

Display Date 4-1-08
Publication Date 4-2-08
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0183]

**Third-Party Certification Programs for Foods and Feeds; Request for
Comments**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on the use of third-party certification programs for foods and feeds, including pet foods. An increasing number of firms that sell foods to the public, such as retailers and food service providers, are requesting that their suppliers become certified as meeting food (and feed) safety and quality standards as a condition of doing business. FDA seeks more information on the existence and use of these types of programs to better understand how they can help to ensure that food products are safe, secure, and meet FDA requirements.

DATES: Submit written or electronic comments by *[insert date 45 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Sharon Lindan Mayl, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION:**I. Background**

Ensuring the safety of food for human and animal use is a shared responsibility between the public and private sectors. FDA has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but it is ultimately the responsibility of industry to ensure that food and feed intended for consumption in the United States meet applicable FDA standards. An increasing number of firms that sell foods and feeds (hereinafter foods) to the public, such as retailers and food service providers, are requesting that their suppliers, both foreign and domestic, become certified as meeting food safety and quality standards as a condition of doing business. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third parties to assist them in meeting U.S. requirements. FDA is seeking comment on current practices of third-party certification programs that work with food products and to ensure the supply chain is safe, secure, and meet FDA requirements.

A. Current Use of Voluntary Third-Party Certification Programs for Foods

A growing number of food firms require their suppliers to ensure their products are produced using “best practices” for food safety, quality, and security and that the supply chain is safe and secure. These firms often require their suppliers to meet nationally or globally recognized food safety standards and to verify that these standards are met through a third-party certification program. For example, the Global Food Safety Initiative requires food suppliers to have a factory audit certification against internationally recognized standards, which include the Safe Quality Food, British Retail Consortium, International Food Standard, and GlobalGAP. The Global Aquaculture Alliance

has also established standards for aquaculture production and processing and created an accrediting body for certifiers from 30 countries. These types of private sector developed programs are being used in many foreign countries, as well as the United States.

B. Interagency Working Group on Import Safety

On July 18, 2007, the President issued Executive Order 13439 to establish the Interagency Working Group on Import Safety (Working Group). On November 6, 2007, the Working Group released an “Action Plan for Import Safety: A Roadmap for Continual Improvement” (Action Plan) (<http://www.importsafety.gov/report/actionplan.pdf>). The Action Plan contains 14 broad recommendations and 50 specific short- and long-term action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. The Action Plan stresses the importance of the private sector’s responsibility for the safety of its products and the importance of ongoing private-sector mechanisms and experience as a basis for ongoing, substantive public-private collaboration. The public and private sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.

Recommendation 2 of the Action Plan is to “verify compliance of foreign producers with United States safety and security standards through certification.” Third-party certification can augment the Federal Government’s and the importing community’s ability to ensure that products imported into the United States meet U.S. safety and security standards. The Action Plan states “[f]or foreign producers, the ability to participate in voluntary certification programs could allow products from firms that comply with U.S. safety and security standards to enter the United States more quickly. This

would facilitate trade, while allowing federal departments and agencies to focus their resources on products from non-certified firms or for which information suggests there may be safety or security concerns. This would allow federal departments and agencies to more effectively target their resources. It may not be necessary to establish certification programs for low-risk products.”

Action Steps 2.2 and 2.4 of the Action Plan call for the development of voluntary third-party certification programs based on risk for foreign producers of certain products who export to the United States and the creation of incentives for foreign firms to participate in voluntary certification programs and for importers to purchase only from certified firms.

In conjunction with the Action Plan, on November 6, 2007, FDA released its Food Protection Plan (FPP), a comprehensive initiative designed to bolster efforts to better protect the Nation’s food supply (<http://www.fda.gov/oc/initiatives/advance/food/plan.html>).

Although certification by an independent third party would not replace an FDA inspection, and FDA would continue to inspect a firm itself, as appropriate based on risk, third-party certification could provide additional assurances of safety. In addition, third-party certification could provide FDA with important information about the ability of specific food suppliers to meet FDA requirements and to better focus the use of our resources based on risk. FDA believes that eligible third parties should include other Federal government, State government, and foreign government agencies and officials.

If FDA were to develop or recognize (or accredit) one or more independent third-party certification programs, we would provide an opportunity for both foreign and domestic firms to voluntarily participate. However, FDA would

need sufficient confidence in the quality of the audits performed and the validity of the decisions to certify by the third parties as well as the independence of the third parties from the firms they certify before we would consider recognizing a third-party certification program.

One action FDA will take to implement the Action Plan and the FPP is to accredit independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements. This notice represents FDA's first step in soliciting public input in the design and development or recognition of third-party certification programs.

II. Request for Information

FDA is seeking information on the use of third-party certification programs. In addition to general information, we are posing several specific questions related to these types of programs.

1. What domestic and foreign third-party certification programs for suppliers are currently in use by U.S. companies?

FDA is aware of several third-party certification programs that are currently being used in the United States. We would like more information regarding these and other certification programs, the standards on which they are based, and who is currently using these third-party programs. In addition, we would like information on the standards and procedures used to ensure that the third parties used are independent (i.e., without conflicts of interest), the standards used to accredit third parties, who accredits these third parties, and how and by whom these third parties are audited and evaluated for performance. We would also like to know how national government bodies interface with or recognize these certification programs.

2. Do the current third-party certification programs ensure compliance with FDA requirements?

Third-party certification programs for foods are used widely in Europe. These types of certification programs are becoming more popular in other parts of the world, including the United States. FDA solicits comment on whether the requirements for certification used by these programs encompass FDA requirements. If not, what modifications need to be made for the U.S. marketplace? Should FDA recognize (or accredit) any of these programs? Should FDA participate in future modifications to any of these programs? If so, in what capacity?

3. What are the obstacles to private sector participation in these third-party certification programs?

Although the use of third-party certification programs is growing, they are not used by the majority of U.S. food firms. FDA seeks information about any barriers that may exist to using third-party certification programs. Are retailers and suppliers aware of these programs? Are these programs widely available? Are they cost effective? Are there particular obstacles for small businesses?

4. What incentives would increase participation in these third-party certification programs?

FDA recognizes that there are business and legal incentives to using third-party certification programs. We would like to know what incentives could increase participation in these certification programs. For example, would expedited treatment at U.S. ports of entry significantly encourage foreign suppliers to participate or domestic firms to make participation by foreign or domestic suppliers a condition of doing business with them? Would making the names of certified firms publicly available, such as through a publicly

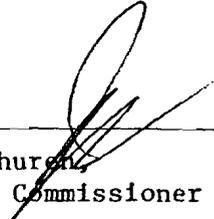
accessible database, significantly encourage participation in these programs by foreign or domestic suppliers? Would FDA considering certification as one factor in determining inspection priorities provide a significant incentive for foreign or domestic firms to participate? Are there other incentives that would increase participation for imported foods? For domestic foods?

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *<http://www.regulations.gov>* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: 3/27/08
March 27, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

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