



# Lions! Tigers! Forms! M-I!

National Conference on Interstate Milk Shipments  
April 4, 2023

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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).

Department of Health and Human Services Public Health Service Food and Drug Administration		MILK PLANT INSPECTION REPORT (Includes Dry Milk/Condensing Plants, Receiving Stations, Transfer Stations, and Milk Tank Truck Cleaners)		INSPECTING AGENCY	
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			MILK PLANT EQUIPMENT TEST REPORT		
TEST NO.	TEST	TEST FREQUENCY	TESTED (X or NA)	RESULTS OF TEST (See Reverse for Working Notes)	
1.	Indicating Thermometers (including air space): Temperature Accuracy	3 months			
2.	Recording Thermometers: Temperature Accuracy	3 months			
3.	Recording Thermometers: Time Accuracy	3 months			
4.	Records				
5.	Flow				

**CULTURAL PROCEDURES-GENERAL REQUIREMENTS**  
FDA/NCIMS Revision 10/19  
[Unless otherwise stated all tolerances are ±5%]  
**APPARATUS & MATERIALS**

**1. Work Area**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT (Submit an original and two (2) copies to the FDA Regional Office)		3-A. COUNTRY	
1. NAME OF SHIPPER		2. CITY		3. STATE	
4. STREET		5. PLANT or BTU #		6. PRODUCT CODE #	
7. SURVEY DATA					
PRODUCT	DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT 1	ENFORCEMENT	
RATING (%)					
DATE OF RATING					
TOTAL NUMBER					
NUMBER INSPECTED					
VOLUME RECEIVED DAILY (CWT)					
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <input type="checkbox"/> YES <input type="checkbox"/> NO			FSR/PCS WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? <input type="checkbox"/> YES <input type="checkbox"/> NO		
RATING AGENCY <input type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER	CERTIFIED RATING OFFICER	OFFICER'S CERTIFICATION EXPIRATION DATE	EARLIEST RATING DATE MONTH DAY YEAR		
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY			EXPIRATION RATING DATE? MONTH DAY YEAR		
8. LABORATORY CONTROL					
APPROVED LABORATORY NUMBER	EXPIRATION DATE	PROCESSED MILK TESTS APPROVED		RAW MILK TESTS APPROVED	
A. _____	A. _____	SPC	COLI	PHOS	RBC
B. _____	B. _____	A. _____	A. _____	A. _____	A. _____
		B. _____	B. _____	B. _____	B. _____
DATE OF LAST TWO (2) SPLIT SAMPLES A. _____ B. _____		APPROVED WATER LABORATORY AND DATE		WATER TESTS APPROVED	
9. PUBLICATION (Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of rating/listing.)					
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input type="checkbox"/> YES <input type="checkbox"/> NO					
10. SUBMISSION OF REPORT BY RATING AGENCY					
DATE OF REPORT	SUBMITTED BY (Signature)				Title

FORM FDA 2359d (11/15)

<sup>1</sup> Submit separate Form for each milk plant.  
<sup>2</sup> The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 9/30/2015, except if the Enforcement Rating is -50, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 3/31/2014.

# 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT <i>(Submit an original and two (2) copies to the FDA Regional Office)</i>		3-A. COUNTRY	
1. NAME OF SHIPPER		2. CITY		3. STATE	
4. STREET		5. PLANT or BTU #		6. PRODUCT CODE #s	
7. SURVEY DATA					
PRODUCT	DAIRY FARMS		RECEIVING OR TRANSFER STATION	MILK PLANT <sup>1</sup>	ENFORCEMENT
	TYPE OF RATING <input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL				
RATING (%)					
DATE OF RATING					
TOTAL NUMBER					
NUMBER INSPECTED					
VOLUME RECEIVED DAILY (Cwt)					
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <input type="checkbox"/> YES <input type="checkbox"/> NO					
RATING AGENCY <input type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER		CERTIFIED RATING OFFICER			
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY					
8. LAB					
APPROVED LABORATORY NUMBER		EXPIRATION DATE		SPC	
A. _____		A. _____		A. _____	
B. _____		B. _____		B. _____	
DATE OF LAST TWO (2) SPLIT SAMPLES		APPROVED			
A. _____		A. _____			
B. _____		B. _____			
9. PUBLICATION <i>(Written permission from a shipper shall be obtained. A letter of permission to publish is transmitted with this form.)</i>					
10. SUBMISSION					
DATE OF REPORT		SUBMITTED BY (Signature)			
_____		_____			
<sup>1</sup> Submit separate Form for each milk plant. <sup>2</sup> The expiration rating date is two (2) years after the earliest rating date. I.e., early Enforcement Dates (EED) have the expiration rating date is six (6) months after the EED.					

FORM FDA 2359i (10/18) FRONT

FORM FDA 2359i (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)

## CULTURAL PROCEDURES-GENERAL REQUIREMENTS

FDA/NCIMS Revision 10/19

[Unless otherwise stated all tolerances are ±5%]

### APPARATUS & MATERIALS

#### 1. Work Area

- Level table or bench, ample working space and utilities
- Clean, well ventilated, temperature 16-27°C reasonably free from dust and drafts
- Well-lighted, > 50 foot-candles at working surface (pref. 100)
- Microbic density of air ≤ 15 colonies/SPC or RAC plate, ≤ 10 colonies/PAC plate or ≤ 5 colonies/PPAC plate in 15 min exposure; if not, corrective actions taken (for plating procedures only)
- Freedom from congestion and traffic; only compatible laboratory functions performed
- Safe working environment – Refer to OSHA
  - Eating and drinking not permitted in laboratory
  - Food and drinks for consumption not stored in laboratory
  - Analyst wear buttoned/snapped lab coats/uniforms and protective eye-wear, lab coats/uniforms remain on-site
  - Safety equipment available
  - Current Safety Data Sheets (SDS) accessible to analysts
  - Has functioning fume hood with acceptable sash (if necessary, see DMSCC procedure)
  - Flammable solvent areas continuously well ventilated and temperature controlled
  - Proper disposal of potentially hazardous materials
    - Contaminated samples disposed of properly
    - Contaminated glassware or plasticware disposed of or decontaminated properly
    - Hazardous material disposed of properly


FORM FDA/NCIMS 2400 (5/20)

FORM FDA/NCIMS 2400 (5/20)

# Future Steps for Forms

- **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



INSPECTING AGENCY

DATE: \_\_\_\_\_

DAILY Milk \_\_\_\_\_

Other Milk Products \_\_\_\_\_

Total \_\_\_\_\_

Permit No. \_\_\_\_\_

NAME AND LOCATION OF PLANT \_\_\_\_\_

Inspection of your plant today involves evaluation according to the terms indicated below. You are further notified that this inspection report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)

<p><b>1. FLOORS:</b> Smooth, impervious; no potholes; good repair; trapped drains _____ (a) _____</p> <p><b>2. WALLS AND CEILINGS:</b> Smooth; washable; light-colored; good repair _____ (a) _____</p> <p><b>3. DOORS AND WINDOWS:</b> All outer openings effectively protected against entry of flies and rodents _____ (a) _____ Outer doors self-closing; screen doors open outward _____ (b) _____ Adequate light in all rooms _____ (a) _____ Well ventilated to preclude odors and condensation; filtered air with pressure systems _____ (b) _____</p> <p><b>4. LIGHTING AND VENTILATION:</b> Adequate light in all rooms _____ (a) _____ Well ventilated to preclude odors and condensation; filtered air with pressure systems _____ (b) _____</p> <p><b>5. SEPARATE ROOMS:</b> Separate rooms as required; adequate size _____ (a) _____ No direct opening to barn or living quarters _____ (b) _____ Storage tanks properly vented _____ (c) _____</p> <p><b>6. TOILET FACILITIES:</b> Complies with local Ordinances _____ (a) _____ No direct opening to processing rooms; self-closing doors _____ (b) _____ Clean; well-lighted and ventilated; proper facilities _____ (c) _____ Sewage and other liquid wastes disposed of in sanitary manner _____ (d) _____</p> <p><b>7. WATER SUPPLY:</b> Constructed and operated in accordance with Ordinance _____ (a) _____ No direct or indirect connection between safe and unsafe water _____ (b) _____ Confessing water and vacuum water in compliance with Ordinance requirements _____ (c) _____ Reclean water complies with Ordinance _____ (d) _____ Complies with bacteriological standards _____ (e) _____</p> <p><b>8. HANDWASHING FACILITIES:</b> Located and equipped as required; clean and in good repair; improper facilities not used _____ (a) _____</p> <p><b>9. MILK PLANT CLEANLINESS:</b> Neat; clean; no evidence of insects or rodents; trash properly handled _____ (a) _____ No unnecessary equipment _____ (b) _____ No excessive product dust _____ (c) _____</p> <p><b>10. SANITARY PIPING:</b> Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection _____ (a) _____ CIP cleaned lines meet Ordinance specifications _____ (b) _____ Pasteurized products conducted in sanitary piping, except as permitted by Ordinance _____ (c) _____</p> <p><b>11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT:</b> Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection _____ (a) _____ Self-draining; strainers and sifters of approved design _____ (b) _____ Approved single-neck articles; not reused _____ (c) _____</p> <p><b>12. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT:</b> Containers, utensils, and equipment effectively cleaned _____ (a) _____ CIP cleaning requirements of Ordinance in compliance; records complete; milk tank trucks cleaned at permitted location _____ (b) _____</p>	<p>Approved sanitation process applied prior to use of product-contact surfaces _____ (a) _____ Required efficiency tests in compliance _____ (b) _____ Multi-use plastic containers in compliance _____ (c) _____</p> <p><b>13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT:</b> Stored to ensure drainage and protected from contamination _____ (a) _____</p> <p><b>14. STORAGE OF SINGLE-SERVE ARTICLES:</b> Received, stored and handled in a sanitary manner; paperboard containers not reused, except as permitted by the Ordinance _____ (a) _____</p> <p><b>15A. PROTECTION FROM CONTAMINATION:</b> Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils _____ (a) _____ Air and steam used to process products in compliance with Ordinance _____ (b) _____ Approved pesticides, safely used _____ (c) _____</p> <p><b>15B. CROSS CONNECTIONS:</b> No direct connections between pasteurized and raw milk or milk products _____ (a) _____ Overflow, spilled and leaked products or ingredients discarded _____ (b) _____ No direct connections between milk and milk products and cleaning and/or sanitizing solutions _____ (c) _____</p> <p><b>15C. FSMA RELATED</b> Food allergen control _____ (a) _____ Harmful food by-products for use as animal food _____ (b) _____</p> <p><b>15A. PASTEURIZATION-BATCH:</b> (1) INDICATING AND RECORDING THERMOMETERS: _____ (a) _____ (2) TIME AND TEMPERATURE CONTROLS: _____ (b) _____ Adequate agitation throughout holding; agitator sufficiently submerged _____ (c) _____ Each pasteurizer equipped with indicating and recording thermometer; bulbs submerged _____ (d) _____ Recording thermometer reads no higher than indicating thermometer _____ (e) _____ Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet _____ (f) _____ No product added after holding began _____ (g) _____ Airspace above product maintained at not less than 5°F (2°C) higher than minimum required pasteurization temperature during holding _____ (h) _____ Approved alginate thermometer; bulb not less than 1 inch (25 mm) above product level _____ (i) _____ Inlet and outlet valves and connections in compliance with Ordinance _____ (j) _____</p> <p><b>15B. PASTEURIZATION-HIGH TEMPERATURE:</b> (1) INDICATING AND RECORDING THERMOMETERS: _____ (a) _____ (2) TIME AND TEMPERATURE CONTROLS: _____ (b) _____ Flow-diversion device complies with Ordinance requirements _____ (c) _____ Recorder controller complies with Ordinance requirements _____ (d) _____ Holding tube complies with Ordinance requirements _____ (e) _____</p>	<p>Flow promoting devices comply with Ordinance requirements _____ (a) _____ Product held minimum pasteurization time and temperature _____ (b) _____ (3) ACIDULATION CONTROLS: _____ (c) _____ Satisfactory means to prevent adulteration with added sugar _____ (d) _____</p> <p><b>15C. REGENERATIVE HEATING:</b> Pasteurized product in regenerator automatically under greater pressure than raw product in regenerator at all times _____ (a) _____ Accurate pressure gauges installed as required; booster pump properly identified, when required, and installed _____ (b) _____ Regenerator pressures meet Ordinance requirements _____ (c) _____</p> <p><b>16D. RECORDING CHARTS:</b> Batch pasteurizer charts comply with applicable Ordinance requirements _____ (a) _____ HST and HST pasteurizer charts comply with applicable Ordinance requirements _____ (b) _____</p> <p><b>17. COOLING OF MILK AND MILK PRODUCTS:</b> Raw milk maintained at 40°F (4°C) or less until processed or as provided for in the Ordinance _____ (a) _____ Pasteurized milk and milk products, except those to be cultured, or as provided for in the Ordinance, cooled immediately to 40°F (4°C) or less in approved equipment; all milk and milk products stored thereat until delivered _____ (b) _____ Approved thermometer properly located in all refrigeration rooms and storage tanks as required _____ (c) _____ Recirculated cooling water from a safe source and properly protected; complies with bacteriological standards _____ (d) _____</p> <p><b>18. BOTTLING, PACKAGING AND CONTAINER FILLING:</b> Performed in a plant where contents finally pasteurized, except for dry milk and whey products _____ (a) _____ Performed in a sanitary manner by approved mechanical equipment _____ (b) _____ Dry milk and whey products packaged in new containers; stored and transported in a sanitary manner _____ (c) _____</p> <p><b>19. CAPPING, CONTAINER CLOSURE AND SEALING:</b> Capping and/or closing/sealing performed in a sanitary manner by approved mechanical equipment _____ (a) _____ Imperfectly capped/closed products properly handled _____ (b) _____ Caps and/or closures comply with Ordinance _____ (c) _____</p> <p><b>20. PERSONNEL CLEANLINESS:</b> Hands thoroughly washed before performing plant functions; reached when contaminated _____ (a) _____ Clean outer garments and hair covering worn _____ (b) _____ No use of tobacco in processing areas _____ (c) _____ Clean boot covers, caps and coveralls worn when entering dryer _____ (d) _____</p> <p><b>21. VEHICLES:</b> Vehicles clean; constructed to transport milk _____ (a) _____ No contaminating substances protected _____ (b) _____</p> <p><b>22. SURROUNDINGS:</b> Neat and clean; free of pooled water, harborages, and breeding areas _____ (a) _____ Tank unloading area properly constructed _____ (b) _____ Approved pesticides, used properly _____ (c) _____</p>
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REMARKS \_\_\_\_\_

DATE \_\_\_\_\_ SANITARIAN \_\_\_\_\_

by the PMO, these items shall be inspected by the PMO, these items shall be inspected

NOTE: Item numbers correspond to required

22. Separation requirements of Item 5 do not apply to (A) & (B), 20, 22 and as climatic and operating conditions require, the same requirements for transfer stations. are dedicated only to the Aseptic Processing and Packaging System, as defined in the applicable requirements of 21 CFR Parts 108, 110 and 113. steurized milk in the Grade "A" Pasteurized Milk Ordinance.

FORM FDA 2359 (10/18)

# Future Steps for Forms

- **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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)		FOR FDA USE ONLY									
				1	2	3	4	5					
IDENTIFICATION													
1. NAME OF SINGLE-SERVICE FABRICATING PLANT			2. CITY		3. STATE/COUNTRY								
4. STREET				5. MFG. CODE NO.		6. CODE							
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION				56	57	58	59	60	61	62			
				PRODUCT CODE (60)		MATERIAL CODE (62)							
				1. Containers		1. Metal							
				2. Closures		2. Paper (Includes laminates)							
				3. Other products		3. Plastic							
				4. Containers and closures		4. Metal and paper							
				5. Containers and other products		5. Metal and plastic							
				6. Closures and other products		6. Paper and plastic							
				7. Containers, closures and other products		7. Metal, paper and plastic							
						8. Glass							
						9. Rubber							
						10. Paper, metal, plastic and glass							
7.a. RATING/CERTIFICATION PERSONNEL		7.b. DATE OF PLANT CERTIFICATION		7.d. EXPIRATION DATE *									
<input type="checkbox"/> SHD <input type="checkbox"/> Other				MONTH	DAY	YEAR							
<input type="checkbox"/> SDA <input type="checkbox"/> TPC		7.c. SANITATION COMPLIANCE RATING		67	68	69	70	71	72				
<input type="checkbox"/> SDL <input type="checkbox"/> SSC								20					
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. <b>NOTE:</b> Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.													
LABORATORY													
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY													
11. INSPECTION RESULTS #													
1	2	3	4	5	6	7	8	9	10	11	12	13	14
12. PERMISSION													
Permission is hereby granted to release and publish the Agency and prospective purchasers.													
It is understood and agreed by the undersigned that review and appraise the single-service fabricating plant certification is in effect. It is further understood that the plant to withdrawal from the IMS Listing. We will notify significant changes made in the operation of this plant.													
12.a. NAME OF PLANT													
12.b. OFFICER AUTHORIZING RELEASE													
13. SUBMISSION OF REPORT BY MILK SANITATION AGENCY													
13.a. DATE OF REPORT				13.b. RECOMMENDED CLASSIFICATION ACCEPTED									
				<input type="checkbox"/> YES <input type="checkbox"/> NO									
FOR FDA													
14. DATE RECEIVED				15. PUBLICATION OF RATING RECOMMENDATION									
16. DATE TRANSMITTED				17. SIGNATURE (FDA Regional Milk Specialist)									
FORM FDA 2359d (11/15)													

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT (Submit an original and two (2) copies to the FDA Regional Office)		3-A. COUNTRY	
1. NAME OF SHIPPER		2. CITY		3. STATE	
4. STREET		5. PLANT or BTU #		6. PRODUCT CODE #	
7. SURVEY DATA					
PRODUCT	DAIRY FARMS		RECEIVING OR TRANSFER STATION	MILK PLANT <sup>1</sup>	ENFORCEMENT
	TYPE OF RATING				
		<input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL			
RATING (%)					
DATE OF RATING					
TOTAL NUMBER					
NUMBER INSPECTED					
VOLUME RECEIVED DAILY (Owt)					
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N?			FSR/PCS WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T?		
<input type="checkbox"/> YES <input type="checkbox"/> NO			<input type="checkbox"/> YES <input type="checkbox"/> NO		
RATING AGENCY		CERTIFIED RATING OFFICER		OFFICER'S CERTIFICATION EXPIRATION DATE	
<input type="checkbox"/> SHD <input type="checkbox"/> SDL				MONTH DAY YEAR	
<input type="checkbox"/> SDA <input type="checkbox"/> TPC					
<input type="checkbox"/> OTHER					
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY				EXPIRATION RATING DATE <sup>2</sup>	
				MONTH DAY YEAR	
8. LABORATORY CONTROL					
APPROVED LABORATORY NUMBER		EXPIRATION DATE		PROCESSED MILK TESTS APPROVED	
A. _____		A. _____		SPC COLI PHOS RBC DRUG RESIDUE TESTS	
B. _____		B. _____		VIABLE COUNTS SOMATIC CELL COUNTS DRUG RESIDUE TESTS	
A. _____		A. _____		A. _____	
B. _____		B. _____		B. _____	
DATE OF LAST TWO (2) SPLIT SAMPLES		APPROVED WATER LABORATORY AND DATE		WATER TESTS APPROVED	
A. _____		A. _____		A. _____	
B. _____		B. _____		B. _____	
9. PUBLICATION (Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of rating/listing.)					
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input type="checkbox"/> YES <input type="checkbox"/> NO					
10. SUBMISSION OF REPORT BY RATING AGENCY					
DATE OF REPORT		SUBMITTED BY (Signature)		TITLE	
<sup>1</sup> Submit separate Form for each milk plant.					
<sup>2</sup> The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 9/30/2015, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 3/31/2014.					

# Future Steps for Forms

- **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 FOOD AND DRUG ADMINISTRATION <small>(See Reverse of Part III for Instructions)</small>		(Check One) <input type="checkbox"/> Certification <input type="checkbox"/> Cancellation	<input type="checkbox"/> Change <input type="checkbox"/> Renewal	Form Approved: OMB No. 0910-0021 Expiration Date: May 31, 2022 See Burden Statement on back of Part III.
<b>SECTION I - COMPLETED BY STATE SHELLFISH CONTROL AUTHORITY</b>				
1. SHELLFISH DEALER / SHIPPER (Name)		2. CERTIFICATION		
FACILITY ADDRESS (Include Street No., City, State, & ZIP)		a) CERTIFICATE NUMBER	b) DATE CERTIFIED	
MAILING ADDRESS (If different than above)		c) STATE	d) EXPIRATION DATE	
TELEPHONE ( )		e) CATEGORY SYMBOL		
		DP - Depuration SP - Shucker-Packer AQ - Aquaculture	RP - Repacker SS - Shell Stock Shipper WS - Wet Storage	RS - Reshipper PHP - Post Harvest Processor
3. DATE OF ON-SITE INSPECTION	4. STATE SHELLFISH STANDARDIZATION INSPECTOR (Print Name)	5. EXPIRATION DATE OF INSPECTOR'S STANDARDIZATION		
6. CANCELLATION DATE	7. REASON FOR CANCELLATION (Check One) <input type="checkbox"/> Decertification <input type="checkbox"/> Out of Business			
STATE SENT TO FDA				
STATE SHELLFISH DEALER'S CERTIFICATE				
<small>Printing Service (01) 443-4740 5F</small>				

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.

# Future Steps for Forms

- **Group #2:** Will remain FDA Forms
- FORM FDA 2359i  
FORM FDA 2359d
- FDA will submit these forms to go through the PRA process
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)		FOR FDA USE ONLY									
				1	2	3	4	5					
IDENTIFICATION													
1. NAME OF SINGLE-SERVICE FABRICATING PLANT				2. CITY		3. STATE/COUNTRY							
4. STREET				5. MFG. CODE NO.		6. CODE							
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION				56	57	58	59	60	61	62			
				PRODUCT CODE (60)			MATERIAL CODE (62)						
7.a. RATING/CERTIFICATION PERSONNEL				7.d. EXPIRATION DATE *			7.c. SANITATION COMPLIANCE RATING						
<input type="checkbox"/> SHD <input type="checkbox"/> Other <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input type="checkbox"/> SSC				MONTH    DAY    YEAR			20						
7.b. DATE OF PLANT CERTIFICATION				7.e. PRODUCT CODE (60)			7.f. MATERIAL CODE (62)						
				1. Closures			1. Metal						
				2. Closures			2. Paper (Includes laminates)						
				3. Other products			3. Plastic						
				4. Closures and closures			4. Metal and paper						
				5. Closures and other products			5. Metal and plastic						
				6. Closures and other products			6. Paper and plastic						
				7. Closures, closures and other products			7. Metal, paper and plastic						
							8. Glass						
							9. Rubber						
							10. Paper, metal, plastic and glass						
							11. Ceramic						
EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. <u>NOTE:</u> Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.													
LABORATORY													
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY													
11. INSPECTION RESULTS (%)													
1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c g,i,h	14 d,e j
12. PERMISSION Permission is hereby granted to release and publish the results of this inspection to Agencies and prospective purchasers.  It is understood and agreed by the undersigned that the results of this inspection and certification is in effect. It is further understood that the results of this inspection and certification shall not be used for any purpose other than that for which it was intended. We will not be held responsible for any significant changes made in the operation of this plant.													
12.3. NAME OF PLANT													
12.2. OFFICER AUTHORIZING RELEASE													
13. SUBMISSION OF REPORT BY MILK SANITATION AGENCY													
13.a. DATE OF REPORT				13.b. RECOMMENDED CLASSIFICATION ACCEPTED									
				<input type="checkbox"/> YES <input type="checkbox"/> NO									
FOR FDA													
14. DATE RECEIVED				15. PUBLICATION OF RATING RECOMMENDATION									
16. DATE TRANSMITTED				17. SIGNATURE (FDA Regional Milk Specialist)									
FORM FDA 2359d (11/15)													
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				INTERSTATE MILK SHIPPER'S REPORT (Submit an original and two (2) copies to the FDA Regional Office)				3-A. COUNTRY					
1. NAME OF SHIPPER			2. CITY		3. STATE								
4. STREET			5. PLANT OR BTU #		6. PRODUCT CODE #								
7. SURVEY DATA													
PRODUCT		DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL		RECEIVING OR TRANSFER STATION		MILK PLANT <sup>1</sup>		ENFORCEMENT					
RATING (%)													
DATE OF RATING													
TOTAL NUMBER													
NUMBER INSPECTED													
VOLUME RECEIVED DAILY (Cwt)													
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <input type="checkbox"/> YES <input type="checkbox"/> NO				FSR/PCS WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? <input type="checkbox"/> YES <input type="checkbox"/> NO									
RATING AGENCY <input type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER		CERTIFIED RATING OFFICER			OFFICER'S CERTIFICATION EXPIRATION DATE		EARLIEST RATING DATE		MONTH    DAY    YEAR				
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY													
EXPIRATION RATING DATE <sup>2</sup>													
MONTH    DAY    YEAR													
8. LABORATORY CONTROL													
APPROVED LABORATORY NUMBER		EXPIRATION DATE		PROCESSED MILK TESTS APPROVED			RAW MILK TESTS APPROVED						
A. _____		A. _____		SPC    COLI    PHOS    RBC    DRUG RESIDUE TESTS			VIABLE COUNTS    SOMATIC CELL COUNTS    DRUG RESIDUE TESTS						
B. _____		B. _____		A. _____ A. _____ A. _____ A. _____ A. _____			A. _____ A. _____ A. _____						
				B. _____ B. _____ B. _____ B. _____ B. _____			B. _____ B. _____ B. _____						
DATE OF LAST TWO (2) SPLIT SAMPLES				APPROVED WATER LABORATORY AND DATE				WATER TESTS APPROVED					
A. _____		A. _____											
B. _____		B. _____											
9. PUBLICATION (Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of rating/listing.)													
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input type="checkbox"/> YES <input type="checkbox"/> NO													
10. SUBMISSION OF REPORT BY RATING AGENCY													
DATE OF REPORT		SUBMITTED BY (Signature)				TITLE							
<sup>1</sup> Submit separate Form for each milk plant.													
<sup>2</sup> The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 9/30/2015, except if the Enforcement Rating is <math>\leq 90</math>, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 3/31/2014.													
FORM FDA 2359i (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)													

# Future Steps for Forms

- 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 HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT <i>Submit an original and two (2) copies to the FDA Regional Office</i>		3-A. COUNTRY					
1. NAME OF SHIPPER		2. CITY		3. STATE					
4. STREET		5. PLANT or BTU #		6. PRODUCT CODE #s					
7. SURVEY DATA									
PRODUCT	DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT <sup>1</sup>	ENFORCEMENT					
RATING (%)									
DATE OF RATING									
TOTAL NUMBER									
NUMBER INSPECTED									
VOLUME RECEIVED DAILY (cwt)									
APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <input type="checkbox"/> YES <input type="checkbox"/> NO		FOP/PCs WHEN APPLICABLE IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? <input type="checkbox"/> YES <input type="checkbox"/> NO							
RATING AGENCY <input type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER	CERTIFIED RATING OFFICER	OFFICER'S CERTIFICATION EXPIRATION DATE	EARLIEST RATING DATE MONTH DAY YEAR						
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY				EXPIRATION RATING DATE <sup>2</sup> MONTH DAY YEAR					
8. LABORATORY CONTROL									
APPROVED LABORATORY NUMBER A. _____ B. _____	EXPIRATION DATE A. _____ B. _____	PROCESSED MILK TESTS APPROVED		RAW MILK TESTS APPROVED					
		SPC	COU	PHOS	RBC	DRUG RESIDUE TESTS	VIBRIE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
		A. _____ B. _____	A. _____ B. _____	A. _____ B. _____	A. _____ B. _____	A. _____ B. _____	A. _____ B. _____	A. _____ B. _____	A. _____ B. _____
DATE OF LAST TWO (2) SPLIT SAMPLES A. _____ B. _____		APPROVED WATER LABORATORY AND DATE			WATER TESTS APPROVED				
9. PUBLICATION <i>(Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of rating/listing.)</i>									
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input type="checkbox"/> YES <input type="checkbox"/> NO									
10. SUBMISSION OF REPORT BY RATING AGENCY									
DATE OF REPORT	SUBMITTED BY (Signature)			Title					
<sup>1</sup> Submit separate Form for each milk plant.									
<sup>2</sup> The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 9/30/2015, except if the Enforcement Rating date is less than the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 3/31/2014.									
FORM FDA 2359i (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE) 9/03 Publishing Services (301) 403-6740 17									



# 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 HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT (Submit an original and two (2) copies to the FDA Regional Office)		3-A. COUNTRY	
1. NAME OF SHIPPER		2. CITY		3. STATE	
4. STREET		5. PLANT or BTL#		6. PRODUCT CODE #	
7. SURVEY DATA					
PRODUCT	DAIRY FARM A. <input type="checkbox"/> FARM B. <input type="checkbox"/> INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT <sup>1</sup>	ENFORCEMENT	
RATING (N)					
DATE OF RATING					
TOTAL NUMBER					
NUMBER INSPECTED					
VOLUME RECEIVED - ONLY ONE					
IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <sup>2</sup> <input type="checkbox"/> YES <input type="checkbox"/> NO			WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? <sup>3</sup> <input type="checkbox"/> YES <input type="checkbox"/> NO		
RATING AGENCY		CERTIFIED RATING OFFICER	OFFICER'S CERTIFICATION EXPIRATION DATE	EARLIEST RATING DATE	
<input type="checkbox"/> DDC <input type="checkbox"/> PCA <input type="checkbox"/> TPC				MONTH DAY YEAR	
<input type="checkbox"/> OTHER				EXPIRATION RATING DATE	
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY				MONTH DAY YEAR	
8. LABORATORY CONTROL					
APPROVED LABORATORY NUMBER	EXPIRATION DATE	PROCESSED MILK TESTS APPROVED		RAW MILK TESTS APPROVED	
A. _____	A. _____	SPC	SDU	SWD	FBC
B. _____	B. _____	TESTS	DRUG RESIDUE	VALUABLE COUNTS	DOMESTIC TESTS
		A. _____	A. _____	A. _____	A. _____
		B. _____	B. _____	B. _____	B. _____
DATE OF LAST TWO (2) DRUG SAMPLES		APPROVED WATER LABORATORY AND DATE		WATER TESTS APPROVED	
A. _____	A. _____				
B. _____	B. _____				
9. PUBLICATION (Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of rating listing.)					
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input type="checkbox"/> YES <input type="checkbox"/> NO					
10. SUBMISSION OF REPORT BY RATING AGENCY					
DATE OF REPORT	SUBMITTED BY (Signature)		TITLE		
<sup>1</sup> Submit separate Form for each milk plant.					
<sup>2</sup> The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/12/11 with a corresponding expiration rating date of 9/30/2013, except if the enforcement rating is 10A, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/12/11 with a corresponding expiration rating date of 3/31/2014.					

FORM FDA 2358 (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION (Fabricator of Single-Service Containers and/or Closures for Milk and/or Milk Products)		FOR FDA USE ONLY	
1. NAME OF SINGLE-SERVICE FABRICATING PLANT		3. STATE/COUNTRY		1 2 3 4 5	
4. STREET		5. CITY		6. CODE	
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION		8. MPG CODE NO.		9. PRODUCT MATERIAL	
12. RATING CERTIFICATION PERSONNEL		13. DATE OF PLANT CERTIFICATION		14. EXPIRATION DATE	
<input type="checkbox"/> DDC <input type="checkbox"/> PCA <input type="checkbox"/> TPC		MONTH DAY YEAR		MONTH DAY YEAR	
<input type="checkbox"/> OTHER		15. SANITATION COMPLIANCE RATING		16. CERTIFICATION RECOMMENDED	
		A. _____		<input type="checkbox"/> YES <input type="checkbox"/> NO	
17. NAME AND ADDRESS (FOR CODE) OF APPROVED LABORATORY		18. LISTERING TYPE		<input type="checkbox"/> FULL <input type="checkbox"/> PARTIAL	
11. INSPECTION RESULTS (Place an "X" under items passing)		19. PERMISSION TO PUBLISH			
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		Permission is hereby granted to release and publish the above stated certification for use by Regulatory/Rating Agencies and prospective purchasers.			
		It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of the plant.			
22. NAME OF PLANT		23. OFFICER AUTHORIZING RELEASE		24. TITLE	
25. DATE OF REPORT		26. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE		27. SIGNATURE (Not Regional Use Signature)	
<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO			
28. DATE RECEIVED		29. PUBLICATION OF RATING RECOMMENDED		<input type="checkbox"/> YES <input type="checkbox"/> NO (If "NO," include why.)	
30. DATE TRANSMITTED		31. SIGNATURE (Not Regional Use Signature)			

FORM FDA 2358 (1/15)

# 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/>

U.S. Department of Health and Human Services Site Optimized for Chrome, Edge or Firefox

**FDA U.S. FOOD & DRUG ADMINISTRATION** | Grade “A” Documents and Information System ?

Table (M-a) <sup>25</sup>
Table (M-b) <sup>465</sup>
Table (M-l) <sup>159</sup>
Table (IMS-a) <sup>24</sup>
Card View (ALL)
EXPORT RESULTS TO EXCEL

Code	Subject	Item	Issue Date	Status	Note	Action
M-a-97 (Revision #2)	Specified Microbial Inhibitors And/Or Preservatives Accepted By FDA For Use In The Production Of Cottage Cheese That Will Be Filled At 13C (55F) Or Less, Cooled To 10C (50F) Or Less Within Twenty-Four (24) Hours Of Filling, And Cooled To 7C (45F) Or Less Within Seventy-Two (72) Hours Of Filling	17p	2021-01-27	Active		<a href="#">VIEW DOCUMENT</a>
M-a-100	Alternate Emergency Procedure for Granting Provisional Certification for New	Candidates that have participated in the LEO Workshop (FD373) or have provided documented evidence of experience may	2020-	Active		<a href="#">VIEW DOCUMENT</a>

# 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:DDEMP: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

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](mailto:monica.metz@fda.hhs.gov).



Monica Metz  
Branch Chief  
Milk and Milk Products Branch

M-I-20-3

1

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

5001 Campus Drive  
College Park, MD 20740-3835

M-I-20-3

March 11, 2020

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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.

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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](mailto:monica.metz@fda.hhs.gov).



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

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.

# 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

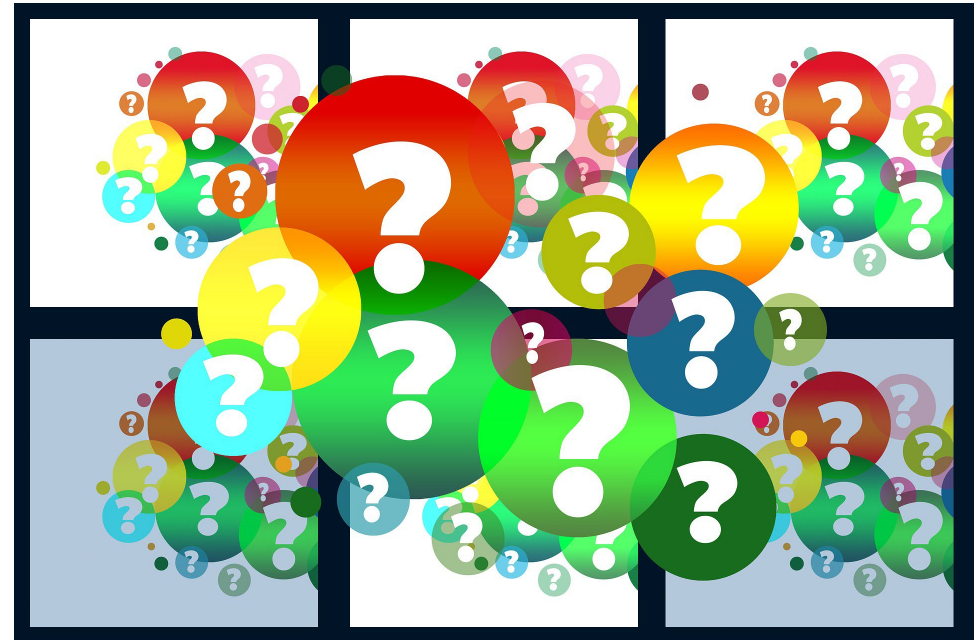
- “Pop-up” box will be added
- M-Is will sunset in October 2023

## Do not meet the M-I Definition

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

# Future Steps for Answering Questions

- 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 not enforceable.
- There are options for answering questions, sharing information.
- We need your help!
  - Explore GAMS (<https://gams.fda.gov/>)



