



**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:** *U.S. Warns EU: Ban on Antibiotics in Animal Feed May Violate WTO*  
**Venue:** Office of the U.S. Trade Representative  
**Contact:** Peter Scher, Special Trade Ambassador, Office of the USTR, at (202) 395-5057.

In an August letter, the Office of the U.S. Trade Representative (USTR) warned Guy Legras, of the European Union (EU) Directorate General for Agriculture (DG VI), that the EU ban on four antibiotics used in animal feed, “may not be consistent with the EU’s obligations in the World Trade Organization.”<sup>1</sup> The USTR letter was signed by Special Trade Ambassador Peter Scher, who alleged that the EU in some cases failed to perform risk assessments complying with WTO rules and in other cases ignored the results of the ones they did perform. He also argued that the EU failed to notify the WTO of the ban in violation of the Sanitary and Phytosanitary (SPS) Agreement.<sup>2</sup>

The European ban on bacitracin zinc, spiramycin, virginiamycin and tylosin phosphate was approved by the European Council on December 17, 1998, and became effective

July 1, 1999.<sup>3</sup> The ban was instituted to protect humans from developing resistance to antibiotics through consumption of animals which have been fed antibiotics.

A growing body of scientific evidence is finding links between antibiotics in the food chain and the development of resistance to those antibiotics in humans. In a background paper on the use of Antimicrobial Drugs as Growth Promoters, the U.S. Center for Disease Control (CDC) concluded: “Compelling scientific evidence indicates that the use of antimicrobial drugs in food producing animals can lead to adverse public health consequences, due to the emergence of resistant bacteria which can be transmitted to humans through the food supply or direct contact with the animals.”<sup>4</sup> The World Health Organization (WHO) strongly recommends that antibiotics used to treat humans should not be used to

promote animal growth.<sup>5</sup> In a statement focused specifically on the EU ban, the CDC declared in 1998 that the decision by the EU to ban human-use antibiotics from livestock feed was “scientifically justifiable” and “protects the public health.”<sup>6</sup>

The Washington, D.C.-based food safety group Center for Science in the Public Interest (CSPI) quickly wrote a letter to U.S. Trade Representative Charlene Barshefsky (September 21, 1999), criticizing her office for taking a position on antibiotics in livestock feed in contradiction to the positions of the CDC, WHO, National Academy of Sciences (NAS), and General Accounting Office (GAO).

“The USTR advocates a policy that undermines the public health. Agricultural uses of antibiotics are promoting the spread of new drug-resistant bacteria, which have become a serious public health hazard,” said Michael F. Jacobsen, Executive Director of CSPI. “Unfortunately, the USTR is trying to invoke a WTO trade agreement to protect U.S. meatpackers’ and drug companies’ sales in Europe regardless of the effect on public health.”<sup>7</sup>

The WTO SPS Agreement sets criteria to which WTO

Members must conform their policies designed to protect human, animal or plant life from pests, disease and toxins in food, beverages or animal feed. The SPS Agreement requires nations to conduct risk assessments to scientifically justify food safety laws. In past WTO challenges regarding these provisions, such as in the Australian salmon case, WTO dispute resolution panels have required such risk assessments not only identify a risk, but also the precise probability it will come to pass.

In this case, the USTR seems to be arguing that -even though independent scientific bodies have concluded that animals should not be fed antibiotics to stimulate growth - since the EU itself has not done a complete risk assessment for each banned antibiotic, it has not lived up to its obligations under the WTO SPS Agreement. Ironically, even though these antibiotics have long been approved for use in animal feeds in the U.S., the Scher letter admits that the U.S. is only now studying the potential causes of the worldwide increase in antibiotic resistant bacteria.<sup>8</sup>

**Topic:** *Citizen Summit and World Trade Organization Ministerial*

**Contact:** To get involved in the Citizens Summit, please visit [www.seattlewto.org](http://www.seattlewto.org) or call the Citizens Trade Campaign at 1-877-STOPWTO. For more information on the WTO Ministerial, see the website of the Seattle Host Organization at [www.wtoseattle.org](http://www.wtoseattle.org) or visit the WTO website at [www.wto.org](http://www.wto.org).

The World Trade Organization’s third Ministerial Conference will take place November 29 - December 3, 1999 in Seattle, Washington. Trade ministers from the 134 WTO Member nations will meet to determine the WTO’s future agenda.

At the same time, thousands of representatives from national and international consumer, environmental, labor, and faith organizations - excluded from the Ministerial negotiations - will be holding teach-ins, rallies, marches, and other events to draw attention to the World Trade Organization’s impact on environmental, public health, food safety and consumer protection laws around the world. The nongovernmental organizations (NGOs) will call on governments to review and

repair existing WTO agreements. Each day of that week, the events will focus on a different area affected by the WTO and globalization: Monday - Environment and Health; Tuesday - Labor and Human Rights; Wednesday - Women, Democracy, Sovereignty, and Development; Thursday - Food and Agriculture; and Friday - Corporate Accountability.

Highlights of the Citizen Summit include: an International Interfaith Service, a Labor and Human Rights March, a Farmer to Farmer Summit, a debate between NGO leaders and WTO representatives, and forums on Corporate Accountability and Biotechnology. A detailed calendar is available at [www.seattlewto.org/calendar.html](http://www.seattlewto.org/calendar.html).

**Harmonization Alert** is a monthly publication of Public Citizen Foundation. It aims to inform a wide audience of interested parties about international standardization activities. Additional information and materials for many of this publication’s listings are available through our harmonization clearing house. If you have information on harmonization-related issues, please contact us so we can share your information with other readers. **Harmonization Alert** is available free of charge by mail, list serve, and on the Internet at [www.harmonizationalert.org](http://www.harmonizationalert.org). Please contact Dion Casey at [dcasey@citizen.org](mailto:dcasey@citizen.org) or Mary Bottari at [mbottari@citizen.org](mailto:mbottari@citizen.org) or call (202) 546-4996 to subscribe or for clearinghouse requests. Public Citizen’s Harmonization Project is supported by grants from the Ford Foundation, the National Association for Public Interest Law, and the Cummings Foundation.

## FOOD SAFETY

**Topic:** *U.S.-EU Mutual Recognition Agreement on Animals and Animal Products*  
**Venue:** U.S. Department of Agriculture  
**Contact:** Michael V. Dunn, Undersecretary for Marketing and Regulatory Programs, USDA, at (202) 720-4256

On July 20, 1999, the U.S. and the European Union (EU) signed a Mutual Recognition Agreement covering trade in live animals and animal products, including meat, fish, pork, and dairy products, pet food, hides, skins, and live horses.<sup>9</sup> The Veterinary MRA affects \$3 billion worth of trade in these goods.<sup>10</sup> The primary U.S. exports affected will be fish products (\$350 million), pet food (\$150 million), and fresh meat (\$150 million), while the primary EU exports affected will be dairy products (\$600 million), fish products (\$170 million), and pork products (\$120 million).<sup>11</sup>

The Veterinary MRA in several sections encourages both parties to "avoid a disruption in trade" due to sanitary policies.<sup>12</sup> The Agreement explicitly states that it does not "limit the rights or obligations of the Parties under the Agreement establishing the World Trade Organization and its Annexes, in particular the SPS [Sanitary and Phytosanitary] Agreement."<sup>13</sup> In fact, in defining several terms, the Veterinary MRA refers to definitions in the WTO SPS Agreement.<sup>14</sup> This means that the WTO's dispute resolution rules will still apply to any SPS disputes between the U.S. and the EU.

The Veterinary MRA requires importing nations to recognize "regionalization" decisions made by exporting nations<sup>15</sup> for seventeen different animal diseases, including foot-and-mouth disease, swine vesicular disease, and Newcastle disease.<sup>16</sup> This means that if one region of an exporting nation is afflicted with one of the listed animal diseases, but the exporting nation determines that other regions are free of that disease, an importing nation must accept that determination and cannot prohibit imports of live animals or animal products from the regions the exporting nation has declared disease-free.

For example, if a region of France is stricken with swine vesicular disease, but French officials determine that other regions of France are free of that disease, the U.S. can prohibit imports of pork products from the stricken region, but not from the other regions. Previously, if an animal disease existed anywhere within an exporting nation's borders, the U.S. considered the entire nation to be afflicted with the disease, and regulated or banned imports of animal and animal products from anywhere in exporting nation accordingly.<sup>17</sup>

EU officials insisted that the U.S. adopt a regionalization rule before they would sign the Veterinary MRA.<sup>18</sup> The U.S. Animal and Plant Health Inspection Service (APHIS) proposed such a rule on June 25, 1999, almost a month before the Veterinary MRA was signed.<sup>19</sup> In that rule, APHIS

also proposed to recognize regions in the EU as free of hog cholera, foot-and-mouth disease, and swine vesicular disease, potentially opening the U.S. market to additional EU pork products.<sup>20</sup>

The National Pork Producers Council (NPPC) came out in opposition to the APHIS proposal, arguing that the EU regions were too small, leaving little margin for error to prevent the spread of an animal disease to a nearby region.<sup>21</sup> The NPPC wants the EU to be separated into larger regions so there will be more of a buffer against spreading infections.<sup>22</sup>

The NPPC is especially concerned with hog cholera, which has a long incubation period - hogs infected with cholera can take up to eight weeks to show recognizable symptoms.<sup>23</sup> Allowing imports of hogs and hog products from a region which is infected but whose hogs have not begun to show signs of cholera could result in the disease spreading to the U.S.<sup>24</sup> The U.S. was determined to be free of hog cholera in 1978, but only after an eradication project costing \$540 million.<sup>25</sup>

The NPPC also pointed out that U.S. law requires farmers attempting to move swine from one state to another to show that their animals are free of disease. European law contains no such requirement.<sup>26</sup>

In exchange for the U.S. adoption of this regionalization rule, the EU agreed that EU veterinarians would no longer directly certify U.S. factories as qualified to export red meat to the EU.<sup>27</sup> Instead, the EU inspectors would accept the certification of the U.S. Food Safety and Inspection Service (FSIS) that factories meet both U.S. and EU requirements for export to EU nations.<sup>28</sup> However, the EU still would be able to inspect U.S. imports at EU ports of entry, assess the U.S. Department of Agriculture's inspection program, and conduct on-site inspections of U.S. plants.<sup>29</sup>

The Veterinary MRA also sets the criteria the U.S. and EU nations must follow when determining whether their sanitary measures are equivalent.<sup>30</sup> The importing nation must explain the objective of its sanitary measure, including an assessment of the risks that the measure is intended to address, and identify its appropriate level of protection.<sup>31</sup> The exporting nation must demonstrate that its sanitary measure achieves the importing nation's appropriate level of protection.<sup>32</sup> However, the Veterinary MRA specifically states that the importing nation makes the final decision on whether an exporting nation's sanitary measures are equivalent to its own.<sup>33</sup>

The Veterinary MRA establishes a Joint Management Committee, consisting of U.S. and EU representatives, to

monitor activities governed by the Agreement.<sup>34</sup>

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**Topic:** *FSIS Allows Imports of Poultry Processed in Mexico*

**Venue:** Food Safety and Inspection Service

**Contact:** For more information, Mark Manis, Director, International Policy Development Division, Office of Policy, Program Development and Evaluation, at (202) 720-6400.

The Food Safety and Inspection Service (FSIS) is adding Mexico to the list of nations able to export poultry products to the U.S. after reviewing Mexico's laws and regulations governing its poultry processing system and determining that their requirements are equivalent to the relevant provisions of U.S. laws and regulations. The final rule was posted in 64 Federal Register 69640 on September 14, 1999. This rule enables certified poultry processing establishments in Mexico to export processed poultry products to the U.S. Only products processed from poultry slaughtered in federally-inspected establishments in the U.S. or in certified slaughter establishments in foreign nations may be exported to the U.S. after processing in certified Mexican establishments. FSIS inspectors will re-inspect poultry products exported from Mexico to the U.S. at the border.

To ensure that all foreign establishments certified to export to the U.S. comply with relevant U.S. laws and regulations, the FSIS conducts periodic on-site audits of each eligible foreign nation's inspection system to verify that its processed poultry products to the U.S. until Mexico has regulatory authority is implementing the system as described in the nation's application to export poultry to the U.S. The

FSIS will not allow any Mexican establishment to export certified that: (1) the establishment is eligible to export processed poultry products to the U.S., (2) establishments randomly selected for review during the on-site audit by the FSIS operate in a way that shows the FSIS that the nation's inspection system is working as described, and (3) the nation has been added to the poultry products inspection regulations as a nation eligible to export poultry products to the U.S.

The FSIS has conducted an on-site audit of Mexico's inspection system and verified that Mexico will enforce Hazard Analysis and Critical Control Points System (HACCP) and Sanitation Standard Operating Procedure (SSOP) rules, as required by U.S. law. The FSIS also analyzed Mexico's program for ensuring that only poultry from eligible nations and establishments is used in poultry products processed in Mexico for export to the U.S. Accordingly, the FSIS found Mexico's poultry inspection system equivalent to the U.S. system. The FSIS is reserving the right to verify that establishments certified by the Mexican government continue to meet U.S. requirements.

The new rule goes into effect October 14, 1999.

## **OTHER NEWS**

**Topic:** *Canada Pressures FDA to Exempt Canadian Produce from Inspection Policy*

A few weeks after the Canadian government warned the Food and Drug Administration (FDA) that a new produce inspection program was jeopardizing U.S.-Canada trade relations, FDA officials exempted Canada's produce from the program.<sup>35</sup> The FDA implemented a new inspection program because of the recent increase in the incidence of foodborne illnesses traced to fresh fruits and vegetables.<sup>36</sup> The FDA program, initiated in March, 1999, sampled eight varieties of imported fresh fruits and vegetables for testing for bacterial contamination.<sup>37</sup>

The FDA program was scheduled to run from March to September 30, 1999, and focused on detecting three types of bacteria (E-coli 157, shigella, and salmonella) on the eight types

of produce (green onions, cilantro, parsley, lettuce, strawberries, celery, broccoli, and cantaloupe). The program is stricter than the normal FDA regimen for imported produce, under which FDA officials perform spot checks and test only a small percentage of the total shipment. The FDA holds imported produce for further microbial testing only if a problem becomes evident from a spot check. However, under the new FDA initiative, produce from several nations, including Canada, Mexico, Brazil, and Chile, is held until the microbial tests are complete, which can take several days.<sup>38</sup>

Canadian exporters claim to have lost thousands of dollars because of the delay and the increased risk of spoilage. The Canadian government warns that the testing program

violates the Sanitary and Phytosanitary Agreement of the WTO and NAFTA, which require equal treatment between domestic and foreign producers and policies to be based on sound science.<sup>39</sup> (See, for example, NAFTA SPS Art. 717(a)).

FDA officials argue that the increase in incidents of foodborne illness connected to imported fresh produce, and the fact that the survey has detected microbial contamination on Canadian produce provide sufficient scientific evidence for the inspection program.<sup>40</sup> Although the FDA has not implemented a similar testing program for U.S.-grown produce, it is considering doing so within the next two years.<sup>41</sup>

In a letter to U.S. Secretary of Agriculture Dan Glickman, dated August 5, 1999, Canadian Agriculture Minister Lyle Vanclief requested that Canadian produce be immediately exempted from the testing program. Vanclief wrote, "Should this not be possible, Canada will need to consider other alternatives, including resolution through recourse to the provisions under NAFTA or the WTO."<sup>42</sup>

The FDA exempted Canadian imports from the testing program soon after, although FDA officials claim they did so because enough samples of Canadian produce had been taken to satisfy the survey.<sup>43</sup>

**Topic:** *Conference on International Food Trade Beyond 2000*

**Date:** October 11-15, 1999

**Location:** Melbourne, Australia

**Contact:** See the related article in the Meetings/Events section below. The 24 "ALICOM" documents are available at [www.fao.org/es/esn/austral/alicom99/alicom-e.htm](http://www.fao.org/es/esn/austral/alicom99/alicom-e.htm).

At a September 16, 1999, meeting of the U.S. delegation to the Codex Alimentarius Commission, the U.S. Food Safety and Inspection Service (FSIS) released an abstract<sup>44</sup> of 24 "ALICOM" documents that have been submitted by various WTO Member nations for consideration at the Melbourne Codex Conference. The ALICOM documents contain recommendations on topics such as harmonization, mutual recognition, equivalence, labeling, consumer participation, and food safety. Following is a brief summary of other nations' recommendations contained in the FSIS abstract, and a summary of the major themes the U.S. will present at the Codex Conference. The name of the nation or organization making the recommendations is in parentheses.

**Food Safety:** (South Africa) In order to evaluate the true status and extent of food safety problems worldwide, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) should maintain a global register of incidents of foodborne illnesses caused by contamination and identify the reasons for them and the associated food safety control deficiencies. The FAO and WHO also should assess the effectiveness of food safety programs. National governments should increase funding of research into emerging foodborne problems.

**International Standards:** (World Trade Organization) Developing nations' participation in the development of international standards must be increased. Both developed and developing nations should base their food safety standards on international standards, even though developed nations may view international standards as a lowest common

denominator and developing nations may view them as unnecessarily stringent. Once established, standards have to be reviewed regularly to keep them up to date, especially as scientific opinions change. Standards must have a scientific justification.

**Consumer Participation:** (Consumers Union) National governments and international agencies should secure funds to enable more consumer organizations to participate more effectively in the development of food policy. National governments should continue to use the Internet to disseminate food policy information and should create interactive web sites so that citizens and consumer organizations can respond to government proposals on-line.

**Appropriate Level of Protection:** (European Union) Codex must make progress on the application of the Precautionary Principle and legitimate factors other than science to food safety policy. The Precautionary Principle must be properly defined.

**U.S. Themes:** The U.S. recommends that Codex continue to base its food safety standards on science and avoid other factors that may be "political in nature." The U.S. sees "no justification for, or purpose served by, Codex defining a separate 'precautionary principle.'" The U.S. supports increased participation of consumer organizations in Codex and recommends increased consumer access to Codex documents. Finally, the U.S. supports the position nations maintain their sovereign right to select their own appropriate levels of protection and to design food safety measures.

## **FEDERAL REGISTER ALERTS**

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- Topic:** *Global Harmonization Task Force Draft Document on Reporting of Use Errors with Medical Devices*
- Action:** Notice of availability
- Venue:** Global Harmonization Task Force (Food and Drug Administration)
- FR Cite:** 64 *Federal Register* 42701 (August 5, 1999)
- Deadline:** For written comments, September 7, 1999
- Contact:** For more information, Deborah Y. Blum, Office of Surveillance and Biometrics (HFZ09520), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. Submit two copies of written comments (with Docket No. 99N-2075 in the heading) to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The draft document is available on the Center for Devices and Radiological Health web site at [www.fda.gov/cdrh](http://www.fda.gov/cdrh).

The Food and Drug Administration (FDA) has been involved in the Global Harmonization Task Force (GHTF) since 1992. The GHTF is made up of representatives from Japan, Canada, Australian, the EU and the U.S. The GHTF's goal is to harmonize medical device regulatory systems to facilitate trade. The GHTF plans to achieve this goal by developing areas of international cooperation to progressively reduce technical and regulatory differences among nations' systems for regulating medical devices.

The GHTF has formed four study groups, each assigned to draft documents and carry on other activities designed to facilitate international harmonization of regulatory requirements concerning medical devices.

Study Group 1 (SG1) cover regulatory requirements and premarket review. Study Group 2 (SG2) covers medical device vigilance and post-market surveillance. Study Group 3

(SG3) focuses on quality system requirements and guidance and Study Group 4 (SG4) works on common auditing procedures.

The FDA is seeking public comments on a draft document that was prepared by SG2. SG2's duties include examining the requirements for the reporting of adverse incidents involving medical devices and recommending ways to harmonize these requirements. It has prepared a draft document - "Proposal for Reporting of Use Errors with Medical Devices" - that serves as a reference for manufacturers on adverse event reporting. The draft document includes information for regulatory authorities about reporting of adverse events that result in death or serious injury or certain types of near incidents. It also suggests that certain types of failures may be exempt from reporting under regulatory vigilance procedures.

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- Topic:** *Global Harmonization Task Force Documents*
- Action:** Notice of availability
- Venue:** Global Harmonization Task Force (Food and Drug Administration)
- FR Cite:** 64 *Federal Register* 43196 (August 9, 1999)
- Deadline:** For written comments, September 30, 1999
- Contact:** For more information, Kimber C. Richter, Office of Device Evaluation (HFZ-400), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville,

MD 20850; Phone: (301) 594-2022. To get copies of these documents, visit [www.fda.gov/cdrh](http://www.fda.gov/cdrh), or fax your request to (301) 443-8818. For more information on the Global Harmonization Task Force, visit [www.ghtf.org](http://www.ghtf.org). Submit two copies of written comments (with Docket No. 99N-2359 in the heading and the full title of the document to which the comments apply) to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, room 1061, Rockville, MD 20852.

The Food and Drug Administration (FDA) is releasing three documents prepared by Study Group 1 of the Global Harmonization Task Force (GHTF) on premarket regulation of medical devices: (1) "Summary Technical File for Premarket Documentation of Conformity with Requirements for Medical Devices," (2) "Recommendation: Role of Standards in the Assessment of Medical Devices," and (3) "Recommendation on Medical Devices Classification." The documents are harmonized recommendations for use by governments developing or updating their premarket regulation schemes for medical devices. According to the FDA, some elements of the proposals set forth in the documents may be inconsistent with U.S. regulatory requirements. FDA seeks public comment on the documents.

The first document - "Summary Technical File for Premarket Documentation of Conformity with Requirements for Medical Devices" - is for use by medical device regulators, conformity assessment bodies, and industry as a harmonized format for a summary technical file to be submitted for premarket approval. It proposes a format that may be used as

an alternative to country-specific submission formats by GHTF member nations and summarizes the technical information needed to demonstrate conformity to premarket requirements that are consistent across various regulatory authorities.

The second document - "Recommendation: Role of Standards in the Assessment of Medical Devices" - provides harmonized guidance for regulatory authorities on the use of standards in premarket regulation of medical devices. It recommends that international standards should serve as the foundation for a harmonized regulatory process. It also suggests that regulatory authorities and industry should develop international standards for medical devices.

The final document - "Recommendation on Medical Devices Classification" - recommends general guidelines for classification of medical devices to achieve eventual harmonization. It identifies the benefits of a globally-harmonized classification system to manufacturers and regulatory authorities, but does not mention any benefits to consumers.

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**Topic:** *ICH Guidance on Validation of Analytical Procedures: Methodology*  
**Action:** Notice of availability  
**Venue:** Food and Drug Administration  
**FR Cite:** 64 *Federal Register* 42392 (August 4, 1999)  
**Deadline:** Written comments may be submitted at any time  
**Contact:** For more information, William G. Marnane, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; Phone: (301) 827-6966; E-mail: [wmarnane@cvm.fda.gov](mailto:wmarnane@cvm.fda.gov). To get a copy of the guidance, visit [www.fda.gov/cvm/fda/TOCs/guideline.html](http://www.fda.gov/cvm/fda/TOCs/guideline.html), or write to Communications Staff (HFV-12), CVM, FDA, 7500 Standish Pl., Rockville, MD 20855. Submit written comments (with Docket No. 99D-0017 in the heading) to Policy and Regulations Team (HFV-6), CVM, FDA, 7500 Standish Pl., Rockville, MD 20855.

The Food and Drug Administration (FDA) is releasing a final guidance for industry entitled "Validation of Analytical Procedures: Methodology." The guidance has been adapted for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance adopted by the International Cooperation on Harmonization (ICH) of

Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidance gives suggestions on how to consider various validation characteristics for each analytical procedure included as part of registration applications for approval of veterinary medicinal products submitted to the European Union (EU), Japan, and the U.S.

The FDA participates in the ICH and the VICH in an

effort to harmonize technical procedures for the development of pharmaceutical products. The FDA's goal is to identify and reduce the differences in technical requirements for drug

development among the regulatory agencies of the EU, Japan, and the U.S. The FDA seeks public comment on this guidance.

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**Topic:** *Harmonization of Braking Systems Airworthiness Standards for Transport Airplanes*

**Action:** Proposed rule

**Venue:** Federal Aviation Administration

**FR Cite:** 64 *Federal Register* 43569 (August 10, 1999)

**Deadline:** For written comments, November 8, 1999

**Contact:** For more information, Mahinder K. Wahi, FAA, Propulsion/Mechanical Systems/Cabin Safety Branch, ANM-112, Transport Airplane Directorate, 1601 Lind Avenue, SW, Renton, WA 98055-4056; Phone: (425) 227-2142; Fax: (425) 227-1320. Submit 2 copies of written comments to U.S. Department of Transportation Dockets, Docket No. FAA-1999-6063, 400 Seventh Street, SW, Room Plaza 401, Washington, DC 20590, or e-mail comments to 9-NPRM-CMTS@faa.dot.gov. To get a copy of the entire notice of proposed rulemaking, visit [www.faa.gov/avr/arm/nprm/nprm.htm](http://www.faa.gov/avr/arm/nprm/nprm.htm).

The Federal Aviation Administration (FAA) is proposing to revise its airworthiness standards for transport category airplanes to harmonize braking systems design and test requirements with standards proposed for the European Joint Aviation Requirements (JAR). These proposed standards were developed in cooperation with the Joint Aviation Authorities (JAA) of Europe and the U.S., and the European aviation industry. They are intended to standardize certain requirements, concepts, and procedures contained in

the airworthiness standards in order to reduce costs to manufacturers. The FAA seeks public comment on these proposed revisions.

The current FAA airworthiness standards are contained in the *Code of Federal Regulations* at 14 CFR part 25. These standards apply to airplanes manufactured in the U.S. for use by U.S.-registered operators, and airplanes manufactured in other nations and exported to the U.S. under a bilateral airworthiness agreement.

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**Topic:** *International Conference on Harmonization's Guidance on Test Procedures and Acceptance Criteria for Biotechnological/Biological Products*

**Action:** Notice of availability

**Venue:** Food and Drug Administration (FDA)

**FR Cite:** 64 *Federal Register* 44928 (August 18, 1999)

**Deadline:** Submit written comments at any time.

**Contact:** For more information, Neil D. Goldman, Center for Biologics Evaluation and Research (HFM-20), FDA, 1401 Rockville Pike, Rockville, MD 20852; Phone: (301) 827-0377. For information on the ICH, Janet J. Showalter, Office of Health Affairs (HFY-20), FDA, 5600 Fishers Lane, Rockville, MD 20857; Phone: (301) 827-0864. Submit written comments - identified with Docket No. 98D-0374 - to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, room 1061, Rockville, MD 20852. Copies of the Guidance are available from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, MD 20857; Phone: (301) 827-4573 or at [www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm).

The Food and Drug Administration (FDA) is releasing a guidance entitled "Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products," which was prepared by the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidance provides advice on the general principles for the selection of test procedures and the setting and justification of acceptance

criteria for biotechnological and biological products, including proteins and polypeptides and their derivatives and conjugates, but not antibiotics, vitamins, conventional vaccines, or whole blood. The FDA intends this guidance to assist in the establishment of uniform international specifications for such products to support new marketing applications.

**Topic:** *FDA's Draft Agenda for International Activities*

**Action:** Notice of availability

**Venue:** Food and Drug Administration, Center for Food Safety and Applied Nutrition

**FR Cite:** 64 *Federal Register* 50518 (September 17, 1999)

**Deadline:** Written comments must be submitted by November 1, 1999

**Contact:** For more information or to obtain a copy of the Draft International Affirmative Agenda, John W. Jones, Office of Constituent Operations, CFSAN (HFS-550), 200 C Street, SW, Washington, DC 20204; Phone: (202) 205-4311. Copies of the agenda also are available at <http://vm.cfsan.fda.gov>. Submit two copies of written comments - with the identifying Docket No. 99N-3089 - to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, room 1061, Rockville, MD 20852.

The Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) participates in several international activities concerning the safety, quality, and labeling of foods and cosmetics. The international environment in which CFSAN operates has changed dramatically in the last 20 years. International trade in food and cosmetics has grown rapidly and international trade agreements - like NAFTA and the Uruguay Round - have introduced new requirements that affect FDA's traditional approaches to regulating such products. In addition, CFSAN has limited resources available to accomplish its international

obligations.

Thus, CFSAN has established priorities that are consistent with FDA's international obligations and available resources. CFSAN's Draft International Affirmative Agenda is intended to present achievable international priorities for the next three years in those areas CFSAN views as critical to the safety of foods and cosmetics. CFSAN requests public comment on this agenda and will, if interest is sufficient, consider holding a public meeting to receive further public comment.

**Topic:** *ICH Guidance on Choice of Control Group in Clinical Trials*

**Action:** Notice of availability

**Venue:** Food and Drug Administration (FDA)

**FR Cite:** 64 *Federal Register* 51767 (September 24, 1999)

**Deadline:** Written comments must be received by December 23, 1999

**Contact:** For more information on the ICH, Janet J. Showalter, Office of Health Affairs (HFY-20); Phone: (301) 827-0864; on the Guidance, Robert Temple, Center for Drug Evaluation and Research (HFD-4); Phone: (301) 594-6758; both can be contacted by mail at FDA, 5600 Fishers Lane, Rockville, MD 20857. Submit two copies of written comments - with the identifying Docket No. 99D-3082 - to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, room 1061, Rockville, MD 20852. Copies of the Guidance can be obtained from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, MD

20857; Phone: (301) 827-4573, or 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 releasing a draft guidance, prepared under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), entitled "E10 Choice of Control Group in Clinical Trials." The draft guidance establishes general principles that are relevant to all controlled trials but are especially pertinent to the major clinical trials intended to demonstrate drug efficacy.

The draft guidance describes the principal types of control groups and analyzes their appropriateness in various situations. It is intended to assist sponsors and investigators in the choice of control groups for clinical trials.

The draft guidance represents the FDA's current thinking on the choice of control group in clinical trials. It does not operate as a formal rule. An alternative approach may be used if it satisfies the requirements of the applicable statute and regulations.

## **MEETINGS/EVENTS**

**Event:** *U.S. Codex Meeting on International Food Trade Beyond 2000*  
**Date:** September 16, 1999, 2:30 p.m. - 4:30 p.m.  
**Location:** Room 104A, Jamie L. Whitten Building, U.S. Department of Agriculture, Washington, DC  
**FR Cite:** 64 *Federal Register* 48137 (September 2, 1999)  
**Contact:** For more information, F. Edward Scarbrough, U.S. Manager for Codex Alimentarius, U.S. Codex Office, FSIS, Room 4861, South Building, 1400 Independence Avenue, SW, Washington, DC 20250-3700; Phone: (202) 205-7760; Fax: (202) 720-3157. Documents related to the Conference are available at [www.fao.org/es/esn/austral/alicom99/alicom-e.htm](http://www.fao.org/es/esn/austral/alicom99/alicom-e.htm). Send an original and two copies of written comments to FSIS Docket Clerk, Docket #99-043N, Room 102, Cotton Annex, 300 12<sup>th</sup> Street, SW, Washington, DC 20250-3700.

The Food Safety and Inspection Service (FSIS), along with several other federal agencies, is sponsoring a public meeting to provide information and receive comments on agenda items for the Conference on International Food Trade Beyond 2000, which will be held in Melbourne, Australia, October 11-15, 1999. The Melbourne conference will address how food quality and safety issues affect trade, health, and development of domestic and international standards under the WTO's Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements.

The agenda for the Melbourne conference will include: (1) the future of the Codex Alimentarius Commission;

(2) the current status of food trade, including food quality and safety problems; (3) a review of the implementation of the SPS and TBT Agreements; (4) challenges for developing countries in meeting the obligations of the SPS and TBT Agreements and Codex; (5) harmonization of food regulations based on Codex standards; (6) emerging technologies in the food industry; (7) emerging problems, including allergens, chemical, and biological; (8) nutritional, environmental, and sustainable food production; (9) changes in cultural and consumer habits; (10) the role of science in setting food safety policies; (11) mutual recognition and equivalence; and (12) labeling issues.

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**Event:** *USTR Meeting on NAFTA's SPS Committee*  
**Date:** September 21, 1999, 9:00 a.m. - 11:00 a.m.  
**Location:** U.S. Department of Agriculture, South Building, 14<sup>th</sup> Street and Independence Avenue, SW, Washington, DC.  
**FR Cite:** 64 *Federal Register* 49267 (September 10, 1999)  
**Contact:** For more information, Carolyn T. Cohen, Foreign Agricultural Service, International Trade Policy, Food Safety and Technical Services Division, Room 5545, South Building, 14<sup>th</sup> Street and Independence

Avenue, SW, Washington, DC 20250; Phone: (202) 720-1301; e-mail: ofsts@fas.usda.gov. Submit five copies of written comments to John Payne, Director for SPS Affairs, Office of the U.S. Trade Representative, 600 17<sup>th</sup> Street, NW, Room 421, Washington, DC 20508, by September 16, 1999.

The Office of the U.S. Trade Representative (USTR) is holding a public meeting to solicit public comment on proposed agenda items for the next scheduled meeting of the North American Free Trade Agreement's (NAFTA) Sanitary and Phytosanitary (SPS) Committee, which will be held in Ottawa, Canada, November 2-3, 1999. USTR also seeks public input in identifying any new issues of concern that should be considered for the agenda. Representatives from each of the NAFTA SPS Committee's eight Technical Working Groups (TWGs) will be present to inform the public of each TWG's progress and to respond to questions.

The purpose of the NAFTA SPS Committee is to address SPS issues affecting the trade of agricultural products among the U.S., Canada, and Mexico. It is responsible for enhancing food safety and SPS conditions in the three nations, promoting equivalence of food safety standards, and consulting on specific bilateral issues. A brief description of each TWG, its contact person, its current and future work, and its meeting schedule follows.

(1) **Animal Health** - Dr. Alfonso Torres, Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA). Current Work: harmonizing veterinary biologics licensing processes and standardization of import policies; and establishing a regional approach on transmissible spongiform encephalopathies (TSEs). Future Work: harmonization of diagnostic services; common approach for disease freedom recognition; emergency preparedness; approach to evaluate veterinary services within member nations. Meeting Schedule: April 10-14, 2000, in Oaxaca, Mexico.

(2) **Plant Health, Seeds & Fertilizers** - Ronald Campbell, Phytosanitary Issues Management, APHIS, USDA. Current Work: harmonization of regulations on the Japanese beetle and the Asian and European Gypsy Moths; equivalency of Greenhouse certifications; and recognition of accredited laboratories for seed certification. Future Work: recognition of private laboratories; and priorities for international standards. Meeting Schedule: October 18-22, 1999, in Cancun, Mexico.

(3) **Fish & Fishery Product Inspection** - Dr. Philip Spiller, Office of Seafood, Food and Drug Administration (FDA). Current Work: development of U.S.-Canada Mutual Recognition Agreement (MRA) on seafood inspection; negotiation of U.S.-Canada equivalence agreement regarding molluscan shellfish inspection programs; and development of criteria for seafood equivalence determinations. Future Work: development of a joint protocol on how to conduct audits of inspection systems; and continuation of MRA and

equivalence negotiations. Meeting Schedule: fall or winter, 1999/2000.

(4) **Meat, Poultry & Egg Inspection** - Dr. John C. Prucha, Food Safety and Inspection Service (FSIS), USDA. Current Work: achieving and maintaining equivalency; exchanging information on foreign system and establishment reviews and import reinspection procedures; and finalizing USDA's position recognizing Mexico's poultry system as equivalent. Future Work: harmonization of inspection procedures; examination of health certificates; and implementation of changes. Meeting Schedule: fall or winter, 1999/2000.

(5) **Dairy, Fruits, Vegetables & Processed Foods** - Dr. Terry Troxell, Office of Plant & Dairy Foods & Beverages, FDA. Current Work: equivalence of U.S.-Canada Grade A dairy inspection systems; and harmonization of U.S.-Canada potato grade system. Future Work: continuation of equivalence negotiations; and full integration of Mexico into the TWG. Meeting Schedule: no meeting scheduled.

(6) **Veterinary Drugs & Feed** - Dr. Robert Livingstone, Center for Veterinary Medicine, FDA. Current Work: harmonization of methods; equivalence of registration systems; and coordination with corresponding Codex activities. Future Work: equivalence of analytical methods for drug residues; and integration of Mexico into the TWG. Meeting Schedule: no meeting scheduled.

(7) **Food Additives & Contaminants** - Dr. Alan Rulis, Office of Pre-Market Approval, FDA. Current Work: harmonization of U.S.-Canada food additive regulations; and discussion of Codex issues. Future Work: development of joint positions for Codex; and joint reviews of food additives petitions. Meeting Schedule: no meeting scheduled.

(8) **Pesticides** - Marcia Mulkey, Office of Pesticide Programs, Environmental Protection Agency. Current Work: reevaluating and reregistering older chemical pesticides; developing clear categories of trade irritants and a procedure for their resolution; harmonizing environmental fate and toxicology protocols; and developing field residue data among NAFTA nations to support registration of pesticides for minor crops. Future Work: developing plan for communicating areas of pesticide regulatory harmonization; identifying and prioritizing registration needs in NAFTA nations to facilitate equal access to pesticides; and harmonizing pesticide certification and training methods. Meeting Schedule: January, 2000, in Mexico City, Mexico, and June, 2000, in Ottawa, Canada.

- Event:** *Public Meeting on Government Activities in International Harmonization of Chemical Classification and Labeling Systems*
- Date:** October 6, 1999, 1:00-3:00 p.m.
- Location:** Room N 4437 C-D, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC
- FR Cite:** 64 *Federal Register* 49834 (September 14, 1999)
- Contact:** Eunice Mourning, U.S. Department of State, OES/ENV, Room 4325, 2201 C Street, NW, Washington, DC 20250, Phone: (202) 647-9266; Fax: (202) 647-5947

A U.S. Department of State interagency group is holding a public meeting to provide interested parties an update on current activities related to international harmonization of chemical hazard classification and labeling systems, a preview of upcoming international meetings, and an opportunity to submit comments for consideration in developing U.S. Government positions. The interagency group is made up of representatives from the Department of State, Environmental Protection Agency (EPA), Department of Transportation (DOT), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), Department of Commerce, Department of Agriculture (USDA), U.S. Trade Representative (USTR), and National Institute of Environmental Health Sciences.

The meeting's agenda includes: reports on the Third

Meeting of the Inter-Organization Program for the Sound Management of Chemicals (IOMC)/International Labor Organization Working Group on Hazard Communication, June 21-23, 1999, in Dublin, Ireland; the Fourteenth Consultation of Coordinating Group for the Harmonization of Chemical Classification Systems, June 24-25, 1999, in Dublin, Ireland; the Fourth Meeting of the Organization for Economic Cooperation and Development Expert Group on Classification Criteria for Mixtures, June 28-29, 1999, in Dublin, Ireland; and the UN Subcommittee of Experts on the Transport of Dangerous Goods, July 5-15, 1999, in Geneva, Switzerland; preparation for the next meetings of these groups, the first three of which will be held in Washington, DC, November 1-4, 5, and 8-9, 1999, while the last will be held in Geneva, Switzerland December 6-17, 1999; and public comments.

- Event:** *New York City Bar Association Symposium on States' Rights v. International Trade: The Massachusetts Burma Law*
- Date:** October 13, 1999, 7:00 p.m. - 9:00 p.m.
- Location:** Stimson Room, New York City Bar Association, 42 West 44<sup>th</sup> Street, New York, NY
- Contact:** Michael Rhee at (212) 431-2865 or mrhee@nyls.edu. If e-mailing, include your name, affiliation, and phone number. For more information on the panelists, visit the Center for International Law's website at [www.nyls.edu/CIL](http://www.nyls.edu/CIL) and click on the Upcoming Events section. There is no charge for admission.

In recent years, a number of state and local governments have passed laws prohibiting governmental purchases from companies that do business with nations with poor human rights records. One such law, the Massachusetts Burma Law, restricts state purchases from companies doing business in Burma (now called Myanmar) because of alleged human rights abuses. The law has come under attack on a number of fronts, and the case raises important issues under state, federal and international law.

The attack on the Massachusetts' selective purchasing law was two-pronged. While Japan and the EU pressed their case in the WTO, an association representing multinational corporations called USA\*Engage<sup>45</sup> challenged the measure in Massachusetts state court as a violation of the

U.S. Constitution.

In the U.S. court challenge, USA\*Engage claimed that the Massachusetts law interfered with the executive branch's exclusive authority to conduct foreign policy. Massachusetts claimed that it was exercising its constitutionally valid right as an economic actor to make choices about its international commerce activity.

On November 4, 1998, the Massachusetts state court ruled in favor of USA\*Engage, holding that municipalities and states may not interfere in foreign policy when it has a "great potential for disruption or embarrassment."<sup>46</sup> An appellate court upheld the ruling in June 1999. The important case is now headed for the U.S. Supreme Court.

Meanwhile, the EU and Japan suspended their

WTO challenge pending the outcome of the domestic case.<sup>47</sup> Should Massachusetts' appeal to the Supreme Court prevail, the EU and Japan would likely reopen the WTO challenge. This potential case will be monitored as an important test of the WTO's encroachment into areas of democratic policymaking regarding the advancement of human rights around the world.

The symposium will consist of a panel discussion of the Massachusetts Burma Law case, followed by a question and answer session. The Moderator will be

Sydney M. Cone, III, C.V. Starr Professor of Law and Director of the Center for International Law, New York Law School. Panelists will be: Thomas A. Barnico, Assistant Attorney General, Commonwealth of Massachusetts; Paul R. Dubinsky, Associate Professor of Law, New York Law School; Peter J. Spiro, Associate Professor of Law, Hofstra University Law School; and Joel P. Trachtman, Professor of International Law, Fletcher School of Law and Diplomacy, Tufts University.

**Event:** *Meeting of NAFTA's Land Transportation Standards Subcommittee*  
**Date:** October 25, 1999, 2:00 p.m. - 5:00 p.m.  
**Location:** Hilton Baltimore and Towers, 20 West Baltimore Street, Baltimore, MD 21201  
**FR Cite:** 64 *Federal Register* 49269 (September 10, 1999)  
**Contact:** Those interested in participating must contact Maria Lameiro, U.S. Department of Transportation, OST/X-20, Room 10300, 400 Seventh Street, SW, Washington, DC 20590; Phone: (202) 366-2892; Fax: (202) 366-7417, by October 12, 1999.

The Land Transportation Standards Subcommittee (LTSS) was established by the North American Free Trade Agreement (NAFTA) Committee on Standards-Related Measures to analyze the land transportation regulatory regimes of the U.S., Canada, and Mexico, and to attempt to harmonize certain standards. The Transportation Consultative Group (TCG) was formed by the departments of transportation of the U.S., Canada, and Mexico to address non-standards related issues that affect cross-border movements among the three nations.

The LTSS and TCG are holding their sixth joint annual plenary session from October 25-28, 1999. The following LTSS working groups will meet during that time: (1) Compliance and Driver and Vehicle Standards; (2) Vehicle Weights and Dimensions; and (3) Hazardous

Materials Transportation Standards. The following TCG working groups also will meet during that time: (1) Cross-Border Operations and Facilitation; (2) Rail Safety and Economic Issues; (3) Automated Data Exchange; (4) Science and Technology; and (5) Maritime and Ports Policy.

While participation in these sessions will be limited to government representatives only, representatives of non-governmental organizations (NGOs) are invited to the listening session on October 25 and a final briefing by the heads of the U.S., Canadian, and Mexican delegations on October 28. At the listening session on October 25, NGO representatives can give oral presentations and submit written comments to voice their concerns, provide technical information, and offer suggestions for improving cross-border trade.

**Event:** *Conference on Coordinating Challenges to Corporate Globalization*  
**Date:** November 12-14, 1999  
**Location:** Midland Hotel, 172 West Adams, Chicago, Illinois  
**Contact:** World Economy Project, Preamble Center, 1737 21<sup>st</sup> Street, NW, Washington, DC 20009; Phone: (202) 265-3263, ext. 330; Fax (202) 234-0981; E-mail: [wep@preamble.org](mailto:wep@preamble.org).

Dozens of groups monitoring the effects of corporate globalization - including organizations working to strengthen environmental regulations, cancel Third World debts, establish living wage laws, close sweatshops, and democratize financial institutions will be meeting in Chicago

in November. The meeting is sponsored by the Preamble Center's World Economy Project and the goal is to bring people of diverse interests together in an effort to develop a coordinated strategy to address many of the negative effects of corporate globalization.

NOTES

1. Peter Scher, Special Trade Ambassador, Letter to Guy Legras, Director General, DG VI, European Union, August 1999, on file with Public Citizen.
2. *Id.*
3. "Scher Warns EU on Antibiotics Ban in Animal Feed, Seeks Clarification," *Inside U.S. Trade*, Sep. 10, 1999.
4. National Center for Infectious Diseases, Center for Disease Control, "NCID/CDC Position on Use of Antimicrobial Drugs as Growth Promotants," Feb. 22, 1999, on file with Public Citizen.
5. World Health Organization, Division of Emerging and Other Communicable Disease Surveillance and Control, "The Medical Impact of the Use of Antimicrobials in Food Animals," Report of WHO Meeting, Berlin, Oct. 13-17, 1997, at 11.
6. National Center for Infectious Diseases, *supra* note 4.
7. Center for Science in the Public Interest, "USTR Position on Feeding Antibiotics to Livestock Directly Conflicts with CDC and WHO Positions," Press Release, Sep. 21, 1999, on file with Public Citizen.
8. Peter Scher, *supra* note 1.
9. The European Union, "European Union and the United States Sign Veterinary Agreement," Press Release, Jul. 20, 1999, found at [www.eurunion.org/news/press/1999/1999048.htm](http://www.eurunion.org/news/press/1999/1999048.htm), on Aug. 16, 1999, on file with Public Citizen.
10. *Id.*
11. *Id.*
12. *Id.* at Arts. 11.3 and 12.
13. Agreement Between the European Community and the United States of America on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal Products, Jul. 20, 1999, at Art. 2, on file with Public Citizen.
14. *Id.* at Art. 5.
15. *Id.* at Art. 6.
16. *Id.* at Annex III.
17. 64 *Fed. Reg.* 34155, Jun. 25, 1999.
18. "Senators Urge U.S. to Examine EU Standards in Absence of Vet Deal," *Inside U.S. Trade*, Oct. 2, 1998, at 11.
19. 64 *Fed. Reg.* 34155, Jun. 25, 1999.
20. *Id.*
21. "Pork Producers Question Proposed USDA Disease Status for EU," *Inside U.S. Trade*, Sep. 10, 1999, at 23.
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.* at 24.
26. *Id.* at 23.

27. "U.S., EU Sign Vet Agreement More Than Two Years After Completion," *Inside U.S. Trade*, Jul. 23, 1999, at 5.
28. *Id.*
29. Veterinary Agreement, *supra* note 4, at Art. 9.1-9.2(b).
30. *Id.* at Art. 7.
31. *Id.* at Art. 7.1(ii).
32. *Id.* at Art. 7.1(iii).
33. *Id.* at Art. 7.4.
34. *Id.* at Art. 14.
35. Joan Murphy, "FDA Removes Canadian Produce from Import Assignment," *World Food Chemical News*, Aug. 18, 1999, at 22.
36. *Id.*
37. "Canada Pressing to Change FDA Inspections of Fresh Produce Imports," *Inside U.S. Trade*, Aug. 13, 1999, at 8.
38. *Id.* at 9.
39. *Id.* at 8.
40. *Id.* at 9.
41. *Id.* at 8.
42. Lyle Vanclief, Canada's Minister of Agriculture, Letter to Dan Glickman, U.S. Secretary of Agriculture, Aug. 5, 1999.
43. Joan Murphy, *supra* note 35, at 23.
44. The abstract is entitled Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition, Melbourne, Australia, 11-15 October, 1999, Recommendations Abstracted from ALICOMS.
45. Prominent USA\*Engage members are: AT&T, Boeing, BP, Calix, Chase Manhattan Bank, Coca-Cola, Dow Chemical, Ericsson, GTE Corp., IBM, Intel, Monsanto, Siemens, and Union Carbide. For a full list, *see* <http://usaengage.org/background/members.htm>, on file with Public Citizen.
46. Civil Action No. 99 12042 (JLT), U.S. District Court, District of Massachusetts.
47. "EU Suspends WTO Panel on Massachusetts Burma Law," *United Press International*, Feb. 8, 1999.