

Vol. 2 No. 7 www.harmonizationalert.org July-October 2001

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.

CONTENTS

Free Trade Area of the Americas Sanitary and Phytosanitary Provisions	L
Federal Register Alerts	.7

FREE TRADE AREA OF THE AMERICAS

Topic: Sanitary and Phytosanitary Provisions

Contact: Richard D. White, Director of SPS Affairs, Office of the U.S. Trade Representative, 600 17th

Street, NW, Washington, DC, 20508; Tel.: 202-395-9582; Fax: 202-395-4579; Email:

rwhite@ustr.gov.

In the summer of 2001, business and citizen groups geared up for another battle over Fast Track in Congress. Fast Track trade authority gives the President sole authority for negotiating new trade agreements and limits Congress' role to a yes or no vote on the implementing legislation with no ability to amend the legislation. The Bush administration has announced that it wants Fast Track in order to negotiate the Free Trade Area of the Americas (FTAA), a proposed expansion of the North American Free Trade Agreement (NAFTA) to all the countries in the Western Hemisphere, except Cuba. The debate surrounding Fast Track makes analysis of the draft FTAA text extremely timely.

Negotiations on the FTAA were launched in Miami in December 1994 at the first Summit of the Americas. There, the trade ministers of thirty-four South, Central and North American and Caribbean nations agreed to a proposal to establish a comprehensive, hemisphere-wide trading bloc no later than 2005. At the second Summit of the Americas held in Santiago, Chile in April 1998, the trade ministers created a Trade Negotiations Committee with a variety of working groups to begin negotiating rules regarding agriculture, services, investment, disputes settlement, intellectual property, government procurement, subsidies, anti-dumping policy, competition policy and market access.

Because FTAA negotiations were conducted behind closed doors, a hemisphere-wide campaign was launched to pressure negotiators to release the draft text. On July 3, 2001 the governments released a preliminary "scrubbed" draft of the agreement. A scrubbed text lacks vital information, such as interpretive notes and references to the identities of the countries supporting the various alternate proposals. The draft text is also heavily bracketed and includes multiple versions of the many proposed provisions. Because the annotations that typically accompany working texts have been removed, it is unclear which of the often conflicting and different alternate versions are likely to be adopted into a final document.

The purpose of this article is to highlight an important section of the FTAA draft text, the Sanitary and Phytosanitary (SPS) provisions **S** which cover food safety and other standards-related issues **S** included in the Chapter on Agriculture.

SPS provisions have been incorporated into both the World Trade Organization (WTO)1 and NAFTA.² Thus, it is not surprising to see SPS language in the draft FTAA.3 The bulk of FTAA member country SPS obligations are found in Section 5 of the Chapter on Agriculture. Other important obligations can be found in Section 2 of the draft agriculture chapter. These provisions establish the rules FTAA member nations must follow when setting policies concerning human, animal or plant life and health. This not only includes food safety measures, such as inspection of imported meat and seafood and the safety testing of genetically modified organisms, but also measures to protect a nation from invasive species that can cost taxpayers billions to eradicate. Like the WTO and NAFTA, FTAA rules will likely apply to all government measures, federal, state and local.

The FTAA draft clearly envisions a close relationship between the FTAA and the WTO. One version of Article 5.1 of the draft goes so far as to state

that "[e]xcept as otherwise provided for in this Agreement, no Party may adopt or maintain any prohibition, restriction, or licensing requirement on the importation of any originating agricultural product of another Party or on the exportation of any agricultural product destined for the territory of another Party, except in accordance with provisions of World Trade Organization agreements which specifically allow such measures."4 Article 6.1 of the draft FTAA agreement mandates that the "[p]arties shall [cooperate] [participate] in the multilateral negotiations on agriculture being held in accordance with Article 20 of the WTO Agreement on Agriculture with the objective of achieving the maximum possible improvement in market access opportunities for all agricultural products."5

In the same vein, the FTAA draft calls for a close connection between FTAA SPS provisions and the WTO SPS agreement. One version of Article 16.1 of the FTAA Chapter on Agriculture S which lays out general provisions and the rights and obligations of the parties S states that "[t]his Section applies to sanitary and phytosanitary measures as defined in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, with any subsequent changes agreed in the WTO to be automatically effective for this Agreement." Yet another provision states that "[t]his Chapter shall not entail greater obligations or commitments than those deriving from the WTO SPS Agreement."

Harmonization and International Standards:

Article 17 of the FTAA draft agreement lays out the harmonization, equivalency, risk assessment, pest and animal disease obligations of the parties. All the language in Article 17 is bracketed. In addition there are on occasions brackets within brackets and multiple versions of individual provisions indicating that the draft could be subject to significant changes.

Harmonization involves taking differing national

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. Please contact Ann Matney at amatney@citizen.org or Mary Bottari at mbottari@citizen.org or call (202) 454-5193 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 Rockfeller Brothers Fund.

standards and regulations and creating a common "harmonized" standard. Harmonization can take place in international standard-setting institutions, which may be incorporated into a trade agreement by reference, or in working groups or committees created by the agreement. The FTAA draft agreement contains harmonization obligations which are largely similar to the WTO SPS agreement. In fact, one bracketed provision of 17.1 (b) b.1 states that "the concept of harmonization shall be the same as that in Article 3 of the WTO Agreement..." and that "Parties shall, whenever possible, seek to coordinate positions at the for where international sanitary and phytosanitary standards, guidelines and recommendations are prepared,"8 raising the possibility that the 34 FTAA countries would coordinate positions and act as a block inside the WTO.

With regard to international standards, the draft text of FTAA 17.1 (a) a.1 states, "parties shall apply to trade among them the international standards recommended by the relevant international bodies and their subsidiaries." The FTAA agreement also names the same international standard-setting organizations referenced by the WTO: the Codex Alimentarius Commission in Rome, which sets international food safety standards; the International Office of Epizootics in Paris, which deals with animal health issues; and various organizations operating under the framework of the 1951 International Plant Protection Convention, which set standards for the control of pests and invasive species.

FTAA 17.1 (a) a.2 goes even further and states that when a party considers an international standard insufficient to ensure the level of protection it requires, "the Party shall notify the other Parties of this and engage in consultations with interested parties to define and adopt the necessary standard for the application in trade among them."10 No similar language exists in the WTO or NAFTA SPS agreements. If adopted, this language could result in a massive hemispheric harmonization effort, which could take place inside or outside of the already recognized international standard-setting bodies. For instance, FTAA members could be obliged to take up new negotiations on genetically modified organisms if the controversial negotiations at the Codex Alimentarius in Rome fail to generate international standards.

Another proposed FTAA SPS provision 17.1 (b) b.2 would have the parties "agree to establish, [whenever possible,] harmonized sanitary and phytosanitary systems for sampling and diagnostic methods, inspection and certification of animals, plants, products and by-products thereof, as well as for food safety."11 Such language can be construed as an affirmative obligation that the parties to the agreement harmonize all their testing systems. It seems highly unlikely, however, that poorer countries can afford to adopt the same standards as wealthier countries. If the developed nations don't back up this language with significant grants for technical assistance, the harmonization obligation is likely to create pressure for weakened food safety, testing and analysis standards. While both the WTO SPS and the NAFTA SPS mention the harmonization of SPS testing systems and procedures, neither agreement establishes a strong affirmative obligation to do so.

Finally, provision 17.1 (b) b.3 only allows a nation to maintain a measure "different" from the harmonized standard "as long as there is scientific justification for doing so." First, this construction repeats one of the most fundamental flaws in existing SPS rules, it eviscerates the precautionary principle. By putting the burden of proof on the country seeking to maintain a standard, it makes precautionary measures based on lack of scientific certainty about safety default violations of the agreement.

Second, while both the WTO and NAFTA SPS agreements place burdens of scientific proof on nations maintaining or developing new SPS standards, what is missing from the FTAA language, however, is any phrase or clause that might be used in a dispute to assist a nation in preserving a higher standard. For instance, NAFTA Article 713(1) states, "without reducing the level of protection of human, animal or plant health" each party shall use international standards as the basis for its own SPS measures.¹³ NAFTA Article 713(2) states that a measure that "results in a level of sanitary or phytosanitary protection different from that which would be achieved by a measure based on a relevant international standard, guideline or recommendation shall not for that reason alone be presumed to be inconsistent with this Section."14 No such language is present in the FTAA, making the harmonization provisions of the FTAA potentially the strictest of the three agreements.

Equivalency: In addition to the adoption of uniform international standards, another mechanism of harmonization required by NAFTA, the WTO and contained in the draft FTAA text, is equivalency agreements. Under the notion of equivalence, significantly different and possibly less protective regulatory systems and standards in other countries can be declared "equivalent" to domestic standards permitting the free flow of goods. Equivalency agreements are designed reduce or eliminate inspections, quarantines and other border checks. Such agreements have been sharply criticized by consumer groups like the Transatlantic Consumer Dialogue which has declared: "[t]he very notion of equivalence allows for imprecise, subjective comparisons that are not appropriate when dealing with issues as important as public health and safety."15

While the harmonization requirements of FTAA are similar to the harmonization provisions of the WTO SPS agreement, the WTO SPS agreement devotes two paragraphs to the topic of equivalence and the FTAA text devotes two pages to the topic. This illustrates the growing importance many countries are giving the notion of equivalence, which is seen by many as easier to achieve than the harmonization of often complex regulatory requirements.

The FTAA draft agreement on equivalence begins by again linking FTAA and WTO obligations. Section 17.1 (c) c.1 states that the "Parties agree on [the general provisions and procedures for the application] [apply the criteria] of the equivalence according to the provisions of Article 4 of the SPS WTO Agreement." Article 4 of the WTO SPS states that members "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." 17

The FTAA section 17.1 (c) c.2 further provides that the parties "shall establish bilateral or [sub-regional] agreements, or agreements among [all] the Parties, in order to determine the equivalence criteria that will ensure an adequate level of sanitary or

phytosanitary protection."¹⁸ Notably negotiators have replaced the term "appropriate level of protection" referenced in the WTO SPS agreement with the lower standard of "adequate level of protection."¹⁹ In addition, the FTAA draft text mandates equivalence negotiations, abandoning the idea that equivalency discussions should only be initiated "upon request" of an interested nation.

The FTAA language departs from previous SPS agreements in other significant ways: First, the language contains a number of provisions to allow developing countries more leeway in demonstrating equivalence. For instance, bracketed language in section 17.1 (c) c.6 states "to establish equivalence, it shall also be taken into account the size of the economies and level of development of the parties."²⁰ Potentially dangerous food pathogens and exotic pests are at least as likely to be present in developing countries as developed countries, thus many public interest representatives would argue that this type of double standard has the potential to undermine public health safeguards. In contrast, public interest groups often call for technical support and resources to ensure developing countries can protect their populations' food safety as well as the safety of food exports.

Secondly, one version of section 17.1 (c) c.4 of the draft FTAA agreement explicitly states that "the specific objective" of equivalency agreements is to "eliminate physical controls that are in place to verify that products that come into the territory of the importing Party fulfill the requirements of the importing Party." While public interest representatives have long worried that this was the goal of equivalency, previous agreements have not put it quite this bluntly. Moreover, U.S. agency officials have long denied that they will drop border controls once equivalency is determined.

Finally, section 17.1 (c) c.7.3 would institute what is known as a "standstill clause." It states that "[w]hen an equivalence agreement is being negotiated and until equivalence is determined, the Parties shall not, in their mutual trade, apply conditions for the products referred to in this [Section] that are more restrictive than those in force, except for those related to sanitary or phytosanitary emergencies."²² Such a provision, which is designed to restrain countries from "unilaterally" improving their consumer protections, is

likely to be highly controversial. Significantly, neither the WTO SPS agreement nor the NAFTA SPS agreement contain standstill clauses with regard to food safety or animal health policies.

While these draft FTAA provisions are particularly worrying, the very notion of equivalency causes concern among consumer and environmental groups. Under equivalency, the standards of the exporting nation apply and the importing nation drops its border checks. The problems with this formula are manifold. It is unfortunate, but true that countries, developed and developing, can not always be trusted to quickly and accurately report potentially dangerous food safety scares or economically damaging SPS problems.

In May of 1999, for instance, the government of Belgium announced that cancer-causing dioxin had been found in animal feed which had contaminated poultry, eggs and other products on store shelves.²³ The announcement prompted an immediate world-wide ban on Belgian chicken, dairy, beef and pork products. When it was revealed that the government had knowledge of a potential problem in March, but had failed to notify the public or its trading partners, high level government officials were forced to resign.²⁴ Just a few short weeks later, the crisis toppled the Belgian government in the nation's general election.²⁵ While border controls do not always uncover such problems, they are a final check before imported foods make it onto grocery market shelves. The FTAA text is designed to greatly reduce or eliminate these safeguards.

Risk Assessment: The FTAA draft text outlines member countries' obligations regarding the assessment of risk and determination of an appropriate level of protection that a member country may adopt in animal, plant and food safety standards. Like the draft FTAA equivalency provisions, the risk assessment provisions also diverge significantly from the risk assessment provisions in the WTO and NAFTA. While one version of Article 17.1 (d) d.1 of the draft FTAA agreement would require the parties to "agree to implement the provisions of Article 5 of the WTO SPS Agreement and to adopt the criteria and guidelines issued by the relevant international organizations,"26 other provisions in the same section lay out even more burdensome requirements than the WTO SPS. For instance, bracketed language in the same section states: "When a Party has reason to believe that a specific sanitary or phytosanitary measure established or maintained by another Party restricts or may restrict its exports and that measure is not based on competent international or subregional standards, it may ask for an explanation for the reasons for these measures and the Parties that maintain these measures must provide an explanation within a period of (30) days..."²⁷

This is one of several risk assessment provisions that include tight time lines for conducting risk assessments and responding to a nation's request for information about an SPS measure. In contrast, WTO SPS and NAFTA are completely devoid of time lines.

The draft FTAA further provides that if a nation fails to meet the time line, if the risk assessment was not conducted properly, or the measure is not scientifically justified, the complaining nation can "take recourse to the FTAA forum competent in the subject area." This is an institution "to be created" states a footnote in the draft text. It is unclear if this is a new administrative committee to assist nations with implementing this chapter of the FTAA or if this is a reference to the binding dispute resolution process created by the agreement.

These risk analysis provisions of the FTAA raise the specter of nations being forced to conduct hundreds of risk assessments or scientifically justify food safety measures that may have been on the books for years with up-to-the-minute data. The U.S. probably spends more on food safety controls than most FTAA nations, yet even with its billion dollar budget, the U.S. foods safety system could easily be overtaxed by a flood of requests for new risk assessments or information on SPS measures already in place. Many will question if these activities are the best way to spend scarce food safety dollars in all FTAA nations.

Bracketed language in another proposed provision in the draft agreement, section 17.1 (d) d.5, would prevent a nation from interrupting trade while conducting a new risk assessment "where a smooth and regular" flow of trade exists.²⁹ This provision could prevent a nation from taking precautionary action when they have indications there may be a problem, but not scientific proof of a problem. In addition, risk assessments may take years and be inconclusive. In the

interim, nations should be allowed to take precautionary actions to protect consumers from potential hazards.

In the case of a SPS emergency, a nation may require the importing party to "immediately present scientific justification for the measure adopted" and be responsible for "promptly adapting the measure to the results of the risk analysis conducted."30 These measures are attempts to limit the ability of a country to establish emergency consumer protections and other "unilateral" SPS measures. Given that it has taken scientists nearly ten years to begin to understand how bovine spongiform encephalopathy ("mad cow" disease) is passed from cows to humans, it is highly unrealistic that nations would be able to comply with the strict time requirements in the FTAA. These proposed provisions go well beyond the obligations required by the NAFTA and WTO SPS agreements. If nations fail to meet the time lines in the FTAA, they could be subject to sanctions in the binding dispute resolution system of the agreement, which will act as the enforcer of all the terms of the agreement. Consumers in FTAA nations could be exposed to danger if nations are forced to live up to these unrealistic time lines.

Finally, while Article 5.7 of the WTO SPS agreement allows nations to take "provisional" (i.e., temporary) measures to protect the public health in the absence of scientific certainty, one formulation of the FTAA agreement could be interpreted to limit this right to developing nations only. Section 17.1 (d) d.8 of the FTAA draft text would allow "countries with small economies" to adopt provisional measures when scientific information is insufficient.³¹ Alternatively, section 17.1 (h) would extend similar rights to all parties of the agreement.

Animal Disease, Pests, and Invasive Species: The FTAA draft SPS agreement also has extensive text regarding animal disease and pests. Not only can the import of animals spread disease across borders, but economically devastating animal or plant pests can hitch hike into the country on the backs of live animals or stow away in shipping cartons. Exotic pests S plants and animals from other geographic areas S are a multimillion dollar problem in the United States and many other nations. Just one so-called invasive specie, the Asian longhorned beetle, which attacks and eventually kills healthy maple, chestnut, birch, poplar, willow, elm, and locust trees, has cost the states of

Illinois and New York millions in unsuccessful attempts at eradication.³² The only effective way to eradicate the pest is to uproot and burn the trees.

Countries have adopted a variety of measures to protect themselves from pests and invasive species. The U.S., for instance, requires that wooden shipping pallets from China and Hong Kong be heat treated, fumigated or treated with preservatives before entering the country.³³ The U.S. found the wooden shipping pallets were a primary manner in which Asian longhorned beetle hitch hiked into the country. Yet many of these safeguards are highly controversial and have been challenged as "trade barriers" by the exporting country.

The draft FTAA language on animal disease and invasive species begins by stating that the parties "shall harmonize the criteria and procedures they use to recognize pest or disease-free areas and areas of low pest or disease prevalence." This provision also seeks to put a requirement on the length of time a country has to recognize pest or disease-free areas and areas of low pest or disease prevalence by stating that a country "shall announce its decision no later than [x] calendar months from the date of the request by the affected Party." This same provision also gives countries with small economies twice as long to comply with such a request.

The FTAA text further provides that each country "shall [[accept] [recognize] automatically] [will request] [among each other] the pest- or disease-free areas and areas of low pest or disease prevalence recognized by the relevant international [or regional guidelines and recommendations] organizations."36 This provision could result in language that would have international organizations, such as the Office of International Epizootics (OIE) in Paris, making the call on what regions are diseased or disease-free rather than national governments. This is likely to conflict with U.S. law which gives this authority to the Animal Plant Health Inspection Service of the Department of Agriculture. While the OIE has little to lose if they make a mistake, national governments have a great deal more at stake.

An alternative version of the same section of the FTAA draft text states that the parties shall recognize the pest or disease-free areas in accordance with international or regional guidelines.³⁷ In the animal health area, this could also conflict with U.S. policy. The OIE has specific rules for designating an area diseased or free of disease.³⁸ Under OIE rules, if there is a outbreak of animal disease in a nation, products should only be banned from the affected region or zone. The longstanding U.S. practice, however, has been to ban products from the entire nation if there is evidence of animal disease.

The FTAA has further provisions that seem deliberately directed toward eliminating this U.S. practice. For instance, FTAA Article 17 (e) e.5 states that *no party* "shall prevent access to its territory of a product from an area/region in an exporting Party that is a specific pest or disease-free area/region or where the prevalence of the pest or disease is low, even though the country as a whole has not been declared country-free from the pest or disease or with low prevalence thereof."³⁹

Nations, however, cannot always be trusted to promptly and accurately report potentially devastating SPS problems. Earlier this year, Argentina was roundly criticized by neighboring countries for not promptly reporting an economically devastating outbreak of footand-mouth disease. ⁴⁰ By the time Argentina admitted it had a problem, it had spread to neighboring countries. A rigorous border surveillance system is the last line of defense against animal disease and invasive species, yet it seems to be the goal of the FTAA to abolish such systems.

Other elements of the SPS portion of the draft FTAA Chapter on Agriculture include provisions to ensure transparency between government in the SPS

regulatory processes and decision making, technical assistance and cooperation, and the establishment of an FTAA committee on SPS measures to ensure compliance with the above and to serve as a forum for holding technical consultations. Creating a SPS scheme in the FTAA that is similar to the WTO and NAFTA SPS agreements means further entrenching the concepts of harmonization and equivalence in international law. This framework, not only prioritizes trade concerns above all others, but it also places primary emphasis on international organizations and standards and creates a presumption of their validity S which contrasts with the notion that a nation should be free to establish SPS measures it considers appropriate to safeguard its domestic public interest. Unfortunately, the draft SPS provisions in the FTAA indicate that the agreement may well place even further constraints on exercise of state sovereignty and democratic governance than its WTO and NAFTA SPS predecessors.

— Jason Bowman and David Desrosiers contributed to this article.

FEDERAL REGISTER ALERTS

For more timely notice of these alerts, please visit our web site at 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. For a document cited as 66 Fed. Reg. 52752 (August 30, 2001), search the 2001 Federal Register for "page 52752" (quotation marks required) and choose the correct title from the results list.

Department of Agriculture

Notice of International Standard-Setting Activities of the Office International des Epizooties, the Secretariat of the International Plant Protection Convention, and the North American Plant Protection Organization (APHIS)

66 Fed. Reg. 43171-43177 (August 17, 2001) Notice and request for public comment.

International Standards Under the International Plant Protection Convention (APHIS)

66 Fed. Reg. 53978-53979 (October 25, 2001)

Notice of meeting.

Department of Commerce

New Regulation Harmonizes the List of Definitions of Terms Found in the Export Administration Regulations (EAR) with the Terms Found in the Wassenaar Arrangement List of Dual-Use Items and Terms Found in the European Union List (BEA)

66 Fed. Reg. 36909-36913 (July 16, 2001) Final Rule. This rule is effective July 16, 2001.

Department of Health and Human Services

International Conference on Harmonization; Guidance on S7A Safety Pharmacology Studies for Human Pharmaceuticals; Availability (FDA)

66 Fed. Reg. 36791-36792 (July 13, 2001)

Notice of availability of FDA guidance.

Submit written comments at any time. This guidance is effective August 13, 2001.

Medical Devices; A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Pre-market Procedures; Draft Guidance for Industry and FDA Staff; Availability (FDA)

66 Fed. Reg. 38714-38716 (July 25, 2001)

Notice. This guidance is neither final nor is it in effect at this time.

Comments concerning this draft guidance due September 24, 2001.

Advance Notice of Proposed Rule-Making to Establish Import Tolerances for Food Products of Animal Origin for Drugs That Are Used in Other Countries, but That Are Unapproved New Animal Drugs in the United States (FDA)

66 Fed. Reg. 42167-42170 (August 10, 2001)

Advance notice. Comments due December 10, 2001.

International Cooperation on Harmonization of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ``Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing" (VICH GL28); Request for Comments; Availability (FDA)

66 Fed. Reg. 45319-45320 (August 28, 2001)

Comments due September 28, 2001.

Single copies of the draft and final guidance available upon written request.

Transcutaneous Electrical Resistance Methods: In Vitro Test Methods Proposed for Assessing the Dermal Corrosivity Potential of Chemicals; Notice of Availability of a Background Review Document and Proposed ICCVAM Test Method Recommendations and Request for Public Comment (NIEHS and NTP)

66 Fed. Reg. 49685-49686 (September 28, 2001)

Request for public comment. Comments due November 13, 2001.

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Pre-market Submission Review and Quality System Inspections Under United States/European Community Mutual Recognition Agreement (HHS)

66 Fed. Reg. 51050-51052 (October 5, 2001)

Notice and request for public comment. Comments due December 4, 2001.

International Conference on Harmonization; Availability of Guidance Document Entitled ``M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use"; Availability (FDA)

66 Fed Reg. 52635 (October 16, 2001)

Notice and request for public comment. Submit comments any time.

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration; Notice (FDA)

66 Fed. Reg. 53836 (October 24, 2001)

Submit general comments on the list and on agency guidance documents any time.

Department of Transportation

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

66 Fed. Reg. 37267 (July 17, 2001)

Notice of public meeting. Meeting August 7, 2001.

Aviation Rulemaking Advisory Committee; Transport Airplane and Engine Issues--New Task (FAA)

66 Fed. Reg. 39074-39075 (July 26, 2001)

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

Aviation Rulemaking Advisory Committee; Rotorcraft Issues--New Task (FAA)

66 Fed. Reg. 39387-39388 (July 30, 2001)

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

Aviation Rulemaking Advisory Committee; Transport Airplane and Engine Issues--New Task (FAA)

66 Fed. Reg. 41298-41299 (August 7, 2001)

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

Proposed Revisions to Advisory Circular 25-7A, Flight Test Guide for Certification of Transport Category Airplanes (FAA)

66 Fed. Reg. 43603-43606 (August 20, 2001)

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

Aviation Rulemaking Advisory Committee; General Aviation Certification and Operations Issues--New Task (FAA)

66 Fed. Reg. 44201-44202 (August 22, 2001)

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

Office of the United States Trade Representative

Termination of Action and Monitoring: European Communities' Regime for the Importation, Sale and Distribution of Bananas (USTR)

66 Fed. Reg. 35689-35690 (July 6, 2001)

Notice of termination of action, monitoring, and request for public comment. Comments due August 7, 2001.

Trade Policy Staff Committee: Request for Public Comments on the Preliminary Draft Consolidated Texts of the Free Trade Area of the Americas (FTAA) Agreement and the FTAA Technical Committee on Institutional Issues (USTR)

66 Fed. Reg. 36614-36615 (July 12, 2001)

Notice and request for public comment. Comments due August 22, 2001.

Trade Policy Staff Committee; Public Comments on the Caribbean Basin Economic Recovery Act and the Caribbean Basin Trade Partnership Act: Report to Congress (USTR)

66 Fed. Reg. 42250-42251 (August 10, 2001)

Notice and request for public comment. Comments due September 14, 2001.

NOTES

- 1. See generally World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures; http://www.wto.org/wto/goods/spsagr.htm [hereinafter WTO SPS].
- 2. See generally North American Free Trade Agreement (NAFTA); http://www.nafta-secalena.org/english/index/htm [hereinafter NAFTA SPS].
- 3. See generally Free Trade Area of the Americas, Draft Agreement, Chapter on Agriculture; http://www.ftaa-alca.org/alca_e.asp [hereinafter FTAA SPS].
- 4. FTAA SPS at Art. 5.1.
- 5. FTAA SPS at Art. 6.1 (emphasis added).
- 6. FTAA SPS at Art.16.1.
- 7. FTAA SPS at Art. 16.1.1.
- 8. FTAA SPS at 17.1 (b) b.1.
- 9. FTAA SPS at Art. 17.1 (a) a.1.
- 10. FTAA SPS at Art. 17.1 (a) a.2.
- 11. FTAA SPS at Art. 17.1 (b) b.2.
- 12. FTAA SPS at Art. 17.1 (b) b.3.
- 13. NAFTA SPS at Art. 713 (1).
- 14. NAFTA SPS at Art. 713 (2).
- 15. Transatlantic Consumer Dialogue (TACD), *Principles of Harmonization*, Feb. 2000, available at http://www.tacd.org/>.
- 16. FTAA SPS at Art. 17.1 (c) c.1.
- 17. WTO SPS at Art. 4 (1) (emphasis added).
- 18. FTAA SPS at Art. 17.1 (c) c.2.
- 19. WTO SPS at Art. 4 (2).
- 20. FTAA Article 17.1 (c) c.6.
- 21. FTAA SPS at Art 17.1 (c) c.4 (emphasis added).
- 22. FTAA SPS at 17.1 (c) c.7.3.
- 23. James Graff, "Fear and the Food Chain," Time, Jun. 14, 1999.

- 24. James Graff, "Fear and the Food Chain," Time, Jun. 14, 1999.
- 25. "Dioxin Crisis Topples Belgian Government," Environmental New Service, Jun. 15, 1999.
- 26. FTAA SPS at Art. 17.1 (d) d.1.
- 27. FTAA SPS at Art. 17.1 (d) d.1.
- 28. FTAA SPS at Art. 17.1 (d)d.4.
- 29. FTAA SPS at Art. 17.1 (d) d.5.
- 30. FTAA SPS at Art. 17.1 (d) d.6.
- 31.FTAA SPS at Art 17.1 (d) d.7.
- 32. For more on Invasive Species, *See, Whose Trade Organization? Corporate Globalization and the Erosion of Democracy*, Public Citizen, 1999, p. 38-39.
- 33. 63 FR 50099 (1998).
- 34. FTAA SPS at Art. 17.1 (e) e.2.
- 35. FTAA SPS at Art. 17.1 (e) e.2.
- 36. FTAA SPS at Art. 17.1 (e) e.3.
- 37. FTAA SPS at Art 17.1 (e) e.3.
- 38. Office International Des Epizooties, International Animal Health Code 2001, Chapter 1.3.4.
- 39. FTAA SPS at Art. 17.1 (e) e.5.
- 40. "South Americans Call Upon Governments to Come Clean on Foot-and-Mouth," *Agence France Press*, Mar. 14, 2001.



215 Pennsylvania Avenue SE Washington, DC 20003