



**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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## FOOD SAFETY/ENVIRONMENT

**Topic:** *Cartagena Biosafety Protocol: New International Agreement Regulating GMOs*

**Contact:** Bernice Slutsky, Foreign Agricultural Service, USDA, at 202-720-4261, or Marilyn Bruno, State Department, at 202-647-2062. The Protocol is available at [www.sustain.org/biotech](http://www.sustain.org/biotech).

On January 29, 2000, in Montreal, Canada, representatives from 131 nations, including the U.S., agreed to a biosafety protocol that establishes rules for international trade in genetically-modified organisms (GMOs). The agreement, referred to as the “Cartagena Biosafety Protocol” because the first such negotiations took place in Cartagena, Columbia last year, will not take effect until at least fifty of the nations ratify it.

The agreement’s conclusion was heralded by both industry and citizen activists, highlighting the ambiguity of the pact’s language and the varying interpretations of its significance. Activists lauded the Protocol as the first international agreement to set binding regulations on a global industry and to promote the Precautionary Principle, which

states that nations should take protective action when faced with uncertain risks or inconclusive scientific knowledge. Notably, the Protocol does not use the words “Precautionary Principle.” Rather it outlines the steps nations may take in a precautionary approach to regulating GMOs. Industry promotes the Protocol as being of limited scope and subject to World Trade Organization (WTO) rules.

The U.S. was unable to participate officially in the negotiations because it never ratified the 1992 Convention on Biological Diversity, and legally cannot become a party to the Biosafety Protocol until it does so. However, the U.S. was able to influence the negotiations significantly as a vocal observer and through nations, like Canada and Australia, that have ratified the Convention on Biological Diversity and

whose aims for international trade parallel the U.S.'s. The U.S. is the largest exporter of genetically-modified (GM) foods, but both Canada and Australia export billions of dollars worth of GM foods as well.

In February 1999, the U.S.-led "Miami Group" - consisting of major food exporters Canada, Australia, Argentina, Uruguay, and Chile - blocked the adoption of a biosafety protocol during negotiations in Cartagena, Colombia, by refusing to allow commodities - such as soybeans and corn, which account for ninety percent of international trade in GMOs - to be included.<sup>1</sup> An estimated fifty percent of U.S. soybeans and thirty-three percent of U.S. corn is grown with GM seeds.<sup>2</sup>

The U.S. agreed to the Biosafety Protocol only after obtaining several concessions. First, the Protocol's proposals to track and regulate international shipments of GM foods will not be implemented for at least two years, other than requiring an ambiguous label indicating a particular shipment "may contain" GMOs.<sup>3</sup> Second, the agreement does not cover human pharmaceuticals that are covered in other international agreements, or grain or animals once they are processed into food products, like flour or cooking oil.<sup>4</sup> Third, although the pact requires international shipments of GMOs to bear labels stating they "may contain" GMOs, it does not require the labels to give specific details as to what GM materials are in the shipment,<sup>5</sup> essentially meaning GM foods do not have to be segregated from non-GM foods.

Finally, the Protocol's legal standing relative to the WTO Sanitary and Phytosanitary (SPS) Agreement is unclear. The U.S. wanted the Protocol to meet the requirements of the SPS Agreement because it prohibits nations from maintaining food safety regulations, including those governing GMOs, that are not based on scientific findings of human health risks. The WTO SPS Agreement also does not allow nations to consider other legitimate factors (e.g. environmental implications and consumer opinions) or employ the Precautionary Principle.

According to U.S. Department of Agriculture (USDA) officials, the U.S. got what it wanted. At the Transatlantic Consumer Dialogue conference in Washington, D.C., February 10-12, 2000, Bernice Slutsky of the USDA's Foreign Agricultural Service, said that the Protocol does not change nations' rights and obligations under WTO rules. European Union officials stated that they were unsure if the

Protocol was subject to WTO rules because the language in the Protocol was equivocal.

The Protocol's Preamble does contain seemingly contradictory clauses:

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements . . . , [but]

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements . . . .<sup>6</sup>

Article 2.4 of the Protocol, which unlike the Preamble, creates binding obligations, adds:

Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol *and is in accordance with its other obligations under international law.*<sup>7</sup>

Deciding whether the Protocol is subject to the rules of the WTO SPS Agreement or creates a new firewall against the SPS Agreement's rules would be a difficult and politically-charged process. Such a decision may be forced if a nation's laws regulating trade in GMOs are ever challenged at the WTO.

Following is a summary of the Protocol's provisions.

The Protocol defines "living modified organism [LMO]," the Protocol's term for GMOs, as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."<sup>8</sup> "Living organism" is defined as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids."<sup>9</sup>

The Protocol applies "to the transboundary movement, transit, handling and use of all [LMOs] that may

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have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”<sup>10</sup>

The Protocol then establishes the scope of the so-called “Advance Informed Agreement (AIA),” which notifies nations that international shipments may contain LMOs. It applies the AIA procedure “to the first intentional transboundary movement of [LMOs] for intentional introduction into the environment of the Party of import,”<sup>11</sup> but excludes LMOs “intended for direct use as food or feed, or for processing.”<sup>12</sup> This means that the AIA process applies only to seed LMOs, and not commodities - soybeans, corn, grain - or processed products containing GM materials - flour, cooking oil.

AIA procedures require exporting nations to notify in writing importing nations prior to the intentional transboundary shipment of the covered LMOs. Importing nations then must inform the exporting nation and the Biosafety Clearing House<sup>13</sup> whether the international transboundary shipment may proceed either: (a) only after the importing nation has given its written consent, or (b) after no less than ninety days without written consent. Within 270 days, the importing nation must notify the exporting nation in writing its decision to: (a) approve the import, with or without conditions, including how the decision will apply to subsequent imports of the same LMO; (b) prohibit the import; (c) request additional information; or (d) extend the period of time for its decision.<sup>14</sup>

AIA procedures also require LMOs intended for intentional introduction into the environment to be accompanied by documentation clearly identifying them as LMOs; specifying the identity and relevant traits and/or characteristics, any requirements for safe handling, the contact point for further information, and the names and addresses of the importer and exporter; and containing a declaration that the movement is in conformity with the requirements of the Protocol.<sup>15</sup>

The process for LMOs intended for direct use as food or feed (food LMOs) is somewhat different. When an exporting nation approves a new food LMO that may be traded internationally, it must post notice at the Biosafety Clearing House within fifteen days of its decision.<sup>16</sup> It is up to each importing nation to monitor the Biosafety Clearing House for such approvals and then decide whether to allow imports of those food LMOs. Shipments of food LMOs must be accompanied by documentation stating the shipment “may contain” LMOs that are not intended for intentional introduction into the environment.<sup>17</sup> The Protocol does not require consumer labeling of either food or seed LMOs.

The Protocol permits importing nations to take a precautionary approach when deciding whether to allow imports of both seed and food LMOs. It reads, in typical convoluted language:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a [LMO] on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the [LMO] in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.<sup>18</sup>

The Protocol also allows nations to take into account “socio-economic considerations,” such as “the value of biological diversity to indigenous and local communities,” as long as nations’ decisions remain “consistent with their international obligations.”<sup>19</sup>

Importing nations still must perform a proper risk assessment. The Protocol requires risk assessments to be performed in a “scientifically sound and transparent manner”<sup>20</sup> and to be based on information provided by the exporting nation and “other available scientific evidence in order to identify and evaluate the possible adverse effects of [LMOs] on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”<sup>21</sup>

This is another example of the Protocol’s contradictory language. The Protocol allows nations to consider socio-economic factors and take a precautionary approach when regulating LMOs, but also requires nations to perform scientific risk assessments and make decisions consistent with their international obligations (read WTO SPS Agreement). If a nation makes a LMO regulatory decision that is inconsistent with its obligations under the WTO SPS Agreement, another nation may be able to successfully challenge that decision in the WTO.

Finally, the Protocol calls on the parties to establish international rules governing who will be liable for potential damage resulting from intentional introduction of LMOs into the environment within four years.<sup>22</sup>

While environmental groups have lauded the Protocol as a significant step forward in both U.S. and international policy toward GMOs, it remains to be seen whether a WTO tribunal will treat the Protocol as equal or subordinate to the WTO’s trade rules. Significantly, if a nation does challenge another nation’s GMO regulations at a WTO tribunal, it is WTO trade bureaucrats who will be making that critical decision, not the environmental, food safety and consumer groups that helped to shape the Biosafety Protocol.

**Topic:** *U.S. Narrowly Averts EU Ban on Imports of U.S. Meat*

**Contact:** Joerg Niederberger, Delegation of the European Commission, EU Veterinary Counselor, Wash., DC, at 202-862-9562. The EU reports are available at <http://europa.eu.int/comm/dg24>.

In January 2000, the European Union (EU) considered a ban on all imports of U.S. meat after a report from the European Commission's Health and Consumer Protection Directorate-General Food and Veterinary Office claiming that the U.S. Food Safety and Inspection Service (FSIS) had falsely certified that meat exported to the EU was free of growth hormones.<sup>23</sup> The EU has prohibited imports of hormone-treated meat for more than a decade, but allows imports of U.S. meat the FSIS has certified as hormone-free.

The EU ban on meat from animals injected with six growth hormones was the subject of a U.S. World Trade Organization (WTO) challenge in 1996. Both the WTO panel and Appellate Body upheld the U.S. challenge and struck down the EU ban, ruling that it was not based on "sound science."<sup>24</sup> Despite this decision, the EU has maintained its ban and continues to face punitive tariffs on some of its exports to the U.S.

The European Food and Veterinary Office (FVO) released the report revealing the FSIS's shortcomings after visiting U.S. farms, laboratories, slaughterhouses, and the FSIS in November 1999. The EU officials were evaluating the implementation and enforcement of FSIS's non-hormone treated cattle (NHTC) program for certifying hormone-free beef for export to the EU. The FVO had last reviewed the FSIS system in July 1999 and had found "serious deficiencies" in the Hormone Free Cattle (HFC) program, the precursor of the NHTC program.<sup>25</sup> The deficiencies included problems in live animal hormone-checks, the range of hormones tested for (FSIS did not test for hormonal growth promoters or banned substances), the number of samples taken, and the analytical competence and independence of the laboratories performing the tests.<sup>26</sup> As a result, the report recommended a suspension of U.S. meat imports. However, the FSIS agreed to suspend the HFC program and establish new measures to increase the security of the program and the credibility of the FSIS certification process (the NHTC program), and the EU agreed to continue to allow imports of U.S. meat.<sup>27</sup>

In their November evaluation of the NHTC program, however, the FVO found many of the same deficiencies. First, the FVO discovered that the Agricultural Marketing Service (AMS) - a division of the U.S. Department of Agriculture that had taken over the process for certifying U.S. meat as free of hormones - had not followed the International Organization for Standardization (ISO) guidelines for such procedures. For example, the report notes, the AMS evaluations did not cover all certification criteria specified in the NHTC program, and the AMS provided advice and consultation services to the applicants,

which is not permitted as it may affect the impartiality and objectivity of the certification.<sup>28</sup>

Second, at the two farms and feedlots FVO officials inspected, they noted "severe non-conformities with the requirements of the NHTC program."<sup>29</sup> For example, one of the feedlots' written program contained no educational program, no provisions for internal audits or production controls by laboratory analysis of feed, and no requirements for record keeping. One of the farms had no written program at all. Under the NHTC program, farms and feedlots are required to create written programs detailing how they will maintain their cattle free of hormones.

Third, at the certified slaughterhouse the FVO officials visited, they discovered that cattle slaughtered for export to the EU had been received without accompanying producer affidavits stating that the cattle were hormone-free. They also noted that the slaughterhouse had not implemented procedures for boning, cutting, and packaging as required by the NHTC program.<sup>30</sup> Fourth, at the certified cutting plant the FVO officials inspected, they found that the plant had no cross-referenced documentation to ensure the traceability of animals and carcasses, and no measures for controlling the segregation of hormone- and non-hormone-treated animals.<sup>31</sup>

Finally, the EU requires all slaughter establishments approved for export to the EU to participate in the Additional Residue Testing Program, which requires testing for the hormonal growth promoters DES, Hexestrol, Dienestrol, Melengestrol Acetate (MGA), Nortestosterone, Trenbolone, and Zeranol. The FVO officials discovered that from the end of April 1999 to the time of the FVO mission, no samples had been taken for the Additional Residue Testing Program. According to FSIS officials, because of a lack of operational testing laboratories, all samples had been "warehoused" until laboratories were available for the testing.

The FVO report noted that these deficiencies occurred just before authorities in Switzerland detected the illegal hormone - and known carcinogen - diethylstilbestrol (DES) in two shipments of U.S. beef.<sup>32</sup> As a result, Swiss authorities banned exports of beef from two U.S. companies.

The FVO had recommended that the European Commission immediately bar all imports of fresh beef, pork, horse, sheep, and goat meat from the U.S., review the system of importing live animals and other animal products from the U.S., and continue negotiations with the U.S. to develop a reliable program to ensure the production of non-hormone-treated meat for export to the EU.<sup>33</sup> The EC delayed a decision on the FVO's recommendations until March 15, 2000, and then on March 10, 2000, approved new USDA

testing procedures, allowing imports of U.S. meat to resume.

## **CONSUMER PROTECTION**

**Topic:** *Transatlantic Consumer Dialogue Sets Policy on International Harmonization*

**Contact:** Nadia Chelafa, TACD Secretariat, London, U.K., at 011 44 171 226 6663.

The Transatlantic Consumer Dialogue (TACD) held its third meeting in Washington, D.C. February 10-12, 2000. At the meeting, the TACD developed a new policy statement on the international harmonization of standards and produced a variety of important new recommendations to protect the consumer interest in the trade arena.

The TACD was formed in 1998 to formalize U.S.- EU consumer group cooperation and input to the U.S. and EU governments on a range of international commerce and other issues. The TACD consists of 65 consumer groups representing some 600 million consumers. Consumer's Union, Public Citizen, Consumer Federation of America, and the U.S. Public Interest Research Group make up the U.S. steering committee of this transatlantic organization.

The TACD has three working committees: food safety, e-commerce, and trade. At the February meeting, the Trade Committee produced a new policy document on the "Principles of Harmonization" which sets guidelines for acceptable and unacceptable forms of international standard setting.

The principles paper recommends that: standards that do not have a health and safety component should be the primary candidates for international harmonization; international standards should be used as a floor rather than a ceiling for consumer and environmental protection; the Precautionary Principle (the legal principle that acknowledges that science does not always provide information necessary to avert environmental or public health threats in a timely manner) should be incorporated more broadly in the international standards-setting process; and that governments should only recognize or be involved in international harmonization activities negotiated in open, accountable, democratic fora, with clear avenues for public input and transparent methods of rulemaking and record-keeping.

The principles paper also tackled the difficult topic of "equivalence" determinations, rejecting the notion of functional equivalence. Under the World Trade Organization (WTO) and North American Free Trade Agreement (NAFTA) provision, nations are required to make determinations about the "equivalence" of other nations' different standards on the same products or issues. The trade rules allow for determinations that foreign standards, which may be different or weaker than a nation's domestic standards, must be treated as equivalent in order to facilitate the free exchange

of goods or services. For example, the U.S. government recognized the equivalence of U.S. and Mexican commercial drivers licenses in 1992 even though the two nations had very different requirements with regard to minimum age, skills tests, medical clearance, and training for the transport of hazardous substances. The "Principles of Harmonization" paper is reproduced in full as an appendix (page 15) to this edition of *Harmonization Alert*.

The TACD also recommended that:

- C The EU and U.S. governments put a halt to the Time Warner-AOL merger until grave concerns about consumer privacy are addressed. Consumer advocates fear that the merger gives the company more far-reaching - and frighteningly more sophisticated - ability to collect information about consumer shopping and browsing habits that will be used in new ways to aggressively market products to them.
- C The governments call a halt to all new WTO challenges in the area of food safety and food labeling.
- C The EU and U.S. governments improve regulation of food labeling to ensure misleading claims prohibited in one region of the world cannot be made by the same company, or a subsidiary, in another region.
- C Both governments require that all genetically modified (GM) foods be labeled. As well, it called on both governments to carefully assessed GM foods before their commercial introduction and release into the environment and to monitor and evaluate them after their release.
- C The EU and U.S. governments adopt the Precautionary Principle the area of food and trade. The TACD applauded the adoption of such a principle in the Cartagena Biosafety Protocol (see related article above) in the area of GM foods, but says it must be incorporated more broadly in the international standards setting process.

For a complete set of recommendations from the February conference and from earlier meetings of the TACD, visit the TACD's web site at [www.tacd.org](http://www.tacd.org).

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## **FEDERAL REGISTER ALERTS**

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**Topic:** *Country-of-Origin Marking for Imported Beef, Lamb, Veal, and Calf Carcasses*  
**Action:** Advance Notice of Proposed Rulemaking  
**Venue:** U.S. Department of Agriculture, Agricultural Marketing Service  
**FR Cite:** 65 *Federal Register* 4780 (February 1, 2000)  
**Deadline:** Written comments must be received by April 3, 2000  
**Contact:** Larry R. Meadows, Chief, Meat Grading and Certification Branch, at 202-720-1246. Submit comments to Mr. Meadows at USDA, AMS, LS, MGC, STOP 0248, Room 2628-S, 1400 Independence Avenue, SW, Washington, DC 20250-0248; fax them to 202-690-4119; or e-mail them to [Larry.Meadows@usda.gov](mailto:Larry.Meadows@usda.gov). Comments must refer to Docket No. LS-99-21 and note the date and page number of the *Federal Register* (cited above).

The Agricultural Marketing Service (AMS) is requesting public comment on the potential elimination of the country-of-origin marking requirements in the U.S. regulations governing official grading of imported beef, lamb, veal, and calf carcasses. AMS regulations implemented under the Agricultural Marketing Act of 1946 permit the official grading of imported carcasses, provided the carcasses comply with all requirements of the applicable standards and are marked with the country of origin. The National Cattlemen's Beef Association (NCBA) and the American Sheep Industry Association (ASI) have requested that AMS discontinue this grading system, while the American Meat Institute (AMI), National Meat Association (NMA), Canadian Embassy, and several members of Congress have written letters in support of the current grading system.

The AMS regulations do not require country-of-origin markings to be maintained at the retail level. In

practice, since the vast majority of meat is marketed as wholesale or retail cuts rather than carcasses, the country-of-origin marks are almost always removed during processing. Thus, consumers have no way of knowing from which country the meat they purchase originated, even though importers and retailers do.

However, legislation has been proposed in previous and the current Congress that would remedy this lack of consumer-level information and require country-of-origin labeling at the retail level.

AMS is considering several options, including: (1) discontinuing the official grading of imported carcasses; (2) revising the grading regulations to require that the country-of-origin mark is retained on the component cuts of meat after an imported carcass that is federally graded is processed; and (3) revising the grading regulations to eliminate the requirement that imported carcasses be marked with their country of origin.

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**Topic:** *Poultry Products from Mexico Transiting the U.S.*  
**Action:** Proposed Rule  
**Venue:** Animal and Plant Health Inspection Service  
**FR Cite:** 65 *Federal Register* 6040 (February 8, 2000)  
**Deadline:** Written comments must be received by April 10, 2000

**Contact:** Dr. Michael David, Senior Staff Veterinarian, Animals Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737; Tel: 301-734-8364. Send written comments and 3 copies to Docket No. 98-094-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

The Animal and Plant Health Inspection Service (APHIS) is proposing a rule that would allow poultry carcasses, parts, and products (but not eggs and egg products), which currently are not eligible for import into the U.S., to move through the U.S. for export to other countries. The products would transit the U.S. via land ports from Mexican states that Mexico considers to be free of exotic Newcastle disease (END) and be exported to other countries from U.S. ports. END is a rapidly-spreading, virus-induced disease of birds and domestic fowl marked by respiratory difficulty, reduced egg production, and, in chicks, paralysis. However, APHIS believes that the land transport of Mexican poultry through the U.S. presents a negligible risk of introducing END in the U.S. and relieves trade restrictions.

Current APHIS regulations prohibit the import of poultry carcasses, parts, products, and eggs from regions where END is considered to exist. Because END exists in certain parts of Mexico, the entire country is considered a region where END exists. Thus, under the regulations, poultry carcasses, parts, and products may be imported into the U.S. from Mexico only if they have been cooked or are consigned directly to an approved establishment in the U.S.

However, the regulations allow poultry carcasses, parts, and products that do not qualify for entry into the U.S.

under one of these conditions may transit the U.S. via air and sea ports. The proposed APHIS rule would extend the regulations to permit land transit through the U.S. for export to other countries.

Mexico's Director of Animal Health requested the change to allow for transit of poultry carcasses, parts, and products from states that Mexico considers free of END. Currently, Mexico recognizes the states of Baja California, Baja California Sur, Campeche, Chihuahua, Coahuila, Durango, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, Tamaulipas, and Yucatan as free of END.

Under the proposed rule, poultry carcasses, parts, and products from these states allowed to transit the U.S. via land ports would still be subject to certain restrictions: (1) the exporter first must obtain a permit from APHIS; (2) the poultry must be packaged in leakproof containers sealed with serially-numbered seals approved by APHIS; (3) the exporter must inform the APHIS officer at the U.S. port of arrival of their arrival; (4) the poultry must transit the U.S. under Customs bond; and (5) the poultry must be exported from the U.S. within the time period specified on the permit. Any poultry violating these requirements may be destroyed or otherwise disposed of at the discretion of the APHIS Administrator.

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**Topic:** *Genetically-Modified Soybeans*

**Action:** Notice of Request for Experimental Use Permit

**Venue:** Environmental Protection Agency

**FR Cite:** 65 *Federal Register* 6370 (February 9, 2000)

**Deadline:** Comments must be received by March 10, 2000

**Contact:** Alan Reynolds, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, EPA, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460; Tel: 703-605-0515; E-mail: reynolds.alan@epa.gov. Submit written comments to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), OPP, EPA, Ariel Rios Bldg, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

The Environmental Protection Agency (EPA) has received an application from Monsanto Company requesting an experimental use permit (EUP) for the Cry1Ac protein and the genetic material necessary for its production in soybeans. Monsanto proposes to test and evaluate soybeans genetically modified to produce a substance deadly to the velvetbean caterpillar, stem borer, and soybean looper. Monsanto plans to plant 66.5 acres of these pesticide-

producing soybeans in Alabama, Arkansas, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Mississippi, Missouri, North Carolina, Pennsylvania, and Tennessee on March 1, 2000. The plantings of soybeans containing the Cry1Ac protein in this experimental program will be contained, and no portion of the crop will be used for food or animal feed.

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**Topic:** *International Conference on Harmonization Common Technical Document*  
**Action:** Notice of availability and request for comments  
**Venue:** Food and Drug Administration  
**FR Cite:** 65 *Federal Register* 7024 (February 11, 2000)  
**Deadline:** Written comments must be received by March 13, 2000  
**Contact:** Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), FDA, 5600 Fishers Lane, Rockville, MD 20857; Tel: 301-594-5476. Submit written comments to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. The components are available on the Internet at [www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm).

The Food and Drug Administration (FDA) is announcing the public availability of initial components of a draft guidance entitled "M4 Common Technical Document," which is being developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). When completed, this draft guidance will describe a harmonized format and content for designated new human pharmaceutical applications for submission to the regulatory authorities in the three ICH regions (the U.S., European Union, and Japan), and pharmaceutical manufacturers will be able to submit the same application for new human pharmaceuticals to the regulatory agencies of each region.

FDA is releasing only some of the components of the draft guidance due to its large size. However, FDA will make the entire draft guidance available once all the components are completed. The released components are: (1) Nonclinical Executive Summary, (2) Nonclinical Written and Tabulated Summaries, (3) Quality table of contents and explanatory notes, (4) Nonclinical Data Study Reports, and (5) Clinical Data Study Reports.

ICH was created by regulatory authorities in the U.S., EU, and Japan to provide an opportunity for harmonization initiatives to be developed with input from regulatory and industry representatives. Public-interest groups are excluded. The ICH is concerned with the harmonization of technical requirements for the registration of pharmaceuticals among the U.S., EU, and Japan.

The six ICH sponsors are the European Commission, European Federation of Pharmaceutical Industries Association, Japanese Ministry of Health and Welfare, Japanese Pharmaceutical Manufacturers Association, U.S. Centers for Drug and Biologics Evaluation and Research, and Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documents, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the six ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Canadian Therapeutics Products Programme, and European Free Trade Area. There are no representatives from consumer organizations.

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**Topic:** *EPA Tolerances for the Pesticide Deltamethrin*  
**Action:** Notice of filing a petition  
**Venue:** Environmental Protection Agency  
**FR Cite:** 65 *Federal Register* 8143 (February 17, 2000)  
**Deadline:** Comments must be received by March 20, 2000  
**Contact:** For more information, Linda Werrell, Registration Support Branch, Registration Division (7508C), Office of Pesticide Programs, EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, Tel: 703-308-8033; E-mail: [werrell.linda@epa.gov](mailto:werrell.linda@epa.gov). Comments must be identified by Docket No. PF-917 and submitted to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or to [opp-docket@epa.gov](mailto:opp-docket@epa.gov).

The Environmental Protection Agency (EPA) is announcing the filing of a pesticide petition by AgrEvo USA Company proposing the establishment of tolerances for

residues of the pesticide Deltamethrin on various food commodities. A "tolerance" is the amount of a particular pesticide residue on a specific fruit, vegetable, or grain

product that the EPA considers safe. If the EPA approves the petition, it will propose a rule establishing the tolerances.

As evidenced by the table below, many of EPA's proposed tolerances are higher than the tolerances proposed or established by the Codex Alimentarius Commission, an international standards-developing body empowered by the World Trade Organization to set presumptively WTO-legal food safety standards. Usually the opposite is true. U.S. pesticide standards generally permit less pesticide residue, and thus provide more consumer protection than, Codex pesticide standards.

Given the U.S. government's zeal in using Codex standards to attack other countries's standards (e.g. the U.S. WTO challenge of the EU's ban on beef hormones), it is ironic that the U.S. also proposes domestic standards that are less health-protective than Codex standards.

Several of EPA's proposed tolerances are higher than Codex's maximum residue levels (MRLs - the same as EPA "tolerances"), but Codex has not established MRLs for Deltamethrin on many of the food commodities for which the EPA is proposing tolerances.

Commodity	EPA Proposed Tolerance (ppm)	Proposed/Current Codex MRL (ppm)
Artichokes	0.5	0.05
Broccoli	0.5	0.2
Bulb vegetables	1.5	0.1
Cabbage (w/o wrapper leaves)	0.15	0.2
Carrots	0.15	0.01
Cauliflower	0.15	0.2
Corn, field grain	0.06	1.0
Corn, fodder (field)	7.0	0.5
Cucurbit vegetables	0.06	0.2
Fruiting vegetables	0.25	0.2
Leafy vegetables	4.5	0.5
Mustard greens	4.5	0.2
Pome fruit	0.2	0.1
Potatoes	0.04	0.01
Poultry, fat	0.05	0.01
Poultry, meat	0.02	0.01
Radishes (roots)	0.15	0.01
Ruminant meat	0.02	0.5
Ruminant fat	0.04	0.5
Ruminant mbyop	0.02	0.5
Sorghum, grain	0.5	1.0
Sorghum, fodder	2.0	0.5
Soybeans	0.05	0.1
Stone fruit	0.6	0.05
Sunflower seed	0.05	0.1
Wheat, grain	2.0	1.0

**Topic:** *Environmental Review of Trade Agreements*

**Action:** Request for public comment

**Venue:** U.S. Trade Representative/Council on Environmental Quality

**FR Cite:** *65 Federal Register 8756 (February 22, 2000)*

- Deadline:** Written comments must be received by April 7, 2000
- Contact:** For further information, Office of the USTR, Environment and Natural Resources Section, at 202-395-7320, or the Council on Environmental Quality at 202-456-6224. Submit 20 copies of comments to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, ATTN: Implementation of Executive Order 13141 - Environmental Review of Trade Agreements, Office of the USTR, Room 122, 600 17<sup>th</sup> Street, NW, Washington, DC 20508

On November 16, 1999, President Clinton issued Executive Order 13141,<sup>34</sup> which requires the Office of the U.S. Trade Representative (USTR) to evaluate the environmental impacts of future trade agreements in certain instances. Trade agreements already in place, including the Uruguay Round agreement establishing the World Trade Organization (WTO) and the North American Free Trade Agreement (NAFTA) are exempted from the Executive Order. See the November/December 1999 issue of *Harmonization Alert* for a comprehensive review of the Executive Order and its

shortcomings according to environmental groups.

The USTR is requesting public comment on the issues the agency should consider in implementing the Order, including: how the environmental review process should work, mechanisms for involving the public, timing and process for conducting a written environmental review for those agreements requiring such a review, and appropriate methodologies for assessing environmental impacts in the context of trade negotiations.

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- Topic:** *USTR Request for Electronic Commerce Experts for FTAA Committee*
- Action:** Notice of request for private sector experts in electronic commerce
- Venue:** Office of the U.S. Trade Representative
- FR Cite:** *65 Federal Register 10847* (February 29, 2000)
- Deadline:** Written expressions of interest must be submitted by March 24, 2000
- Contact:** For procedural questions, Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the USTR, Room 122, 600 17<sup>th</sup> Street, NW, Washington, DC 20508; Tel: 202-395-3475. For questions on the Joint Government-Private Sector Committee of Experts on Electronic Commerce, Regina Vargo, Deputy Assistant Secretary for the Western Hemisphere, U.S. Department of Commerce, at 202-482-5324. Written submissions of interest should be sent to Gloria Blue at the address above. The official FTAA website is [www.ftaa-alca.org](http://www.ftaa-alca.org).

The Office of the U.S. Trade Representative (USTR) is searching for U.S. private-sector experts on electronic commerce who may be interested in participating in the work of the Free Trade Area of the Americas (FTAA) Joint Government-Private Sector Committee of Experts on Electronic Commerce (Joint Committee). The Joint Committee was established by the 34 nations participating in the Free Trade Area of the Americas - a push to form a NAFTA-style free trade agreement among the nations of North and South America begun in 1994 and scheduled to be completed by 2005 - to make recommendations on ways to increase and broaden the benefits of electronic commerce.

The Joint Committee's most recent report with its recommendations is available at the official FTAA website ([www.ftaa-alca.org](http://www.ftaa-alca.org)) and the U.S. Government Electronic Commerce website ([www.ecommerce.gov](http://www.ecommerce.gov)). The Joint

Committee last met January 25-26, 2000, in Miami, Florida, to discuss issues related to access and infrastructure, small and medium-sized enterprises, authentication, online payments, intellectual property, taxation, and consumer protection.

Members of the public interested in participating in the Joint Committee's work must submit written notice to the USTR and describe their qualifications, including: demonstrated expertise in one or more aspects of electronic commerce; knowledge of the Western Hemisphere, including established contacts with foreign private-sector interests in the region; an ability and willingness to solicit views from and disseminate information to private-sector interests; and familiarity with U.S. and foreign trade and investment policies and obligations and developments in electronic commerce fora.

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## MEETINGS/EVENTS

**Event:** *FDA Meetings on the Safety of Imported Foods*  
**Date:** February 10 and 17, 2000, 9:00 a.m. - noon  
**Location:** February 10 - Los Angeles District Office, 19900 MacArthur Boulevard, Suite 300, Irvine, CA 92612; February 17 - Hubert H. Humphrey Building, 200 D Street, SW, Room 800, Washington, DC 20204  
**FR Cite:** 65 *Federal Register* 3461 (January 21, 2000)  
**Contact:** Mary J. Ayling, Center for Food Safety and Applied Nutrition (HFS-32), Food and Drug Administration, 200 C Street, SW, Room 3823, Washington, DC 20204; Tel: 202-260-5348; Fax: 202-260-9653; E-mail: mayling@bangate.fda.gov. The Clinton Administration's comprehensive plan for imported food safety is available at [www.foodsafety.gov](http://www.foodsafety.gov).

The Food and Drug Administration (FDA) and the U.S. Customs Service held two public meetings on the safety of imported foods. FDA representatives discussed and provided the public an opportunity to comment on the six objectives of the proposed food safety plan announced by President Clinton in his December 11, 1999, radio address.

The six objectives are: (1) preventing distribution of unsafe imported food by means such as requiring food to be held until reviewed by the FDA; (2) destroying imported food that poses a serious public health threat; (3) prohibiting the re-importation of food that previously has been refused admission and has not been brought into compliance; (4) setting standards for the use of private laboratories for the collection and analysis of samples of imported food; (5)

increasing the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the U.S.; and (6) enhancing enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary fines.

The meetings also included an overview of the Clinton Administration's directive and a review of the new operational procedures proposed by the FDA and the U.S. Customs Service to accomplish each of the six objectives. Three breakout sessions discussed the following: (1) secured storage, increased bonds, and enforcement activities; (2) destruction and marking of refused foods; and (3) standards for the use of private laboratories.

**Event:** *Codex Meeting on Food Additives and Contaminants*  
**Date:** February 4, 2000, 1:30 - 3:00 p.m.  
**Location:** Room 1409, Federal Office Building 8, 200 C Street, SW, Washington, DC  
**FR Cite:** 65 *Federal Register* 3652 (January 24, 2000)  
**Contact:** Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue, SW, Washington, DC, 20250; Tel: 202-205-7760; Fax: 202-720-3157. Submit an original and two copies of written comments to FSIS Docket Clerk, Docket #00-001N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex, 300 12<sup>th</sup> Street, SW, Washington, DC 20250-3700.

The U.S. Food Safety and Inspection Service (FSIS), Office of the Under Secretary for Food Safety, and Food and Drug Administration (FDA) sponsored a public meeting to provide information and receive comments on agenda items that will be discussed at the 32<sup>nd</sup> Session of the Codex Committee on Food Additives and Contaminants (CCFAC), which will be held in Beijing, China, March 20- 24, 2000. The Codex Alimentarius Commission (Codex) is the international

body empowered by the WTO's Agreement on Sanitary and Phytosanitary Measures to set presumptively WTO-legal food safety standards.

Issues discussed at the meeting included: (1) the application of risk analysis principles for food additives and contaminants; (2) endorsement and revision of maximum levels for food additives and contaminants in Codex standards; (3) the use of colors in foods; (4) proposed

revisions to the Codex general standard for irradiated foods; (5) consideration of the Codex general standard for contaminants and toxins in foods; (6) mycotoxins in food and

feed; (7) aflatoxin in milk; and (8) industrial and environmental contaminants in food.

**Event:** *Codex Meeting on Milk and Milk Products*  
**Date:** February 15, 2000, 9:00 a.m. - noon  
**Location:** Room 0745, South Agriculture Building, U.S. Department of Agriculture, 14<sup>th</sup> Street and Independence Avenue, SW, Washington, DC 20250  
**FR Cite:** 65 *Federal Register* 3651 (January 24, 2000)  
**Contact:** Patrick J. Clerkin, contact information above. Submit an original and two copies of written comments to the FSIS Docket Clerk, address above, and refer to Docket #00-002N.

The U.S. Agricultural Marketing Service (AMS), Food Safety and Inspection Service (FSIS), and Food and Drug Administration (FDA) held a public meeting to provide information and receive comments on agenda items that will be discussed at the 4<sup>th</sup> Session of the Codex Committee on Milk and Milk Products (CCMMP), which will be held in Wellington, New Zealand, from February 28 to March 3, 2000.

Issues discussed at the public meeting included: (1)

draft standard for unripened cheese, including fresh cheese; (2) heat treatment definitions; (3) model export certificate for milk products; (4) proposals for new standards for “parmesan” and “cheese speciality”; and (5) proposed draft and draft revised standards for cream, fermented milk products, dairy spreads, processed cheese, individual cheeses, whey powders, and edible casein products.

**Event:** *FSIS Public Meeting on Beef Products Contaminated with E. coli O157:H7*  
**Date:** February 29, 2000, 9:00 a.m.-5:00 p.m.  
**Location:** Holiday Inn Rosslyn Westpark Hotel, 1900 North Fort Myer Drive, Arlington, VA; Tel: 703-807-2000  
**FR Cite:** 65 *Federal Register* 6881 (February 11, 2000)  
**Deadline:** Written comments must be received by April 11, 2000  
**Contact:** For more information, Daniel Engeljohn, Ph.D., Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, FSIS, Room 112 Cotton Annex, 300 12<sup>th</sup> Street, SW, Washington, DC 20250; Tel: 202-720-5627; Fax: 202-690-0486. To register for the meeting, Mary Gioglio, Tel: 202-501-7244; Fax: 202-501-7642.

The U.S. Food Safety and Inspection Service (FSIS) held a public meeting to discuss the agency’s policy on *Escherichia coli* (*E. coli*) O157:H7 and new information concerning the pathogen and its relation to human health. In November 1999, the FSIS released a White Paper on *E. coli*<sup>35</sup> documenting this new information and discussed the implications this new information will have on FSIS policies at the public meeting.

**1994 Policies:** In 1994, the FSIS declared *E. coli* an adulterant in ground beef and implemented a testing program for the pathogen. However, since it was found at a low rate in such tests, FSIS did not consider the pathogen a hazard “reasonably likely to occur,” and thus did not require meat establishments to address it in their Hazard Analysis and Critical Control Point (HACCP) plans.<sup>36</sup> In addition, because

*E. coli* was so difficult to find, once the FSIS found a single positive test from a meat-grinding plant, the agency required fifteen consecutive negative tests from daily sampling before it would allow the plant to return to routine testing.

Since outbreaks attributed to *E. coli* were associated with ground beef, the FSIS concentrated its regulatory program on ground products and exempted intact meat products, such as steaks, from the regulations. Because FSIS believed that cooking meat products contaminated with *E. coli* was the only effective intervention, the agency advised that when the pathogen was found in ground or non-intact meat products, they must be diverted or cooked under the control of the FSIS.<sup>37</sup>

**New Information:** Now, however, the FSIS has new information suggesting that *E. coli* is not as rare as

previously thought. In September 1999, the FSIS began using a testing method that is four times more sensitive than the previous method. As a result, forty percent of all of the positive samples found since the testing program began in 1994 have been found since the new test was initiated, a span of only a few months.<sup>38</sup> This suggests that the low rate of positive findings may have had more to do with the sensitivity of the test being used rather than the rarity of the pathogen.

Furthermore, the Centers for Disease Control and Prevention (CDC) released data showing a much higher rate of illness from *E. coli* than had previously been reported by CDC, due mainly to milder cases of illness revealed by surveillance data. The CDC data indicated that most *E. coli* cases are limited to relatively mild symptoms that are unlikely to result in the infected person seeking medical care or reporting it to public health officials.

In addition, research performed at Kansas State University on blade-tenderized roasts and steaks - considered intact products - shows that the blade tenderization process transfers three to four percent of surface contamination to the interior of the product.<sup>39</sup> Thus, the FSIS is considering expanding the scope of its *E. coli* policy to include intact meat products.

Finally, the FSIS believes there may be interventions other than cooking contaminated meat products effective in eliminating *E. coli*. The agency is considering food irradiation as one such alternative, but will consider other alternatives.

Food irradiation is the subject of considerable controversy. Irradiation is the process of exposing food products to high levels of radiation to kill potentially

dangerous microorganisms like *E. coli*. In December 1997, the Food and Drug Administration (FDA) concluded that irradiation is safe for raw meat, and on December 23, 1999, the U.S. Department of Agriculture (USDA) approved the use of irradiation for raw meat and meat products, including ground beef, steaks, and pork chops.<sup>40</sup>

However, some consumer groups have sharply questioned the safety of food irradiation. For example, Public Citizen 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, rather than ensuring clean and sanitary practices, in food processing establishments.

**Proposed Changes:** In light of the new information described above, some of the specific issues that were discussed at the public meeting included: (1) whether the FSIS should re-design its testing program; (2) how the FSIS should treat intact product; and (3) whether the FSIS should consider a plant's generic *E. coli* and *Salmonella* results in deciding whether to target the plant's products for sampling.

- Event:** *Meeting of the President's Advisory Committee on Trade Policy and Negotiations*
- Date:** March 1, 2000, 8:00 a.m. - 12:00 noon
- Location:** USTR ANNEX Building, Conference Rooms 1 and 2, 1724 F Street, NW, Washington, DC
- FR Cite:** 65 *Federal Register* 9039 (February 23, 2000)
- Contact:** Ladan Manteghi, Office of the USTR, at 202-395-6120

The Office of the U.S. Trade Representative (USTR) hosted a meeting of the President's Advisory Committee on Trade Policy and Negotiations. The meeting included a review and discussion of current issues in U.S. trade policy.

However, the meeting was open to the public and press for only thirty minutes, from 11:30 a.m. to noon, because the USTR has "determined that this meeting [was] concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any

trade agreement and other matters arising in connection with the development, implementation, and administration of the trade policy of the United States." Even then, individuals who are not members of the committee were only able to observe, not comment.

On February 24, 2000, three labor leaders - John J. Sweeney, president of the AFL-CIO; Jay Mazur, president of UNITE; and Lenore Miller, head of the Retail, Wholesale, and Department Store Union - resigned from the ACTPN to protest the committee's limited focus and indicate their frustration with the Clinton Administration. The

administration was using the ACTPN to persuade Congress to grant China permanent normal trade relations, a proposal American unions vehemently oppose. The labor leaders told the *New York Times* that the administration has failed to

include labor demands for worker protections when developing international trade policy and negotiating trade deals.<sup>41</sup>

**Event:** *Public Meetings on FAA Harmonization Initiatives*  
**Dates:** March 7 and 9  
**Location:** JAA Headquarters, Saturnusstraat 8-10, 2132 HB Hoofddorp, the Netherlands  
**FR Cite:** 65 *Federal Register* 9039 (February 23, 2000)  
**Contact:** Brenda Courtney, Office of Rulemaking, 800 Independence Avenue, SW, Washington, DC 20591; Tel: 202-267-3327; Fax: 202-267-5075

The U.S. Federal Aviation Administration (FAA) and the European Union's Joint Aviation Authorities (JAA) held public meetings to solicit public comment on the Harmonization Work Program. Through this program, the FAA and JAA harmonize U.S. and EU rules regarding the operation and maintenance of civil aircraft, and the standards, practices, and procedures governing the design

materials, workmanship, and construction of civil aircraft, aircraft engines, and other components.

According to the published agenda, FAA and JAA officials were to listen to industry issues and concerns at the March 7 meeting, and then respond to them at the March 9 meeting.

**Event:** *Public Meeting of the Codex Biotechnology Task Force*  
**Date:** March 8, 2000, 1:00 - 4:00 p.m.  
**Location:** Room 1813, FDA Office Building, 200 C Street, SW, Washington, DC  
**Contact:** L. Robert Lake, U.S. Delegate, Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology, at 202-205-4160

The U.S. Delegation to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology held a public meeting to discuss and receive public comment on U.S. Government positions on the Task

Force's agenda. The Task Force was created in an attempt to reach consensus on several issues involving genetically-modified (GM) foods, including a working definition of GM foods and a position on the labeling of GM foods.

**Event:** *North American Agreement on Labor Cooperation Hearing*  
**Date:** March 23, 2000, at 9:00 a.m.  
**Location:** Department of Labor, 200 Constitution Avenue, NW, Room N-5437, Washington, DC  
**FR Cite:** 65 *Federal Register* 9299 (February 24, 2000)  
**Contact:** For more information, Lewis Karesh, Acting Secretary, U.S. National Administrative Office, Department of Labor, 200 Constitution Avenue, NW, Room C-4327, Washington, DC 20210; Tel: 202-501-6653.

The U.S. National Administrative Office (NAO) of the Bureau of International Labor Affairs, is holding a public hearing on Submission #9901, which was filed on November 10, 1999, by the Association of Flight Attendants (AFA) and the Association of Flight Attendants of Mexico (ASSA) under Article 16 (3) of the North American Agreement on

Labor Cooperation, the labor side agreement to NAFTA. Article 16 (3) provides for review of labor law matters in Canada and Mexico by the NAO in accordance with U.S. domestic procedures. Workers from Canada or Mexico may file a complaint with the NAO, and the NAO is empowered to decide whether the Canadian or Mexican national

government has complied with its own labor laws. However, the NAO has very little enforcement powers.

At the hearing, the NAO will receive written statements and briefs as well as oral testimony concerning the freedom of association, right to organize, and health and safety issues raised in Submission #9901. The NAO has not released the submission. However, in a January 13, 2000 *Federal Register* notice, the NAO did provide some of the issues raised in the submission.<sup>42</sup>

According to the NAO, "The submission raises concerns about freedom of association and occupational safety and health at the privately owned Mexican airline company, Executive Air Transport, Inc. (TAESA)."<sup>43</sup> The

complaint focuses on the flight attendants' attempts to organize a union at TAESA. The flight attendants assert that these efforts were prevented by Mexico's federal labor board and TAESA management. They allege that the Mexican government has failed "to enforce levels of protection, government enforcement action, private action, and procedural guarantees in connection with freedom of association, the right to bargain collectively, minimum labor standards, and prevention of occupational injuries and illnesses."<sup>44</sup>

Under NAALC rules, the NAO will review the submission and issue a public report within 120 to 180 days.

## APPENDIX

# TACD

Trans Atlantic  
Consumer Dialogue

Dialogue Transatlantique  
des Consommateurs

DOC NO. TRADE-8-00

DATE ISSUED: FEBRUARY, 2000

## PRINCIPLES OF HARMONIZATION

International harmonization can occur at the lowest or highest level of public health, worker safety, or environmental protection. However, the TACD strongly believes that in the instances when international harmonization of standards is appropriate, it must result in the adoption of best available technology and embody the highest levels of consumer protection. Unfortunately, the actual provisions of the WTO requiring harmonization or providing incentives for harmonization generally promote the lowering of the best existing domestic public health, food safety, economic justice, natural resource conservation and product safety standards. For instance, under the WTO, international standards do not serve as a floor that all countries must meet. Rather, they serve as a ceiling. The agreements provide for the challenge of any domestic standards that go beyond international standards in providing greater citizen safeguards, but contain no provisions for challenging lax standards. Thus, as outlined in its position paper in preparation for the Seattle Ministerial, the TACD is concerned that as currently written, the permanent WTO agreements and provisions will serve only as a one-way downward ratchet on domestic standards. In the wake of Seattle, TACD affirms that the review and repair of the WTO's Technical Barrier to Trade Agreement and the Sanitary and Phytosanitary Agreement is an urgent priority that is more attainable than ever.

### Principles for International Harmonization:

1. **Standards that do not have a health and safety component should be the primary candidates for international harmonization.** We must distinguish between standards and procedures that do not

directly involve health and safety concerns (i.e. the size of a floppy disk, credit card, or customs and accounting procedures) and those that impact health and safety (i.e. auto standards, medical device standards, and allowable pesticide residues in food.). Many standards, like pesticide residues, are impacted by factors such as cultural norms, dietary intake which make a "one size fits all" standard hard to achieve.

2. **Some issues must remain outside the scope of international commercial rules altogether.** We reject the movement fostered in the WTO to turn basic necessities or elements of life (like genetic materials) into commodities. Rather they should be recognized as common goods and precious resources for government to protect, distribute and regulate. For example, we reject the commodification of bulk water, and the patenting of life forms and seeds.
3. **TACD favors international standards being used as a floor rather than a ceiling.** The harmonization mechanisms in the TBT and SPS Agreements encourage the challenge of higher domestic standards but not the challenge of lower standards. The current mechanism can only result in a ratcheting down of standards. At a minimum, the harmonization provisions of the SPS and TBT agreements need to be rewritten to ensure that the role of democratically-achieved international standards is not to discourage cutting-edge domestic innovations geared toward solving some of our most pressing problems.
4. **TACD is concerned about current WTO use of international standards in deciding disputes regarding health, safety and the environment.** TACD believes that international standards, while helpful in some contexts, should be voluntary and that the WTO SPS and TBT Agreements' current elevation of all such standards, regardless of the forum in which they are set or the level of protection provide, is inappropriate. For instance, international standards should not be used to undermine non-discriminatory domestic standards merely because those domestic standards provide a higher level of health, safety or environmental protection. TACD is particularly concerned at the practical application of international standards in the dispute resolution procedure. Not enough emphasis is being placed on the exception which allows nation states to adopt higher standards or requirements. This is compounded by the inability to challenge international standards themselves for not embodying a sufficiently high level of consumer protection.
5. **The Precautionary Principle should be incorporated more broadly in the international standards setting process.** Ironically, while the U.S. government challenges the EU beef hormone and genetically modified organisms (GMO) policies at the WTO, it undercuts the underlying basis for regulatory policy in the U.S. For example, the FDA's pharmaceutical safety rules, the burden of proof is on the producer to show a drug is safe. Until there is scientific evidence to make that showing, the drug is kept off the market. If a precautionary approach had been systematically applied, it might have prevented some of the recent and deadly food safety crises in Europe. Bringing such a principle to life is merely a matter of setting the right rules. The obvious test as to a standard's trade effect -- and the one that would have safeguarded the beef hormone policy -- is whether the measure is discriminatory as between domestic and foreign goods. The rule we demand is that standards based on the Precautionary Principle and applied equally to domestic and foreign producers are inherently permissible.
6. **Governments should only recognize or be involved in harmonization activities negotiated in open, accountable democratic fora,** with clear avenues for public input and transparent methods of rulemaking and record keeping. Non-transparent private industry groups for example, are not the place to be setting WTO-presumptively legal standards which impact public health, consumer safety or the environment. If differing regional and international standards are to be harmonized then this

should take place within an open and transparent framework. This framework must allow for participation by consumer representatives at all levels and all stages of the standards-writing process. Greater co-operation between government officials is also required to agree on essential safety requirements, which should be applied to international standards. Provision should also be made for public and/or government review and possible challenge of the right of a particular international standard to give any presumption of compliance with legal requirements. Other, quasi-governmental organizations like the Codex Alimentarius must also be reformed to give consumers and equal voice with industry in the process.

7. **a. We reject the notion of functional equivalence.** In Europe, equivalency decisions have been a conspicuous failure that has eventually resulted in the writing of over 5,000 new European standards with some 8,000 more on the way. Standards provide a bright line test whereby precise comparisons can be made. The very notion of equivalence allows for imprecise, subjective comparisons that are not appropriate when dealing with issues as important as public health and safety. However, given that equivalency decisions between nations are moving forward with increasing frequency, we must develop strict rules for making equivalence determinations. A standard or a regulatory system should be determined equivalent only if it provides the same or greater level of substantive protection for health, safety or the environment. Criteria for determining equivalency should be clearly outlined and equivalency proposals should have substantive public input before they reached. (Thus, the NAFTA equivalence finding on Canadian beef that did not even review, much less compare, the varying regulatory systems and numerous standards, is unacceptable.)  
  
**b. Any equivalence decision or MRA must ensure that the procedural safeguards of the countries involved are equally strong** -- meaning there is a democratic process that assures consumer input and redress and government enforcement. To this end we recommend readiness criteria under which potential MRA and equivalency agreement must be reviewed. We urge nations to adopt strong freedom of information provisions, on-the-record rulemaking procedures, laws providing for open meetings of governmental agencies and balance on advisory committees among other reform measures to encourage citizen input into trade-related and standards-related proceedings.
8. **Harmonization activities including MRAs and equivalency agreements are only ever appropriate if they enhance the well-being of the people of the nations involved.** If these agreements are not negotiated with the input of the citizenry and if there is not a clearly defined public benefit, there is no reason for governments to spend public resources to accomplish harmonization. The cost of harmonization which only benefits industry should be shifted back to the private sector to execute voluntary standards. (For example, the FDA estimates that the 1998 U.S.-EU MRA will cost them over \$10 million and 125 full-time employees to implement.)
9. **We oppose the TABD's call for increased reliance on "suppliers declaration of conformity,"** especially in sensitive areas including: public health, food, product and worker safety and the environment. Conformity assessment procedures are only one component of the framework which ensures that products actually comply with the appropriate standards. This framework includes the product liability regime and market surveillance in particular. The role that each of these components will play can legitimately differ from one jurisdiction to another. There is a danger that focussing on only one aspect i.e. conformity assessment will upset the balance of the whole framework. Some equivalency decisions and MRAs (i.e., 1998 U.S.-EU MRA) are leading to situations where one country is handing over federal regulatory authority to private entities in a second country. TACD believes it is entirely inappropriate to privatize key public safety functions via MRAs and equivalency decisions, even if national governments retain ultimate responsibility for the safety of products.

**NOTES**

1. Jeremy Lennard, "US Sabotages Biosafety Protocol," *Guardian* (London), Feb. 23, 1999.
2. Lucette Lagnado, "Group Sows Seeds of Revolt Against Genetically Altered Foods in U.S.," *The Wall Street Journal*, Oct. 12, 1999, at B1.
3. John Burgess, "Trade Rules Set on Food Genetics," *Washington Post*, Jan. 30, 2000, at A1.
4. Helene Cooper, "Trade Rules on Biocrops Benign to U.S.," *The Wall Street Journal*, Jan. 31, 2000, at A1.
5. *Id.*
6. Final Draft of Biosafety Protocol, Jan. 29, 2000, Preamble.
7. *Id.* at Art. 2.4, emphasis added.
8. *Id.* at Art. 3(g).
9. *Id.* at Art. 3(h).
10. *Id.* at Art. 4.
11. *Id.* at Art. 7.1.
12. *Id.* at Art. 7.2.
13. The Biosafety Clearing House will be a permanent, central information center set up on the Internet. Exporting nations will post notification of each new approved GMO to the web site, and importing nations will have to monitor the site for such approvals to decide whether they will allow imports of each GMO. Each nation also will have to provide to the Clearing House its laws, regulations, and guidelines for implementing the Protocol; any other international agreements covering LMOs; summaries of its risk assessments or environmental reviews of LMOs; and its final decisions on the importation or release of LMOs. *See* Final Draft of Biosafety Protocol, Jan. 29, 2000, at Art. 20.3.
14. Final Draft of Biosafety Protocol, Jan. 29, 2000, at Arts. 10.2-10.3.
15. *Id.* at Art. 18.2.
16. *Id.* at Art. 11.1.
17. *Id.* at Art. 18.2.
18. *Id.* at Art. 10.6.
19. *Id.* at Art. 26.
20. *Id.* at Annex II.3.
21. *Id.* at Art. 15.1.
22. *Id.* at Art. 27.

23. EC Health & Consumer Protection Directorate-General, Food and Veterinary Office, *Final Report of a Mission Carried Out in the United States of America from 4 November to 12 November 1999 in Order to Evaluate the Implementation and the Enforcement of the Non-Hormone Treated Cattle (NHTC) Programme*, DG(SANCO)/1076/1999-MR, Dec. 11, 1999, on file with Public Citizen.
24. *See* WTO, European Communities - Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body, AB-1997-4, Jan. 16, 1998.
25. *Id.* at 4.
26. EC Health & Consumer Protection Directorate-General, Food and Veterinary Office, *Final Report of a Mission Carried Out in the USA from the 28<sup>th</sup> June to the 2<sup>nd</sup> July 1999 to Assess the Implementation of a New Testing Regime in the Framework of the US/EU Interim Agreement of April 1989 Concerning Trade in Non-Hormone Treated Bovine Meat*, XXIV/1186/99-MR, Oct. 15, 1999, on file with Public Citizen, at 5.
27. *Id.* at 6.
28. FVO, November 4-12, 1999 Report, *supra* note 23, at 6.
29. *Id.*
30. *Id.* at 7.
31. *Id.* at 8.
32. *See* Bruce Ingersoll, "U.S. Launches Probe After Switzerland Finds Illegal Hormone in American Beef," *The Wall Street Journal*, Feb. 2, 2000, at A2.
33. FVO, November 4-12, 1999 Report, *supra* note 23, at 10.
34. *See* 64 *Fed. Reg.* 63169, Nov. 18, 1999. Both notices contain the full text of the Executive Order.
35. Food Safety and Inspection Service, "White Paper on *Escherichia coli* O157:H7," Nov. 1999, available as of Feb. 17, 1999, at [www.fsis.usda.gov/OA/update/110599\\_att.htm](http://www.fsis.usda.gov/OA/update/110599_att.htm).
36. *Id.* at 1.
37. *Id.* at 2.
38. *Id.*
39. *Id.* at 3.
40. 64 *Fed. Reg.* 72149, Dec. 23, 1999.
41. *See* Joseph Kahn, "Labor Leaders Leave Panel on China Trade," *The New York Times*, Feb. 24, 2000.
42. *See* 65 *Fed. Reg.* 2193, Jan. 13, 2000.
43. *Id.* at 2194.
44. *Id.*