

2017 NCIMS CONFERENCE ACTIONS

RESULTS OF THE 2017 NCIMS

42 PROPOSALS PASSED

- **SIGNIFICANCE TO THE GRADE “A” MILK SAFETY PROGRAM -**
 - **JC-2 (FSMA) – Aligns the **PMO** with the requirements of **FSMA** and the **PCHF Rule**.**

RESULTS OF THE 2017 NCIMS

42 PROPOSALS PASSED

- **SIGNIFICANCE TO THE GRADE “A” MILK SAFETY PROGRAM -**
 - **JC-2 (FSMA) – Adds a new Appendix T. to the PMO, and the supporting milk-plant specific procedures required herein, which shall constitute a milk plant’s food safety plan as required by 21 CFR 117.126 to the extent...**

RESULTS OF THE 2017 NCIMS

42 PROPOSALS PASSED

- **JC-2 (FSMA) –**
... that the procedures address **all the hazards identified by the milk plant as applicable for that milk plant.** A milk plant shall have a **written Food Safety Plan prepared or its preparation overseen by one or more PCQIs.**

RESULTS OF THE 2017 NCIMS

42 PROPOSALS PASSED

- **JC-2 (FSMA) –**

A milk plant shall have a **written Hazard Analysis** for each kind or group of milk and/or milk products processed.

RESULTS OF THE 2017 NCIMS

42 PROPOSALS PASSED

- **SIGNIFICANCE TO THE GRADE “A” MILK SAFETY PROGRAM -**
 - **JC-4 (FSMA) – Addresses Appendix K-HACCP Program of the PMO and aligned the PMO with the requirements of FSMA and the PCHF Rule.**

RESULTS OF THE 2017 NCIMS

42 PROPOSALS PASSED

➤ SPECIFIED EFFECTIVE DATES

- JC-2 and JC-4

EFFECTIVE DATE: September 17,
2018.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

QQ. PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL: A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

RR. QUALIFIED INDIVIDUAL: A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe milk and/or milk products as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the milk plant.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

AAA. SUPPLY-CHAIN-APPLIED CONTROL: A preventive control for a hazard in a raw material or other ingredients when the hazard in the raw material or other ingredient is controlled before its receipt.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

EEE. VERY SMALL BUSINESS: A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the three (3) year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., held for a fee) as outlined in 21 CFR Part 117 subparts A and F.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (**PMO**-Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS)

3.c. Inspections of a milk plant for **compliance with Appendix T. of this Ordinance** may be conducted by the Regulatory Agency at least once every **thirty-six (36) months**. Inspection for compliance by the Regulatory Agency **can only occur after the completion of the Grade “A” PMO Preventive Controls Training for Regulatory Agencies.**

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (ITEM 4p. LIGHTING AND VENTILATION)

ADMINISTRATIVE PROCEDURES

1. Adequate light sources are provided ... Shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass breakage shall be provided where milk or milk products are handled, processed, packaged, or stored; or where containers, utensils and/or equipment are washed.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (ITEM 15p. PROTECTION FROM CONTAMINATION)

Milk plant operations, equipment and facilities shall be located and conducted to prevent ...

Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be accurately identified, labeled by the common or usual name and held under conditions that will protect against contamination.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (PMO-ITEM 15p.(C))

1. FOOD ALLERGEN CONTROL: ...

d. Prevention of food allergen cross-contact from insanitary objects, from personnel and from non-milk allergen-containing foods to milk and/or milk products, milk and/or milk products packaging material and other milk and/or milk product-contact surfaces.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (ITEM 15p(C))

**ENVIRONMENTAL MONITORING
MOVED TO THE NEW APPENDIX T.**

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (ITEM 15p(C))

**SUPPLY-CHAIN PROGRAM MOVED TO
THE NEW APPENDIX T.**

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

2. HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD:

a. Human food by-products held for
distribution as animal food without additional
manufacturing or processing by the milk
plant shall be held under conditions that will
protect against contamination as appropriate
for their final use in animal food.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

b. Labeling that identifies the by-product shall be affixed to or accompany the human food by-products for use as animal food when distributed.

c. Shipping containers, i.e., totes, drums, tubs, etc., and bulk vehicles used to distribute human food by-products for use as animal food shall be appropriate for transporting the human food by-products for use as animal food and protecting against contamination during transport.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

7. Each refrigerated room in which ~~pasteurized~~ milk and/or milk products are stored, is equipped with an accurate indicating thermometer, temperature-measuring device, or temperature-recording device that complies with the applicable specifications of Appendix H. of this *Ordinance*.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

(ITEM 20p. PERSONNEL-CLEANLINESS AND PRACTICES)

45. The use of tobacco products, chewing gum or eating food or drinking beverages is prohibited in all rooms in which milk or milk products are handled, processed or store, or in which milk or milk product containers, utensils and/or equipment are washed.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (**PMO-APPENDIX J.**)

4. LIGHTING AND VENTILATION

a. All rooms shall be adequately lighted ... Shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass breakage shall be provided in fabricating areas. Packaging, sealing, wrapping, labeling and similar procedures are considered part of the fabricating area.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

10.LOCKER AND LUNCHROOMS ...

b. Eating, drinking beverages and/or storage of food are prohibited in fabricating and storage areas.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

d. The use of tobacco products or chewing gum is prohibited in fabricating, regrind and storage areas. ...

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

**(PMO-APPENDIX T. PREVENTATIVE
CONTROLS FOR HUMAN FOOD
REQUIREMENTS FOR GRADE “A” MILK
AND MILK PRODUCTS)**

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

Food Safety Plan:

This *Ordinance*, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

... The milk plant's food safety plan shall be in writing and shall be prepared, or its preparation overseen by one (1) or more PCQIs. The milk plant's written food safety plan and its contents shall include the following:

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

1. The written Recall Plan;
2. The written Hazard Analysis;
3. The written Preventive Controls, as appropriate, for hazards not addressed by this *Ordinance*;
4. The written Supply-Chain Program, as appropriate, for hazards not addressed by this *Ordinance*;

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

5. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by this Ordinance;

6. The written Corrective Action Procedures, as appropriate, for hazards not addressed by this Ordinance; and

7. The written Verification Procedures, as appropriate, for hazards not addressed by this Ordinance.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

Records:

The milk plant shall establish and maintain the following records documenting the implementation of the food safety plan:

1. The food safety plan;
2. Records that document the monitoring of preventive controls;
3. Records that document corrective actions;

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

4. Records that document verification, including, as applicable, those related to:

a. Validation;

b. Verification of monitoring;

c. Verification of corrective actions;

d. Calibration of process monitoring and verification instruments;

e. Product testing as appropriate;

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

f. Environmental monitoring;

g. Records review; and

h. Reanalysis;

5. Records that document the supply-chain program; and

6. Records that document the applicable training for milk plant employees and the PCQI(s), including the date of training, the type of training and the person(s) trained.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

Records that are required in the milk plant's food safety plan shall be:

1. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

2. Onsite and available for reviewed by the Regulatory Agency. Electronic records are considered to be onsite if they are accessible from an onsite location; and

3. Retained for at least two (2) years after the date they were created. Offsite storage of these records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

Qualification of Individuals:

1. The owner, operator or person-in-charge of a milk plant shall ensure that all individuals who receive, handle, process, package, etc. milk and/or milk products are qualified to perform their assigned duties.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

The following milk plant's food safety plan activities are required to be performed or overseen by one (1) or more PCQIs:

1. Preparation of the food safety plan;
2. Validation that the preventive controls identified and implemented are adequate to control the hazards appropriate to the nature of the preventive control and its role in the milk plant's food safety system;
3. Review of records; and
4. The reanalysis of the food safety plan.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

Environmental Monitoring:

A milk plant shall have a written environmental monitoring program that is implemented and supported by records for ready-to-eat milk and/or milk products exposed to the environment prior to packaging and the packaged milk and/or milk products do not subsequently receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. ...

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

Supply-Chain Program:

A milk plant shall establish and implement a written risk-based supply-chain program for those raw materials and other ingredients for which the milk plant has identified a hazard requiring a supply-chain-applied control.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

**NOTE: A very small business is exempt
from Appendix T.**

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2 (PMO- Definitions)

EEE. VERY SMALL BUSINESS: A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the three (3) year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., held for a fee) as outlined in 21 CFR Part 117 subparts A and F.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2 (MMSR-MILK PLANT)

During a PHS/FDA check rating/audit, it is necessary to determine compliance of the milk plant with the requirements of Appendix T. Preventive Controls for Human Food Requirements for Grade “A” Milk and Milk Products of the Grade “A” PMO related to the requirement that the milk plant shall have a written food safety plan. The following criteria are to be used in making that determination:

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

a. Record Review

Determine from records stored in a manner as required in the *Grade “A” PMO* that the milk plant’s food safety plan is in compliance. **Significant deficiencies involving one (1) or more of the following constitutes grounds for the re-inspection of a milk plant’s IMS listing.** Milk plants shall be deemed in compliance if the following criteria are met:

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

1.) The milk plant's food safety plan is in writing and was prepared, or its preparation overseen by one (1) or more preventive controls qualified individuals (PCQIs).

2.) The milk plant's written food safety plan and its contents included the following:

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

A.) The written Recall Plan;

B.) The written Hazard Analysis;

C.) The written Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;

D.) The written Supply-Chain Program, as appropriate, for hazards not addressed by the *Grade "A" PMO*;

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

E.) The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by the *Grade “A” PMO*;

F.) The written Corrective Action Procedures, as appropriate, for hazards not addressed by the *Grade “A” PMO*; and

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

G.) The written Verification Procedures, as appropriate, for hazards not addressed by the Grade “A” PMO.

3. A reanalysis of the milk plant’s food safety plan, as a whole, or portion of the food safety plan, was conducted as required and was performed, or overseen, by a PCQI.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

4.) The milk plant has a written Hazard Analysis for each kind or group of milk and/or milk products processed. A milk plant may group similar types of milk and milk products, or similar types of production methods together, if the hazards and procedures are essentially identical.

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

During a **check rating**, if the milk plant is determined **not to be in substantial compliance** with Appendix T. of the *Grade “A” PMO*, PHS/FDA shall formally notify the **Rating Agency** that a **re-inspection/re-audit of the milk plant shall be required within sixty (60) days.**

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

NOTE: If a re-inspection/re-audit is required following a PHS/FDA check rating/audit because of the milk plant not being in substantial compliance with Appendix T. of the Grade “A” PMO, then the milk plant shall initially be determined to be in substantial compliance with Appendix T. of the Grade “A” PMO and then shall achieve a SCR of ninety percent (90%) or higher on the re-inspection or shall receive an acceptable listing audit for NCIMS HACCP milk plants on a re-audit in order to be eligible for a listing on the IMS List.

RESULTS OF THE 2017 NCIMS

PROPOSAL JC-2

(**PROCEDURES**-SECTION V. QUALIFICATIONS AND CERTIFICATIONS)

F. FOOD SAFETY PLAN COMPLIANCE

An IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined on a PHS/FDA check rating. **Check ratings and any required re-inspection to determine compliance with Appendix T. shall be conducted only by personnel who have completed PHS/FDA *Grade "A" PMO* Preventive Controls training for Regulatory/Rating**

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

FORM FDA 2359-MILK PLANT INSPECTION REPORT (11/15)

15c.

Food allergen control (a) _____

~~Environmental monitoring..... (b) _____~~

~~Supplier Control program (c) _____~~

Human food by-products for
use as animal food (b) _____

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

FORM FDA 2359h-INTERSTATE MILK SHIPPER'S CHECK RATING REPORT (11/15)

Add a new box with the following text:

FOOD SAFETY PLAN/PREVENTIVE CONTROLS

IS THIS MILK PLANT IN COMPLIANCE WITH THE PROVISIONS

OF APPENDIX T?

YES

NO

15c.AB (In two (2) locations.)

RESULTS OF THE 2017 NCIMS PROPOSAL JC-2

FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT (10/13)

Add a new box with the following text:

FOOD SAFETY PLAN/PREVENTIVE CONTROLS
WHEN APPLICABLE, IS THIS MILK PLANT IN COMPLIANCE
WITH THE PROVISIONS OF APPENDIX T?

YES

NO

RESULTS OF THE 2017 NCIMS PROPOSALS JC-2 and JC-4

***Note: These Proposals
shall take effect on
September 17, 2018.***

SUMMARY

Questions?