tandon, International South Group Network, Zimbabwe; Luis Jalandoni, National Democratic Front, Netherlands; and Prof. James Petras, Binghamton University, USA.

Deadline: For registration - October 30, 1998.

Speakers will cover topics such as the MAI, IMF, and WTO; transnational corporations and the emergence of corporate rule; strategies for solving the current global financial crisis; globalization's impacts

on the environment, marginalized societies, and indigenous peoples; and the strategies of women's, workers', citizens', and peasants' movements in fighting globalization.

Event: *Public Comment Period*

Subject: Guidelines for accepting citizen submissions regarding environmental enforcement.

Venue: Joint Public Advisory Committee of the North American Commission for Environmental Cooperation (NAFTA Environmental Side Agreement)

Contact: Send comments to: Joint Public Advisory Committee, Commission for Environmental Cooperation, 393 St. Jacques West, Suite 200, Montreal, Quebec H2Y 1N9; Fax: (514) 350-4314; e-mail: mpepin@ccemtl.org; or Comite Consultivo Publico Conjunto, Comision para la cooperacion ambiental, Progreso No. 3 (Viveros de Coyoacan), Col. Del Carmen Coyoacan, Delegacion Coyoacan, Mexico, D.F. 04110; Phone/Fax: (525) 659-50-21. Comments must include submitter's name, firm or organization, address, telephone and fax numbers, and e-mail address.

Deadline: December 9, 1998

The Commission for Environmental Cooperation (CEC), an environmental NAFTA side agreement institution, was created in 1994 by the North American Agreement on Environmental Cooperation (NAAEC). Its charge is to enhance cooperation among Mexico, Canada, and the U.S., and to study and enforce environmental laws related to toxics, chemicals, and water, but not natural resources. The institution provides a lengthy process to get studies prepared on claims of non-enforcement of a country's environmental laws.

The CEC consists of a Council (composed of Carol Browner, Administrator of the U.S.

Environmental Protection Agency; Christine Stewart, Canadian Environment Minister; and Julia Carabias, Mexico's Secretary of the Environment, Natural Resources and Fisheries), a Secretariat, and the Joint Public Advisory Committee (JPAC). The JPAC has fifteen members, five from each of the three NAFTA countries, appointed by their respective governments. The JPAC acts as a transnational body, and it may provide advice to the Council on any matters within the scope of the NAAEC.

Under Article 14 of the NAAEC, the Secretariat of the CEC can consider a submission from any non-governmental organization or individual

claiming that one of the Parties (the governments of Canada, Mexico, and the U.S.) to the NAAEC is not effectively enforcing its environmental laws. If the Secretariat determines that the claim merits requesting a response from the Party, the Party must respond to the claim. If, after reviewing the Party's response, the Secretariat determines the claim warrants developing a factual record, it informs the Council and provides its reasons. Then the Council can instruct the Secretariat to develop a factual record on the claim. This record can be made available to the public only after a two-thirds vote by the Council.

Citizen submissions made under Article 14 to the Secretariat must follow certain guidelines. The JPAC is proposing modifications and additions to these guidelines and is seeking public comment and recommendations on these proposals to form the basis for its advice to the Council. The guidelines and the

proposed changes can be found at the CEC web site (<http://www.cec.org>) under the heading *Citizen Submissions* and the section *Revised Guidelines*. Those without Internet access can receive a copy of these documents by mail by sending a request to Manon Pepin by e-mail to (mpepin@ccemtl.org) or by fax to (514) 350-4314 in Montreal or to (525) 659-51-21 in Mexico City.

A JPAC working group will hold a workshop in January, 1999, at the CEC Secretariat in Montreal. The working group will select representatives of various groups and interests from Canada, Mexico, and the U.S. to attend this workshop. The selections will be based on those who made the most substantive comments to the proposed changes to the guidelines. For more information, contact the CEC Secretariat directly by e-mail at info@ccemtl.org, fax at (514) 350-4314, or phone at (514) 350-4338.

AGRICULTURAL AND FOOD STANDARDS

Topic: *Citrus Fruit from Argentina*
Venue: Animal and Plant Health Inspection Service (APHIS)
ID: Notice of proposed change in regulations.
Deadline: For public comments - October 13, 1998
FSTSD#: 98.0147
Contacts: For more information, fax the FSTSD# to the attention of Deborah A. Thompson, Food Safety & Technical Services Division, U.S. Department of Agriculture, Foreign Agricultural Service, at (202) 690-0677, or call Carolyn Wilson at (202) 720-2239.

APHIS is soliciting public comment on its proposal to amend current citrus fruit regulations by recognizing certain areas within Argentina as being free from the following citrus diseases: citrus canker, sweet orange scab, and citrus black spot. APHIS is relying on

surveys conducted by Argentine plant health authorities as proof that these areas are disease-free. The proposed changes would allow grapefruit, lemons, and oranges from these areas in Argentina to be imported into the United States under certain conditions.

Topic: *Shell Eggs*
Venue: Food Safety and Inspection Service (FSIS)
ID: Notice of proposed change in regulations.
Deadline: For public comments - October 26, 1998
FSTSD#: 98.0162
Contacts: For more information, fax the FSTSD# to the attention of Deborah A. Thompson, Food Safety & Technical Services Division, U.S. Department of Agriculture, Foreign

Agricultural Service, at (202) 690-0677, or call Carolyn Wilson at (202) 720-2239.

FSIS is soliciting public comment on its proposed revisions to regulations governing the inspection and labeling of eggs and egg products. The revisions would require shell eggs packed for consumer use to be stored and transported under refrigeration at an ambient temperature not to exceed 45 degrees Fahrenheit (7.2 degrees Celsius). The revisions would also require

packed shell eggs to carry labels stating that refrigeration is required and any shell eggs imported into the United States packed for consumer use to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45 degrees Fahrenheit.

Topic: *Orchids*
Venue: Animal and Plant Health Inspection Service (APHIS)
ID: Notice of proposed change in regulations.
Deadline: For public comment - November 2, 1998
FSTSD#: 98.0163
Contacts: For more information, fax the FSTSD# to the attention of Deborah A. Thompson, Food Safety & Technical Services Division, U.S. Department of Agriculture, Foreign Agriculture Service, at (202) 690-0677, or call Carolyn Wilson at (202) 720-2239.

APHIS is soliciting public comment on its proposed amendment to the regulations governing the importation of plants and plant products. The amendment would add orchids to the list of plants that may be imported into the United States, subject to

certain growing, inspection, and certification requirements. APHIS has determined that the pest risks associated with the import of orchids is no greater than the pest risk associated with the import of plants which may be imported under the regulations.

NOTES

1. 63 Fed. Reg. At 44,314.
2. *Id.*
3. Mary Sutter, "Mexico Asks Arbitration to Force Open Border," *Journal of Commerce*, Sep. 24, 1998, at 11A.
4. Kevin G. Hall, "Mexico-US Truck Talks to Go Another Round," *Journal of Commerce*, Aug. 21, 1998.
5. Mark Langford, "Nugent: Mexican Trucks Breaking State Law," *UPI*, Oct. 28, 1997.
6. *Id.*
7. *Id.*
8. *NAFTA: The Facts*, CRASH Document.
9. "Mexican Official Says Progress Achieved in NAFTA Truck Consultations," *Inside U.S. Trade*, 8/21/98, at 3, 4.

10. *Id.*, at 3.
11. See Scott Morrison and Edward Alden, "Ottawa Faces Claim Over PCB Waste Ban," *Financial Times*, 9/2/98.
12. R. Blassnig, "US Company Seeks Compensation for Losses Due to Canadian Ban," *Chem. Reg. Rep.*, 9/4/98.
13. See C. Tower, "Canada Backs Away From US Firm's NAFTA Challenge," *Journal of Commerce*, 7/22/98.
14. See Laura Eggerston, "Liberals Lift Ban on Controversial Gas Additive," *Toronto Star*, Jul. 21, 1998.
15. L. Herman, "'Expropriation' Takes on New Meaning: MMT Case Sets Precedent," *The Financial Post*, 7/28/98.
16. Heather Scoffield, "U.S. Firm Hits Ottawa with NAFTA Lawsuit," *Toronto Globe & Mail*, Aug. 21, 1998.
17. See "Guatemala Plans September Raspberry Exports to U.S. After FDA Finds Farms in Compliance," *World Food Chemical News*, Jul. 22, 1998, at 6.
18. See "U.S. Will Not Allow Imports of Guatemalan Raspberries This Season," *World FCN*, Jul. 8, 1998, at 34.
19. See *id.*
20. See "Guatemala Plans. . .," *supra* note 17, at 7.
21. See *id.*, at 6.
22. *Id.*, at 7.
23. A. Gordenker, "Senate Approves Country-of-Origin Labeling for Produce, Meat," *World FCN*, 7/22/98, at 16.
24. *Id.*, at 17.
25. See "U.S., Canada Hold Consultations Under NAFTA on Meat Labeling Proposal," *Intn'l Trade Rep.*, 9/9/98.
26. See *id.*
27. See William New, "Confidential Memo Urges USDA Official to Oppose Senate Meat Labeling Bill," *Inside U.S. Trade*, Aug. 21, 1998, at 1, 13.
28. See *id.* The memo, dated July 31, 1998, is reprinted in full in this article.
29. See *id.*
30. See Gordenker, *supra* note 23, at 17.

31. *See* Testimony of Charles Ludolph, Before the Subcommittee on Oversight and Investigations, 10/2/98, at 2.
32. *See* Testimony of Sharon S. Holston, Before the Subcommittee on Oversight and Investigations, 10/2/98, at 12.
33. *Id.*, at 13.
34. *Id.*, at 14-15.
35. FDA, A Plan That Establishes a Framework for Achieving Mutual Recognition of Good Manufacturing Practices Inspections, at 3, addendum to *id.*
36. All of the above information was taken from Kahn-Tineta Horn, "Canada and US to Hold Tricky NAFTA 'First Nations' Summit in Calgary," *Mohawk Nation News*, Sep. 5, 1998.