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**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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## AVIATION SAFETY

**Topic:** *FAA Ramps Up Harmonization Efforts*

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During the last few years, the Federal Aviation Administration (FAA) has responded to industry pressure by accelerating its program for harmonizing U.S. aviation standards with European aviation standards. In particular, FAA has implemented an industry proposal for a Fast Track Harmonization Program (FTHP), which is intended to speed up the elimination of differences between certain FAA regulations and the corresponding regulations of the European Joint Aviation Authorities (JAA).<sup>1</sup> FTHP operates within the context of FAA's Aviation Rulemaking Advisory Committee (ARAC). This advisory committee,

which is industry-dominated, provides rulemaking suggestions to FAA.

In the U.S., civil aviation is regulated by FAA, which, among other things, sets and administers safety standards, aircraft design standards known as type certification requirements, and operational standards for aircraft manufactured for use by U.S.-registered operators. JAA sets similar standards for aircraft manufactured for use in Europe.<sup>2</sup> U.S. law does not require FAA to harmonize its regulations with those of other countries.

Nevertheless, FAA has chosen to make harmonization with JAA “a high priority.”<sup>3</sup> FAA asserts that eliminating differences between U.S. and European aviation safety standards should lead to reduced costs for industry and increased safety for travelers and aviation industry employees.<sup>4</sup> FAA has discussed harmonization of regulations with JAA in annual Harmonization Meetings since 1984. The first actual standards harmonization efforts by FAA and JAA began in 1988.<sup>5</sup>

In 1991, FAA revamped its rulemaking process by creating ARAC, which FAA describes as a federal advisory committee that provides “advice and recommendations” to FAA.<sup>6</sup> In practice, however, ARAC serves as a forum in which industry representatives carry out a substantial amount of the work of modifying existing FAA regulations and creating new ones. According to a top FAA official in 1991, FAA wants ARAC to generate most of FAA’s regulatory activity.<sup>7</sup> The international president of the Association of Flight Attendants has accordingly called ARAC a “shadow FAA” for rulemaking.<sup>8</sup>

By outsourcing to industry via ARAC the primary phases of its rulemaking work in some situations, FAA hoped to “develop better rules in less overall time and using fewer FAA resources.”<sup>9</sup> Additionally, FAA hoped that involving industry in the rulemaking process at the early stages would lead to the creation of regulations that are more acceptable to industry, thereby reducing the frequency of costly administrative and legal challenges to its regulations by industry.

From the public interest perspective, ARAC suffers from two notable flaws. First and foremost is its lack of transparency. Under U.S. law, both federal rulemaking and federal advisory committee activities must take place subject to requirements of openness and public participation.<sup>10</sup> The Federal Advisory Committee Act (FACA) requires advisory committee meetings to be open to the public, and requires detailed record-keeping and public availability of committee documents.<sup>11</sup> But ARAC avoids these requirements by assigning its actual work to forty-six Working Groups.<sup>12</sup> These Working Groups meet behind closed doors—often at aircraft manufacturers’ facilities—and do not have to release their documents or

reports to the public. Although the Working Groups must keep simple chronologies of their meetings and lists of attendees, they do not have to maintain any records of their substantive activities.<sup>13</sup>

The second major flaw of ARAC is its imbalanced, industry-heavy membership. Although Public Citizen and a handful of other consumer and passenger organizations hold seats on ARAC, none of those groups can devote substantial resources to ARAC activities. Most of the committee’s seventy-odd members are drawn from the aviation industry.<sup>14</sup> The most prominent members of ARAC are Boeing and Airbus Industrie, which are the world’s two largest aircraft manufacturers. Boeing and Airbus also are members of the TransAtlantic Business Dialogue, which has pushed strongly for harmonization of U.S. and European aviation regulations. Significantly, the Working Groups in which the regulations are actually crafted do not necessarily include any representatives of civil society. In one recent ARAC working group, 226 members were from aviation companies such as Boeing and Airbus, 13 were union representatives, and none were from passenger or consumer groups.<sup>15</sup>

This membership imbalance becomes particularly significant when it comes time for ARAC members to attend and vote in ARAC meetings. Because public interest groups hold only a small percentage of ARAC seats, and because decisions are taken by consensus or majority vote, industry essentially controls the decision-making process within ARAC. As a result, according to the executive director of the Aviation Consumer Action Project, “the Boeing Corporation and other aviation industry representatives now control all ARAC’s venues, chairmanships, agenda, and schedule of meetings,”<sup>16</sup> which contributes to the perception that ARAC is “tailor-made to limit the participation of public interest groups.”<sup>17</sup>

Even when public interest groups have secured seats on working groups, their participation has been made difficult by certain FAA policies. For example, FAA recently has been holding a substantial percentage of its working group meetings near Boeing’s headquarters in Seattle, Washington instead of in Washington, D.C., in order to facilitate industry participation. Because many of these nonindustry groups are headquartered in

Washington, D.C. and cannot afford to send staff across the country to multiple meetings each year, locating the meetings on the west coast has seriously undermined public interest participation. In December 2000, FAA pledged to implement a policy of locating meetings in Washington, D.C. unless a member requests an alternate venue and shows adequate need for it. It remains to be seen whether this policy will be successful in helping to address the public participation problem within ARAC.

In 1992, FAA delegated much of its harmonization work to ARAC as part of its joint Harmonization Work Program (HWP) with JAA. FAA assigned ARAC to be the main U.S. participant in HWP and to “undertake the entire harmonization effort” because it is “an ideal vehicle for assisting in resolving harmonization issues.”<sup>18</sup> FAA describes HWP as a “structure and formal procedure” for the harmonization of standards relating to design, operation, and maintenance of civil aircraft, noise and emissions from aircraft, and flight crew licensing.<sup>19</sup> In HWP, FAA and JAA officials identify U.S. and EU regulations that differ and then assign the task of harmonizing the differing regulations to ARAC on the U.S. side and to a JAA Study Group on the European side.<sup>20</sup> Before 1999, industry representatives on ARAC wrote harmonized regulations and submitted them to the U.S. and European regulators as “complete rulemaking packages” that could be published as a Notice of Proposed Rulemaking (NPRM).<sup>21</sup>

In 1999, FAA created FTHP in order to expedite the harmonization of certain FAA and JAA regulations.<sup>22</sup> Under FTHP, ARAC is assigned the responsibility of harmonizing at least 122 standards.<sup>23</sup> FAA states that

FTHP’s goals are achieved when ARAC considers industry’s harmonization proposals and then works to adopt them.<sup>24</sup> FTHP essentially involves categorizing FAA and JAA regulations as either easy to harmonize or difficult to harmonize. FAA and JAA then harmonize standards in the first category by choosing the more stringent of the two, and harmonize standards in the second category by undertaking more involved negotiations in order to craft new common standards.<sup>25</sup> Because a new common standard may be lower than the existing U.S. standard, this harmonization process can result in a relaxation of U.S. aviation safety standards. Instead of following the pre-FTHP practice of submitting ready-made proposed rules to FAA, ARAC working groups now submit reports to FAA, and an FAA rulemaking team writes the proposed rules.

An example of a passenger safety standard currently under attack by industry in FTHP is FAA’s requirement that certain emergency exit aisles in jetliners be at least 20 inches wide.<sup>26</sup> European regulators have proposed to allow aisles as narrow as 9-10 inches.<sup>27</sup> A review of evacuation studies shows that the narrower emergency exit aisles increase the risk of injury or death for passengers in emergency situations.<sup>28</sup> Nevertheless, aviation industry representatives have lobbied FAA to change its standard to 13 inches.<sup>29</sup> In light of the push to harmonize FAA standards with European standards, and in light of the aviation industry’s domination of the rulemaking process within FAA, this harmonization process could threaten FAA’s 20-inch standard with serious consequences for American airline passenger safety.

## **FOOD SAFETY**

**Topic:** *Food Equivalence Procedures Fast-tracked in Codex*

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On December 11-15, 2000, the Codex Committee on Food Import/Export Inspection and Certification Systems (CCFICS) met in Perth, Australia. There, the committee decided to fast-track the Codex procedure for

determining equivalence of food standards and moved the draft from Step 3 to Step 8 in the eight-step process that Codex employs to the finalize documents. The committee took this decision over the objection of the sole consumer

group in attendance, as well as several national delegations.

“Codex Alimentarius” is Latin for food law. The Codex Alimentarius Commission (Codex) in Rome was established as a voluntary standard-setting body in 1962 by the World Health Organization and the U.N. Food and Agriculture Organization, primarily to facilitate international trade of food and agriculture products. Codex standards were elevated to a new role by the North American Free Trade Agreement (NAFTA) and World Trade Organization (WTO) agreements, which specifically recognize Codex as setting the world’s presumptively “trade-legal” food safety standards. As a consequence, consumer organizations around the world have become increasingly concerned about Codex standards and have struggled to open up a closed-door process that traditionally has been dominated by industry.<sup>30</sup>

At the Perth meeting, CCFICS took up two proposed standards establishing mechanisms by which governments can judge whether foreign food safety requirements or other foreign regulatory requirements such as food labeling are “equivalent” to domestic requirements.<sup>31</sup>

The WTO Sanitary and Phytosanitary Agreement (SPS), governing health and safety aspects of the international food trade, and the WTO Technical Barriers to Trade Agreement (TBT), governing consumer protection requirements for foods and other products, both require WTO member countries to engage in equivalency negotiations.<sup>32</sup> Under the WTO’s notion of equivalence, significantly different—and possibly less protective—regulatory systems and standards in other countries can be declared “equivalent” to domestic regulatory systems. Once a foreign system is declared equivalent, it must be treated as if it were a domestic system, even if it differs from the domestic system in significant ways. Equivalence determinations are designed to allow foreign goods produced under equivalent systems free passage into other countries’ markets.

U.S. consumer groups have focused on the Codex equivalency procedures because the U.S. experience with equivalency has been troubling. In 1999, for example, the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) declared 36 national meat inspection systems equivalent to the U.S. system. A year later, however, the Department’s own Inspector General issued a scathing report of how FSIS handled those cases.

The report found that FSIS allowed meat to be imported into the U.S. when 19 out of 36 countries had not certified their establishments as meeting U.S. standards. In addition, when individual foreign plants were found ineligible for export to the U.S. because of unsanitary conditions, FSIS failed to update its system in a timely fashion, which allowed millions of pounds of beef from delisted plants to enter the U.S.<sup>33</sup> Controversy continues to surround a separate 1999 determination by FSIS that a highly privatized meat inspection system in Australia is equivalent to the U.S. system even though the program turned a significant number of duties normally performed by U.S. federal inspectors over to company employees.<sup>34</sup>

The Codex procedure under discussion would establish an eight-step process for determining equivalence. First, the exporting country identifies a sanitary measure of the importing country for which it wishes to use its own, different standard. Second, the importing country provides an explanation for their domestic sanitary measure. Third, the countries negotiate with a view to agreeing upon an objective basis for comparing the two standards. Fourth, the exporting country develops a document to demonstrate that its different domestic measure is equivalent. Fifth, the importing country is given the opportunity to raise objections or concerns. Sixth, the exporting country replies to those concerns. Seventh, the importing country notifies the exporting country of its decision as to whether or not it accepts the exporting country’s standard as equivalent. Finally, the countries continue to negotiate as necessary to resolve differences or reach a final decision.<sup>35</sup>

Neither the WTO nor the Codex lay out precisely the substantive criteria for determining equivalence. Further, while the eight-step procedure is seemingly cooperative, it could cause an enormous resource drain on the importing country. The importing country would be obligated to explain its laws and regulations and engage in lengthy negotiation with any WTO member country that asks to initiate this process. If the importing country ultimately turns down an equivalency agreement, that decision could be challenged under WTO rules as an unfair barrier to trade. Under the powerful rules of the WTO dispute settlement system, the importing country could be ordered to change its decision or pay punitive tariffs on its products.

For these reasons and others, the Transatlantic Consumer Dialogue has taken a position against equivalency decisions on consumer health and safety

standards, stating that “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.”<sup>36</sup>

Prior to the Perth meeting, one consumer organization with observer status,<sup>37</sup> the International Association of Consumer Food Organizations (IACFO),<sup>38</sup> filed critical comments on the Codex proposals. The organization said that the proposed draft guidelines for food safety measures “fail to ensure that equivalency agreements will not result in a lowering of public health standards in order to facilitate trade.”<sup>39</sup>

IACFO made specific recommendations on the food equivalency procedure, several of which were partially adopted in the final text. IACFO urged that:

equivalency determinations be made more transparent;  
Codex clarify that the burden of demonstration equivalency rests with the exporting country;  
various factors that affect food safety, such as transportation infrastructure be considered;  
verification requirements be built into equivalency agreements; and that  
equivalency determinations be periodically reviewed to ensure that systems are still equivalent.

The transparency language caused the most controversy at the Perth meeting. During the meeting, IACFO proposed language recommending that countries ensure transparency by consulting “all interested parties” prior to making a judgement of equivalence. This modest proposal was met with a barrage of objections. India, Malaysia, Uruguay, Argentina, Brazil, and Cuba opposed it. Others thought the term “interested parties” was too broad. Because U.S. food safety agencies have already

developed procedures for consulting the public when making equivalency determinations, IACFO thought the U.S. would be an ally in promoting this change. But the U.S. negotiators refused to weigh in on the matter.<sup>40</sup>

In the end, the committee settled on language calling for countries to ensure transparency in the demonstration and judgment of equivalency by consulting all interested parties to the extent “practical and reasonable.” The committee also agreed to changes clarifying that the importing country retains the right to determine whether the exporting country’s measure is equivalent and adding transportation infrastructure to the list of factors to be considered. In addition, the committee postponed discussion of equivalency of food labeling laws and other consumer protections under the WTO’s TBT agreement.<sup>41</sup>

Even though the proposal was substantially changed from the earlier draft, the chair moved the proposal from the preliminary third stage to the final stage of Codex’s eight-step approval process. The chair, Digby Gascoine, a long-time official in the Australian Quarantine and Inspection Service (AQIS), has been instrumental in Australia’s push to convince other nations, including the U.S., to adopt the nation’s privatized meat inspection system as equivalent. Codex member countries will now be given one last chance to review the document before voting to finalize it at the committee’s next meeting, which is to be held in Geneva, Switzerland in July 2001.

In a variety of fora, the U.S. government has assured concerned consumer and environmental groups that it wants to prevent a “race to the bottom” in standards and that transparency is one of its highest priorities in these international fora. Yet, as in other instances, U.S. negotiators agreed to lower standards than those required by U.S. law and failed to champion the cause of transparency.

## **TRANSATLANTIC TRADE**

**Topic:** *TransAtlantic Business Dialogue Circles the Wagons in Cincinnati*

**Contact:** Lisa Schroeter, TABD U.S. Director, 1401 I Street, NW, Suite 600, Washington, DC 20005; Tel: 202-336-7485. For TABD’s Cincinnati report please see the TABD webpage at [www.tabd.org](http://www.tabd.org)

For years, the TransAtlantic Business Dialogue (TABD), a little known but effective corporate coalition

specializing in international harmonization, has avoided public scrutiny by quietly lobbying governments behind

closed doors. This changed dramatically when TABD's Cincinnati CEO conference on November 18, 2000 became the subject of public education and organizing by local environmental, labor, and religious activists. Informed citizens wearing "Ask me about the TABD!" T-shirts spent several weeks in Cincinnati neighborhoods conducting education and outreach before TABD met for its annual CEO Conference.

TABD is a coalition of U.S. and European CEOs, largely from transnational corporations, that was created in 1995 at the urging of former U.S. Commerce Secretary Ron Brown. TABD has been a key player in shaping the forward agenda for expansion of the World Trade Organization (WTO). Additionally, TABD makes scores of specific policy demands that are geared toward removing what it views as being "nontariff barriers to trade." TABD's list of such measures has included important worker, consumer health and safety, and environmental laws and regulations.

At the Cincinnati meeting, 120 leading U.S. and European Union (EU) CEOs such as America Online's Stephen Case and Bayer Corporation's Werner Spinner met with top-ranking U.S. and EU officials, including European Trade Commissioner Pascal Lamy and U.S. Secretary of the Treasury Lawrence Summers.

Meanwhile, a local coalition called the Committee for a Humane Economy (CHE) sponsored educational events, marches, and rallies geared toward generating public interest in the conference.<sup>42</sup> Rachel Belz of Ohio Citizen Action said that the demonstrators' goal was to open such trade policy meetings to ordinary people, "where you hear the other side of the argument from the perspective of workers, consumers, farmers, and people who are concerned about the environment."<sup>43</sup> CHE requested a formal role in the TABD conference, but was rejected.

Public Citizen was a co-sponsor of the largest of the teach-ins, which was held at Cincinnati's St. Peter-in-Chains Cathedral and was attended by over 500 people. The educational event featured speakers from near and far, including Lori Wallach of Public Citizen; Dan Seligman of the Sierra Club; Rob Weissman of Essential Action; Ellen Gould, a Canadian health policy researcher; Jason Tochman of the Buckeye Forest Council; Atherton Martin, a banana farmer from the Caribbean island of Dominica, whose trade has been devastated by the WTO banana case; and Ohio's own Baldemar Velasquez, founder of the

Farm Labor Organizing Committee, who spoke about globalization's impact on food and farm workers.

TABD's overarching goals were succinctly summarized in its May 2000 Mid-Year Report: "The new obstacles to trade are now domestic regulations."<sup>44</sup> TABD pursues an agenda to reduce such regulations in a number of ways. First, TABD has been a powerful backer of the WTO's dispute resolution system, in which tribunals comprised of trade experts meet in secrecy without basic due process safeguards. These tribunals can decide that a country's worker, consumer, or environmental protections or other public interest laws constitute barriers to trade even if they treat domestic and foreign goods the same.

Second, TABD wants the U.S. and EU to move development of product regulations to global standard-setting bodies that often provide for corporate, but not consumer, representation. TABD's desire is that globally harmonized standards will meet TABD's goal of a "tested once and approved everywhere" policy. Such an approach would make product approvals in one country acceptable to all countries in a trading bloc. To achieve this goal, TABD puts forward dozens of precise consensus recommendations to the U.S. and EU governments for the global harmonization of regulations in the areas of aerospace, biotechnology, cosmetics, dietary supplements, medical devices, pharmaceuticals, telecommunications, and others.

Finally, TABD attempts to chill regulations even before the regulations are issued. TABD has convinced the U.S. and EU governments to implement an "early warning system" for identifying and blocking nascent domestic regulations—including those pertaining to the environment and public health and safety—that TABD views as potential barriers to trade. Items placed on the early warning list become subject to intergovernmental consultation with the understanding that failure to settle an issue could result in a WTO challenge. Items that TABD has targeted for the early warning list include a draft U.S. Environmental Protection Agency (EPA) regulation for setting emissions standards for recreational marine craft and an EU animal welfare measure that restricts the marketing of cosmetic products tested on animals.

*Emissions Standards:* TABD has sought for some time to harmonize emissions standards between the U.S. and the EU for recreational marine craft. The EU recently finalized emissions standards that have the backing of TABD. EPA also has been in the process of developing

emissions standards under the Clean Air Act. TABD wants the U.S. agency to harmonize to the European regulation. While TABD has been urging EPA to delay its regulations, the Sierra Club has been pushing EPA to keep to a timeline set out in the Clean Air Act and has taken the agency to court over the issue. According to one report of the TABD meeting in Cincinnati, EPA initially refused to harmonize, "claiming that the Clean Air Act is obliging the agency to set stricter limits than the ones included in the EU draft." However, EPA later modified its position.<sup>45</sup> Instead, EPA and the industry agreed to participate in each other's research and development programs in an attempt to resolve their differences. Further, EPA agreed to consider entering into a Memorandum of Understanding (MOU) with the industry and the State of California, in which the agency would agree to delay the new regulations while participating in "real world" tests with both parties.

After the Cincinnati meeting, EPA reported that industry has not come forward with a specific proposal, and that any such MOU would have to be reviewed by the court that is overseeing EPA's activities in the matter.<sup>46</sup> EPA issued an advanced notice for proposed rulemaking on its emissions standards in November 2000. EPA plans to move to the next step, a proposed rule, in November 2001. It remains to be seen whether TABD will succeed in disrupting this schedule.

*Animal Testing Standards:* TABD succeeded in watering down a proposed EU directive that would have phased out animal testing for cosmetics. In 1993, the European Commission (EC) passed a popular measure that would ban the sale of cosmetics tested on animals. The ban was to take effect in January 1998, but a clause in the legislation gave the Commission the option of postponing the ban in the absence of alternative testing methods. The EC took advantage of this clause in 1997 to postpone the effective date until 2000, and later postponed the date again to 2002.<sup>47</sup> At the TABD meeting in Cincinnati, the EC touted a new amendment to the directive that would weaken the legislation further. The proposed amendment would switch the legislation from a complete ban of all cosmetic products marketed in the EU to a less rigorous testing ban for cosmetics produced by EU member nations only.<sup>48</sup>

According to David Wilkins, Director of Eurogroup, which has fought for a phase-out of animal testing, "The Commission's U-turn illustrates once again that pressure from multinational companies and the WTO have taken

precedence over the views of European citizens and the European Parliament."<sup>49</sup> The European Parliament will take up the new amendment in January 2001. Opponents of the proposal are hopeful that they may be able to defeat it in the Environment Committee.

Other reports from the Cincinnati meeting indicate that there is a growing concern among some TABD CEOs that the WTO's controversial dispute resolution system might be causing more problems in transatlantic trade than it is solving. With high-profile WTO disputes between the U.S. and the EU such as the beef hormone, banana, and the Foreign Sales Corporation cases<sup>50</sup> still unresolved and increasingly affecting transatlantic businesses, TABD CEOs said that the WTO's powerful dispute settlement system should only be used as a "mechanism of last resort" in U.S.-EU disputes. They called for a greater reliance on the early warning system and increased mediation and arbitration.<sup>51</sup> This waning of enthusiasm for the dispute resolution system prompted a *Financial Times* article on the Cincinnati TABD event entitled "Gloom Descends Over Former Supporters of the WTO's Procedures for Disputes."<sup>52</sup>

In response to these concerns, Stuart Eizenstat, then-U.S. Deputy Secretary of the Treasury, promised TABD in Cincinnati that the U.S. would bring only WTO cases that industry supports, would consult TABD specifically on new cases, and would consider other fora for resolving transatlantic disputes.<sup>53</sup> Interestingly, while TABD urged restraint and alternative methods of negotiations for U.S.-EU disputes, this same restraint was not shown with regard to disputes with developing countries. TABD called for a full and timely implementation of the WTO intellectual property agreement—known as TRIPS—by all WTO members, and expressed enthusiasm for cases against developing countries that moved slowly to adopt the agreement, which has been criticized for blocking access to essential medicines in developing countries.<sup>54</sup>

Because of the protesters, the entire TABD CEO Conference was conducted at a hotel that was continuously surrounded by two lines of police—one on foot, another on horseback. At the closing press conference, EU Trade Commissioner Pascal Lamy commented, "The day we have a sophisticated (environmental dialogue) and business is demonstrating in the streets, we will have reached our goal."<sup>55</sup> Ironically, later that same month, the Transatlantic Environmental Dialogue, made up of major environmental organizations and created to balance the influence of the TABD,

announced that it was shutting its doors due to lack of

support from the U.S. government.

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## **FEDERAL REGISTER ALERTS**

For more timely notice of these alerts, please visit our web site at [www.harmonizationalert.org](http://www.harmonizationalert.org) and sign up for one of four listserves. The full texts of these notices are available at [http://www.access.gpo.gov/su\\_docs/aces/aces140.html](http://www.access.gpo.gov/su_docs/aces/aces140.html). For a document cited as 65 Fed. Reg. 52752 (August 30, 2000), search the 2000 Federal Register for “page 52752” (quotation marks required) and choose the correct title from the results list.

### **Department of Agriculture**

#### ***National Organic Program; Final Rule (Agricultural Marketing Service)***

65 Fed. Reg. 80596 (Dec. 21, 2000).

Final rule with request for comments. Comments due March 21, 2000.

### **Department of Commerce**

#### ***National Voluntary Laboratory Accreditation Program; Operating Procedures (NIST)***

65 Fed. Reg. 66659 (Nov. 7, 2000).

Notice of proposed rulemaking; request for comments. Comments due January 8, 2001.

### **Department of Health and Human Services**

#### ***Biological Products: Reporting of Biological Product Deviations in Manufacturing (FDA)***

65 Fed. Reg. 66621 (Nov. 7, 2000).

Final Rule. Rule is effective May 7, 2001.

#### ***International Conference on Harmonisation; Guidance on E11 Clinical Investigation of Medicinal Products in the Pediatric Population; Availability (FDA)***

65 Fed. Reg. 78493 (Dec. 15, 2000).

Notice. Guidance effective Dec. 15, 2000. Comments on agency guidances can be submitted at any time.

#### ***International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances for Industry on “Effectiveness of Anthelmintics: Specific Recommendations for Feline” (VICH GL20) and “Effectiveness of Anthelmintics: Specific Recommendations for Poultry” (VICH GL21); Availability; Request for Comments (FDA)***

65 Fed. Reg. 79113 (Dec. 18, 2000).

Notice; request for comments. Comments due January 17, 2001.



***International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" (VICH GL24); Availability; Request for comments (FDA)***

65 Fed. Reg. 79111 (Dec. 18, 2000).

Notice; request for comments. Comments due January 17, 2001.

***International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Products (VICH); Draft Guidance on "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22); Availability; Request for Comments (FDA)***

65 Fed. Reg. 79373 (Dec. 19, 2000).

Request for comments. Comments due February 20, 2001.

***Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels; Proposed Rule (FDA)***

65 Fed. Reg. 81081 (Dec. 22, 2000).

Proposed rule. Comments due March 22, 2001.

***International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substance (FDA)***

65 Fed. Reg. 83041 (Dec. 29, 2000).

Notice. Comments due March 29, 2001.

## **Department of Transportation**

***Session of the United Nations Economic Commission for Europe; World Forum for the Harmonization of Vehicle Regulations WP 29 (NHTSA)***

65 Fed. Reg. 66801 (Nov. 7, 2000).

Notice of UN/ECE WP.29 Session in Geneva, Switzerland. Meeting November 7-10, 2000.

***Certification; Federal Motor Vehicle Safety Standards; Tire Identification and Recordkeeping; Consumer Information Regulations (NHTSA)***

65 Fed. Reg. 75222 (Dec. 1, 2000).

Advance notice of proposed rulemaking (ANPRM). Comments due January 30, 2001.

***International Standards on the Transportation of Dangerous Goods; Public Meetings (RSPA)***

65 Fed. Reg. 69802 (Nov. 20, 2000).

Notice of public meetings. Meetings November 28, 2000 and January 11, 2000.

***Development of a North American Standard for Protection Against Shifting and Falling Cargo (FMCSA)***

65 Fed. Reg. 79050 (Dec. 18, 2000).

Notice of proposed rulemaking (NRPM); request for comments. Comments due March 19, 2001.

***FAR/JAR Harmonization Actions; Revisions to Requirements Concerning Airplane Operating Limitation and the Content of Airplane Flight Manuals for Transport Category Airplanes; Proposed Rule (FAA)***

65 Fed. Reg. 79293 (Dec. 18, 2000).

Notice of proposed rulemaking. Comments due February 16, 2001.

***Revision of Braking Systems; Airworthiness Standards to Harmonize With European Airworthiness Standards for Transport Category Airplanes; Proposed Rule (FAA)***

65 Fed. Reg. 79277 (Dec. 18, 2000).

Supplemental notice of proposed rulemaking (SNPRM). Comments due February 16, 2001.

***Fire Protection Requirements for Powerplant Installations on Transport Category; Final Rule (FAA)***

65 Fed. Reg. 79705 (Dec. 19, 2000).

Final rule.

***Aviation Rulemaking Advisory Committee Air Carrier Operations Issues— New Tasks (FAA)***

65 Fed. Reg. 82445 (Dec. 28, 2000).

Notice of new task assignment for the Aviation Rulemaking Advisory Committee (ARAC).

**Office of the United States Trade Representative*****Guidelines for Implementation of Executive Order 13141: Environmental Review of Trade Agreements***

65 Fed. Reg. 79442 (Dec. 19, 2000).

Guidelines for implementation of Executive Order 13141: environmental review of trade agreements; final.

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**NOTES**

<sup>1</sup> 65 Fed. Reg. 36979 (June 12, 2000).

<sup>2</sup> *Id.* Although JAA does not have the enforcement powers of FAA, twenty-three European countries recognize JAA standards and accept aircraft conforming to JAA standards.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Speech by Patricia A. Friend, International President, Association of Flight Attendants, Jan. 27, 1997, at 3–4, on file with Public Citizen.

<sup>8</sup> *Id.* at 4.

<sup>9</sup> 65 Fed. Reg. 36979 (June 12, 2000).

<sup>10</sup> Federal Advisory Committee Act, 5 U.S.C. App (1994); Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706, 1305, 3105, 3344, 4301, 5335, 5372, 7521 (1994 & Supp. IV 1998).

<sup>11</sup> Federal Advisory Committee Act, 5 U.S.C. App. §§ 10, 11 (1994).

<sup>12</sup> Friend, *supra* note 7, at 3.

<sup>13</sup> FAA asserts that the few public interest groups that hold seats on ARAC should be able to use their ARAC membership privileges to effectively monitor the Working Groups, but this has not yet been shown to be true.

<sup>14</sup> See FAA Order 1110.119F, May 17, 2000, available in <<http://www.faa.gov/avr/arm/araccharter.htm>> and on file with Public Citizen.

<sup>15</sup> Friend, *supra* note 7, at 3.

<sup>16</sup> Letter from Paul Hudson, Executive Director of the Aviation Consumer Action Project, to FAA Administrator Jane Garvey, May 10, 2000, at 2, on file with Public Citizen.

<sup>17</sup> Friend, *supra* note 7, at 1.

<sup>18</sup> 65 Fed. Reg. 36979 (June 12, 2000).

<sup>19</sup> FAA-JAA Harmonization Work Program (HWP) manual, 9<sup>th</sup> ed., [hereinafter HWP] §§ 1.1, 1.3.

<sup>20</sup> HWP § 2.2.6.2.1.

<sup>21</sup> HWP § 2.2.6.2.3.

<sup>22</sup> 65 Fed. Reg. 36979 (June 12, 2000).

<sup>23</sup> *Id.* FAA plans to have ARAC “process approximately fifty-four regulatory changes over the next two to four years.” *Fast Track ARAC*, FAA PowerPoint presentation, June 2, 1999, on file with Public Citizen.

<sup>24</sup> 65 Fed. Reg. 36979 (June 12, 2000).

<sup>25</sup> *Id.*

<sup>26</sup> 14 CFR 25.813(c)(1)(i).

<sup>27</sup> JAA NPA 26-2, NPA 25D-270.

<sup>28</sup> Review of Type III Emergency Exit Evacuation Research: Final Report, International Transport Workers Federation, April 24, 2000, at 27–29.

<sup>29</sup> Air Transport Association petition for rulemaking, Oct 5, 1992, cited in 57 Fed. Reg. 54346 (Nov. 18, 1992).

<sup>30</sup> To learn more about the Codex Alimentarius Commission, see Public Citizen’s Harmonization Handbook, June 2000, *available in* <[www.harmonizationalert.org](http://www.harmonizationalert.org)>.

<sup>31</sup> Codex Alimentarius Commission, Proposed Draft Guidelines on the Judgement of Equivalency of Sanitary Measures Associated with Food Inspection and Certification Systems, CX/FICS 00/6, August 2000; Codex Alimentarius Commission, Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems, CX/FICS 00/7, August 2000. These draft standards are available on the Codex webpage at <[http://www.fao.org/esn/codex/ccfics9/fc00\\_01e.htm](http://www.fao.org/esn/codex/ccfics9/fc00_01e.htm)>.

<sup>32</sup> For example, the WTO SPS Agreement states that “[m]embers shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member’s appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.” WTO SPS Agreement, Articles 4.1, 4.2.

<sup>33</sup> For more information regarding the U.S. Department of Agriculture’s Office of the Inspector General Report, see Harmonization Alert, Vol. 1. No. 2, May/June 2000, at 4. The complete report is available at <[http://www.usda.gov/oig/auditprt/full\\_fsis.pdf](http://www.usda.gov/oig/auditprt/full_fsis.pdf)>.

<sup>34</sup> 64 Fed. Reg. 30299 (June 7, 1999).

<sup>35</sup> Codex Alimentarius Commission, Proposed Draft Guidelines on the Judgement of Equivalency of Sanitary Measures Associated with Food Inspection and Certification Systems, CX/FICS 00/6, August 2000, at 5.

<sup>36</sup> The Transatlantic Consumer Dialogue is made up of the largest consumer organizations in the U.S. and Europe. It was formed in 1998 to give consensus recommendations on trade and consumer-related matters to the U.S. and European governments. Transatlantic Consumer Dialogue, Principles of Harmonization, at 2, available at <<http://www.tacd.org>>.

<sup>37</sup> Under Codex rules, only governments can be full, voting members of Codex. Internationally incorporated nongovernmental organizations can attend Codex meetings as observers or as members of a governmental delegation, but they cannot vote. U.S. delegations to the Codex are regularly dominated by giant agribusiness corporations and trade associations. Rarely are public interest organizations invited to be members of a delegation.

<sup>38</sup> IACFO was founded by the Center for Science in the Public Interest (USA, Canada), the Food Commission (UK), and the Japan Offspring Fund (Japan).

<sup>39</sup> International Association of Consumer Food Organizations, Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems, September 29, 2000.

<sup>40</sup> Bruce Silverglade, International Association of Consumer Food Organizations, Report on the Codex Committee on Food Imports/Export Inspection and Certification Systems, Perth, Australia December 11-15, 2000, at 3-4.

<sup>41</sup> *Id.* at 4-6.

<sup>42</sup> Bob Driehaus, *Protests Loom at Trade Meeting*, CINCINNATI POST, November 11, 2000.

<sup>43</sup> Bill Sloat, *Cincinnati Braces for Trade Summit Street Protests*, CLEVELAND PLAIN DEALER, Nov 13, 2000.

<sup>44</sup> TABD, 2000 Mid Year Report, May 23, 2000, at 3.

<sup>45</sup> European Commission, Report on the CEO Conference of the TransAtlantic Business Dialogue, Cincinnati Ohio, 16-18 November 2000, at 3.

<sup>46</sup> Conversation between Harmonization Project staff and Ken Feith, EPA, January 26, 2001.

<sup>47</sup> *Ban on Animal Testing For Cosmetics Postponed Again*, EUROPE INFORMATION SERVICE, April 5, 2000.

<sup>48</sup> European Commission, Comments on the TABD Status of Early Warning Candidates as of October 2000.

<sup>49</sup> *European Commission Bows to WTO Pressure on Animal Testing of Cosmetics*, press release, EUROGROUP, April 6, 2000.

<sup>50</sup> In 1997, a WTO panel ruled in favor of the U.S. and against an EU ban on certain artificial hormones in beef. The EU is currently paying \$113 million in punitive tariffs in order to avoid repealing this public health measure. In the same year, another WTO panel ruled in favor of the U.S. and against the EU's preference for buying a small portion of its bananas from small farms in former Caribbean colonies. Again, the EU is paying \$190 million in punitive tariffs while it attempts to make its purchasing plan WTO-legal. In response to these challenges by the U.S., the EU challenged the U.S. Foreign Sales Corporation law, which allows certain U.S. companies to exempt 15-30% of export income from taxation. In 1999, a WTO panel ruled against the program and it is possible that up to \$4 billion in punitive tariffs will be applied to U.S. products.

<sup>51</sup> TABD, Cincinnati Recommendations, November 16-18, 2000, at 33.

<sup>52</sup> Edward Alden, *Gloom Descends Over Former Supporters of WTO's Procedure for Disputes*, FINANCIAL TIMES, Dec. 6, 2000.

<sup>53</sup> European Commission, *supra* note 45, at 11.

<sup>54</sup> *Id.* at 12.

<sup>55</sup> John Byczkowski, *Business Leaders Note the Protesters Outside*, CINCINNATI ENQUIRER, Nov. 19, 2000.