

NCIMS/MST UPDATE

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Office of Food Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration**



RESULTS OF THE 2013 NCIMS

63 PROPOSALS WERE DELIBERATED:

- COUNCIL I - 25 PROPOSALS**
- COUNCIL II - 31 PROPOSALS**
- COUNCIL III - 7 PROPOSALS**

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED:

- CHANGES TO PMO – 22
- CHANGES TO PROCEDURES – 4
- CHANGES TO MMSR – 4
- CHANGES TO CONSTITUTION/
BYLAWS – 2
- CHANGES TO THE EML – 6

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED (cont.):

– FORMATION OF STUDY COMMITTEES – 5

- **220 (Appendix N Modification Study Committee)** – Examine the Issue when Drug Residue Screening is Conducted with an Unapproved Test for Contractual or Export Obligations and at a Testing Level Different than the Safe/Tolerance Level when a FDA Approved Test Does Exist.

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED (cont.):

– FORMATION OF STUDY COMMITTEES – 5 (cont.)

- **222 (Laboratory Committee)** – Review the EPA Final Revised Total Coliform Rule Signed by the EPA Administrator on December 20, 2012 for Publication in the Federal Register.

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED (cont.) :

– FORMATION OF STUDY COMMITTEES – 5 (cont.)

- **301 (Single Service Committee and Methods Committees) – Develop Listing and Withdrawal of Listing Criteria for SSCC Manufacturers. Consultants that Currently have SSCC Listings on the IMS List Shall Participate on the Committees.**

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED (cont.):

– FORMATION OF STUDY COMMITTEES – 5 (cont.)

- **301 and 305 (Single Service Committee) –** Develop Qualifications, Authorization, Certification/Recertification Procedures, etc. for Consultants that Currently Certify or Wish to Certify SSCC Manufacturers Located Outside the Geographical Boundaries of the NCIMS Member States. Consultants that Currently have SSCC Listings on the IMS List Shall Participate on the Committee.

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED (cont.):

– FORMATION OF STUDY COMMITTEES – 5 (cont.)

- **304 (Aseptic Program Committee) – Aseptic Pilot Program to Look at Aseptically Processed and Packaged Grade “A” Acidified and Fermented High-Acid Milk and/or Milk Products.**

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED:

– SPECIFIED EFFECTIVE DATES

- **206** (Defines inspection frequency interval for bulk milk hauler/industry and dairy plant samplers – 24 month period the remaining days of the month in which the inspection is due)
- **207** (Laboratory Tests For Grade “A” Milk And Milk Products And Grade “A” Dairy Farm And Milk Plant Water, appropriate references citing M-a-98 are proposed to be added to the PMO and the MMSR.).
- **EFFECTIVE DATE: ISSUANCE OF IMS-a-49**

RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED:

– SPECIFIED EFFECTIVE DATES

- **304 (RETORT PROCESSING AFTER PACKAGING MILK AND MILK PRODUCTS AND EXTEND THE ASEPTIC PILOT TO ADDRESS ASEPTICALLY PROCESSED AND PACKAGED GRADE “A” ACIDIFIED AND FERMENTED HIGH-ACID MILK AND/OR MILK PRODUCTS)**
- **EFFECTIVE DATE: ISSUANCE OF IMS-a-49**



RESULTS OF THE 2013 NCIMS

35 PROPOSALS PASSED:

- SPECIFIED EFFECTIVE DATES
 - 305 (INTERNATIONAL CERTIFICATION PROGRAM)
 - EFFECTIVE DATE: ISSUANCE OF IMS-a-49

RESULTS OF THE 2013 NCIMS

PROPOSAL 305

**(PMO, MMSR, CONSTITUTION/BYLAWS,
PROCEDURES and EML)**

This Proposal incorporates the findings of the ICPPC into the NCIMS documents and transform 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.

RESULTS OF THE 2013 NCIMS

PROPOSAL 305

(PMO, MMSR, CONSTITUTION/BYLAWS,
PROCEDURES and EML)

The program will utilize Third Party Certifiers (TPCs) who will act as Regulatory, Rating, and Laboratory Evaluation Agencies in the regulation of foreign milk companies (MCs) and their associated farms, haulers, receiving stations, transfer stations, laboratories, etc.

RESULTS OF THE 2013 NCIMS

PROPOSAL 305

- **Comply** with all requirements of the PMO and related NCIMS documents.
- Continue to assure at least the **same level of milk safety** provided within the current NCIMS program.
- Provide **reciprocity** between NCIMS member States for the importation of Grade “A” milk and/or milk products from IMS Listed foreign firms.

HIGHLIGHTS **305**

- Changes to the PMO:
- TPCs may **NOT**:
 - Allow “emergency” or ungraded milk to be shipped to the US
 - Use the monetary penalty provisions of the PMO
 - Use the Certified Industry Inspection provisions of the PMO
 - Authorize the reprocessing of “returned” milk or milk products for sale in the US

HIGHLIGHTS **305**

- TPCs may **NOT**:
 - Use in the event of an emergency situation, inclement weather, natural disaster, etc for a variance from the PMO requirements.
 - Authorize the shipment of non-grade “A” cottage cheese to the US
 - Authorize the option to utilize inspections of bulk milk hauler/samplers conducted by other Regulatory Agencies.

HIGHLIGHTS **305**

- **Modifications to Procedures:**
 - Added a **New Section** - Governing the NCIMS Voluntary International Certification Program (ICP)
 - International Certification Program Committee to **oversee** ICP
 - ICP **reviews** TPC applications and **makes recommendations** to NCIMS Executive Board
 - TPC **must have US Grade “A” experience** to even make an application

HIGHLIGHTS **305**

- **Modifications to Procedures (cont.):**
 - SRO, SSO, and LEO **must meet same criteria** as US counterpart
 - **Recourse** for those TPCs not accepted by ICP committee or NCIMS Executive Board
 - NCIMS Executive **Board accepts or rejects** TPC applicants
 - Accepted TPC must **sign a LOU with the NCIMS** to operate

HIGHLIGHTS 305

■ Modifications to Procedures (cont):

■ TPCs

- **May terminate an MOA with an MC.** This will cause the MC to be immediately withdrawn from the IMS List.
- **May withdraw from the ICP.** This will cause all MCs represented by the TPC to be immediately withdrawn from the IMS List
- **May be removed from the ICP.** This will cause all MCs represented by the TPC to be immediately withdrawn from the IMS List

HIGHLIGHTS **305**

- **Modifications to Procedures (cont):**
- **TPCs**
- **May be removed** from the ICP due to:
 - **Non-compliance** with NCIMS requirements
 - The TPC **ceasing to provide oversight** for it's IMS Listed MCs
 - **Non-compliance** with the **Code of Ethics** listed in Procedures

HIGHLIGHTS 305

■ Modifications to Procedures (cont):

■ MCs

- **May terminate an MOA.** This will cause the MC to be immediately removed from the IMS List
- **May be removed from the IMS List for:**
 - **Failing to pass a rating or check rating**
 - **Their TPC fails to provide oversight**
 - **The MC or its laboratory not meeting NCIMS requirements as determined by FDA MST or FDA LPET**

HIGHLIGHTS **305**

- **Modifications to the Constitution:**
 - TPCs will have **a representative** on the NCIMS Executive Board as a **non-voting member**
 - TPCs may be **committee voting members** representing Regulatory/Rating Agencies
 - TPCs may be **council voting members** representing Regulatory/Rating Agencies
 - TPCs **will not have a delegate vote** at the NCIMS Conference

INTERNATIONAL CERTIFICATION PROGRAM

- IMS LISTINGS (*SEPARATE SECTION TITLED “FOREIGN COUNTRIES”*)

4 - CANADA

- *3 PLANTS AND 1 BTU (ONTARIO)*

2 - GERMANY

- *1 PLANT AND 1 BTU*

3 - MEXICO

- *2 PLANTS (same plant has both aseptic and PMO listings) AND 1 BTU*



INTERNATIONAL CERTIFICATION PROGRAM

THIRD PARTY CERTIFIERS (TPCs)

**KEN ANDERSON (HAROLD WAINESS
& ASSOCIATES): 5 Listings**

**LYNN YOUNG (MILK REGULATORY
CONSULTANTS): 4 Listings**

2015 NCIMS CONFERENCE



DOUBLETREE BY HILTON PORTLAND, OREGON

APRIL 24-29, 2015



CODED MEMORANDA

ISSUED IN 2013

- **M-a-98** (*Official Grade “A” Pasteurized Milk Ordinance (PMO) Regulatory Laboratory Tests For Grade “A” Milk And Milk Products And Grade “A” Dairy Farm And Milk Plant Water*) - **3/1/2013**
- **M-I-13-1** (*2013 Revisions Of The Indexes Of Coded Memoranda*) - **1/2/2013**
- **M-I-13-2** (*Charm Sciences, Inc. EZ Reader*) - **2/11/2013**

CODED MEMORANDA

ISSUED IN 2013

- **M-I-13-3** (*NCIMS Grade “A” Milk Safety Program Regulatory Agency Options for the Testing and Resealing of Public Health Controls and Adjustment Access Points on Pasteurization Equipment Following Notification from Milk Plant Personnel of a Broken or Removed Regulatory Seal(s)*)-
5/29/2013

CODED MEMORANDA

ISSUED IN 2013

- **M-I-13-4** (*Clarification of a Milk Plant's and a Regulatory Agency's PMO Requirements Related to the Temperature Exceptions Cited in Item 17p-Cooling of Milk and Milk Products and the Sampling Requirements of These Specifically Identified Milk and Milk Products in Item 17p as Addressed in Section 6-The Examination of Milk and Milk Products of the Grade "A" Pasteurized Milk Ordinance (PMO)*) - **5/20/2013**

CODED MEMORANDA

ISSUED IN 2013

- **M-I-13-5** (*IMS Listing “Product Codes” Clarification For Aseptic and Ultra-Pasteurized Milk and Milk Products*) - **7/26/2013**
- **M-I-13-6** (*Questions And Answers Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During Fiscal Year 2012*) - **10/31/2013**

CODED MEMORANDA

ISSUED IN 2013

- **M-I-13-7** (Addition of a Claim for Goat Milk to the IDEXX Laboratories, Inc. New SNAP Beta-Lactam Test Kit) - **10/31/2013**
- **M-b-370** (*Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System*) - **8/15/2013**

CODED MEMORANDA

ISSUED IN 2013

- **M-b-371** (*Siemens Industry, Inc. SITRANS F M 1100F Magnetic Flow Meter, Model Numbers 7ME6140-2Rxxx-xxxx (1 ½”), 7ME6140-2Yxxx-xxxx (2”), 7ME6140-3Fxxx-xxxx (2 ½”), 7ME6140-3Mxxx-xxxx (3”) and 7ME6140-3Txxx-xxxx (4”) with MAG5000 Transmitter, Model Number 7ME6910-xxxxxx-xxxx*) - **10/23/2013**

CODED MEMORANDA BEING WORKED ON

- *IMS-a-49 (Actions From The 2013 NCIMS Conference) ~ 350 pages - Scheduled to be issued on 11/08/2013*
- *M-I-13-8 (International Pilot Program Application Notice and Information) - Scheduled to be issued on 11/08/2013*

CODED MEMORANDA BEING WORKED ON

M-I-13-? (AMI Criteria)

*M-I-13-? (Questions And Answers Received
From The Field; Regional Milk Seminars; And
FDA Training Courses Held During Fiscal
Year 2013)*

FDA MILK SAFETY COURSES

❖ *FD371-Milk Pasteurization Controls and Tests*

Vancouver, WA – May 5 – 9, 2014

❖ *FD372-Milk Plant Sanitation & Inspection*

Vancouver, WA – Jan. 27 – 31, 2014

Nashville, TN - April 28 – May 2, 2014



FDA MILK SAFETY COURSES

❖ *FD375-Dairy Farm Sanitation & Inspection*

Vancouver, WA – June 16 – 20, 2014

Stephenville, TX – Sept. 15 – 19, 2014

Tallahassee, FL - TBD

❖ *FD577-Special Problems in Milk Protection*

Richmond, VA – Aug. 18 – 22, 2014

Rockford, IL - TBD



FDA MILK SAFETY COURSES

❖ *FD578-Advanced Milk Processing*

Boise, ID - TBD

Minneapolis, MN – May 19 – 23, 2014

FD373-LEO Course

New Orleans, LA – Feb. 10 – 14, 2014

FD374-Analysist Course

Portland, OR – March 17 – 21, 2014



PROJECTS

GRADE “A” EQUIVALENCY DETERMINATIONS

➤ **New Zealand**

- November 2010, 4 U.S. teams visited 12 plants, 22 farms and 4 laboratories in New Zealand
- Main emphasis was to accompany a Recognized Person or a Farm Dairy Assessor from a Recognized Agency while they were conducting a heat treatment verification at the milk plants or an assessment of the farms’ Risk Management Program, respectively
- August 19-29, 2013-Additional visit to New Zealand to review records and national oversight



GRADE “A” EQUIVALENCY DETERMINATIONS

➤ **Canada**

- Canada has postponed all work on this project. No activity since 2011

➤ **EU**

- EU is to identify three (3) or four (4) individual member states to undergo an equivalency determination
- FDA has informed the EU that we do not have the personnel to conduct this equivalency determination at this time and will not be able to do this until New Zealand has been resolved
- EC is requesting that EU equivalency work be completed by October 2014.

DAIRY AND EGG BRANCH (DEB)

Food Safety Modernization Act (FSMA)

- Work groups are being developed within FDA to review comments and develop draft guidance relevant to the rule.
- FDA will be reviewing all comments and input from the various groups and determining what changes are appropriate based on the information provided.

CVM RAW MILK SAMPLING

ASSIGNMENT

- ~ 1900 samples from dairy farms have been analyzed (~ 950 targeted and 950 random)
- CVM Division of Residue Chemistry audit of the results – report is completed
- Draft report is currently being reviewed within CVM and CFSAN
- Sharing of draft report with NCIMS Board – Date TBD

DRUG RESIDUE RISK ASSESSMENT

- Risk Assessment will evaluate:
 - Likelihood and magnitude of drug use in cattle and drug presence in raw milk
 - Likelihood and magnitude of drug survival in milk and milk products after processing
 - Magnitude of human exposure to a drug via consumption of milk and milk products
 - Consequence of human exposure (acute or chronic)
- Final Result – A risk estimation score for a drug based on likelihood and severity of potential health effects

DRUG RESIDUE RISK ASSESSMENT

- Current Status
 - Methodology paper has been written
 - Methodology paper will go out for external peer review in December
 - Peer reviewed methodology paper receives internal FDA review during 1st quarter of calendar year 2014
- FR Notice along with the methodology paper is tentatively scheduled for release in 2nd quarter of calendar year 2014
- Goal is to use the finalized risk ranking data for potential submission of a proposal at the 2015 NCIMS Conf.

FDA FY 2014 REGIONAL MILK SEMINARS

❖ *Central Region*

❖ *Olgebay Resort - Wheeling, WV -
May 12-16, 2014*

❖ *Pacific/Southwest Regional*

❖ *Portland, Oregon - April 7-11, 2014*

QUESTIONS???