



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

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WORLD TRADE ORGANIZATION

Topic: *Seattle WTO Ministerial Conference*

On Friday, December 3, 1999, labor, environmental, consumer, human rights, religious, and other non-governmental organizations (NGOs) from around the world celebrated in Seattle, Washington, when Michael Moore, Director General of the World Trade Organization (WTO), announced the demise of a planned WTO expansion. The launch of a so-called "Millennium Round" failed, according to Moore, because of a lack of consensus among WTO Member nations on the agenda for future WTO negotiations. The momentous victory was the culmination of years of work for many in the NGO coalition, a year-long international campaign dubbed "WTO: No New Round, Turnaround," and months of preparation and planning for the on-the-ground activities at the Seattle Ministerial itself.

The WTO Ministerial was officially scheduled to begin on Tuesday, November 30. NGOs had been preparing for the conference - publishing position papers, building NGO attendance, lobbying their governments, and securing meeting space, equipment, and accommodations in Seattle - for almost a year. Public Citizen had conducted a year-long "Road to Seattle" public education campaign across the U.S. An array of NGOs had a comprehensive schedule of alternative events planned for Seattle proper, including educational workshops, teach-ins, lectures, and meetings on the WTO's impacts on workers, women, the environment, democratic accountability, consumer health and safety, agriculture, food security, animals, and health care.

Monday, November 29, was NGO Environment and Public Health Day. The day began with panels of citizens from around the world testifying about the actual effects of the WTO, and educational workshops on the WTO's effects on fisheries, forests, toxic waste, sustainable development, investment rules, genetically-modified organisms, and public health.

At noon a crowd of thousands led by environmental groups, including hundreds of activists dressed as sea turtles, rallied at First United Methodist Church and marched to the Washington Trade and Convention Center - where the official WTO negotiations were set to take place. The rally was a protest of the environmental degradation caused by WTO policies and decisions.

That night religious groups held a multi-faith ceremony featuring the singing of Sweet Honey in the Rock. Then approximately ten thousand people, demanding the cancellation of debt for the world's poorest nations, marched toward the Exhibition Center. There the corporate coalition hosting the WTO (co-chaired by Microsoft and Boeing) was holding a black-tie, invitation-only opening gala for WTO bureaucrats, diplomats, and negotiators. The goal of encircling the venue for a silent vigil was frustrated by the police, who kept the march away from the Exhibition Center.

Across town, an invitation-everyone People's Opening Gala was beginning. After the event was forced out of the Kingdome (located across from the Exhibition Center) for "security reasons," the Seattle Mayor provided use of Key Arena for no charge. He greeted the crowd at the Gala's start. Eight thousand people jammed into Key Arena for this combination rally, party, and concert featuring radio personality Jim Hightower, and movie and television director and star Michael Moore. The event ended as labor, environmental, and other activists danced to the music of Spearhead.

Tuesday was NGO Labor, Livelihood, and Human Rights Day, coinciding with the official start of the actual WTO negotiations. Before sunrise, the Direct Action Network, Ruckus Society, Rainforest Action Network, and others who had trained hundreds of people in non-violent, civil disobedience techniques, shut down all the intersections leading to the Trade and Convention Center. The Seattle Student/Worker Walkout Committee organized

a mass walkout of students and employees from local schools and businesses. At the same time, the International Longshore and Warehouse Union shut down ports on the entire West Coast. Activists linked arm-in-arm and sometimes chained themselves together to shut down the start of the WTO negotiations.

This action, premised on the non-violent civil disobedience techniques of Martin Luther King, Jr. and Mahatma Gandhi, had been planned over the course of months. The organizers had met with the Seattle police both to make clear their commitment to non-violence and to prepare the police for the massive civil disobedience arrests that would be necessary to clear the streets. Indeed, at one point the police offered to begin the arrests at sunrise so the process could be reported by the news media.

For reasons which remain unclear, on November 30 the Seattle police never began arresting the civil disobedience protesters and bussing them away from Seattle's downtown.

Mid-morning, several dozen young people dressed in identical black garb and wearing face masks appeared and started marching in formation down one of Seattle's main streets, near the Convention Center. Despite their highly-regimented paramilitary appearance, they identified themselves as anarchists. They began smashing the windows of downtown stores, including Old Navy, Starbucks, Niketown, and FAO Schwarz. The peaceful protesters conducting the sit-in shouted "Shame!" and "Non-violent protest!" at the youths. Some grabbed the window-breakers, attempting to halt the property damage. Hundreds of Seattle police officers dressed in full riot gear stood by and watched, actively refusing to arrest the masked window-smashers even when peaceful protesters asked for assistance.

Meanwhile, at noon, tens of thousands of labor unionists, family farm, consumer, religious, and environmental activists rallied at Memorial Stadium to listen to AFL-CIO president John Sweeney, Teamsters president James Hoffa, Jr., Steelworkers president George Becker, and other U.S. and international labor, environmental, and other NGO leaders speak on the WTO's impacts on people around the globe. The massive labor rally - sponsored by the national, state, and local AFL-CIO and many international unions (with Ron Judd, president of the King County AFL-CIO receiving kudos from all) - then marched

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toward downtown Seattle. The plan was for the march to proceed to the Convention Center and then head back to the stadium, where hundreds of buses awaited the labor participants.

By mid-afternoon, the 40,000-plus students, activists, and labor representatives thronged into downtown Seattle to demonstrate peacefully against the WTO. The scene that greeted the labor marchers was surreal. Riot police dressed in Robocop costumes (even the police horses had eye guards to protect them from the tear gas) had begun randomly attacking the circles of protesters sitting at intersections with an array of weaponry including tear gas, pepper spray, concussion grenades, and rubber bullets.

Instead of asking the crowds to disperse, the police randomly charged protesters, beating them with nightsticks, shocking them with stun-guns, and continuously firing rounds of tear gas. Meanwhile, police shot into the crowds at close range with rubber bullets (not aimed at feet and legs as protocols require) and set off concussion grenades.

Given many protesters were literally chained or tied together and had been given no notice to disperse, the impact of this weaponry was vicious. Each sit-down group had a person designated as a "medic" equipped with water and vinegar spray for eyes in case tear gas was used. However, police targeted those with medic IDs and also the protesters (many volunteer lawyers and law students) identified with "legal observer" IDs for beatings and arrest. All this time the police allowed the violent marauders to continue to spray-paint graffiti and smash store and car windows.

As many of the labor marchers came onto these repeated scenes of police violence, they intervened to protect the sit-down protesters. The result was groups of beefy Teamsters and Longshoremen trying to protect a diverse array of protesters - including those in turtle costumes and other with a rainbow of hair colors - at numerous intersections from platoons of police marching in military formation and slapping their nightsticks in rhythm on their metallic shin guards.

Mike Dolan, deputy director of Public Citizen's Global Trade Watch and the coordinator of many of the NGO activities and protests in Seattle, blamed the police for not acting quickly enough to stop the small group of looters. Indeed, he was acting as a go-between for the mayor, seeking an end to a stand-off when the most intense gassing occurred without warning and Dolan himself was brought to the pavement by CS gas, a potent form of aerosolized tear gas. Dolan told the *Washington Post*, "The ugliness at the end of the day could have been avoided."

The sit-down protesters did achieve their goal -

most of the WTO negotiators were prevented from reaching the Trade and Convention Center. U.S. Trade Representative Charlene Barshefsky and many other officials were stuck in their hotels. The WTO had to postpone and then cancel the Ministerial's opening ceremonies. Seattle Police Chief Norm Stamper told the *Seattle Post-Intelligencer*, "Those who were arguing that they were going to shut the WTO down were in fact successful today."

The skirmishes between protesters and the police continued well into the night, with the police firing tear gas indiscriminately into the crowds and pushing them into Seattle's Capitol Hill residential section and protesters setting fire to garbage bins. Police ended up arresting only twenty people. There were no major injuries. Ironically, by dousing a residential area with tear gas, the police added many more Seattle residents to the following days' protests. Local television played over and over an interview of a man in his pajamas holding his small daughter with both their faces red and tear-stained from being gassed in their home.

In what was widely condemned as an over-reaction, Seattle Mayor Paul Schell declared a state of emergency and imposed a curfew from 7 p.m. to 7:30 a.m. in a 50-block area of downtown. Only persons with WTO credentials, which had to have been obtained from the WTO's Geneva headquarters weeks before, were allowed in the vast curfew zone. Washington Governor Gary Locke called in the National Guard.

Meanwhile, Tuesday night at Seattle Town Hall a long-planned event featuring Ralph Nader, Vandana Shiva, a leading critic of globalization from India, and IPS Director John Cavanagh debating David Aaron, Undersecretary of Commerce, Jagdish Bhagwati, a professor of economics at Columbia University, and Scott Miller, director of government relations for Procter & Gamble Co., went ahead. The issue under debate: the merits of the WTO. A sold-out audience of 800 people, almost all of whom favored Nader's position, attended. At the debate's conclusion, Nader challenged Aaron to a five-hour debate on the WTO's merits in front of a pro-WTO crowd, and Aaron accepted. No date for the debate has been set.

Wednesday was NGO Women, Democracy, Sovereignty, and Development Day, with panel discussions and teach-ins at the Methodist Church NGO Center on a variety of topics, including the precautionary principle, biotechnology and intellectual property rules, women's responses to globalization, the WTO's impacts on indigenous peoples. Fortunately, the venue for the programming all week was the First United Methodist Church, located outside the lock-down zone.

Wednesday morning the police announced a total ban on all protests within the restricted area around the

Trade and Convention Center that would remain in place all week. This ban was immediately condemned as unconstitutional and, along with police mistreatment of protesters, was targeted by the ACLU for a lawsuit, filed in December 1999. Hundreds of protesters made their way into the restricted zone and were arrested.

That night several hundred protesters tried to march down Seattle's Broadway toward downtown but were met by police with more tear gas and concussion grenades. The police were dressed in full body armor, boots, helmets, and gas masks and carried long billy clubs, pepper spray, and guns with rubber bullets. They marched up Broadway behind armored vehicles. As the police chased protesters up Broadway toward the Capitol Hill area, the restaurants and businesses that line the street quickly closed.

Criticism of the police's heavy-handed tactics escalated as residents and community leaders were outraged when police officers sparked a confrontation with protesters outside the "no protest" zone. One worker in the Capitol Hill area reportedly said, "Our city has been turned into a war zone." And residents of Capitol Hill demanded that the police leave, shouting, "This is our neighborhood!"

Thursday was NGO Food and Agriculture Day, with workshops on the impacts of globalization on food safety and family farmers, the WTO's Sanitary and Phytosanitary Agreement, genetic engineering of crops, and intellectual property rules for seeds.

At noon, thousands of family farmers, environmentalists, and other activists rallied at Victor Steinbruck Park overlooking Seattle's harbor to listen to Ralph Nader, Jim Hightower, Vandana Shiva, and Jose Bove, the leader of the French farmers' movement against globalization and genetically-modified foods.

That afternoon several hundred protesters gathered in front of King County Jail, where many of the protesters who were arrested on Wednesday were being held. They demanded that all protesters be released immediately and the charges against them be dropped. They also called for a public apology and for the WTO to be shut down.

The protesters remained peaceful. In fact, the mood outside the jail was festive, with a band playing jazz music and many people dancing and chanting. The Steelworkers and Teamsters unions brought food for the crowd. The protesters stayed until early in the evening when a deal was brokered that allowed defense attorneys and protest leaders into the jail to see the imprisoned

protesters, who until that point had been held *incommunicado*, with most not processed or charged.

The majority of the 600 jailed protesters refused to speak to police trying to process them, even to identify themselves, and they were carrying no identification. Police had to identify them with fingerprints. One jailed protester said, "They're going to have trouble processing us. We're gumming up the system, and they're going to want to just get rid of us."

Friday night, hundreds of protesters again gathered outside the King County Jail to demand better treatment of jailed protesters and to negotiate for their release. There were rumors of mistreatment of protesters in the jail, but jail officials denied any such mistreatment.

At 10 p.m. on Friday, the WTO announced it was unable to reach any consensus on the agenda for new talks, and the negotiations ceased. NGO delegates on the inside reported that the U.S., EU, Japan, and a few other powerful nations attempted to hammer out an agreement while excluding developing nations (the so-called "Green Room Process"). The developing nations, already enraged at President Clinton's earlier proposal for a WTO Working Group on labor issues - which developing nations believe is just a form of disguised protectionism - walked out, refusing to sign any agreement and condemning the U.S. action.

The protesters claimed victory and celebrated well into the night. WTO officials claimed the impasse had nothing to do with the protests in Seattle's streets but was a result of the irreconcilable differences between developed and developing countries. On the contrary, protesters must be credited with shortening the time for negotiations which accelerated the controversial "Green Room" process, putting pressure on President Clinton to request concessions on labor issues, and prompting Seattle Mayor Paul Schell to refuse to extend the WTO's stay. Mike Dolan said, "We won the day and made a little history. This movement can't and won't be ignored."

After the WTO left town in disgrace, Seattle Chief of Police Norm Stamper announced he would resign in March. Several groups, including the American Civil Liberties Union (ACLU) and Amnesty International, called for an investigation of police responses to protesters - the use of tear gas and rubber bullets, and the implementation of the "no protest" zone and curfew. Subsequently, the Seattle City Council held several public meetings at which hundreds of Seattle residents complained about police tactics.

PHARMACEUTICALS

Topic: *Public Meeting on the Pharmaceutical Annex to the U.S.-EU MRA*

Date: December 8, 1999

Contact: Charles A. Gaylord, Office of International and Constituent Relations (HFG-1), FDA, 5600 Fishers Lane, Rockville, MD 20857; Tel: 301 827-0909; Fax: 301 443-0235. See also the FDA's web site at www.fda.gov/oia/homepage.htm, under the International section. The FDA maintains an open docket (#98S1064) for MRA materials.

A year and a day after the final rule implementing the U.S.-E.U. Mutual Recognition Agreement (MRA) became effective, the Food and Drug Administration (FDA) held its first public meeting to discuss progress on the MRA.¹ An MRA is an agreement between countries that they will treat each other's regulatory systems or conformity assessment procedures as if they were their own. Conformity assessment practices relate to the recognition of the results of product testing and quality systems audits or the exchange of reports from such testing or audits. The U.S.-EU MRA affects billions of dollars worth of commerce between the two countries.

The MRA consists of a general framework (the "umbrella agreement") and six sectoral annexes which cover telecommunications, electromagnetic compatibility, electrical safety, recreational craft safety, medical devices, and pharmaceutical good manufacturing practices (GMPs). The pharmaceutical GMP annex covers post- and pre-approval GMPs for human and animal drugs, vaccines, therapeutic biologicals, and active pharmaceutical ingredients. It does not cover veterinary biologicals, human blood and plasma, tissue and organs, medical gases, radio pharmaceuticals, investigational new drugs, or biological in-vitro diagnostics (IVDs).

The GMP annex is geared to result in the exchange and normal endorsement of pharmaceutical GMP inspection reports between the U.S. and the EU. To achieve this goal, the U.S. will examine the GMPs of each of the 15 EU nations and determine (or not determine) whether each is "equivalent" to U.S. practices. Once the FDA declares a nation's GMPs equivalent, drug manufacturers in that nation will be able to export drugs to the U.S. without having to submit them for re-inspection by the FDA. The FDA recently estimated that it will take 125 full time employees and approximately \$10 million dollars to implement this aspect of the MRA.²

The meeting dealt with the implementation of the pharmaceutical GMP annex of the MRA, but not the medical device annex. The FDA announced that it is still in the early stages of implementation, still performing paper reviews of various EU regulatory authorities. No system audits or inspection audits have yet taken place.

The MRA is concluding the first year of its three-year "implementation stage." At the end of this stage, the governing body for the pharmaceutical annex, called the Joint Sectoral Committee, will determine which regulatory authorities are ready to be deemed "equivalent." The Joint Sectoral Committee is made up of representatives from the U.S. government and the European Commission. Each government has one vote on any equivalency decision, and all decisions are made by unanimous consent.

At the December 8, 1999 meeting the FDA indicated for the first time that the Joint Sectoral Committee meetings will be closed to the public.³ Equivalency will be determined based on criteria listed in Appendix 4 of the MRA, which include: appropriate statutory mandate and jurisdiction; authority to make inspections, review documents, and collect evidence; ability to enforce requirements and remove products from the market; mechanism to assure appropriate professional standards and avoidance of conflicts of interest; appropriate staffing and resources; and standards of qualifications and training.⁴ The U.S. General Accounting Office (GAO) criticized the FDA for not clearly delineating how the criteria will be used to determine equivalency, i.e. how they will be weighted and which are deal-breakers.⁵

The FDA also indicated that it is still in the process of gathering information about the regulatory processes of the EU and the EU member nations. The FDA is also in the early stages of setting up a "rapid alert system" via which countries will be able to report recalls, quality defects, counterfeiting and quality problems. The next steps in the implementation of the MRA will include on-site joint systems audits followed by inspection audits, but the FDA could not say when such audits would begin.

The FDA intends to assess equivalence of EU member states between October 1999 and August 2001. December 2001 marks the end of the transition period and the beginning of the operational period of the agreement.

CONSUMER CONCERNS WITH THE MRA

Equivalency vs. Harmonization: The MRA GMP Annex defines equivalence to mean that "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.”⁶ Speakers at the meeting stressed that the agreement did not mean that standards would be harmonized. However, in response to an audience question, Joseph Famulare of the Center for Drug Evaluation and Research of the FDA responded, “There is certainly no prohibition against certain harmonizations taking place. I think it’s just a natural outcome of the process.” Both the determination of equivalency, which will involve subjective and political judgements on behalf of the FDA, and the potential harmonization of standards under the MRA will be watched closely by consumer organizations to ensure that there is no weakening of consumer protections.

Public Input into Equivalency Decisions: The FDA responded to questions from industry, press and consumer groups at the briefing. Some questioners raised concerns about public input into equivalency determinations. The FDA announced that it will examine the equivalency of each country on a case by case basis. However, in response to a question on whether or not the FDA will notice a pending equivalency decision between nations as a proposed rule so as to provide an opportunity for public comment, the FDA indicated that the agency did not think this was necessary.

The FDA is undertaking an enormous and costly task of examining the equivalency of 21 regulatory systems over the next two years. While the FDA will maintain an open docket for any comments regarding equivalency decisions, interested consumers will have no way of knowing which equivalency decisions are pending at any moment. Industry, however, is likely to be aware simply because it will be their facilities that will be inspected.

Further, the FDA indicated that if a determination of equivalence is made in a closed Joint Sectoral Committee

meeting, the FDA will notify the public via the Federal Register and give its reasoning for the decision. However, if the FDA rejects an equivalency determination, the FDA will notify the country involved but will not make this information available to the public. U.S. consumers will remain unaware of what problems have been identified and will be unable to measure progress on those problems.

Accessibility of MRA-Related Documents: Concerns were also expressed about what documents currently available to the public would remain available once the FDA’s inspection duties are turned over to regulators in other nations. Raymond Mars, of the FDA’s Division of Emergency and Investigational Operations, reported that “confidentiality was a big issue” at the May 18-19, 1999 Joint Sectoral Committee Meeting. He reported that only a few EU member states had a law similar to the U.S. Freedom of Information Act and that not all countries published recall information.

In a presentation regarding transparency in the MRA process, Merton Smith, the FDA’s Associate Director for International Agreements, explained the complexity of aligning the FDA’s general disclosure policy with the privacy rights of corporations and rules governing the exchange of information with foreign governments. At one point in the presentation Merton suggested that the FDA might rely on the “national security information” exemption⁷ to the Freedom of Information Act if it needed to keep certain information confidential.

The MRA was negotiated within the culture of secrecy surrounding U.S. trade negotiations, while the standards it covers must be made under the requirements for openness and on-the-record rule-making incumbent upon federal agencies. While the FDA stated its commitment to transparency and to maintaining U.S. recall procedures, time will tell if EU nations unaccustomed to U.S. transparency requirements will comply with these new demands.

FOOD SAFETY

Topic: *FSIS Equivalence Process for Foreign Meat and Poultry Systems*
Venue: U.S. Department of Agriculture, Food Safety and Inspection Service
Contact: Clark Danford, Acting Director, International Policy Division, Office of Policy, Program Development, and Evaluation, USDA, at 202-720-6400, or clark.danford@usda.gov.

On March 12, 1999, the Food Safety and Inspection Service (FSIS) published a document - entitled “FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems - that explains

the procedures the FSIS uses to determine whether foreign countries’ meat and poultry regulatory systems are equivalent to the U.S. system. Equivalence determination is a process required by the North American Free Trade

Agreement (NAFTA) and World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreements. Meat from the thirty-six countries the USDA has certified as equivalent can enter the U.S. and be stamped "USDA Choice."

On December 14, 1999, FSIS held a public meeting to discuss the document,⁸ and on December 17, 1999, published a final rule in the *Federal Register*,⁹ making the paper U.S. policy. Following is a brief summary of the new FSIS policy.

The agency's new policy paper begins with a summary of U.S. obligations under the WTO SPS Agreement. The SPS Agreement requires the U.S. to accept the food regulatory systems of other nations as equivalent, even if they differ from the U.S. system, if the nations demonstrate that their systems achieve the U.S.'s "appropriate level" of public health protection.¹⁰ Under the WTO SPS Agreement, the foreign nations bear the burden of demonstrating equivalence to the U.S. The FSIS notes that despite these WTO rules, the U.S. is "free to set any level of protection it deems appropriate to control or eliminate a food safety hazard."¹¹

However, early on the FSIS document reveals the SPS Agreement's focus on international trade rather than food safety: "a central purpose of the SPS Agreement is to encourage the development of international food safety standards that Members will adopt domestically for 'harmonization' and the facilitation of international trade."¹² In fact, Article 3 of the WTO SPS Agreement requires WTO member countries to harmonize their food safety measures by basing them on international standards, such as those set by the Codex Alimentarius Commission. Food safety measures which are based on such international standards are presumed to be WTO-legal. Food safety measures that provide citizens with a higher level of protection than international standards must be "based on scientific principles" and "not maintained without sufficient scientific evidence."¹³

Thus, if a U.S. food safety law provides more consumer protection than the relevant international standard, it is subject to challenge by any WTO Member. And if a Member does challenge such a U.S. food safety law in a WTO tribunal, the U.S. bears the burden of proving that it is based on "sound science," or the WTO could rule the law an illegal barrier to trade, and the U.S. would be required to change the law or pay reparations to the challenging nation.

The FSIS document attempts to debunk this fact of WTO operation with a paragraph on "appropriate level of protection": "The SPS Agreement explicitly affirms the right of each government to choose its levels of protection, including a "zero risk" level if it so chooses. A government may establish its levels of protection by any means available under its law, including by referendum. In the

end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgment."¹⁴

Interestingly, this text was taken from an "Administrative Action Statement" which accompanied the U.S. legislation implementing the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), which created the WTO. Thus, not only does it have no legal significance internationally and little weight domestically, but also it is contrary to the basis on which the U.S. successfully challenged the EU's ban on beef from animals injected with artificial growth hormones.

Finally, the FSIS document explains the steps the FSIS will take in determining equivalence. First, the U.S. gives notice to its trading partners that it will require a particular food safety measure to achieve a level of protection it deems appropriate. Second, a foreign nation requests an explanation of the U.S.'s appropriate level of protection that is achieved by the food safety measure. Third, the U.S. provides the explanation. Fourth, the foreign nation uses the explanation as a guide to develop sufficient evidence to prove that its different food safety measure is equivalent to the U.S. measure. Finally, the U.S. evaluates that evidence and (1) determines that the foreign nation's different food safety measure is equivalent; (2) requests more information; or (3) determines that the foreign nation's alternative measure is not equivalent and provides reasons for the decision.¹⁵

The FSIS document also explains the process the FSIS will use to verify that foreign food regulatory systems continue to be equivalent. First, every year the FSIS plans to analyze each foreign nation's laws, regulations, and implementing policies in conjunction with U.S. government policies to ensure that an adequate legal and regulatory structure is maintained. Second, the FSIS generally will conduct "systems" audit of the foreign nation's meat regulatory system, spending much more time examining their plans on paper and much less time in the actual plants. Significantly, though, the FSIS informs the foreign nation *which* meat and poultry establishments they will visit and *when* they will visit them.¹⁶ Finally, the FSIS claims it will randomly re-inspect meat products shipped from the foreign nation.¹⁷

The FSIS claims to have 75 inspectors assigned to 150 import establishments who perform these re-inspections. According to the FSIS, "At these establishments, all incoming lots of meat and poultry are reinspected for transportation damage, labeling, proper certification, general condition, and accurate count."¹⁸ However, the imported meat is not checked for salmonella, E-coli, or other contaminants.

Products that pass this cursory re-inspection are

stamped with the USDA seal of approval and allowed to enter the U.S. as if they were produced domestically. Products that fail “are stamped ‘U.S. Refused Entry’ and must be exported, destroyed, or converted to animal food.”¹⁹

Currently the FSIS has granted thirty-six countries equivalency status; approved plants in those countries are allowed to ship meat products to the U.S. The thirty-six

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.²⁰

OTHER NEWS

Topic: *White House Issues (Another) Order on Environmental Review of Trade Agreements*

On November 16, 1999, President Clinton issued an executive order mandating a review of the environmental impacts of trade agreements. Unfortunately, this latest call for such environmental reviews still does not require the Executive Branch to comply with existing federal law, the National Environmental Policy Act (NEPA),²¹ under which environmental impact statements are required for all major federal actions. Indeed, the Clinton Administration unsuccessfully fought up to the U.S. Supreme Court a lawsuit filed by Public Citizen and several environmental groups demanding that trade agreements comply with NEPA. With this new order, the administration’s stated policy goal is to “factor environmental considerations into the development of [U.S.] trade negotiating objectives.”²² The order requires relevant federal agencies to fulfill this policy “through a process of ongoing assessment and evaluation, and, in certain instances, written environmental reviews.”²³

Unfortunately, the order vests the U.S. Trade Representative (USTR) with the power to conduct these environmental reviews rather than the Environmental Protection Agency (EPA), the more environment-oriented choice. In fact, the order gives the USTR the discretion to “determine whether an environmental review of an agreement or category of agreements is warranted.”²⁴ This prompted Carl Pope, Executive Director of the Sierra Club, to say, “Unfortunately, this review process also puts the fox in charge of the henhouse. Environmental officials - not the U.S. Trade Representative - should oversee the review process to make sure that future trade agreements protect our families’ health, safety and environment.”²⁵

The order requires environmental reviews only of certain trade agreements, including: “comprehensive multilateral trade rounds; bilateral or plurilateral free trade agreements; and major new trade liberalization agreements in natural resource sectors.”²⁶ Presumably the order would cover such trade agreements as NAFTA and the Uruguay Round of GATT, which created the WTO.

However, the order does not require environmental reviews of “agreements reached in connection with enforcement and dispute resolution actions.”²⁷ This means that there is no requirement for an environmental review before the U.S. brings WTO or NAFTA challenges or threatens to bring such challenges against other countries. Similarly, if the U.S. is sued by another nation in a WTO or NAFTA tribunal, and loses the case, there is no requirement for an environmental review before the U.S. decides how to handle the ruling, i.e. eliminate a U.S. environmental law or pay the sanctions. Thus, for example, under this order, the USTR will not have to review the environmental impacts of the Shrimp-Turtle WTO case the U.S. lost last year, which requires the U.S. to change aspects of its Endangered Species Act which protect endangered sea turtles.

Ironically, the executive order requires less than what U.S. law already mandates. As noted above, NEPA directs federal agencies to perform written assessments of the environmental impacts of all major federal actions. The U.S. District Court for the District of Columbia, the only court to rule on the issue, held that NEPA does apply to international trade agreements.

Topic: *U.S. Court Orders USTR to Add Environmentalists to Trade Advisory Committees; Clinton Administration Appeals Decision*

On November 9, 1999, a federal district judge ordered the U.S. Trade Representative (USTR) to include at least one environmentalist to each of two committees that advise the Clinton Administration on timber-trade policy.²⁸ Currently the membership of the paper and wood products committees is limited to representatives of the timber industry.

The Clinton Administration has decided to appeal the environmentalists' victory. Indeed, during the same week President Clinton gave a major policy speech on opening trade policy-making to new NGO "voices," the Clinton Administration decided to appeal this decision which mandated such new balance.

Judge Barbara Rothstein, of the U.S. District Court for the Western District of Washington, ruled that the USTR and the Secretary of Commerce violated the Federal Advisory Committee Act (FACA) by excluding environmentalists from these committees. The FACA requires advisory panels to be "fairly balanced," and Judge Rothstein held that excluding environmentalists made the committees imbalanced.²⁹

In her 25-page opinion, Judge Rothstein wrote that "matters affecting the wood and paper products sector are dramatically and inextricably intertwined with the environmental health and protection of this nation."³⁰ She continued, "The forest ISACs [Industry Sector Advisory Committees] offer advice on diverse and far-reaching issues that affect others, especially those who promote forest conservation. The composition of the forest product ISACs, thus, violates [the law's] requirement to be fairly balanced in terms of viewpoints to be represented."³¹

The suit was brought by six environmental groups, including the Earthjustice Legal Defense Fund and the Pacific Environment and Resources Center, last summer. "Finally, a long-existing wrong is slowly being righted," said Patti Goldman, the attorney from Earthjustice who argued the case. "It is both unfair and illegal to load up these panels with industry representatives."³² Goldman has fought to have FACA applied to trade advisory committees since the early 1990s, including through earlier FACA litigation.

The two forest ISACs, without any environmental representatives, have argued for the reduction or elimination of tariffs on wood and paper products. Indeed, this industry demand became a core element of the U.S. position for the Seattle World Trade Organization (WTO) Ministerial. An industry paper revealed that the U.S. WTO "free-logging" proposal would have increased global logging by two to three percent. Environmentalists also noted that tariff cuts would increase global consumption of paper and wood products, resulting in more logging. They want the tariff reductions delayed until environmental safeguards can be implemented.³³

"Sometimes tariffs are the only limits on how much is logged if there aren't environmental standards in place," Goldman said. "Removing tariffs means a lot more logging can happen."³⁴

This WTO "free-logging" issue was scheduled to be discussed at the WTO Ministerial Conference in Seattle. However, with the conference ending in turmoil, no agreement on this issue was reached.

Topic: *USDA Approves Meat Irradiation*

On December 14, 1999, the U.S. Department of Agriculture (USDA) announced that it has approved the use of irradiation on raw meat and meat products, including ground beef, steaks, and pork chops.³⁵ The USDA published its final rule on irradiation in the *Federal Register* on December 23, 1999.³⁶ The rule will take effect on February 23, 1999.

Food irradiation is the process of exposing food to high levels of radiation to kill potentially dangerous microorganisms. The Food and Drug Administration (FDA), which regulates food additives like irradiation, determined in December 1997 that irradiation is safe for raw meat.

Under the USDA's plan, industry will be able to treat refrigerated or frozen raw meat and meat products with radiation. These products still will be required to meet all

other USDA regulations, including sanitation and pathogen reduction requirements.

The USDA's plan also will require irradiated meat and meat products to be labeled with the "radura" international symbol for irradiation and a statement that the product was treated by irradiation. Irradiated meat used in other products such as sausages and bologna will have to be labeled as well. For unpackaged meat without labels, the logo and statement will have to be displayed at the point of sale to consumers. However, food purchased at food service operations, such as restaurants, will not have to bear labels.

In addition, the USDA is considering ending the requirement that food additives be approved by both the USDA and the FDA. Currently, if the FDA approves a food additive, the USDA still must conduct separate

rulemaking procedures for the same additive to be approved for use in meat and poultry. The USDA hopes this will pave the way for the use of irradiation on ready-to-eat products like lunch meats.

Some consumer groups have sharply questioned the safety of food irradiation. For example, Public Citizen's Critical Mass Energy Project (CMEP) has expressed concerns about the potential toxicity, nutritional impact, microbiological risks, and environmental threats associated with food irradiation.

The levels of certain vitamins in foods may be reduced as a result of irradiation, and consumers may mistakenly believe that irradiated food is immune from subsequent microbiological (e.g. *Salmonella*, *E. coli*, *Listeria*) contamination as a result of cross-contamination or improper storage or handling. Potential harm to the environment and workers could result from the transportation and disposal of the radioactive materials involved in the irradiation process. Finally, consumer

groups worry that reliance on irradiation to kill pathogens may encourage the food industry to pay scant attention to sanitary and other pathogen-reduction measures in their operations instead of ensuring clean and sanitary practices in food processing establishments.

CMEP has called on the U.S. government to require irradiated food labels to be clear and conspicuous. Currently the FDA requires irradiation disclosure statements to be only as prominent as the declaration of ingredients, which is usually in small print on the back or side of the package. Moreover, CMEP has urged the FDA to require the disclosure statement to use the terms "radiation" or "irradiation" rather than "electronic pasteurization" or "cold pasteurization," which are favored by the industry but, unfamiliar to consumers. Finally, the CMEP believes that labels on irradiated foods should not be allowed to indicate that the foods are "free of pathogens" because this could mislead consumers and encourage careless handling of foods.

FEDERAL REGISTER ALERTS

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- Topic:** *Equivalence of Canada's Poultry Inspection Program*
- Action:** Notice and request for comments
- Venue:** Food Safety and Inspection Service
- FR Cite:** 64 *Federal Register* 66606
- Deadline:** Written comments must be received by January 28, 2000
- Contact:** For more information on Canada's Modern Poultry Inspection Program (MPIP) document, Clark Danford, Acting Director, International Policy Division, Office of Policy, Program Development, and Evaluation, at 202-720-6400 or clark.danford@usda.gov. The document is available at www.cfia-acia.agr.ca/english/animal/meat/mmop/mpip/mpiptoce.html. Submit one original and two copies of comments to: FSIS Docket Clerk, Docket #99-048N, Room 102 Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700.

The Canadian government has formally requested that the U.S. Food Safety Inspection Service (FSIS) determine its new Modern Poultry Inspection Program (MPIP) to be equivalent to the U.S. system of poultry inspection. If the FSIS finds MPIP to be equivalent, any Canadian poultry processing establishment that is certified under MPIP will be able to export poultry to the U.S. without having it inspected by the FSIS.

MPIP is Canada's answer to the U.S. Hazard Analysis and Critical Control Point (HACCP) system.

According to the Canadian Food Inspection Agency (CFIA), "MPIP is a HACCP and science-based inspection system. It enhances the safety and wholesomeness of Canadian poultry products, and as a result, contributes to the viability of the Canadian poultry industry."³⁷ It will be used in Canadian establishments that slaughter chicken, turkey, and fowl.

The Canadian government's objectives for the MPIP program include: "Facilitate the transition of CFIA [government] staff from hands-on inspection to audit-

based verification activities for poultry slaughter establishments operating under a HACCP system; Facilitate the assumption by industry of the detection and handling of all carcasses with defects (previously performed by [government] inspectors) under continuous government oversight; and respond to changing international trade requirements, e.g., Pathogen Reduction and HACCP Program Rule in the U.S.”³⁸

Under the World Trade Organization (WTO) and North American Free Trade Agreement (NAFTA) Agreements on Sanitary and Phytosanitary Measures (SPS Agreements), the U.S. is required to harmonize its human, animal, and plant health standards by basing its SPS import regulations on international standards. The SPS

Agreements also require the U.S. to consider requests by other WTO and NAFTA member countries to establish the equivalence of their inspection systems to the U.S. inspection system. Thus, the FSIS must determine whether Canada’s MPIP is equivalent to the U.S. HACCP system.

The FSIS will evaluate the MPIP using two criteria for equivalence: (1) whether the MPIP meets all USDA requirements for the import of poultry products to the U.S.; and (2) whether the MPIP affords American consumers the same level of public health protection provided by USDA domestic poultry slaughter inspection. Before making the equivalence determination, however, the U.S. Administrative Procedures Act requires the FSIS to accept public comment on the Canadian proposal.

MEETINGS/EVENTS

- Event:** *Codex Biotechnology Task Force Public Meeting*
Date: December 15, 1999, 9 a.m.-12 noon
Location: Room 1409, FDA Office Building, 200 C Street, SW, Washington, DC
Contact: Dr. H. Michael Wehr, Office of Constituent Operations, CFSAN, FDA, HFS 550, 200 C Street, SW, Washington, DC 20250; Tel: 202-260-2786; E-mail: MWehr@cfsan.fda.gov.

The U.S. Delegation to the Codex Biotechnology Task Force held a public meeting to discuss the Task Force’s areas of work and work priorities; key concepts and definitions; and principles of risk assessment, management, and communication. The U.S. Delegation also received comments to help them prepare a Discussion Paper covering those topics.

The Codex Alimentarius Commission (Codex) is the international body empowered by the WTO SPS Agreement to set presumptively-WTO legal food safety standards. The Task Force is a temporary group created by Codex to formulate standards and guidelines for foods derived from biotechnology (also known as genetically-engineered (GE) foods). The First Session of the Task Force is set for March 14-17, 2000, in Chiba, Japan.

The U.S. Delegation identified guidance for food safety and nutritional assessment of food and food ingredients obtained from plants, microorganisms, and animals developed using modern biotechnology as the work of the Task Force. This would include crops genetically-engineered to resist pests and herbicides; milk from cows injected with rBST, a hormone that increases milk production; and beef from cattle injected with growth hormones.

The U.S. Delegation also identified further areas of work, including: evaluation of possible allergic reactions in

humans to proteins introduced into GE foods; evaluation of the use of antibiotic resistance marker genes, which critics have linked to possible increased antibiotic resistance in humans; evaluation of food composition and molecular and genetic information; and considerations related to feeding studies in animals. This Task Force, however, is not responsible for elaborating standards or guidelines on the labeling of GE foods.

The U.S. Delegation listed their working priorities - in descending order of priority - as: (1) foods and food ingredients obtained from GE plants; (2) guidance documents that support food safety and nutritional assessment of GE plants; (3) foods and food ingredients obtained from GE microorganisms; and (4) foods and food ingredients obtained from GE animals. The U.S. Delegation noted that it emphasized GE plants because such plants are at the center of the controversy over genetic engineering that is taking place in Europe.

The Task Force must define “foods and food ingredients obtained through modern biotechnology.” Once Codex sets the definition, the WTO SPS Agreement will give it binding legal authority in any trade disputes involving GE foods.

Currently there are two definitions under consideration. The first one, which the U.S. supports, defines GE foods as foods significantly different from

conventional foods in composition, nutritional value, or intended use as a result of the genetic modification. The second definition, which the European Union and many developing countries support, defines GE foods as any foods developed using modern genetic modification techniques. The U.S. Delegation admitted that most nations are leaning toward the second definition.

When asked why the U.S. favored such an unpopular definition, the U.S. Delegation stated that the definition was based on U.S. law. Currently U.S. law requires GE foods to be treated differently (i.e. labeled) only if they differ significantly from conventional foods in composition, nutritional value, or intended use as a result

of the genetic modification. The U.S. Delegation stated that its starting position in any Codex discussions must be based on U.S. law because they are sworn to uphold U.S. law.

Finally, the U.S. Delegation discussed principles of risk assessment and management. The U.S. Delegation, and several representatives of corporations and industry groups, were concerned that other nations would attempt to introduce issues outside the scope of Codex (which establishes food safety standards), such as environmental concerns and the precautionary principle. Industry representatives urged the U.S. Delegation to exclude such issues from future discussions and focus on science.

Event: *Codex Committee on Food Labeling Public Meeting*
Date: January 7, 2000, 2-5 p.m.
Location: Room 1409, FDA Office Building, 200 C Street, SW, Washington, DC
Deadline: For written comments, January 11, 2000
Contact: Dr. H. Michael Wehr, contact information above

The U.S. Delegation to the Codex Committee on Food Labeling *Ad Hoc* Working Group on the Labeling of Foods Obtained Through Biotechnology held a public meeting to discuss proposed revisions in the texts of the Definitions and Terms and the Additional Mandatory Provisions Sections and to receive public comment on them. The Working Group is responsible for establishing standards for the labeling of genetically-engineered (GE) foods and food ingredients. It last met November 3-5, 1999, in Rio de Janeiro, Brazil, where these revisions were proposed.

Currently there are two proposals for the labeling of GE foods and food ingredients. The first, supported by the U.S., would require a GE food or food ingredient to be labeled only if it is “no longer equivalent to the corresponding existing food or food ingredient as regards composition, nutritional value, or intended use.”³⁹ This Working Group revised this proposal by removing the

word “substantially” from the text. It originally read “. . . substantially equivalent. . .”

The second proposal, supported by the European Union and most developing nations, would require all GE foods and food ingredients to be labeled. The Working Group made no revisions to the text of this proposal.

GE foods and food ingredients are defined as “food and food ingredients composed of or containing genetically modified organisms (obtained through recombinant DNA techniques), or food and food ingredients produced from, but not containing genetically modified organisms.”⁴⁰ The Working Group proposed to define “no longer equivalent” as “a food or food ingredient obtained through modern biotechnology where a scientific assessment demonstrates, through an appropriate analysis of data, that the characteristics assessed are different in comparison to those of the corresponding existing food or food ingredient.”⁴¹

Event: *Codex Committee on Food Import and Export Inspection and Certification Systems Public Meetings*
Dates: January 13, 2000, 1-4 p.m. and February 10, 2000, 1-4 p.m.
Location: Room 1409, Federal Office Building 8, 200 C Street, SW, Washington, DC
FR Cite: 64 *Federal Register* 69685 (December 14, 1999)
Deadline: For written comments, February 4, 2000

Contact: Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, FSIS, Room 4861, South Building, 1400 Independence Avenue, SW, Washington, DC 20250-3700; Tel: 202-205-7760; Fax: 202-720-3157. Submit an original and two copies of comments to: FSIS Docket Clerk, Docket #99-061N, USDA, FSIS, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. Submitted comments will be available for view M-F, 8:30-4:30.

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) held two public meetings to provide information and accept public comment on issues that will be discussed at the Eighth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), which will be held in Adelaide, Australia, February 21-25, 2000. CCFICS develops principles and guidelines for food import and export inspection and certification systems to facilitate trade through harmonization of standards.

Topics for discussion at both public meetings include: (1) proposed draft guidelines for food import control systems; (2) proposed draft guidelines and criteria for official certificate format and rules relating to the production and issuance of certificates; (3) proposed draft guidelines for the utilization and promotion of quality assurance systems; and (4) discussion papers on the judgement of equivalence on sanitary measures and technical regulations associated with food inspection and certification systems.

NOTES

1. The U.S.-EU MRA was signed by U.S. Trade Representative Charlene Barshefsky and former EU Trade Minister Leon Brittan on June 20, 1997. The MRA was noticed in the *Federal Register* November 6, 1998 (63 Fed. Reg. 60122), and became effective December 7, 1998. The MRA has six sectoral annexes: pharmaceutical GMPs, medical devices, electromagnetic compatibility, telecommunications, electrical safety, and recreational craft safety.
2. GAO/HEHS-99-143R Mutual Recognition Agreement, August 13, 1999, at 2.
3. The first meeting of the Joint Sectoral Committee was May 18-19, 1999.
4. Agreement on Mutual Recognition Between the United States of America and the European Community, Appendix 4, at 73, on file with Public Citizen.
5. GAO/HEHS-99-143R Mutual Recognition Agreement, August 13, 1999, at 5.
6. Agreement on Mutual Recognition Between the United States of America and the European Community, at 55, on file with Public Citizen.
7. 5 U.S.C. §552(b)(1).
8. 64 Federal Reg. 66161.
9. 64 Federal Reg. 70690.
10. World Trade Organization, SPS Agreement, Art. 4.1.

11. U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development, and Evaluation, International Policy Division, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," March 1999, at 3.

12. *Id.*

13. WTO, SPS Agreement, Art. 2.2.

14. U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development, and Evaluation, International Policy Division, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," March 1999, at 6, quoting Administrative Action Statement accompanying "The Uruguay Round Agreements Act," (P.L. 103-465, Dec. 8, 1994), at A.3.

15. U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development, and Evaluation, International Policy Division, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," March 1999, at 8.

16. *Id.* at 10.

17. *Id.* at 9.

18. *Id.* at 11.

19. *Id.*

20. FSIS, "Equivalence Evaluation of Pathogen Reduction and HACCP Requirements," Dec. 14, 1999.

21. 42 U.S.C. §4321.

22. White House, "Executive Order - Environmental Review of Trade Agreements," Nov. 16, 1999, at Section 1.

23. *Id.*

24. *Id.* at Section 4(c).

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

26. White House, "Executive Order - Environmental Review of Trade Agreements", Nov. 16, 1999, at Section 4(a)(i)-(iii).

27. *Id.* at Section 4(b).

28. David Postman, "Environmentalists Win Seats on Trade Panels - Judge: Committees Can't Be Limited to Timber Industry," *Seattle Times*, Nov. 10, 1999, at A5.

29. "Clinton Administration Faces Court Order: Include Environmental Representation or Cancel Next Timber Advisory Meeting," *U.S. Newswire*, Dec. 8, 1999.

30. Jim Lobe, "Trade - U.S. Environmentalists to Sit on Trade Panels," *Inter Press Service*, Nov. 10, 1999.

31. *Id.*

32. "Ecologists Gain Spot on Trade Panels; Judge Rules They Can Advise on Wood Talks," *Seattle Post-Intelligencer*, Nov. 10, 1999, at A6.

33. *Id.*

34. Gordon Hamilton, "Eco-groups Win Right to Advise Softwood Panel," *The Vancouver Sun*, Nov. 13, 1999, at D1.

35. U.S. Department of Agriculture, "USDA Approves Irradiation of Meat to Help Improve Food Safety," News Release, Dec. 14, 1999.

36. 64 Fed. Reg. 72149, Dec. 23, 1999.

37. 64 Fed. Reg. 66607, Nov. 29, 1999.

38. *Id.*

39. Proposed Draft Recommendations for the Labelling of Foods Obtained Through Biotechnology, ALINORM 99/22, Appendix VIII, on file with Public Citizen.

40. Proposed Draft Recommendations for the Labelling of Food and Food Ingredients Obtained Through Modern Biotechnology, Draft Discussion Document, Section 2, on file with Public Citizen.

41. *Id.*