# OVERVIEW OF THE NCIMS DAIRY HACCP PROGRAM
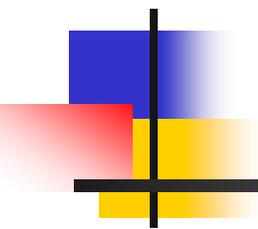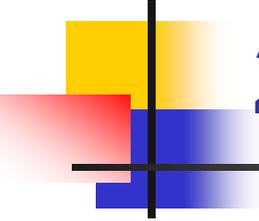
NCIMS Proposal 316 Adopted by 2003 NCIMS Conference

- Passed following four years of pilot evaluation
  - Phase I   1999-2001
  - Phase II   2001-2003

- Allows manufacturers to implement a HACCP system as an alternative to the traditional inspection system

- Milk plants, receiving stations and transfer stations permitted under the NCIMS HACCP Program <u>shall</u> meet the applicable provisions of the PMO, including Appendix K.
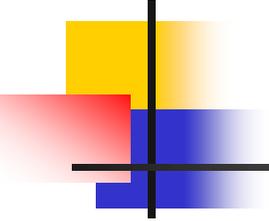
Overview of the NCIMS HACCP Program

- Proposal is accepted at 2003 NCIMS Conference

- Effective Date: January 1, 2004

- Changes per 2005 & 2007 NCIMS Conference

- Minor changes at 2009 and 2011 NCIMS Conferences
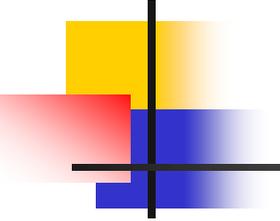
7 States Committed
13 Plants Currently Listed

- CT - Yofarm
- ME - Garelick Farms, Oakhurst
- NJ - Tropical Cheese, Farmland
- PA - Meadow Brook Dairy, Dutch Valley
    Schneider Dairy, Schneider Valley Fms
    Carl Colteryahn Dairy
- UT - Gossner Foods
- VT - St. Alban's
- WA - Safeway
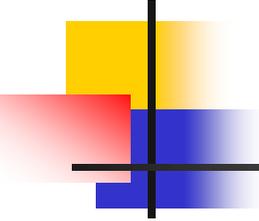
NCIMS Grade A HACCP

- HACCP System may be implemented, evaluated, monitored and enforced under the NCIMS as an <u>alternative</u> to the traditional Inspection/Rating/Check Rating System

- Utilizes current National Advisory Committee on Microbiological Criteria for Food (NACMCF) HACCP principles consistent with current FDA HACCP recommendations.
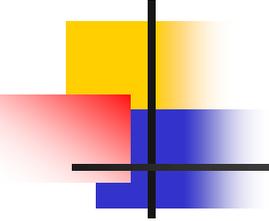
NCIMS Grade A HACCP

- Continues to assure at least the <u>same level of milk safety</u> provided by the traditional NCIMS Inspection/Rating/Check Rating System

- Continues to provide <u>uniformity and reciprocity</u> under the HACCP alternative and to the traditional Inspection/Rating/Check Rating System
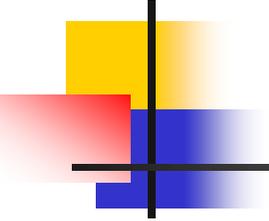
Criteria for Participation

- Voluntary

- The Regulatory Agency and the milk plant, receiving station or transfer station must agree to participate

- Both parties must provide written commitment to each other that the necessary resources to support participation in the NCIMS Voluntary HACCP Program will be made available
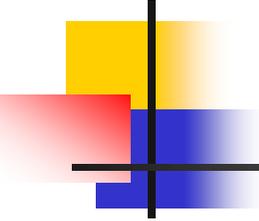
Cultural Changes Required

- Plant must provide and maintain sufficient oversight of their operations to assure product safety and compliance with NCIMS requirements on a continual basis

- Plant must maintain open communication with regulatory

- Plant and regulatory must have commitment for funding and training from top management

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Initial & Subsequent Plant Listing	May be done immediately. Frequency is a minimum of once every 2 years	First rating only after 60 days of records accumulated, thereafter, a minimum of once every 2 years.
Listing Personnel	FDA Certified State Rating Officer (SRO)	FDA HACCP Certified SRO with additional HACCP Audit Training
State Rating / Listing Audit Form	*Form FDA 2359* *Milk Plant Inspection Report*	*Form FDA 2359m* *Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report*

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Listing Pass/Fail Criteria	Passing = score of 90 or better on a rating	Passing = no violation of any ***Critical Listing Element*** (CLE's) on a rating. A CLE is one of nine essential elements that each plant must effectively address and control in its HACCP system to assure the production of safe dairy products on a daily basis. (CLE's defined on next slide)

HACCP
Critical Listing Elements (CLE's)

1. Flow Diagram and Hazard Analysis conducted & written for each kind of group of milk or milk product processed (Item 1. A.).

2. Written HACCP plan prepared for each kind or group of milk or milk product processed (Item 2. A.).

3. CL(s) are adequate to control the hazard identified (Item 4. B.).

4. Corrective action taken for products produced during a deviation from critical limits defined in the HACCP plan (Item 6. C.).

5. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP plan (Item 7. D.).

6. Information on HACCP records not falsified (Item 8. F.).

7. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing (Item 10. A.).

8. Drug residue control program implemented (Item 10. B.).

9. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to food safety (Item 12. C.).

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
State Enforcement Rating	*Form FDA 2359j - Report of Enforcement Rating Page 2 Parts II and III* Conducted as part of a rating. Enforcement score must be 90 or higher for Grade "A" products to be acceptable in NCIMS system. If score is below 90% on a rating, a re-rating must occur within six (6) months of the first rating. Both the Milk Sanitation Compliance and Enforcement Ratings must equal or exceed 90% on the re-rating or the plant is in violation (delisted).	*Form FDA 2359n - NCIMS HACCP System Regulatory Agency Review Report* Conducted as part of a HACCP rating. Completed report must be submitted to FDA RMS, who will evaluate it. In the event that FDA finds reason to doubt the safety of any State's milk or milk products that are HACCP listed, FDA shall immediately investigate and may evaluate/audit plants, RS,TS. If substantial product safety program weaknesses after **30 days** FDA shall notify affected industry & receiving States. After **180 days**, if product safety remains in doubt FDA will not accept new HACCP listings from State and FDA may audit the existing listings.

| Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Regulatory Oversight	State inspections	State audits by state employees that have completed required Core Curriculum HACCP training (basic HACCP and an orientation to the requirements of the NCIMS HACCP Program and also specialized training for HACCP system audits).
Regulatory Inspection/ Audit Frequency	Every 3 months	Initial Audit after 60 days of HACCP records generated; second audit within 30 to 45 days, then every 4 months the first year*; 6 months there after *if* no repeat violations, no CLE on last 2 audits and no product or water sample warning letters.* ** Unless the Regulatory Agency determines that a greater frequency is warranted*

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Regulatory Insp./Audit Checklist	*Form FDA 2359* *MILK PLANT INSPECTION REPORT*	*Form FDA 2359m* *MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT*
Establishing Timelines for Correction of Inspectional or Audit Items Noted by the Regulatory Inspector or Auditor	Correction is expected to avoid two (2) consecutive violations of the same inspection item unless another time frame is agreed upon by the plant and regulator. The regulator may establish written correction timelines when deemed necessary by the regulator	Determined by State Auditor after consultation with industry (except in cases of imminent health hazard). State Auditor is <u>required</u> to establish in writing, timelines for correction of all marked items (findings); done in consultation with plant management.

FORM FDA 2359 (10/06)

MILK PLANT INSPECTION REPORT

(including Dry Milk/Condensing Plants, receiving States, Transfer Stations and Milk Tank Truck Cleaning Facilities)

No.	Item	No.	Item
1.	Floors	12.	Cleaning & Sanitizing
2.	Walls & Ceilings	13.	Storage ...containers
3.	Doors & Windows	14.	Storage ... Single service
4.	Lighting & Ventilation	15.	Protection Contamination/Adulteration
5.	Separate rooms	16.	Pasteurization
6.	Toilet facilities	17.	Cooling of milk
7.	Water Supply	18.	Bottling, Packaging …
8.	Hand Washing Facility	19.	Capping, Container Closure
9.	Milk Plant Cleanliness	20.	Personnel Cleanliness
10.	Sanitary Piping	21.	Vehicles
11.	Construction & Repair	22.	Surroundings

FORM FDA 2359m (10/11)

MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT

Department of Health and Human Services Food and Drug Administration	MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT		

DATE	TYPE OF AUDIT ☐ STATE REGULATORY* ☐ STATE REGULATORY FOLLOW-UP ☐ STATE LISTING ☐ FDA AUDIT OF LISTING		

FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.

ADDRESS *(Line 1)*			

ADDRESS *(Line 2)*	CITY	STATE	ZIP CODE

IMS LISTED PRODUCT(S) MANUFACTURED AND REVIEWED	Prerequisite Program(s) Issue Date(s)

Hazard Analysis
  Issue Date(s) _____
	HACCP Plan
	  Issue Date(s) _____

1. Hazard Analysis
2. HACCP Plan
3. HACCP Plan CCPs
4. HACCP Plan Critical Limits
5. HACCP Plan Monitoring
6. HACCP Plan Corrective Actions
7. HACCP Plan Verification/Validation
8. HACCP System Records
9. HACCP System Prerequisite Programs
10. Other NCIMS Requirements
11. HACCP System Training
12. HACCP System Audit Follow-Up Action

HACCP PROGRAM CRITERIA DESCRIBED BELOW
Critical Listing Elements

station, or transfer station serves as a notification of the intent to suspend your ... e next regulatory audit or within established timelines. (Refer to PMO Sections 3

Section 6   HACCP PLAN CORRECTIVE ACTION

☐ A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred.

☐ B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected.

☐ C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.**

☐ D. Affected milk or milk product produced during the deviation segregated and held, **AND** a review to determine product acceptability performed, **AND** corrective action taken to ensure that no adulterated milk and/or milk product that is injurious to health enters commerce.

☐ E. Cause of deviation was corrected.

☐ F. Reassessment of HACCP Plan performed and modified accordingly.

☐ G. Corrective actions documented.

Section 7   HACCP PLAN VERIFICATION & VALIDATION

☐ A. HACCP plan defines verification procedures, including frequency.

☐ B. Verification activities are conducted and comply with HACCP Plan.

☐ C. Reassessment of HACCP Plan conducted annually, **OR**

  ☐ 1. After changes that could affect the hazard analysis, **OR**

  ☐ 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.

☐ D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.**

☐ E. CCP monitoring records reviewed and document that values are within CL(s) as required.

☐ F. Corrective action record reviewed as required.

☐ G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required.

☐ H. Records reviewed as required, including date and signature.

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Corrective Actions after a Critical Limit (*CL*) violation of a Critical Control Point (*CCP*)	CL/CCP Not Applicable - For violative product, correction determined by State Reg. Agency consulting with industry (*except in cases of imminent heath hazard*; e.g., not meeting pasteuriztion requirements)	Required, may be pre-establish or follow five requirements listed in Appendix K

Critical Limit: A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk or milk product safety hazard.

Critical Control Point: A step at which control can be applied and is essential to prevent or eliminate a milk or milk product safety hazard or reduce it to an acceptable level.
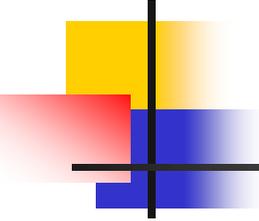
Corrective Actions – Appendix K

a. Segregate and hold the affected milk or milk product, at least until the requirements of paragraphs 2.b and 2.c of this Section are met;

b. Perform or obtain a review to determine the acceptability of the affected milk product for distribution. Review shall be performed by an individual qualified by training or experience …..;

c. Take corrective action, when necessary, with respect to the affected milk product to ensure that no product is allowed to enter commerce that is injurious to health or otherwise adulterated ….;

d. Take corrective action, when necessary, to correct the cause of the deviation; and

e. Perform a timely validation by a qualified individual(s), as required … to determine whether modification of the HACCP Plan is required to reduce risk of recurrence of the deviation; modify HACCP Plan as needed.

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Regulatory <u>Water</u> Sample Frequency	Every 6 months	Same as traditional PMO-based inspection program – Every 6 months
Regulatory Action - Water Samples	Comply with PMO: Applicable parts of Sections 3 and 6; and 7p *Administrative Procedures* 7&8	Same, plus plant must document action taken on any violative samples
Regulatory <u>Product</u> Sample Frequency	4 times in 6 months	Same as traditional PMO-based inspection program – 4 times in 6 months
Regulatory Action – Product Samples	Comply with PMO, Section 6	Same, plus plant must document action taken on any violative samples

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
FDA Responsibility	*Form FDA 2359* FDA Check Ratings reported to the rating agency - sanitation compliance rating score of 80 or higher is required to remain on the IMS list. Performed approximately every 3 years.	*Form FDA 2359m* FDA check audit reported to the rating agency - no CLE violations in order to remain on the IMS list. Performed approx. every 3 years. In the event that there is reason to doubt the safety of any State's milk or milk products that are HACCP listed, FDA shall immediately investigate the State's Milk Safety Program and may evaluate/audit the plants, receiving stations or transfer stations affected. This applies even if the HACCP listing of the milk plant, receiving station or transfer station being audited is sustained.

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
FDA Responsibility (continued)	*Form FDA 2359J Report of Enforcement Rating Page 2 parts II and III* Enforcement rating conducted as part of check rating - must score ≥ 90 Conducted approximately once every 3 years.	Form FDA 2359n *NCIMS HACCP System Regulatory Agency Review Report (**see notes below)*

**Report completed as part of FDA check audit.
Based on this report, if FDA finds there may be reason to doubt the safety of the State's milk or milk products that are NCIMS HACCP listed, FDA shall immediately investigate the State's Milk Safety Program and may evaluate/audit the plant, receiving station or transfer station affected. This applies even if the *Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report* finds that the listing of the milk plant, receiving station or transfer station is satisfactory. In the event that FDA identifies substantial milk or milk product safety program weaknesses, after **thirty (30) days** FDA shall notify the affected industry and receiving States. After the **180 days**, if milk or milk product safety remains in doubt FDA will not accept new HACCP listings from the State & FDA may audit the existing listings as necessary to protect public health.

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
FDA Responsibility (continued)	Approximately every 3 years conduct State Program Evaluations. Must be in substantial compliance as defined by FDA and the NCIMS Liaison Committee	Approximately every 3 years conduct State Program Evaluations. Must be in substantial compliance as defined by FDA, the NCIMS Liaison Committee and the NCIMS HACCP Implementation Committee.

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Pasteurization	Comply with PMO item 16p	Comply with PMO item 16p (*Pasteurization is a required CCP*)
Pasteurization Equipment Checks	Only State Regulatory may conduct official equipment checks. Allowances for State Certification of temporary industry sealers. Pasteurizer testing recorded on FDA form 2359b, *Milk Plant Equipment Testing Report* & the testing and frequency is evaluated on FDA form 2359j, *Report of Enforcement Rating Page 2 part II, Item #7* (a 15 point pro-rated debit).	State *may* authorize industry testing and sealing, but must supervise pasteurizer testing and conduct timing checks at least once each 6 months. Daily seal checks are required (a verification activity). Pasteurizer testing is recorded on FDA form 2359b, *Milk Plant Equipment Testing Report* and testing and frequency of tests is evaluated as a CLE according to the *NCIMS HACCP SYSTEM REGULATORY AUDIT REPORT check-list* under Verification (there is no pro-rating) .

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
State Personnel-Required Training	**State Inspectors** No specified NCIMS training required. State may require specific training and education for job eligibility.	State regulatory auditors shall have successfully completed training in the application of HACCP principles for milk and milk product processing and also specialized training for HACCP system audits at least equivalent to that specified under the Dairy HACCP Core Curriculum, Appendix K , PMO. State may require specific training and education for job eligibility.
	SRO's and State Sampling Surveillance Officers (SSO's) Must be trained and FDA-certified and recertified every three years as specified in the applicable NCIMS documents.	State HACCP Listing Officers shall be FDA-certified SROs <u>and</u> shall have met the requirements for initial HACCP Certification and be HACCP recertified every three years thereafter as specified in SECTION VIII of the "*Procedures*" doc.*

*"Procedures Governing the Certification of Milk Plant, Receiving Station and Transfer Station NCIMS HACCP Systems for IMS Listed Shippers" of the document, *PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS* .

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
FDA Personnel – Required Training	FDA Regional Milk Specialists must be trained and FDA Standardized and Recertified every three years as specified in the "*Methods*" Document**	FDA Regional Milk Specialists making HACCP Audits shall have met the same requirements for a State HACCP Listing Officer (see previous slide) as specified in the "*Methods*" Document**

** *METHODS OF MAKING SANITATION RATINGS* and *PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD and DRUG ADMINISTRATION PROGRAM of the NATIONAL CONFERENCE on INTERSTATE MILK SHIPMENTS*

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Industry Personnel - Required Training	None specified. Results of training are evaluated indirectly in the inspection and rating process.	Formal HACCP training (standardized *Dairy HACCP Core Curriculum* including basic HACCP training and an orientation to the requirements of the NCIMS HACCP program) is *recommended* for those developing PPs; developing the hazard analysis, including delineating control measures; developing, validating and modifying the HACCP Plan; and performing required HACCP Plan records reviews. Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Required Records	Raw milk source, raw milk receiving wash tags, product storage temperature records, pasteurization recording charts, pasteurization equipment check records, records for Appendix N compliance, processing CIP/ equipment cleaning records, water and product sampling results.	In addition to records to left, written HACCP documents are required: • HACCP Program Table of Contents, • Prerequisite Program • Flow Diagram(s) & Hazard Analysis; • HACCP Plan & Corrective Actions, • Central Deviation Log • Annual Verification & Validation exercises; • Verification of CCP Monitoring Records, • HACCP Records Summary Table • Plus other records documenting implementation of the HACCP program.

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Required Records (continued)		Additional plant records are required to document compliance with the "Other provisions of the PMO." These include:
		• Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing. • Drug residue control program implemented. • Drug residue control program records complete. • Labeling compliance as required. • Prevention of adulteration of milk products. • Regulatory samples comply with standards. • Pasteurization equipment design and construction. • Approved laboratory utilized

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Records Retention	The records identified above shall be readily available upon request for the time specified in the PMO, "*Methods*" or "*Procedures*" documents. The regulatory agency shall maintain their records at least back to the last Rating.	All HACCP records must be available within 24 hours of request if stored off-site. Records must be retained : - 1 yr after date product was prepared or - 2 yrs for shelf stable/preserved products, unless a longer time is required by other regulations. Records that relate to the adequacy of equipment or processes used shall be retained for at least 2 years. The **regulatory agency** shall maintain their records at least back to the last HACCP listing audit.

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Written Prerequisite Program (PP)	None, although the PMO Section 7 has requirements in all 8 required prerequisite programs under HACCP.	Eight (8) Mandatory PP's (*see list on next slide*)
Employee Health PP	Comply with PMO, Section 13 & 14	Required Prerequisite Program (one of required 8) Use PMO section 13 & 14 as guideline (*the elements of 13 & 14 to be included*)

Mandatory Prerequisite Programs

1. Safety of the water that comes into contact with milk or milk products or product-contact surfaces, including steam and ice;
2. Condition and cleanliness of equipment product-contact surface;
3. Prevention of cross-contamination from insanitary objects and/or practices to milk or milk products or product-contact surfaces, packaging material and other food-contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
4. Maintenance of hand-washing, hand-sanitizing, and toilet facilities;
5. Protection of milk or milk product, packaging material, and product-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate & other chemical, physical & biological contaminants;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions, including employee exposure to high risk situations, that could result in the microbiological contamination of milk or milk products, packaging materials, and product-contact surfaces; and
8. Pest exclusion from the milk plant.

Others are required if they are "being relied upon in the Hazard Analysis to reduce the likelihood of hazards such that they are not reasonably likely to occur"

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Product flow diagrams	None Required	Required for each Grade "A" product (*similar products may share flow diagrams*)
Written Hazard Analysis	None Required Effective and proven requirements common to all plants assure the safety of dairy products.	Written Hazard Analysis Required. Evaluates and determines likelihood of occurrence of hazards for consideration in the HACCP Plan. Effectively control each hazard specific to the product and plant to assure dairy product safety.
Central Deviation Log	None	Required (*a centralized record of all documented deviations of critical limits at all critical control points*)

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Verification - industry responsibility	Routine state inspections serve as verification of compliance with NCIMS requirements .	Required annual reassessment of HACCP Plan documented by plant personnel; CCP record review verification "*shall occur at a frequency appropriate to the records importance ..as specified in Plan*"; * Corrective action record review "*at a frequency that is appropriate to the importance of the record ….*"; * Required calibration of CCP monitoring instruments (e.g., past. equip. testing) and records reviewed (opt. end-prod testing)

Pasteurized Milk Ordinance Inspection - HACCP Audit Comparison

Requirement	PMO *Inspection Based Milk Safety Program*	PMO *HACCP Audit Based Milk Safety Program*
Validation - industry responsibility	Routine state inspections serve as validation of compliance with NCIMS requirements that the plant is capable of producing safe product.	Annual validation of HACCP Plan/Hazard Analyses required and documented by HACCP plant personnel. May be more frequent based on other triggers.*

* Reassessment of the HACCP Plan/HA is required if there are changes that could affect the hazard analyses and/or after significant changes in operation including raw materials and/or source, product formulation, processing methods/systems, distribution, intended use or consumer.
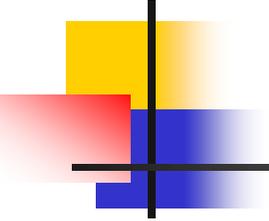
Cultural Changes Required

- Regulators must audit plant HACCP systems rather than inspect.

- Regulators must note and analyze observations made during an audit to determine if they justify a "finding."

- HACCP system shortcomings/failures (findings) must be documented on audit report and timeline for corrections shall be established (for regulatory audits).
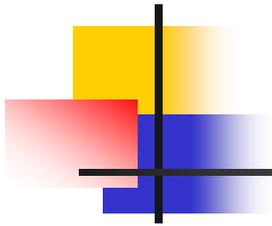
Technical Resource Team

Answer questions from industry, states or FDA on interpretation of NCIMS HACCP Program Requirements

FDA   Steve Sims, Milk Safety Branch
               Steve Pierson, FDA Regional Milk Specialist

Academia   Steve Murphy, Cornell University

State   Alan Talarsky, NJ Public Health   Jim Allyn, CY Dept. of Ag.
               Greg Lockwood, VT Ag, Food, & Markets
               Cody Huft, UT Agriculture

Industry   Jason Crafts, Gossner (HIC Chair)   Dave Jelle, Foremost Farms
               Rebecca Piston, HP Hood   Emil Nashed, Farmland
               Bob Hagberg, Land O' Lakes
               Allen Sayler, Center for Food Safety & Regulatory Solutions.

HACCP Information

http://www.fda.gov/Food/FoodSafety/default.htm

http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm

http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/DairyGradeAVoluntaryHACCP/default.htm
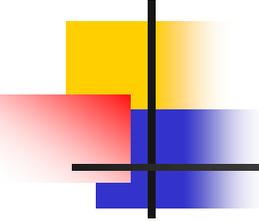
- NCIMS HACCP Forms for Industry

- Regulatory HACCP forms
  - HACCP Audit Form – FD 2359m
  - HACCP Regulatory Agency Review Report FD 2359n
  - Permission to Publish FD 2359o

- NCIMS HACCP Commitment Letter (example)

- References, Program Documents, Technical Q & A's

- Hazard Guide
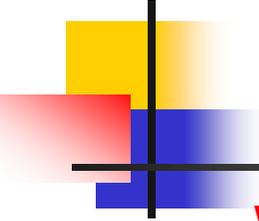
HACCP Information

www.ncims.org

- HACCP Implementation Committee List
- Hazard Guide
- Hyperlinks to FDA Website for other HACCP documents, e.g. forms
- NCIMS HACCP Overview Presentation
- NCIMS HACCP Comparison Table
- NCIMS HACCP Transition Checklist
- MI - 074 (Technical Questions & Answers)
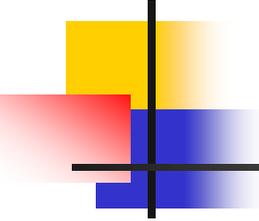
Summary

The NCIMS Voluntary HACCP System:

- May be implemented, evaluated, monitored and enforced under the NCIMS as an alternative to the traditional Inspection/Rating/Check Rating System

- Utilizes current National Advisory Committee on Microbiological Criteria for Food (NACMCF) HACCP principles consistent with current FDA HACCP recommendations.
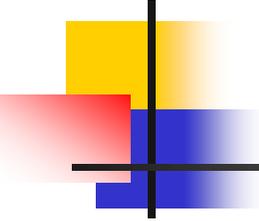
Summary

The NCIMS Voluntary HACCP System:

- Continues to assure at least the same level of milk safety provided by the traditional NCIMS Inspection/Rating/Check Rating System

- Continues to provide uniformity and reciprocity to the traditional Inspection/Rating/Check Rating System