

CFSAN/DEB/MST UPDATE

11-07-2014

Dennis Gaalswyk

Consumer Safety Officer

Dairy and Egg Branch

Division of Plant and Dairy Food Safety

Office of Food Safety

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration



Grade “A” CHECK RATINGS FY’13

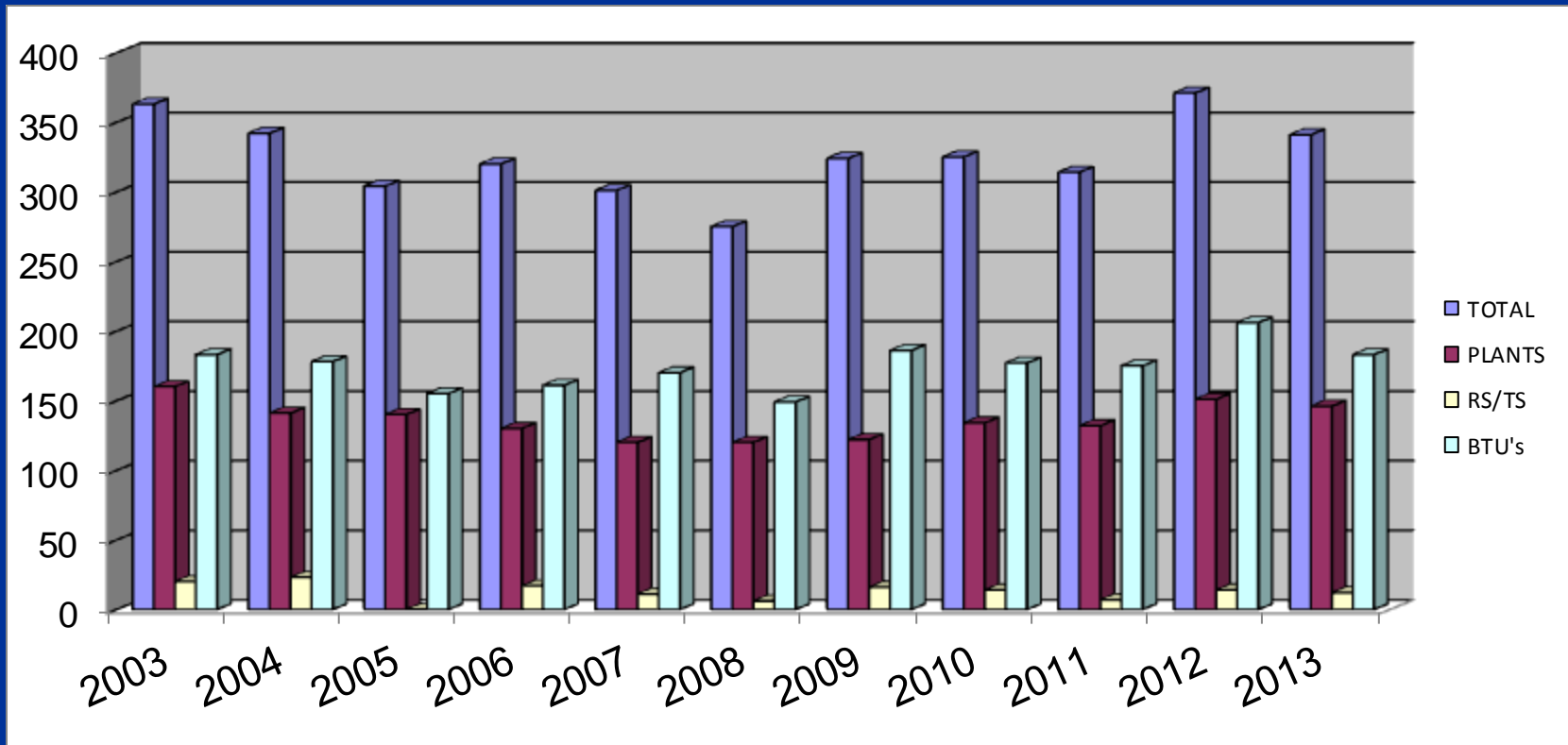
| <u>REGION</u> | <u>BTU’s</u> | <u>PLANTS</u> | <u>RS/TS</u> | <u>TOTAL</u> | <u>Single Service</u> |
|---------------|--------------|---------------|--------------|--------------|-----------------------|
| NE | 23 | 20 | 2 | 45 | 7 |
| CEN | 60 | 45 | 6 | 111 | 18 |
| SE | 21 | 19 | 0 | 40 | 13 |
| SW | 55 | 25 | 4 | 84 | 11 |
| PAC | 24 | 37 | 0 | 61 | 11 |
| TOTALS | 183 | 146 | 12 | 341 | 60 |

CHECK RATINGS

PLANTS, RS/TS AND BTU's

FY 2003-2013

■ Average FY Total Number = 340



ADVERSE ACTION RATES (%) -
CHECK RATINGS
FY 2013

| | |
|----------------|-------------------------------------|
| PLANTS | $17/146 = 11.6\%$ |
| RS/TS | $2/12 = 16.7\%$ |
| BTU's | $33/183 = 18.0\%$ |
| OVERALL | $52/341 = 15.2\%$ |

TOTAL ADVERSE ACTION RATES (%) -CHECK RATINGS

| FY | PLANTS | RS/TS | BTU's | ALL |
|-------------|---------------|--------------|--------------|--------------|
| 2013 | 11.6% | 16.7% | 18.0% | 15.2% |
| 2012 | 6.6% | 7.1% | 20.4% | 14.3% |
| 2011 | 6.8% | 0.0% | 17.7% | 12.7% |
| 2010 | 6.7% | 7.1% | 9.6% | 8.3% |
| 2009 | 5.7% | 6.3% | 15.1% | 11.1% |
| 2008 | 8.3% | 0.0% | 16.8% | 12.7% |
| 2007 | 7.5% | 18.2% | 14.1% | 11.6% |
| 2006 | 8.5% | 23.5% | 16.8% | 13.6% |
| 2005 | 8.6% | 0.0% | 18.7% | 13.5% |
| 2004 | 13.5% | 8.7% | 15.7% | 14.3% |

WITHDRAWAL RATES (%) -
CHECK RATINGS
FY 2013

| | |
|----------------|------------------------------------|
| PLANTS | $5/146 = 3.4\%$ |
| RS/TS | $0/12 = 0.0\%$ |
| BTU's | $6/183 = 3.3\%$ |
| OVERALL | $11/341 = 3.2\%$ |

TOTAL **WITHDRAWAL** RATES

(%) -CHECK RATINGS

| FY | PLANTS | RS/TS | BTU's | ALL |
|-------------|---------------|--------------|--------------|-------------|
| 2013 | 3.4% | 0.0% | 3.3% | 3.2% |
| 2012 | 2.6% | 7.1% | 4.9% | 4.0% |
| 2011 | 1.5% | 0.0% | 6.9% | 4.5% |
| 2010 | 1.5% | 0.0% | 2.8% | 2.2% |
| 2009 | 3.3% | 6.3% | 4.8% | 4.3% |
| 2008 | 1.6% | 0.0% | 6.7% | 4.4% |
| 2007 | 4.2% | 9.1% | 2.4% | 3.3% |
| 2006 | 2.3% | 11.8% | 5.6% | 4.5% |
| 2005 | 1.4% | 0.0% | 3.9% | 2.6% |
| 2004 | 4.3% | 4.3% | 5.1% | 4.7% |

CODED MEMORANDA **ISSUED IN 2014**

M-I-14-1 (2014 Revisions Of The Indexes Of Coded Memoranda) - **1/10/2014**

M-I-14-2 (Signing Of Letters Of Understanding With Two (2) Third Party Certifiers Authorizing Them To Participate In The National Conference On Interstate Milk Shipments' Voluntary International Certification Program) - **1/24/2014**



CODED MEMORANDA ISSUED IN 2014

M-I-14-3 (2013 Revision of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* on FDA's Web Site) - **1/24/2014**

M-I-14-4 (CFSAN's Laboratory Proficiency And Evaluation Team Personnel's New Telephone Numbers and FAX Number) - **1/28/2014**



CODED MEMORANDA ISSUED IN 2014

M-I-14-5 (Questions And Answers Related To
The National Conference on Interstate Milk
Shipments Voluntary International
Certification Program) - **1/28/2014**

M-I-14-6 - (2013 Revision of the *Methods of
Making Sanitation Ratings of Milk Shippers*)
- **1/30/2014**

M-I-14-7 (2013 Revision of the *Grade “A”
Pasteurized Milk Ordinance*) - **3/14/2014**



CODED MEMORANDA

ISSUED IN 2014

M-I-14-8 (Guidance Related To The Requirements For Automatic Milking Installations (AMIs) As Addressed In Section 7-Standards For Grade “A” Raw Milk For Pasteurization, Ultra-pasteurization, Aseptic Processing And Packaging Or Retort Processed After Packaging And Appendix Q-Operation Of Automatic Milking Installations For The Production Of Grade “A” Raw Milk For Pasteurization, Ultra-pasteurization, Aseptic Processing And Packaging Or Retort Processed After Packaging Of The Grade “A” Pasteurized Milk Ordinance) - **4/21/2014**



CODED MEMORANDA ISSUED IN 2014

M-I-14-9 (Removal of the Listing of
Certified Industry Supervisors on the
IMS List) - **4/25/2014**

CODED MEMORANDA BEING WORKED ON

- **M-a-85 (REVISION #15)**-Beta lactam and Other Tests for Use under Appendix N and Section 6 of the PMO
- **M-I-96 -10 (REVISION #9)**-Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back

GRADE “A” EQUIVALENCY DETERMINATIONS

➤ **Canada**

- Last U.S. on-site plant visits were conducted in Quebec/Ontario in October 2010
- Canada performed an on-site evaluation of the Grade “A” Milk Safety Program’s Laboratory Program in Oregon in July 2011
- U.S. visit to farms in Alberta scheduled for late 2011 were postponed due to budgetary issues and have not been rescheduled
- Canada has postponed all work on this project

GRADE “A” EQUIVALENCY DETERMINATIONS

➤ **New Zealand**

- November 2010, 4 U.S. teams visited 12 plants, 22 farms and 4 laboratories in New Zealand
- August 16-29, 2013-Additional visit to New Zealand to review records and national oversight
- Currently awaiting a formal response from New Zealand on the 2013 trip report

GRADE “A” EQUIVALENCY DETERMINATIONS

➤ EU

- EU has identified three (3) individual member States to undergo an equivalency determination:
Netherlands, France and Ireland
- Visit to Ireland in September 2014
- Visit to the Netherlands tentatively scheduled for January 2015
- Visit to France tentatively scheduled for February 2015

RAW MILK FIELD SAMPLING

ASSIGNMENT FOR EU

- ~320 were collected
- All samples collected as investigational samples (INV)
- Samples were tested for aflatoxin, chemicals, metals and drug residues utilizing three (3) separate FDA laboratories
- Results obtained will be presented to the EU and used to address observations from the 2010 EU audit of the entire U.S. dairy program (FDA, State and USDA).

CVM RAW MILK SAMPLING

ASSIGNMENT

- Issued February 2012 for completion in FY 2012; extended into FY 2013 (Oct – Nov 2012)
- ~1800 samples from dairy farms (~900 targeted and ~900 random)
- All samples have been collected and analyzed
- Draft report is going through final clearance
- Final report to be released ?????

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

- Originally issued in April 2010, sampling completed mid-2011
- Assignments also extended into FY 2012 and FY 2013
- Firms in 27 States have been inspected/sampled

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

Environmental Sampling: Location

High
Risk



Low
Risk

Zone 1 – Product contact surfaces: conveyors, tables, racks, vats, tanks, pumps, slicers, packaging machines, etc.

Zone 2 – Non-product contact surfaces in close proximity to product: equipment exterior, refrigeration units, floors, etc.

Zone 3 – Telephones, forklifts, walls, drains

Zone 4 – Locker rooms, cafeteria, hallways

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

■ 2010/2011 Results

- 124 cheese manufacturers were inspected
- 30 firms (24%) were found to have *Listeria monocytogenes* in their environments
- Of the 124 firms, 41 (33%) were artisanal cheese manufacturers
- 8 artisanal firms (20%) were found to have *L. monocytogenes* in their environments

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

■ 2010/2011 Results

- Zone 1 – Approximately 3% positive samples
 - Zone 2 – Approximately 6% positive samples
 - Zone 3 – Approximately 3% positive samples
 - Zone 4 – No positives
- Finished product samples taken at 8 artisanal cheese firms were tested for *E. coli*.
- all samples were negative

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

■ 2012 Results

- 42 cheese manufacturers inspected
- Samples taken from Zones 1 and 2
- 7 firms (16.6%) were found to have *Listeria monocytogenes* in their environment

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

■ 2013 Aged/Gouda Results

- 44 cheese manufacturers inspected
- 79 product samples were tested
- 7 product samples (8.9%) were found to contain generic *E. coli*
- All samples tested negative for *Listeria monocytogenes*, *E. coli* O157:H7

ENVIRONMENTAL SAMPLING FOR *SALMONELLA* AT DRIED MILK FIRMS

- 11 firms inspected in FY 2012
- Perennially positive firms as per USDA data
- 9 (82%) of the firms had at least 1 (one) environmental positive for *Salmonella*

ENVIRONMENTAL SAMPLING FOR *SALMONELLA* AT DRIED MILK FIRMS

- Approximately 4% of the swabs were positive
 - Zone 1 – No positives
 - Zone 2 – Approximately 2% positive samples
 - Zone 3 – Approximately 3% positive samples
 - Zone 4 – No positives

ONGOING FDA FIELD ASSIGNMENTS - STATUS

- Microbiological Pilot Assignment - Retail
 - Domestic Cheese – 3% complete; no violations
 - Import Cheeses – 19% complete; no violations
- Semi-softs (e.g. Gouda) – Continuation of the 2013 Assignment
 - Specific to one District

ONGOING FDA FIELD ASSIGNMENTS - STATUS

- EU related assignment (Chemicals, metals, aflatoxin and drug residues)
 - Milk – samples collected at retail
 - 97% complete

ONGOING FDA FIELD ASSIGNMENTS - STATUS

- Raw Milk Cheese risk profile
 - Nearing completion
 - Will be very comprehensive
 - Will provide science to support proposed changes being contemplated for the cheese standards

PROPOSED FDA FIELD ASSIGNMENTS - STATUS

- Powder assignment
 - To determine baseline presence of *Salmonella* and *Cronobacter sakazakii* in spray-drying facilities generally
 - Pending issuance

DRUG RESIDUE RISK

ASSESSMENT (Proposal 243 from 2005 NCIMS)

- Risk Assessment evaluates:
 - Likelihood and magnitude of drug use in dairy cattle
 - Likelihood of the drug residue in bulk-tank milk
 - Impact of processing on drug residue concentrations present in raw milk
 - Magnitude of consumption of dairy products
 - Health effects from human exposure to a drug residue

DRUG RESIDUE RISK

ASSESSMENT (Proposal 243 from 2005 NCIMS)

■ Final Result

- A semi-quantitative/qualitative risk scoring model to derive a risk ranking for a drug or drug family
- Will aid NCIMS Appendix N Committee in its deliberations on changes to Appendix N

DRUG RESIDUE RISK ASSESSMENT

- External peer review completed
 - Comments generally supportive
 - Additional expert elicitation and changes made to the model were consistent with recommendations received
- October - NCIMS Appendix N Committee members received a demonstration and provided comments/recommendations for the draft model
- November - Review by FDA risk managers
- Early 2015 - Publication of draft

3-A[®] INC. NEW PROCESS

- 3-A[®] has finalized a general standard (ANSI/3-A 00-00-2014) for general requirements that contains definitions and text describing materials and fabrications that are common to most types of equipment (radii etc.).
- This document is now the normative (required) reference for all new 3-A[®] sanitary standards for general requirements.

3-A[®] INC. NEW PROCESS

- As new 3-A[®] Sanitary Standards are written they will be much shorter and contain only additions, deletions, and exceptions to the general standard.
- All existing 3-A[®] Sanitary Standards will be rewritten in this new format over the next five (5) years.

Food Safety Modernization Act (FSMA)

- 6 of 7 Major Proposed Rules Impact the Dairy Industry
 - Preventive Controls for Human Food - Published Jan. 2013
 - Foreign Supplier Verification Program – Published July 2013
 - Accreditation of Third Party Auditors – Published July 2013

Food Safety Modernization Act (FSMA)

- 6 of 7 Major Proposed Rules Impact the Dairy Industry
 - Preventive Controls for Animal Food - Published Oct. 2013
 - Intentional Contamination – Published Dec. 2013
 - Sanitary Transportation of Human and Animal Food – Published Feb. 2014

Food Safety Modernization Act (FSMA)

- 4 Supplemental Notices Issued Sept. 29, 2014 For Public Comment On New Content
 - Preventive Controls for Human Food
 - Preventive Controls for Animal Food
 - Foreign Supplier Verification Programs
 - Produce Safety
- Comment period closes Dec. 15, 2014
- Public Meeting Nov. 13, 2014 at CFSAN in College Park, MD



Food Safety Modernization Act (FSMA)

- Briefly Cover:

- Proposed Preventive Controls for Human Food Rule
- Proposed Sanitary Transportation of Human and Animal Food Rule

Proposed Preventive Controls for Human Food - Status

- ❑ Initial comment period ended 11/22/2013
- ❑ Over 8000 comments received
- ❑ A revised proposed rule addressing only certain key provisions and definitions published 9/29/2014
- ❑ Public comment period only with respect to specific issues identified in the revised proposed rule - ends 12/15/2014

Proposed Preventive Controls for Human Food - Status

- ❑ Due to a court consent decree, the Final Rule must be published in the Federal Register NLT August 30, 2015
- ❑ Compliance dates vary based on size of business as follows:

Proposed Preventive Controls for Human Food - Status

- ❑ Large Business - 1 year after publication of the final rule
- ❑ Small Business (employs fewer than 500 personnel) - 2 years after publication of the final rule
- ❑ Very Small Business (< \$1,000,000 annual sales) – 3 years after publication of the final rule. Facility is subject to modified requirements

Proposed Preventive Controls for Human Food

- ❑ Proposed PCR similar but not identical to HACCP and primarily differs in that:
 - ❑ Preventive controls may be required at points other than at critical control points, and those preventive controls must also have documented procedures, monitoring frequency, corrective actions and verification
 - ❑ PCR does not require critical limits for any/all preventive controls - instead the PCR utilizes the term “parameter”

Proposed Preventive Controls for Human Food

- ❑ Requires hazard analysis to evaluate specific potential hazards and the food safety plan to include several additional preventive controls
 - Process controls
 - Food allergen controls
 - Sanitation controls
 - Recall plan
 - Radiological hazard
 - Transportation Practices (in and out)
 - Equipment Preventive Maintenance Program

Proposed Preventive Controls for Human Food

- ❑ Revised Proposed PCR added potential requirements and requested comment on:
 - Environmental Monitoring
 - Product Testing
 - Supplier Program
 - Economically Motivated Adulteration
- ❑ Requires records that support the preventive controls to be kept for not less than 2 years

Proposed Preventive Controls for Human Food

- ❑ Dairy farms that conduct manufacturing/processing activities on food not consumed on that farm or that pack or hold food not grown, raised or consumed on that farm are subject to registration under section 415 of the FD&C Act and would be subject to requirements of the Preventive Controls Rule unless a specific exemption applies
- ❑ Currently no determination has been made by FDA whether to exempt or not exempt PMO regulated facilities from the PCR

Proposed Sanitary Transportation of Human & Animal Feed - Status

- ❑ Comment period ended 5/31/2014
- ❑ ~ 300 comments received
- ❑ Due to a court consent decree, the Final Rule must be published in the Federal Register NLT March 31, 2016
- ❑ Compliance dates are 1 year after publication of the final rule for businesses other than small businesses and 2 years for small businesses

Proposed Sanitary Transportation of Human & Animal Feed

- ❑ Proposed rule includes a proposed waiver for “Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products.”

FY 2015 REGIONAL MILK SEMINARS

❖ *NE Region*

Sept. 21-24, 2015 in East Syracuse, NY

❖ *SE Region*

*August/Sept. 2015 in Ashville or
Charlotte, NC*

2015 NCIMS CONFERENCE



DOUBLETREE BY HILTON PORTLAND, OREGON

APRIL 24-29, 2015

