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5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-14-5

January 28, 2014

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

FROM: Dairy and Egg Branch/Milk Safety Team (HFS-316)

SUBJECT: Questions And Answers Related To The National Conference on Interstate Milk Shipments Voluntary International Certification Program

At the 2013 National Conference on Interstate Milk Shipments (NCIMS) Conference held in Indianapolis, IN April 19-24, 2013, Proposal 305 was passed by the State voting delegates and concurred with by FDA that incorporates the findings of the International Certification Pilot Program Committee (ICPPC) into the NCIMS documents and transforms the International Certification Pilot Program (ICPP) into the International Certification Program (ICP) making it a permanent part of the NCIMS Grade "A" Milk Safety Program. The ICP formalizes a fourth (4^{th}) option for the listing of ICP foreign milk companies on the Interstate Milk Shippers (IMS) List to provide a means for NCIMS member States to accept Grade "A" milk and/or milk products from these IMS Listed ICP Milk Companies being shipped into their States. (Refer to Proposal 305 contained within IMS-a-49 and the latest Revision of the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments as referenced below.)

http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM375907.pdf

http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM378829.pdf

The ICP will utilize Third Party Certifiers (TPCs) who will act as regulatory, rating, and laboratory evaluation agencies in the regulation of foreign milk companies and their associated dairy farms, bulk milk hauler/samplers, 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” Pasteurized Milk Ordinance (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 TPC IMS Listed milk companies.

TPCs that are authorized to participate in the ICP will implement, regulate, enforce, rate and verify compliance with the regulations contained in the most current revision of the PMO and related NCIMS documents for the purpose of listing ICP milk companies located 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/or milk products into the United States from those milk 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 questions and answers that are included in this M-I were formulated during the ICPP and are still valid. They are provided to assist prospective and existing TPCs in completing the application form, if applicable, and provide additional details addressing the requirements of the ICP.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation 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.

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CAPT U.S. Public Health Service
Dairy and Egg Branch/Milk Safety Team

QUESTIONS AND ANSWERS RELATED TO THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS (NCIMS) VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM (ICP)
JANUARY 28, 2014

1. **Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (PROCEDURES)-Sections I and IX**

   Does the International Certification Program (ICP) preclude a foreign government from applying to become a Third Party Certifier (TPC)?

   Yes. The definition of a TPC states that a TPC is a non-governmental individual (s) or organization authorized under the National Conference on Interstate Milk Shipments (NCIMS) voluntary ICP.

2. **PROCEDURES-Sections V and IX**

   May a TPC share FDA certified Milk Sanitation Rating Officers (SROs), Sampling Surveillance Officers (SSOs) and/or Laboratory Evaluation Officers (LEOs)?

   Yes.

3. **PROCEDURES-Sections V and IX**

   What are the certification requirements for a potential TPC SRO, SSO and/or LEO that was previously FDA certified as a State SRO, SSO or LEO?

   If the SRO's, SSO's or LEO's FDA certification is still valid (not expired) and they have conducted ratings, sampler evaluations or laboratory evaluations, respectively, within the preceding eighteen (18) months, their current FDA certification would be valid through the expiration date. However, if they do not comply with this or their certification has expired, they will be required to be recertified in accordance with Section V-Qualifications and Certifications of the Procedures: (SRO-five (5) milk plants, twenty-five (25) dairy farms and one (1) single-service container and/or closure manufacturing plant); SSO-five (5) bulk milk hauler/samplers, one (1) plant sampler (raw and pasteurized milk and/or milk products and single-service containers/closures collection), if applicable; and LEO-one (1) laboratory).

   The above criteria would also apply to retired FDA employees, who have conducted check ratings, Regional Milk Specialist (RMS) standardizations, or laboratory evaluations, who plan to work with a TPC as a SRO, SSO or LEO within the ICP.

4. **PROCEDURES-Sections V and IX**

Who is responsible to make the arrangements with the State Regulatory Agency(ies) for dairy farms, milk plants, bulk milk hauler/samplers, plant samplers, laboratories, etc. where FDA will conduct the certification of the TPC's SRO(s), SSO(s) and/or LEO(s), respectively?

The TPC is responsible to contact and identify a State(s) where such FDA certifications will be conducted. If a TPC is having difficulty in obtaining a State(s) to conduct the certifications, then it is recommended that the TPC contact the International Certification Program Committee (ICPC) and ask for assistance.

5. **PROCEDURES-Sections V and IX**

a) Who is responsible to submit the formal written request to FDA for the certification of a TPC's SRO(s), SSO(s) and/or LEO(s)?

The identified TPC Owner, President, etc. would be required to submit the formal written request to FDA's Milk Safety Team (MST).

b) Who should the formal written request for FDA standardization/certification be sent to?

For a SRO or SSO, it shall be sent to:

CAPT Robert Hennes, Team Leader
Milk Safety Team (HFS-316)
Food and Drug Administration
5100 Paint Branch Parkway, Room 3B-008
College Park, MD 20740

For a LEO, it shall be sent to:

Dr. Thomas Graham, Team Leader
Laboratory Proficiency and Evaluation Team (HFS-450)
Food and Drug Administration
6502 S. Archer Road
Bedford Park, IL 60501-1957

6. **PROCEDURES-Sections V and IX**

May arrangements be made to notify the TPCs of training courses and Regional Milk Seminars?

Yes. The MST and/or the RMSs will include the TPCs in any notifications of upcoming training courses and Regional Milk Seminars.

7. **PROCEDURES-Sections V and IX**

May a TPC's SRO certify and IMS list foreign single-service container and/or closure manufacturing plants?

Yes, if FDA certified for single-service containers and closures.

8. **PROCEDURES-Section IX**

Is it acceptable for the regulated Milk Company (MC) to pay the TPC for the costs of evaluating a commercial laboratory that they plan to utilize under the ICP*?*

Yes.

***NOTE**: It is understood that the cost of all regulatory services provided by the TPCs will ultimately be borne by the MC benefiting from those services. The preferable solution would be for the TPC to incorporate the cost of laboratory evaluations into the contract with the MC.*

9. **PROCEDURES-Section IX; and TPC Application Form included in M-I-13-8**

The following questions related to the TPC Application Form for the NCIMS Voluntary ICP:

a) Page 5, **Item I-Prevention of Conflicts of Interest**: In addition to the previous answers provided in the application and the resumes for all personnel what are additional ICP conflicts of interest policies?

Item I also requires a copy of the TPC's written policies and procedures that they have established to ensure that the firm and their employees are free from any conflicts of interest.

Section IX-Procedures Governing the NCIMS Voluntary International Certification Program, C-Third Party Certifier (TPC) Responsibilities, 3-Code of Ethics also provides additional information that would be useful in addressing Item I.

Item 6-Third Party Certifier is not to Engage in Conflicting Activities of the Memorandum of Agreement (MOA) between a TPC and a MC also provides additional information that would be useful in addressing Item I.

b) Page 5, **Item K-Personnel Qualifications**: If a TPC's management and other personnel have been involved in the regulatory/consulting areas of the field for many years and they feel that their resumes and answers to other questions in the application address this Item, would additional material be required?

If the TPC feels that their resume and previous answers to other questions adequately cover Item K then that should be sufficient; however, they should make sure that they cover the specific factors identified in Item K, especially in relationship to all employees and designated personnel.

c) Page 6, **Item L-Affirmations**: Where can the ICP Code of Ethics be found?

It is contained in Section IX-Procedures Governing the NCIMS Voluntary International Certification Program, C-Third Party Certifier (TPC) Responsibilities, 3-Code of Ethics of the Procedures.

http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM378829.pdf

d) Page 6, **Item M-Training Requirements**: What amount of training is required?

Persons not familiar with or having limited experience in an area of designated work may be required to attend training courses offered by State Regulatory/Rating Agencies or FDA. All SROs and LEOs are required to meet the applicable training requirement of the NCIMS Grade "A" Milk Safety Program as cited in Section V. Qualifications and Certifications, D. Milk Sanitation Rating Personnel and G. Milk Laboratory Evaluation Personnel and Section VIII. Procedures Governing the Certification of Milk Plant, Receiving Station and Transfer Station NCIMS HACCP Systems for IMS Listed Shippers, E. Qualifications and Certifications, 4. HACCP Listing Personnel and 6. Certification Procedures for SRO's Who Will Conduct HACCP Listing Audits of the Procedures.

e) Page 6. **Item N-Additional Required Documents**: Will the previous answered questions in the TPC Application Form, resumes and training in the field be acceptable for this Item?

No. The two (2) specific documents cited in Item N shall accompany the submitted TPC Application Form.

10. **PROCEDURES-Section IX**

Section IX-Procedures Governing the NCIMS Voluntary International Certification Program, C-Third Party Certifier (TPC) Responsibilities, 2.a. of the Procedures requires the routine regulatory inspectors to be "adequately trained to perform their duties"; what is considered to be "adequately trained"?

Currently, the PMO or other NCIMS documents do not specifically address the issue of educational requirements or training for routine regulatory inspectors. That training is left entirely up to each individual State Regulatory Agency. Within the TPC Application, it asks for the identification of individuals that will conduct the regulatory, rating and laboratory program functions and their appropriate training,

education and experience, including required NCIMS Grade "A" Milk Safety Program related. As part of the selection process, the ICPC will consider several factors with respect to personnel qualifications including:

- *NCIMS Grade "A" Milk Safety Program related experience;*
- *Previous milk program related training;*
- *Knowledge of the sanitation requirements of the PMO;*
- *Technical knowledge of milk plant and dairy farm operations;*
- *FDA certification (SRO, SSO and/or LEO);*
- *Training and preparedness of the TPC's employees to conduct the routine regulatory functions of the program within the guidelines of the program, etc.*

The real proof of adequate training will be demonstrated by the IMS listing of milk shippers and the validation of such IMS listings through FDA check ratings.

11. **PMO-SECTION 3; and PROCEDURES-Section IX**

a) It is stated that the Memorandum of Agreement (MOA) is equivalent to a "permit". What is the procedure when a dairy farm's, milk plant's, bulk milk hauler/sampler's, etc. permit is required to be suspended in accordance with the PMO?

The same enforcement permit action(s) that is currently required within the PMO and the NCIMS Grade "A" Milk Safety Program shall be taken by the TPC. The dairy farm or milk plant permit holder or permitted bulk milk hauler/sampler shall be officially notified by the TPC that their "permit" (MOA) will be suspended until the appropriate corrections have been made. Within the ICP, the TPC is considered equivalent to a State Regulatory Agency; therefore, this shall occur just like it is currently being performed within the program.

b) May the TPC provide for a milk plant to take milk and/or milk product stop sale actions similar to what is currently provided in Section 3-Permits of the PMO?

Yes.

12. **PMO-SECTION 3; and PROCEDURES-Section IX**

A MC has one (1) main milk plant that produces milk and/or milk products for export to the U.S. They also have a supply milk plant located at a different location that produces condensed and powder for use at the main plant. May both of these milk plants be listed under the same permit (MOA)?

No.

13. **PROCEDURES-Section IX; and MOA**

a) Will Federal Import Milk Act (FIMA) Permits still be required for ICP MCs to import bovine fluid milk and/or milk products into the U.S.?

Yes.

b) What milk and/or milk products does the FIMA apply to or where can that information be found?

Compliance Policy Guide, Section 560.400 Imported Milk and Cream – Federal Import Milk Act (CPG 7119.05)

http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg560-400.html

Milk and Cream (raw and pasteurized) from domesticated (dairy) cows (genus Bos.)

- *Milk, Lowfat Milk, Skim or Nonfat Milk, Fortified Milk, Flavored Milk, Concentrated Milk, and Ultrafiltered Milk.*
- *Cream, Half-and-Half, Heavy Cream, Light Cream and Light Whipping Cream.*
- *Does not apply to the following:*

  - *Sour Cream, Cultured Milk, Acidified Milk, Yogurt, Cheese, Ice Cream and Eggnog.*
  - *Sweetened Condensed Milk, Evaporated Milk, Dried Milk, Nonfat Dry Milk, Nonfat Dry Milk fortified with vitamins A and D, and other dehydrated milk products.*
  - *Any of the dairy products for which a permit is otherwise required if they have been processed and packaged in hermetically sealed containers so as to be commercially sterile in accordance with the requirements of 21 CFR 108.35 and 113.*

14. **PROCEDURES-Sections IV and IX**

How will U.S. customs and FDA import officials be informed of the TPC's IMS listing of a specific milk plant and the milk and/or milk products that they are listed for?

Import officials will use the IMS list to identify milk plants and milk and/or milk products that are acceptable to be imported into the U.S. under the ICP.

15. **PROCEDURES-Section IX**

Are all documents, including forms, contracts and written communication between the TPC and regulated MC that are utilized and exchanged within the ICP to be in English or translated by the MC into English?

Yes.

16. **PROCEDURES-Section IX**

If any personnel change is made to a TPC once it has signed the Letter of Understanding (LOU) and has been authorized under the ICP, is it required for the TPC to notify the ICPC and MST of the change?

Yes.

17. **PROCEDURES-Section IX**

Where should the signed and dated Letter of Intent (LOI) and MOA be sent to from the TPCs?

To either one (1) of the ICPC Co-chairs:

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

18. **PMO-APPENDIX M; METHODS OF MAKING SANITATION RATING OF MILK SHIPPERS; and PROCEDURES-Section IX**

Are all of the Grade "A" Milk Safety Program inspection and rating reports and forms available on the web?

Yes. All of the current inspection and rating reports and forms (FORM FDA 2359 series and FORM FDA 2399 series) are available at the following website:

http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/FoodForms/default.htm

19. **FDA TRAINING COURSES**

Are current copies of manuals for the following FDA training course available: Dairy Farm Sanitation and Inspection, Milk Plant Sanitation and Milk Pasteurization Controls and Test, LEO course and Analyst course?

The training manuals that are utilized in these FDA/State training courses may be obtained from FDA/ORA/Division of Human Resource Development (DHRD) from Audrey Vigil at: audry.vigil@fda.hhs.gov

20. **BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS; and PROCEDURES-Section IX**

a) Could an interested party participate on the ICPC if they have a commercial relationship with a TPC?

Yes, as a non-voting member.

b) Could an interested party participate on the ICPC if they do not have any commercial relationship with a TPC?

Yes.

21. **INTERNATIONAL CERTIFICATION PROGRAM COMMITTEE**

May an employee of a MC or other interested party participate on the ICPC conference calls with the TPCs?

Yes, if acceptable to the TPCs then the ICPC would not have a concern with their participation.