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M-I-06-17

October 2, 2006

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

FROM: Milk Safety Branch (HFS-626)

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

The National Conference on Interstate Milk Shipments (NCIMS) International Certification Pilot Program (ICPP) Committee is soliciting applications from Third Party Certifiers (TPCs), which are non-governmental entities, interested in participating in the NCIMS Voluntary International Certification Pilot Program. The ICPP will institute a fourth (4th) option for the listing of ICPP milk companies (MCs) in 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 ICPP milk companies. The ICPP Committee will select a maximum of three (3) TPCs to participate in the ICPP, which will implement, regulate, enforce, rate and verify compliance with the regulations contained in the most current edition of the Grade "A" Pasteurized Milk Ordinance (PMO) and related NCIMS documents for the purpose of listing ICPP milk companies in areas outside of the boundaries of the United States. Listing of milk companies in the IMS List during the NCIMS voluntary ICPP 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 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 in the IMS List. The IMS List may be viewed at the following Web Site: <http://www.cfsan.fda.gov/~ear/prime.html>.

For imported Grade "A" milk and milk products, the United States Food and Drug Administration (FDA) and the NCIMS have currently accepted three (3) options by which a foreign milk processing plant may become listed in the IMS List. These three 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 importing 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.

The NCIMS Voluntary International Certification Pilot Program will pilot a fourth (4th) option for milk companies located outside of the United States. The ICPP 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.
- Provide a means for NCIMS member States to accept Grade "A" milk and milk products from IMS Listed TPC milk companies.

The ICPP Committee is charged with evaluating the ICPP and reporting back to the 2007 NCIMS Conference (May 5-10, 2007 in Salt Lake City, Utah) on the progress of the ICPP and to make recommendations regarding its viability as an NCIMS function. This ICPP is scheduled to operate through December 31, 2007 unless it is extended by way of future NCIMS conference action. The ICPP Committee plans to submit a Proposal seeking an extension of the voluntary pilot program to operate through December 31, 2009 at the 2007 Conference.

DEFINITIONS APPLICABLE TO THE ICPP:

- **NCIMS Voluntary International Certification Pilot Program (ICPP):** A voluntary pilot program designed to evaluate the use of third party certifiers in applying the requirements of the NCIMS Grade “A” Milk Safety Program for milk companies located outside the geographic boundaries of NCIMS member States that desire to produce and process Grade “A” milk and milk products for importation into the United States. This term replaces the term “Third Party Certification Pilot Program” as used in the 2005 NCIMS Proposal 316 Substitute Solution.
- **Third Party Certifier (TPC):** The individual or organization that conducts the routine regulatory functions and enforcement requirements of the PMO in relation to a milk company participating in the ICPP and that provides the means for the rating and listing of dairy plants and their related raw milk sources and the certification and listing of servicing milk and water laboratories and single-service container and closure manufacturers in the Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List. This term replaces the term “Third Party Certification Pilot Program Firm” as used in the 2005 NCIMS Proposal 316 Substitute Solution.
- **Milk Company (MC):** A private entity that is seeking listing on the IMS List through participation in the ICPP including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk tank truck cleaning facilities, milk plants, receiving stations, transfer stations, dairy plant samplers, industry samplers, milk distributors and their servicing milk and water laboratories, as defined in the PMO, located outside the geographic boundaries of NCIMS member States. If an individual citation is made of a specific term as cited above and defined in the PMO, it shall only apply to that specific defined term, i.e., “dairy farm” or “milk plant”. This term replaces the term “Third Party Certification Pilot Program Facility” as used in 2005 NCIMS Proposal 316 Substitute Solution.

WRITTEN AGREEMENTS APPLICABLE TO THE ICPP:

- **Letter of Intent (LOI):** A TPC selected to participate in the ICPP shall sign a formal written agreement with any MC (maximum of two (2)) that it intends to certify under the ICPP. A copy of each agreement, signed by the TPC and the MC, shall be submitted to the ICPP Committee within sixty (60) days of being selected to participate in the ICPP. An example of an LOI is provided with the Third Party Certifier (TPC) Application Form for the NCIMS Voluntary International Certification Pilot Program (ICPP).
- **Letter of Understanding (LOU):** Upon acceptance into the ICPP, a TPC shall sign a formal written LOU with the NCIMS that acknowledges the TPC’s responsibilities under the ICPP, its agreement to perform them, and its

understanding of the consequences for failing to do so. The LOU must include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary ICPP.

- **Memorandum of Agreement (MOA):** This formal written signed memorandum states the requirements and responsibilities of each party (TPC and MC) to participate and execute the NCIMS voluntary ICPP. The MOA must include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary ICPP. This agreement will be considered the MC's permit to operate in the context of the NCIMS Grade "A" Milk Safety Program. An example of an MOA is provided with the Third Party Certifier (TPC) Application Form for the NCIMS Voluntary International Certification Pilot Program (ICPP).

The MOA will be reviewed by the ICPP Committee and FDA/MST/LQAT to determine whether it contains all provisions set forth herein. FDA/MST/LQAT will provide comments to the ICPP Committee concerning the MOA. There shall be no listing of the MCs in the IMS List until the ICPP Committee and FDA/MST/LQAT have indicated that the MOA complies with the requirements herein stated.

TPCs will be selected based on their 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 and rating services necessary to list a maximum of two (2) milk companies in the IMS List. The timeline for this process will be as follows:

October 2, 2006: Request for Applications is Announced.

November 15, 2006: Final Date of Application Acceptance. **NOTE:** All applications must be completed in English and must be received by the NCIMS Executive Secretary by this date.

January 2, 2007: Selection Committee announces selection of TPCs and provides a formal Letter of Understanding (LOU) to each selected TPC.

January 16, 2007: Deadline for selected TPC to submit a signed LOU to the ICPP Committee.

March 1, 2007: Deadline for selected TPC to submit a signed Letter of Intent (LOI) to the ICPP Committee.

April 2, 2007: Deadline for selected TPC to submit a signed Memorandum of Agreement (MOA) to the ICPP Committee.

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

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NCIMS International Certification Pilot Program (ICPP) Committee

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U.S. Food and Drug Administration (FDA)

www.cfsan.fda.gov/~ear/mi-index.html

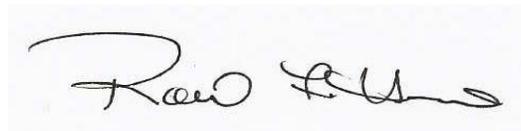
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The informational packet includes the following:

- Cover Letter;
- Third Party Certifier (TPC) Application Form for the NCIMS - Voluntary International Certification Pilot Program (ICPP);
- Policies and Procedures Document - National Conference on Interstate Milk Shipments Voluntary International Certification Pilot Program;
- Example of a Letter of Understanding Between the National Conference on Interstate Milk Shipments and a Third Party Certifier;
- Example of a Letter of Intent to Participate in the National Conference on Interstate Milk Shipments Voluntary International Certification Pilot Program; and
- Example of a National Conference on Interstate Milk Shipments Voluntary International Certification Pilot Program Memorandum of Agreement Between a Third Party Certifier and a Milk Company.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, 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.cfsan.fda.gov>.

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

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

CAPT Robert F. Hennes, RS, MPH, Chief
Milk Safety Branch

Attachments:
Informational Packet Materials