INTERNATIONAL CERTIFICATION PROGRAM
QUESTIONS AND ANSWERS

JANUARY 1, 2014

1. May a Third Party Certifier's (TPC's) Milk Sanitation Rating Officer (SRO) certify and IMS list foreign single-service container and/or closure manufacturing plants?

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

2. What are the certification requirements for a potential TPC SRO, Sampling Surveillance Officer (SSO) or Laboratory Evaluation Officer (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 State 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 Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shippers (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/caps collection, if applicable; and LEO- one (1) laboratory).

   The above criteria would also apply to retired FDA employees (conducting check ratings, Regional Milk Specialist (RMSs) standardization, or laboratory evaluations), which plan to work within the ICP.

3. May a TPC share FDA certified SROs, SSOs or LEOs?

   Yes.

4. Does the ICP preclude a foreign government from applying to be a TPC?

   Yes. See Pasteurized Milk Ordinance definition of TPC.

5. 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 International Certification Program Committee (ICPC) will consider several factors with respect to personal 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 certifications, (SRO, SSO 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.

6. 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 will 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 taking place now within the program.

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

   Yes.

7. Will Federal Import Milk Act (FIMA) Permits still be required for International Certification Program (ICP) Milk Companies (MC's) to import bovine fluid milk and milk products into the U.S.?

   Yes.

8. How will U.S. customs and FDA import officials be informed of the TPC's IMS listing of a specified milk plant and the milk and 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.

9. The following questions related to the Third Party Certifier (TPC) Application for the NCIMS Voluntary International Certification Program (ICP)

a) Page 5, Item I: In addition to the previous answers 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 of the Procedures 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 Between a Third Party Certifier and a Milk Company also provides additional information that would be useful in addressing Item I.

b) Page 5, Item K: 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 their resumes and answers to other questions in the application address this Item is there additional material required?

If you feel that your resume and previous answers to other questions adequately cover Item K then that should be sufficient; however, you 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: What is the ICP Code of Ethics?

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.

d) Page 6, Item M: 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 or FDA. All SROs and LEOs are required to meet the applicable training requirement of the National Conference on Interstate Milk Shipments (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

f. Page 6. Item N: Will the previous answered questions in the TPC Application, 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. May arrangements be made to notify the TPCs of training courses and regional milk seminars?

Yes. The Milk Safety Team (MST) and/or the Regional Milk Specialists will include the TPCs in any notifications of upcoming training courses and regional milk seminars.

11. What milk and milk products does the Federal Import Milk Act (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 Ultra Filtered 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.*

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

No.

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

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

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

14. 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 workshop and laboratory workshop?

    The training manuals that are utilized in these training courses may be obtained from FDA/ORA/Division of Human Resource Development (DHRD) from

15. If personnel changes are made to a TPC once it has been authorized under the NCIMS ICP, is it required for the TPC to notify the ICPC of such changes?

    Yes.

16. Where should the Letter of Intent (LOI) and Memorandum of Agreement (MOA) be sent to from the TPCs?

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

    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

    or

    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) 544-2386
    FAX: (317) 974-2011
    Email: tford@boah.in.gov

17. Who is responsible to make the arrangements with the State Regulatory Agency(ies) (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)?

    The TPC is initially responsible to contact and identify a State(s) where such FDA certifications can 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 ICPC *and ask for assistance.*

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

    The identified TPC Owner or President is required to submit the formal written request to ***F****DA.*

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

    For a LEO, it shall be sent ~~it~~ to:

    Dr. ***Thomas Graham****, Team Leader*
    Laboratory Proficiency and Evaluation Team
    Food and Drug Administration
    502 S. Archer Road, HFH-450
    Summit Argo, IL 60501-1957

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

    CAPT Robert Hennes, Team Leader
    Milk Safety Team
    Food and Drug Administration
    5100 Paint Branch Parkway, Room 2C-059
    College Park, MD 20740

19. Are all documents, including forms, contracts and written communication between the TPC and regulated Milk Company (MC) that are utilized and exchanged within the NCIMS Voluntary ICP to be in English or translated by the MC into English?

    Yes.

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

    Yes.

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

Yes.

22. May an employee of a milk company (MC) or other interested party participate on the ICPC conference calls with the TPCs?

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

23. Is it acceptable for the regulated milk plant to pay the TPC for the costs of evaluating a commercial laboratory*?*

    Yes

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