

Dated: July 2, 2008.

**Maryam I. Daneshvar,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Refugee Resettlement

**AGENCY:** Office of Refugee Resettlement, Administration for Children and Families.

**ACTION:** Single-Source Program Expansion Supplement.

CFDA#: 93.583.

**Legislative Authority:** The Refugee Act of 1980 as amended, Wilson-Fish Amendment, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

**Amount of Award:** \$1,312,414 supplement for current year.

**Project Period:** 09/30/2005-09/29/2010.

**Justification for the Exception to Competition:** The Wilson-Fish program is an alternative to the traditional State-administered welfare system for providing integrated assistance and services to refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, and Trafficking Victims. San Diego County is one of 12 sites that has chosen this alternative approach.

The supplemental funds will allow the grantee, Catholic Charities Diocese of San Diego, to provide refugee cash assistance through the end of this fiscal year to eligible refugees (and others eligible for refugee benefits) under the San Diego Wilson-Fish Program.

The primary reason for the grantee's supplemental request is a higher number of arrivals than anticipated when the grantee's budget was submitted and approved last year. The Refugee Act of 1980 mandates that the Office of Refugee Resettlement (ORR) reimburse States and Wilson-Fish projects for the costs of cash and medical assistance for newly arriving refugees. Since 1991, ORR has reimbursed States and Wilson-Fish agencies for providing cash and medical assistance to eligible individuals during their first eight months in the United States.

Hence, the supplement is consistent with the purposes of the Wilson-Fish Program, the Refugee Act of 1980, and ORR policy.

**FOR FURTHER INFORMATION CONTACT:** Carl Rubenstein, Wilson-Fish Program Manager, Office of Refugee Resettlement, Aerospace Building, 8th Floor West, 901 D Street, SW., Washington, DC 20447. Telephone: 202-205-5933.

Dated: July 1, 2008.

**David H. Siegel,**

*Acting Director, Office of Refugee Resettlement.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0381]

#### Draft Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Voluntary Third-Party Certification Programs for Foods and Feeds." This draft guidance describes the general attributes FDA believes a voluntary third-party certification program should have in order to help ensure its certification is a reliable reflection that the foods and feeds from certified establishments are safe and meet applicable FDA requirements.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by September 8, 2008.

**ADDRESSES:** Submit written comments on the draft guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

## SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Voluntary Third-Party Certification Programs for Foods and Feeds." This draft guidance is issued in response to the recommendations contained in the Action Plan for Import Safety: A Roadmap for Continual Improvement (Action Plan) issued on November 6, 2007, by the Interagency Working Group on Import Safety (Working Group) established by Executive Order 13439, as well as FDA's Food Protection Plan released on the same date. Both those plans emphasize certification as a way to help verify the safety of products from a growing food establishment inventory, both domestic and foreign.

In the **Federal Register** of April 2, 2008 (73 FR 17989), FDA issued a notice requesting comments on the use of third-party certification programs for foods and animal feeds. FDA received approximately 70 comments in response to that notice. The comments were generally supportive of the use of third-party certification programs. Many encouraged FDA to recognize such programs as a way to increase participation and improve the safety and security of foods.

This draft guidance, when finalized, will represent FDA's current thinking on the certification process and will describe the general attributes FDA believes a voluntary third-party certification program should have in order to provide FDA with confidence in that program. If FDA has such confidence, we may choose to recognize the program and provide incentives for establishments to obtain certification by recognized certification programs. Recognition in this context means that FDA has determined that certification may be a reliable reflection that the foods from the certified establishment are safe and meet applicable FDA requirements. Such recognition would be tailored to particular categories of products and would occur in a separate document that builds upon the general attributes set forth in this document. Therefore, this draft guidance is intended as one of the steps in FDA's future recognition of one or more voluntary third-party certification programs for particular product types.

To further that process, FDA is also announcing, in a separate notice issued in this **Federal Register**, a voluntary pilot program for third-party certification bodies that certify foreign processors of aquacultured shrimp. This pilot is intended to gather technical and operational information that will assist

FDA in determining its infrastructure needs, as well as the process for evaluating third-party certification programs. The criteria for selection for that pilot are based upon the attributes set forth in the draft guidance.

As with the pilot, the 12 attributes discussed in the draft guidance are intended to provide a model that could be tailored for particular categories of products and incorporated by FDA as it recognizes third-party certification programs for those products. These attributes incorporate such things as the authority of the certification body to adequately inspect the establishments seeking certification, qualifications, and training for the third-party inspectors, self-assessment of the certification programs and its inspectors, elements of an effective inspection program, notification to FDA, and preventing conflicts of interest. While FDA invites comments on all aspects of the draft guidance, FDA is particularly interested in receiving comments on this list of attributes for the certification program. More specifically, we would like to know whether there are some attributes that should be removed or added and whether the draft guidance provides sufficient information about each attribute. We are also interested in knowing how this list compares with existing, well-accepted guidelines or requirements for certification programs.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on Voluntary Third-Party Certification Programs for Foods and Feeds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination 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 only through FDMS at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/oc/guidance/thirdpartycert.html> or <http://www.regulations.gov>.

Dated: July 7, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0382]

#### Voluntary Third-Party Certification Programs for Imported Aquacultured Shrimp; Notice of Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is seeking third-party certification bodies that certify foreign processors of aquacultured shrimp for compliance with FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) regulations to volunteer to participate in a pilot program to be conducted by FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA). The goal of the pilot program is to gather technical and operational information that will assist FDA in determining its infrastructure needs, as well as the process for evaluating third-party certification programs, in order to assist FDA in moving towards broader recognition of voluntary third-party certification programs, including third-party certification programs for aquacultured shrimp, at a later time.

**DATES:** Submit written and electronic requests to participate in the pilot program by August 25, 2008.

**ADDRESSES:** Submit written requests to participate in the pilot program to the

Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Submit electronic requests to participate to [aquaculture@fda.hhs.gov](mailto:aquaculture@fda.hhs.gov). We strongly encourage interested persons to electronically submit their request to participate.

#### FOR FURTHER INFORMATION CONTACT:

Brett Koonse, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1700.

#### 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 primarily the responsibility of industry to ensure that foods products intended for human and animal consumption in the United States are safe and meet applicable FDA standards. An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requesting, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as quality) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. requirements.

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