

Lions! Tigers! Forms! M-I!

National Conference on Interstate Milk Shipments April 4, 2023

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Office of Food Safety
U.S. FDA-Center for Food Safety and Applied Nutrition

Dairy Cooperative Program Forms

- The Grade "A" Program uses over 65 forms.
- Forms that FDA uses are required to comply with the Paperwork Reduction Act (PRA).

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FORM FDA 2359d (11/15)															
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Paperwork Reduction Act (PRA)

- PRA involves a formal process by which the federal government reviews, clears and issues surveys or forms.
- FDA Forms used the Grade "A" program must go through that process.

FORM FDA 2359i (10/18) FRONT

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FORM FDA/NCIMS 2400 (5/20)

- Group #1: Outside of the scope of PRA
- Transition from FDA Forms to NCIMS Forms
- Edit to reflect these are NCIMS Forms (headers, names)
- Update Conference documents
- Move forms from FDA.gov to NCIMS.org

Department of Health and Human Services Public Health Service Food and Drug Administration

MII

NAME AND LOCATION OF PLANT



1. FLOORS:	Approved sanitization process applied prior to use of	Flow promoting devices comply with Ordinance
Smooth; impervious; no pools; good repair; trapped drains (a)	product-contact surfaces	requirements
2. WALLS AND CEILINGS:	Required efficiency tests in compliance (d) Multi-use plastic containers in compliance (e)	Product held minimum pasteurization time and
Smooth; washable; light-colored; good repair	12. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT:	temperature
All outer openings effectively protected against entry of flies	Stored to assure drainage and protected from contamination (a)	(3) ADULTERATION CONTROLS:
and rodents(a)	14. STORAGE OF SINGLE-SERVICE ARTICLES:	Satisfactory means to prevent adulteration with added water
Outer doors self-closing; screen doors open outward (b)	Received, stored and handled in a sanitary manner;	16C. RECENERATIVE HEATING:
4. LIGHTING AND VENTILATION:	paperboard containers not reused, except as permitted by the Ordinance (a)	Pasteurized product in regenerator automatically under great
Adequate light in all rooms	15A. PROTECTION FROM CONTAMINATION:	pressure than raw product in regenerator at all times
air with pressure systems(b)	Operations conducted and located so as to preclude	Accurate pressure gauges installed as required; booster pur
5. SEPARATE ROOMS:	contamination of milk, milk products, ingredients,	properly identified, when required, and installed
Separate rooms as required; adequate size	containers, equipment, and utersils	Regenerator pressures meet Ordinance requirements
No direct opening to barn or living quarters (b) Storage tanks properly vented (c)	Air and steam used to process products in compliance with Ordinance (b)	16D, RECORDING CHARTS:
6. TOILET FACILITIES:	Approved pesticides, safely used (c)	Batch pasteurizer charts comply with applicable Ordinance
Complies with local Ordinances	15B. CROSS CONNECTIONS:	requirements
No direct opening to processing rooms; self-closing	No direct connections between pasteurized and raw milk or	HTST and HHST pasteurizer charts comply with applicable Ordinance requirements
doors(b)	milk products	17. COOLING OF MILK AND MILK PRODUCTS:
Clean; well-lighted and ventilated; proper facilities	Overflow, spilled and leaked products or ingredients discarded(b)	Raw milk maintained at 45°F (7°C) or less until processed or
Sewage and other liquid wastes disposed of in sanitary manner (d)	No direct connections between milk or milk products and	provided for in the Ordinance
7. WATER SUPPLY:	cleaning and/or sanitizing solutions	Pasteurized milk and milk products, except those to be
Constructed and operated in accordance with Ordinance (a)	15C. FSMA RELATED	oultured, or as provided for in the Ordinance, cooled
No direct or indirect connection between safe and unsafe	Food allergen control	immediately to 45°F (7°C) or less in approved equipment; all milk and milk products stored thereat until delivered
water (b)	Human food by-products for use as animal food(b)	Approved thermometer properly located in all refrigeration
Condensing water and vacuum water in compliance with Ordinance requirements	16A. PASTEURIZATION-BATCH:	rooms and storage tanks as required
Reclaim water complies with Ordinance	(1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance specifications	Recirculated cooling water from a safe source and properly
Complies with bacteriological standards(e)	(2) TIME AND TEMPERATURE CONTROLS:	protected; complies with bacteriological standards
8. HÄNDWASHING FACILITIES:	Adequate agitation throughout holding; agitator sufficiently	18. BOTTLING, PACKAGING AND CONTAINER FILLING:
Located and equipped as required; clean and in good repair;	submerged(a)	Performed in a plant where contents finally pasteurized, except for dry milk and whey products
improper facilities not used	Each pasteurizer equipped with indicating and recording	Performed in a sanitary manner by approved mechanical
9. MILK PLANT CLEANLINESS: Nest: clean: no evidence of insects or rodents: trash properly	thermometer; bulb submerged	equipment
handled(a)	Recording thermometer reads no higher than indicating thermometer (c)	Dry milk and whey products packaged in new containers;
No unnecessary equipment(b)	Product held minimum pasteurization temperature	stored and transported in a sanitary manner 19. CAPPING, CONTAINER CLOSURE AND SEALING:
No excessive product dust(c)	continuously for 30 minutes, plus filling time if product	Capping and/or closing/sealing performed in a sanitary
10. SANITARY PIPING: Smooth: impervious. corrosion-resistant. non-toxic. easily clean-	preheated before entering vat, plus emptying time, if cooling is begun after opening outlet	manner by approved mechanical equipment
able materials; good repair; accessible for inspection (a)		Imperfectly capped/closed products properly handled
CIP cleaned lines meet Ordinance specifications	No product added after holding begun	Caps and/or closures comply with Ordinance
Pasteurized products conducted in sanitary piping, except as	higher than minimum required pasteurization temperature	20. PERSONNEL CLEANLINESS:
permitted by Ordinance(c)	during holding(f)	Hands thoroughly washed before performing plant functions rewashed when contaminated
11. CONSTRUCTION AND REPAIR OF CONTAINERS AND FOUIPMENT:	Approved airspace thermometer; bulb not less than 1 inch	Clean outer garments and hair covering worn
Smooth, impervious, corrosion-resistant, non-toxic, easily	(25 mm) above product level	No use of tobacco in processing areas
cleanable materials; good repair; accessible for	Ordinance	Clean boot covers, caps and coveralls worn when entering
inspection(a)	16B. PASTEURIZATION-HIGH TEMPERATURE:	dryer
Self-draining: strainers and sifters of approved design(b) Approved simile-service articles: not reused	(1) INDICATING AND RECORDING THERMOMETERS:	21. VEHICLES: Vehicles clean; constructed to protect milk
Approved single-service articles; not reused	Comply with Ordinance specifications	Vehicles clean; constructed to protect milk
EQUIPMENT:	(2) TIME AND TEMPERATURE CONTROLS: Flow-diversion device complies with Ordinance	22. SURROUNDINGS:
Containers, utensils, and equipment effectively cleaned (a)	requirements (a)	Neat and clean; free of pooled water, harborages, and
CIP cleaning requirements of Ordinance in compliance;	Recorder controller complies with Ordinance	breeding areas
records complete; milk tank trucks cleaned at permitted location	requirements(b)	Tank unloading areas properly constructed
	Holding tube complies with Ordinance requirements (c)	- The state of the
REMARKS		

by the PMO, these Items shall be Inspecte. 22. Separation required that the required to the property of the pr

NOTE: Item numbers correspond to required

PSC Publishing Services (301) 443-6740 EF

- Group #2: Will remain FDA Forms
- FORM FDA 2359i
 FORM FDA 2359d
- FDA will submit these forms to go through the PRA process
- FDA Forms will be available on fda.gov

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SDA TPC	7.c. SANITATION COMPLIANCE RATING					20		product 7. Contain	ners, closures		Rubber			1							
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					FORM	M FDA :	2359i (10/18) FRO	NT	(PREVIOU	S EDITI	ONS ARE O	OBSOLETE)						PSC Publishing	Services (301) 443-	5-6740 EF

- Group #2: Will remain FDA Forms
- FORM FDA 2359i
 FORM FDA 2359d

Form Approved: OMB No. 0910-0021 Expiration Date: May 31, 2022

See Burden Statement on back of Part III.

DEPARTMENT OF HEALTH AND HUMAN SERVICES	(Check Op	Form Approved: OMB No. 0910-0021
FOOD AND DRUG ADMINISTRATION	Certification Change	Expiration Date: May 31, 2022
(See Reverse of Part III for Instructions)	Cancellation Renewal	See Burden Statement on back of Part III.
SECTION I - COMPLE	TED BY STATE SHELLFISH CONTINUE	UTHORITY
SHELLFISH DEALER / SHIPPER (Name)	2. CEI	RTIFICATION
	a) CERTIFICATE NUMBER	b) DATE CERTIFIED
FACILITY ADDRESS (Include Street No., City, State, & ZIP)		
	c) STATE	d) EXPIRATION DATE
MAILING ADDRESS (If different than above)	e) CATEGORY SYMBOL	
	DP - Depuration RP	- Repacker RS - Reshipper
TELEPHONE	SP - Shucker-Packer SS	- Shell Stock Shipper PHP - Post Harvest
()	AQ - Aquaculture WS	- Wet Storage
A DATE OF ON OUTS INCOPPORTION		-
DATE OF ON-SITE INSPECTION 4. STATE SHE Name)	ELFISH STANDARDIZATION INSPECTOR (P.	Print 5. EXPIRATION DATE OF INSPECTOR'S STANDARDIZATION
6. CANCELLATION DATE 7. REASON FO	OR CANCELLATION (Check One)	
	Decertification	Out of Business
		out or business

This section applies only to requirements of the Paperwork Reduction Act of 1995.

Public reporting burden for this collection of information is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Operations PRAStaff@fda.hhs.gov Do NOT send your completed form to the PRA Staff email address to the left.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

- Group #2: Will remain FDA Forms
- FORM FDA 2359i
 FORM FDA 2359d
- FDA will submit these forms to go through the PRA process
- FDA Forms will be available on fda.gov

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- The NCIMS Executive Board has agreed that Form names can be updated as an editorial change by FDA – on the Forms and in Conference documents.
- Changes to the content or use of a Form will require a Conference proposal.
 - See Proposal #309.

DEPARTMENT OF HEAD			ES	INTE) u	bmit an	LK SHI original i	and two	(2)	ORT	3-A	COUNTRY	
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1 Submit separate Form for each	milk plant.								_				
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Take Home Message: Forms

- The names of the majority of Forms in the Grade "A" Program will be changing.
 - With the exception of Form FDA 2359i and Form FDA 2359d
- After 2023, all Grade "A" Program
 Forms will comply with PRA, with
 minimal impact on the
 Conference.

DEPARTMENT OF HEAL			ES	IN				LK SHI				ORT			A O	OUN	TRY	
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	REPORT OF CERTIFICATION FOR FDA USE ONLY KNDON (Fabrication of Single-Service Containers and/or 1 2 3 4																		
DEPARTMENT OF HEALTH AND HUMAN FOOD AND DRUG ADMINISTRAT	DERVICES TON									lor -	1	Ŧ	2	-	3	4	5		
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Memoranda in the Grade "A" Program

- IMS-a: Memorandum of Conference Actions
- M-a: Memorandum of Interpretation
- M-b: Memorandum of Milk Ordinance Equipment Compliance
- M-I: Memorandum of Information

(NCIMS Procedures, page 5)

PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

2019 Revision

Includes the

- CONSTITUTION AND BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
- MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
- RELATED DOCUMENTS



U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
AND THE
NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

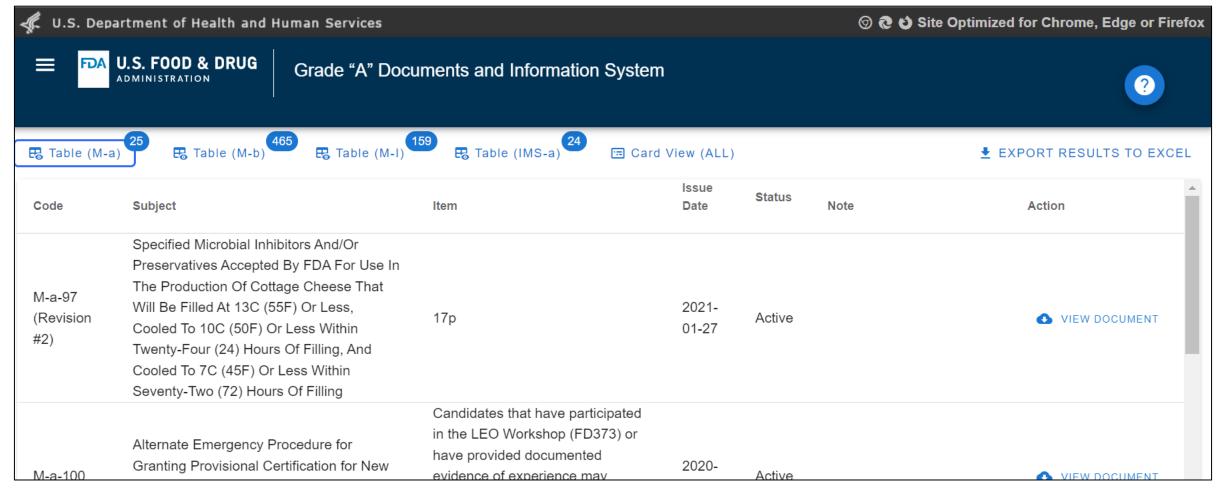
Memoranda in the Grade "A" Program

Memorandum	Definition
IMS-a Memorandum of Conference Actions	Provides the transmittal of information related to actions taken at the NCIMS Conferences
M-a Memorandum of Interpretation	Provides clarification of the intent or meaning of wording related to the PMO or EML
M-b Memorandum of Milk Ordinance Equipment Compliance	Provides notice of FDA's review of equipment related to compliance with the PMO
M-I Memorandum of Information	Provides the transmittal of administrative and miscellaneous information



Grade "A" Milk Search (GAMS)

https://gams.fda.gov/



Memorandum of Information (M-I)

- M-I: Provides the transmittal of administrative and miscellaneous information
 - Do not create program requirements
 - Do not convey agency interpretation
- M-a: Provides clarification of the intent or meaning of wording related to the PMO or EML

HHS:PHS:FDA:CFSAN:OFS:DDEMPS:MMPB

5001 Campus Drive College Park, MD 20740-3835

M-I-20-3

March 11, 2020

Director, Office of State Cooperative Programs

Attn: All Staff, Division of Milk Safety

Milk and Milk Products Branch (HFS-316)

SUBJECT: Answers to Questions Received From The Field: Regional Milk

Seminars; And FDA Training Courses Held During Fiscal Year 2017

Following are answers to questions received from the field; Milk Seminars; and FDA training courses (Special Problems in Milk Protection, Milk Plant Sanitation and Inspection, Milk Pasteurization Controls and Tests, and Dairy Farm Sanitation and Inspection) held during fiscal year 2017.

In accordance with procedures established through the National Conference on Interstate Milk Shipments (NCIMS), if an answer to these questions results in a new understanding of a long-standing situation or installation, and the condition as it exists does not present an immediate public health hazard, reasonable judgment should be exercised and adequate time provided for modification and correction.

An electronic version of this memorandum is available for distribution to Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and also will be available on the FDA Web Site at http://www.fda.gov at a later date

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to monica.metz@fda.hhs.gov.

Mania Met

Monica Metz **Branch Chief** Milk and Milk Products Branch

M-I-20-3 March 20 2020



Groupings of M-Is

Meet the M-I Definition

Related to a Conference Proposal

Do not meet the M-I Definition

Group 1: Meet the M-I Definition

- These documents will remain in GAMS, without change
- Examples:
 - M-I-20-3: 2019 PMO is available
 - M-I-20-5: Drug residue test kit review/acceptance
 - M-I-16-9: Change of CFSAN mailing address
 - M-I-16-17: Aseptic sampling protocol

HHS:PHS:FDA:CFSAN:OFS:DDEMPS:MMPB

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M-I-20-3

March 11, 2020

TO: Director, Office of State Cooperative Programs

Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

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Monia Met

Monica Metz Branch Chief Milk and Milk Products Branch

M-I-20-3 1 March 20, 2020



Group 2: Related to a Conference Proposal

- These documents contain information that was submitted as a current or previous Conference.
- These documents will have a "pop-up box" in GAMS, and will sunset in October 2023.

Previous Conference Proposals	Current Conference Proposals
M-I-18-11: 2019 NCIMS (Conditional certification for lab method)	M-I-06-5: Proposal #108 (Drug use)
M-I-16-16: 2017 NCIMS (Vit D fortification)	M-I-12-15: Proposal #203 (Definition JJ)
M-I-12-11: 2013 NCIMS (Drug storage)	M-I-03-12: Proposal #306 (SPE process)
	M-I-17-2: Proposal #214 (App N flowchart)

Group 3: Do not meet the M-I Definition

- Do not contain "administrative or miscellaneous information"
- These documents will have a "pop-up box" in GAMS, and will sunset in October 2025.
- Examples:
 - M-I-13-3: Testing and resealing following broken seal notification
 - M-I-03-14: Standard of Identity and Labeling Q&A
 - M-I-20-3: Q&A from FY 2017

HHS:PHS:FDA:CFSAN:OFS:DDEMPS:MMPB

5001 Campus Drive College Park, MD 20740-3835

M-I-20-3

March 11, 2020

TO: Director, Office of State Cooperative Programs

Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Answers to Questions Received From The Field; Regional Milk

Seminars; And FDA Training Courses Held During Fiscal Year 2017

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Group 3: Do not meet the M-I Definition

- M-Is cannot create program requirements
- These documents will have a "pop-up box" in GAMS, and will sunset in October 2025.
- Examples:
 - M-I-15-3, Question #9: Process when a change of ownership occurs
 - M-I-12-9, Question #12: Electronic records requirements
 - M-I-10-6, Question #29: Applying air pressure to move potable water in a delivery system and a debit under 8r

29. PMO-Section 7, Items 8r

On non-electric dairy farms (Amish), air is being injected directly into the well for the pressurization of their water system.

a) Is the air supply required to be free of oil, dust rust, excessive moisture, extraneous materials and odors?

Yes.

b) Does this mean that they are required to have a properly installed and maintained final filter in the air line as close as possible to the point of application?

Yes.

c) If a) or b) above is not being complied with, would either one of these or both of these be considered a violation of Item 8r-Water Supply or Item 14r-Protection from Contamination of the PMO?

Both would be considered a violation of Item 8r (2 point debit).



Future Steps for M-Is

Meet the M-I Definition

• Remain unaffected, no change

Related to a Conference Proposal

- "Pop-up" box will be added
- M-Is will sunset in October 2023

Do not meet the M-I Definition

- "Pop-up" box will be added
- M-Is will sunset in October 2025





- FDA will provide direct responses, not publish compilations
- FDA responses will not include interpretations
- Potential means for sharing information:
 - Proposal at Conference
 - Modification to a training course
 - Guidance document
 - Rulemaking process
 - FDA FAQ Page for the Grade "A" Program
 - M-Is



Take Home Message: M-Is

- We are beginning a multi-year process to align with Conference expectations for FDA communications
- M-Is are <u>not</u> enforceable.
- There are options for answering questions, sharing information.
- We need your help!Explore GAMS (https://gams.fda.gov/)



