

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-13-8

November 8, 2013

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Announcing The Solicitation Of Applications By The National Conference On Interstate Milk Shipments For Third Party Certifiers To Participate In The National Conference On Interstate Milk Shipments Voluntary International Certification Program

The National Conference on Interstate Milk Shipments (NCIMS) is soliciting applications from individuals that are interested in becoming Third Party Certifiers (TPCs), which are non-governmental entities, to participate in the NCIMS Voluntary International Certification Program (ICP). The ICP will institute a fourth (4th) option for the listing of ICP milk companies on the Interstate Milk Shippers (IMS) List to provide a means for NCIMS member States to accept Grade "A" milk and milk products from these IMS Listed ICP milk companies being shipped into their States. TPCs that are selected to participate in the ICP will implement, regulate, enforce, rate and verify compliance with the regulations contained in the most current revision of the Grade "A" Pasteurized Milk Ordinance (PMO) and related NCIMS documents for the purpose of listing ICP milk companies in areas outside of the boundaries of the United States. Listing of milk companies on the IMS List under the ICP will enable the importation of Grade "A" milk and milk products into the United States from those milk processing plants located outside of the U.S. boundaries.

The NCIMS Grade "A" Milk Safety Program and the PMO require that all Grade "A" milk and milk products in interstate commerce and all Grade "A" milk and milk products submitted for importation into the United States come from a source listed on the IMS List. The IMS List may be viewed at the following Web Site:

<http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2007965.htm>

For imported Grade “A” milk and milk products, the United States Food and Drug Administration (FDA) and the NCIMS have previously accepted three (3) options by which a foreign milk processing plant may become listed on the IMS List. These three (3) options are:

1. A dairy firm outside the United States could contract with any current NCIMS member’s regulatory/rating agency to provide the “Grade A” milk safety program in total. This would include the regulatory licensing, dairy farm and milk plant inspection and sampling, pasteurization equipment testing, laboratory certification and rating/NCIMS listing certification. To use this option the firm would be required to abide by all applicable NCIMS regulatory and rating requirements and the regulatory/rating agency would have to agree to treat the firm as if it were located within its jurisdiction for all purposes, including inspection and enforcement. Ratings of the firm would be check rated by FDA.
2. The exporting country, or a political subdivision thereof, may become a full member of the NCIMS subject to all NCIMS rules and enjoying all privileges of a U.S. State. This would require, among other things, that the milk regulatory agency(ies) of the exporting countries adopt and enforce rules and regulations which are the same as those required in the United States and abide by all applicable NCIMS regulatory and rating requirements. Their ratings would be check rated by FDA in the same way as State ratings. FDA would certify their rating, sampling surveillance and laboratory evaluation officers.
3. FDA can evaluate the exporting country’s system of ensuring the safety of dairy products and compare the effect of that system with the effect of the United States system on the safety of dairy products produced domestically. The NCIMS has adopted a procedure to accept FDA findings of equivalence and to allow NCIMS member States to accept products produced within the scope of such a finding.

At the 2013 NCIMS Conference, Proposal 305 was passed providing a 4th option that incorporates the findings of the International Certification Pilot Program Committee (ICPPC) into the NCIMS documents and transforms the ICPP into the International Certification Program (ICP) making it a permanent part of the NCIMS Grade “A” Milk Safety Program. (Refer to Proposal 305 contained within IMS-a-49.)

The ICP will utilize TPCs who will act as regulatory, rating, and laboratory evaluation agencies in the regulation of foreign milk companies and their associated farms, haulers, receiving stations, transfer stations, laboratories, etc. FDA will conduct check ratings, laboratory evaluations and program evaluations in accordance with the NCIMS “Methods” and “Procedures” documents. The ICP shall:

- Comply with all of the applicable requirements of the Grade “A” PMO and related NCIMS documents;
- Continue to ensure the same level of milk safety provided within the current NCIMS program; and

- Provide a means for NCIMS member States to accept Grade “A” milk and milk products from IMS Listed TPC milk companies.

Also, the ICP Committee has been identified as a NCIMS standing committee to provide the required oversight of the ICP.

DEFINITIONS APPLICABLE TO THE ICP:

- **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.
- **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the IMS List by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributors, etc. and their servicing milk and/or water laboratories, as defined in the *Grade “A” PMO*, located outside the geographic boundaries of NCIMS Member States.
- **THIRD PARTY CERTIFIER (TPC):** A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade “A” PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

WRITTEN AGREEMENTS APPLICABLE TO THE ICP:

- **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS’ authorization of the Third Party Certifier (TPC) to

operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier's (TPC's) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

- **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).
- **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company's (MC's) permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

NOTE: Each MOA will be reviewed by the ICP Committee and FDA/Milk Safety Team (MST)/Laboratory Proficiency Evaluation Team (LPET) to determine whether it contains all provisions set forth herein. FDA/MST/LPET will provide comments to the ICP Committee concerning each MOA. There shall not be any listing of milk companies on the IMS List until the ICP Committee and FDA/MST/LPET have indicated that the MOA complies with the requirements herein stated.

TPCs will be selected based on their personnel's Grade "A" Milk Safety Program experience and ability, as described in their application, to provide NCIMS and PMO regulatory, laboratory, rating, and all other required program requirements and activities.

The TPCs selected and signing a Letter of Understanding (LOU) with the NCIMS will each be authorized to provide the regulatory, rating and laboratory services necessary to list milk companies in areas outside of the boundaries of the United States on the IMS List.

An Application Form and additional informational packet materials are attached to this M-I and can also be obtained from the following web sites and/or contacts:

National Conference on Interstate Milk Shipments (NCIMS)

www.ncims.org

Ms. Marlena Bordson
NCIMS Executive Secretary
P.O. Box 108
Monticello, IL 61856

Phone/Fax (217) 762-2656
ncims.bordson@gmail.com

NCIMS International Certification Program (ICP) Committee

Ms. Claudia Coles, Co-Chair
WA Dept. Of Agriculture
111 Washington Street
P.O. Box 42560
Olympia, WA 98504-2560

Phone: (360) 902-1905
Fax: (360) 902-2087
Email: ccoles@agr.wa.gov

Mr. Thomas Ford, Co-Chair
Dairy Division
IN State Board of Animal Health
Discovery Hall, Suite 100
1202 E. 38th Street
Indiana State Fairgrounds
Indianapolis, IN 46205

Phone: (317) 544-2388
FAX: (317) 542-1415
Email: tford@boah.in.gov

U.S. Food and Drug Administration (FDA)

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm287572.htm>

CAPT Robert Hennes
MST Team Leader
CFSAN/OFS/DPDFS/DEB/MST
Food and Drug Administration
HFS-316, Room 3B008

5100 Paint Branch Parkway
College Park, MD 20740

Tel: (240) 402-2175
Fax: (301) 436-2632
Robert.Hennes@fda.hhs.gov

The informational packet includes the following:

- Letter from the NCIMS;
- Third Party Certifier (TPC) Application for the NCIMS Voluntary International Certification Program (ICP);
- A fillable template of a Letter of Intent to Participate in the National Conference on Interstate Milk Shipments Voluntary International Certification Program; and
- A fillable template of a National Conference on Interstate Milk Shipments Voluntary International Certification Program Memorandum of Agreement Between a Third Party Certifier and a Milk Company.

NOTE: For additional information related to the Procedures Governing the NCIMS Voluntary International Certification Program (ICP), please refer to Proposal 305 contained within IMS-a-49 at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007974.htm>

or the Section titled “Procedures Governing the NCIMS Voluntary International Certification Program” within the latest revision of the *Procedures Governing the State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*.

Perspective TCPs shall complete and submit applications electronically (e-mail, CD ROM, flash drive) to either one of the NCIMS International Certification Program (ICP) Committee Co-Chairs cited on page 5 of this M-I. All e-mail electronic submissions shall state in the subject line: “NCIMS ICP TPC Application”. Every electronic submission shall be followed up with a telephone call to either one of the ICP Co-Chairs.

NOTE: All submitted applications and associated documentation shall be completed in English.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, Laboratory Evaluation Officers and State Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA web site at <http://www.fda.gov>.

If you would like an electronic version of this document prior to it being available on the FDA web site, please e-mail your request to robert.hennes@fda.hhs.gov.

A handwritten signature in black ink, appearing to read "Robert Hennes". The signature is written in a cursive style with a large initial "R".

Robert F. Hennes, RS, MPH
CAPT U.S. Public Health Service
Dairy and Egg Branch/Milk Safety Team

Attachments:
Informational Packet Materials