Department of Health and Human Services,

Food and Drug Administration (Docket No. FDA-2008-N-0183)

Request for comments on Third Party Certification Programs for Foods and Feeds

May 19, 2008

The Institute for Agriculture and Trade Policy (IATP) is grateful for the opportunity to comment on Third Party Certification (TPC) Programs for Food and Feed.[1] IATP is a non-profit, non-governmental organization headquartered in Minneapolis, Minnesota, with an office in Geneva, Switzerland. These comments are submitted by Steve Suppan, Senior Policy Analyst at IATP.

General Comment

The request for comment on TPC, a key component of the Food and Drug Administration's proposed *Food Protection Plan*, comes as the U.S. Congress is pressuring FDA to overhaul its food safety management programs and to make the planning and implementation of these programs comprehensive and transparent.[2] Private TPC programs involve Third Parties who are neither exporting nor importing companies, but are private certification agencies. FDA's *Plan* requests new statutory authority from Congress to allow FDA to delegate its authority over food safety and quality by accrediting private entities or governments as Third Parties to certify that export facilities in their countries meet FDA requirements.[3] Such a delegation of FDA authority provides a means for leveraging the very low FDA food safety budget and other resources for food safety relative to the imported food and feed boom of the past decade.

Foreign governments would be deputized, in effect, to ensure that facilities in the export supply chain meet FDA requirements. However, whereas U.S. legal actions contemplated in the "Food and Drug Administration Globalization Act"[4] can be applied to the certifying corporate "persons" that fail to duly exercise the delegated authority that FDA requests, it is not at all clear how such actions can be applied if the accredited Third Party is a government. Though TPC may leverage FDA resources more efficiently, an overhauled FDA food safety program will need at least the level of financial resources and reform recommended by FDA's Science Board.[5]

According to Congressional testimony by the General Accountability Office, "FDA officials told us that they have internal plans for implementing the *Food Protection Plan* that detail timelines, staff actions, and specific deliverables. While the FDA officials told us they do not intend to make these plans public,

they do plan to keep the public informed of their progress."[6] IATP urges FDA to make these operational plans public in testimony to Congress and by other means, including further Federal Register requests for comment on different elements of the Plan. Some of these plans concern the prevention of the intentional contamination of food ("food defense"). IATP trusts that FDA and Congress will ensure that invocation of "food defense" will be limited to those programs operationally devoted to prevention of intentional contamination and that such invocation will not be used to justify lack of transparency over other FDA program planning. Where internal FDA plans on "food defense" cannot be publicly divulged without compromising the operational efficacy of those plans, IATP urges FDA to discuss its internal "food defense" plans at a closed session(s) of the appropriate Congressional committees in order to ensure timely and effective oversight.

IATP's Experience with Third Party Certification

IATP has indirect experience with TPC as the only shareholder of a for-profit trading company, Headwaters International, whose flagship product is Peace Coffee, a fair traded coffee certified by TransFair U.S.A.[7] The success of TPCs depend on whether the certification criteria can be verified and enforced and whether certification is implemented in a transparent, consistent and predictable manner that provides value for farmers, processors and consumers. TransFair U.S.A.'s certification of Peace Coffee as a fair trade coffee involves verification of documentation and on-site inspection concerning social, economic and environmental criteria. Publicizing certification criteria and the verification process are part of the very successful fair trade "brand" and of Peace Coffee's commercial success.

However, it is important to recognize first, what private certification does not cover and what it should not presume to cover. Second, FDA should seek comment through the Federal Register process on problems in scaling up private TPC systems with a relatively limited number of stakeholders to a public certification system for all exporting facilities, as the agency proposes in its *Food Protection Plan*.

TPCs are no substitute for government authority over food safety and quality, particularly with regards to product inspection and testing that verify that other food safety and management controls are working to protect public health. For example, TransFair U.S.A. inspects to ensure use of Good Agricultural Practices, but it does not inspect at the port of export or port of entry for invasive species or for evidence of phyto-sanitary diseases in coffee shipments. Indeed, TransFair would be interfering with the statutory responsibilities of government authorities if it were to claim that its TPC verification involved such inspection. Scaling up the TransFair U.S.A. certification program to include such port inspections would not only be technically difficult, but legally impermissible. TransFair U.S.A.'s ability to implement its certification program partly derives from the relatively limited number of farmers and coffee processors involved in the TPC. Modeling a public TPC on the basis of private TPCs, given the scale and complexity of government responsibilities and authorities, is a much more complicated process.

FDA's Plan for Third Party Certification

As IATP understands TPC within the *Food Protection Plan*, chief motivations for implementing the TPC component are an anticipated increase in U.S. food and feed import dependence and FDA's often "very limited information regarding conditions under which most food is produced in foreign countries."[8]

Whether or not greater food and feed import dependence is desirable in an era of climate change affected supply and distribution chains, FDA definitely needs more information about the production of imported foods and feeds if those imports are to be safe to enter domestic commerce. TPCs are one way of gathering that much needed and long overdue information and using it to ensure fair trade and to protect consumers.

The "Supplementary Information" in FDA's request for comments indicates that it intends to model FDA-authorized TPCs on the basis of private TPC criteria frameworks such as that of the transnational food retailers' Global Food Safety Initiative or of private TPCs, such as GlobalGAP. IATP wishes to point out at least four problems with scaling up these private TPCs to the status of an FDA program to be applied to the approximately 150 countries from which the United States imports food.

1. The food safety dimension of private TPCs is usually limited to pesticide residue testing and assurance that agricultural chemicals have been used safely. There is little or no private TPC capacity to certify the food safety management programs that regulate microbial contamination and related hazards in the farm-to-fork continuum for FDA regulated products, e.g. farm-raised fish and fresh produce.[9] Indeed, most governments cannot ensure "farm-to-fork" safety because of lack of statutory authority for farm-level food safety programs, lack of coordination among government ministries responsible for food and feed regulations, and/or lack of technical capacity. Given the inequitable market power between primary producers and transnational agribusiness and food enterprises, primary producers often do not receive prices that compensate for the infra-structural and training cost of meeting farm-level food safety requirements. Internalizing the cost of food safety measures, particularly for such higher risk products as seafood, meat and dairy, remains a major unresolved food safety governance issue.[10]

2. Private standards in TPCs are not based on peer reviewed risk assessments, as is the case with international public sanitary and phyto-sanitary standards, however controversial those risk assessments may be. While food safety management certification of export supply chain facilities based on Hazard Analysis and Critical Control Point (HACCP) programs may employ public standards to determine which CCPs to monitor, there is no requirement to use public standards. As compliance with private standards becomes a contract condition for supplying importers, conflicts among private standards and public standards threaten to instigate trade disputes at the World Trade Organization Committee on Sanitary and Phytosanitary Measures.[11] The Office of the U.S. Trade Representative has warned Congress about authorizing or budgeting for FDA food safety measures that might conflict with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[12] The SPS Agreement allows each WTO member to determine an Appropriate Level of Protection (ALOPs) for its citizens and requires that only ALOPs higher than those indicated by international public standards be justified by a risk assessment as defined by the SPS Agreement. Whether private standards provide greater or lesser ALOPs, neither the SPS Agreement nor the international standards organizations provide any guidance on the use of private standards in TPCs.

3. The Supplementary Information notes that "Third party certification programs are used widely in Europe." What it fails to note is that European inspection and testing rate is far higher than in the United States, e.g. about 20 to 50 times higher for EU seafood imports, depending on the risk presented by a particular species.[13] U.S. food industry executives lobbied the Interagency Working Group (IWG) on Import Safety to not recommend an increase in what the FDA Science Board called FDA's "appallingly low inspection rate"[14] and the IWG duly complied.[15] FDA should not likewise assume that implementation of TPC may substitute for or be used to justify the maintenance of this "appallingly low inspection rate" and concomitant low product testing rate. Any degree of delegation of FDA's statutory responsibilities to Third Parties to certify that export facilities meet FDA requirements must be accompanied by a large increase in FDA's import re-inspection and testing rate, resources and capacity. This increase in re-inspection and testing is not only needed to provide another line of defense against food contamination and other hazards, but also to verify that TPC is working.

4. A Government Accountability Office review of FDA data concluded that FDA's on-site audits of about 190,000 foreign food processing plants exporting to the United States had "decreased from 211 in fiscal year 2001 to fewer than a hundred in fiscal year 2007."[16] It is, of course, lamentable that FDA's on-site audits decreased in the midst of a food import boom. Just as import re-inspection and testing should greatly increase in an overhauled FDA import food safety practice, so too should on-site audits. FDA's plans to establish a foreign inspectorate are commendable, though IATP is concerned that the very small size of the inspectorate will limit it to reporting on the TPC facilities certification. Evidently, FDA must verify TPC facilities certification with its own on-site inspections, both announced and unannounced. Details concerning the protocols, frequency and thoroughness of those on-site audits should be the subject of another Federal Register request for comments. While much has been made of basing every aspect of the *Food Protection Plan* on risk, there is very little publicly available data with which to construct risk profiles to prioritize products, processing methods and facilities for less or more frequent and intensified on-site auditing. To take a stereotypical example, the farm-raised fish supply chain will require intensified oversight, whereas imported cookies will likely require far less. But beyond such generalities, there are not many publicly available studies or data to determine how to prioritize facilities for on-site audits.

Conclusion

FDA's request for comment on its TPC planning is an important step in revising the *Food Protection Plan* and any legislation towards its implementation. IATP has identified problems with TPC both in concept and in relation to other food safety programs, particularly in relation to import re-inspection and product testing. We believe that TPC shortcomings should be addressed jointly with reform of other FDA food safety programs, lest the certification of facilities as meeting FDA requirements become a substitute for resolving the main problems that have gone unaddressed during three decades of food safety deregulation and budget cuts. IATP hopes that FDA will continue

to invite public comment on its food safety management reforms and the implementation of those reforms. We look forward to contributing to this public comment and legislative process.

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[1] Some of these comments are based on Steve Suppan. "Import Food Safety in the Twilight of the Bush Administration." Institute for Agriculture and Trade Policy." May 2008. <http://www.iatp.org.>

[2] *Inside U.S Trade*. "FDA Must Develop Food Safety Plan To Receive Some Omnibus Funding." January 11, 2008.

[3] "Food Protection Plan: An integrated strategy for protecting the nation's food supply." U.S.Food and Drug Administration. November 2007. 20-21. <http://www.fda.gov/oc/initiatives/advance/food/plan.html.>

[4] U.S. House of Representatives Committee on Commerce and Energy. Discussion draft of "Food and Drug Administration Globalization Act." Section 210. May 1, 2008. <http://energycommerce.house.gov/FDAGlobalAct-08/Dingel_60AXML.pdf>

[5] "FDA Science and Mission At Risk: Estimated Resources Required For Implementation." FDA Science Board's Subcommittee on Science and Technology. February 25, 2008. 5-7. <http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.EstimatedResources.pdf>

[6] General Accountability Office. "Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes First Steps, but Capacity to Carry Them Out Is Critical." Statement of Lisa Shames, Acting director, Natural Resources and Environment. Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. January 29, 2008. GAO-08-435T. 11.

[7] For more information on fair trade certification, see http://www.transfairusa.org/content/resources/faq.php#What and http://www.peacecoffee.com/fairtrade.htm

[8] "Food Protection Plan." *Op. cit.* 9.

[9] United Nations Conference on Trade and Development. "Challenges and Opportunities Arising From Private Standards on Food Safety and Environment for Exporters of Fresh Fruit and Vegetables in Asia: Experiences of Malaysia, Thailand and Viet Nam." 2007. 8-10.

[10] Steve Suppan. "Meat trade: food safety needs a new global fund." *Food Ethics*. Winter 2007. <http://www.iatp.org/iatp/commentaries.cfm?refID=101011>

[11] Gretchen H. Stanton. "Private (Commercial) Standards and the SPS Agreement." World Food Law Institute. Round Table on The Role of Standards in International Food Trade. September 24, 2007. Washington, DC. <http://www.law.howard.edu/worldfoodlaw/word_docs/Stanton.doc>

[12] *Inside U.S.Trade*. "USTR Urges Caution on Import Safety, Producers Demand Tough Actions." October 5, 2007.

[13] Food and Water Watch. "Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections." July 2007. 1. <http://www.foodandwaterwatch.org>

[14] *FDA Science and Mission At Risk: Report of the Subcommittee on Science and Technology*. November 2007. 21. <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA Report on Science and Technology.pdf>

[15] *Inside U.S.Trade*. "Durbin Urges White House To Change Food, Product Safety Group." August 10, 2007.

[16] "Federal Oversight of Food Safety." *Op. cit.* 6.