

**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***MILK PLANT :***  
***STATE REGULATORY***  
***INSPECTIONS,***  
***STATE IMS RATINGS AND***  
***FDA CHECK RATINGS***



# **NCIMS ASEPTIC PILOT** **PROGRAM**

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# **NCIMS ASEPTIC PILOT** **PROGRAM**

## ■ *PRESENTATION TOPICS:*

- *NUMBER OF IMS LISTED FACILITIES*
  - *ASEPTIC PROCESSED/PACKAGED GRADE "A" MILK AND MILK PRODUCTS*
  - *STATE REGULATORY INSPECTIONS*
  - *STATE IMS RATINGS*
  - *FDA CHECK RATINGS*
  - *FDA CFR INSPECTIONS*
- 

# **NCIMS ASEPTIC PILOT** **PROGRAM**

- ***NUMBER OF IMS LISTED FACILITIES:***

***ALL ASEPTIC PROCESSING AND PACKAGING PLANTS THAT PRODUCE GRADE "A" DEFINED MILK OR MILK PRODUCTS ARE REQUIRED TO BE IMS LISTED AND ARE INCLUDED IN THE PILOT.***

# NCIMS ASEPTIC PILOT PROGRAM

## ■ NUMBER OF IMS LISTED FACILITIES:

### ■ PILOT OFFICIALLY BECAME EFFECTIVE IN MARCH 2008

#### ■ 22 IMS LISTED FACILITIES IN 14 STATES + PUERTO RICO

- AZ
- KS
- MN(2)
- OR
- TX(2)

CA(2)  
MD  
MO  
PA  
UT

CT  
MI(2)  
NY(3)  
PR  
VA(2)

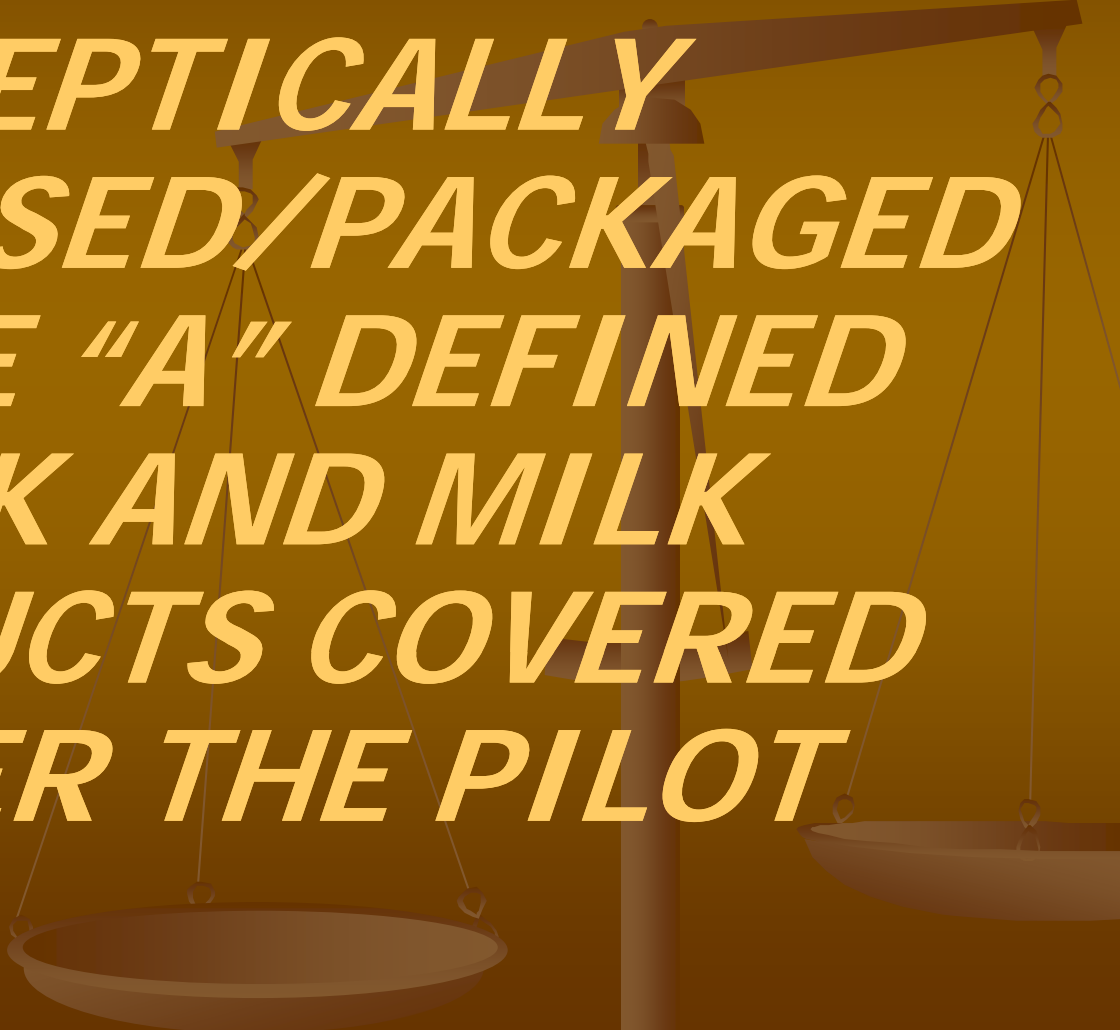


# NCIMS ASEPTIC PILOT PROGRAM

- **NUMBER OF IMS LISTED FACILITIES:**
  - **CURRENTLY THE PILOT INCLUDES:**
    - **26 IMS LISTED FACILITIES IN 17 STATES + PUERTO RICO + MEXICO**
    - **GA (WAS PREVIOUSLY IMS LISTED BUT HAD NOT PRODUCED GRADE "A" DEFINE MILK/MILK PRODUCTS FOR A PERIOD OF TIME.)**
    - **IN (NEW PLANT FACILITY)**
    - **WI (PREVIOUSLY DID NOT PRODUCE GRADE 'A" DEFINE MILK/MILK PRODUCTS.)**
    - **MEXICO (NCIMS INTERNATIONAL CERTIFICATION PILOT PROGRAM)**

**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***ASEPTICALLY  
PROCESSED/PACKAGED  
GRADE "A" DEFINED  
MILK AND MILK  
PRODUCTS COVERED  
UNDER THE PILOT***



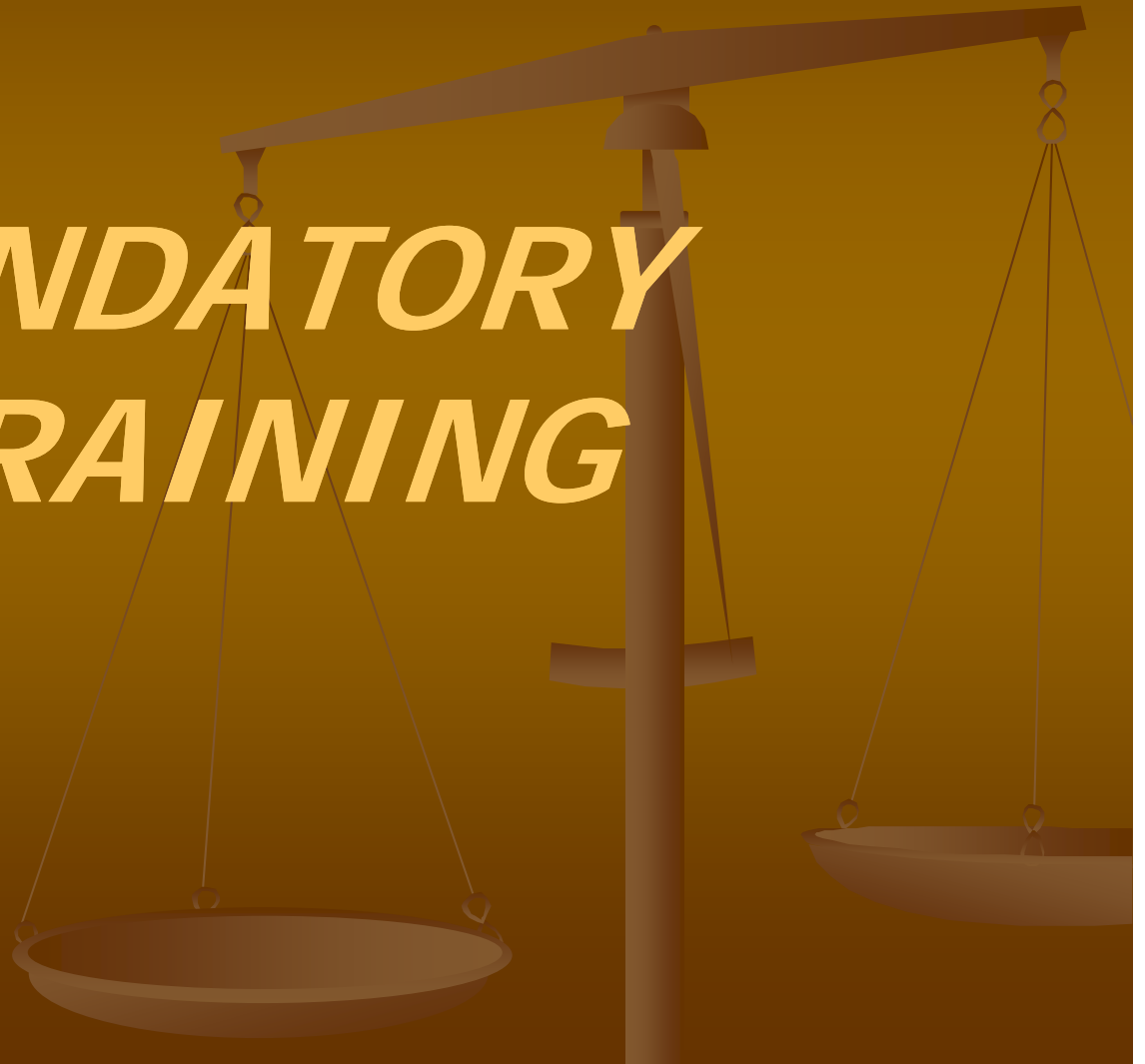
# **NCIMS ASEPTIC PILOT PROGRAM**

- **LOW-ACID ASEPTIC MILK AND MILK PRODUCTS (21 CFR 108, 110 AND 113)**
  - **FERMENTED HIGH-ACID ASEPTIC MILK AND MILK PRODUCTS (21 CFR 108, 110 AND 113)**
  - **ACIDIFIED ASEPTIC MILK AND MILK PRODUCTS (21 CFR 108, 110 AND 114)**
- 



**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***MANDATORY***  
***TRAINING***



# **NCIMS ASEPTIC PILOT** **PROGRAM**

***EFFECTIVE DATE OF THE PILOT:***

***“THIS PROVISION SHALL TAKE IMMEDIATE EFFECT UPON EACH PARTICIPATING STATE’S REGULATORY AND RATING PERSONNEL BEING TRAINED IN THE IMPLEMENTATION OF THE ASEPTIC PILOT PROGRAM. UNTIL SUCH TIME, ASEPTIC PLANTS WILL BE INSPECTED AND RATED USING THE CURRENT SYSTEM.”***

# **NCIMS ASEPTIC PILOT** **PROGRAM**

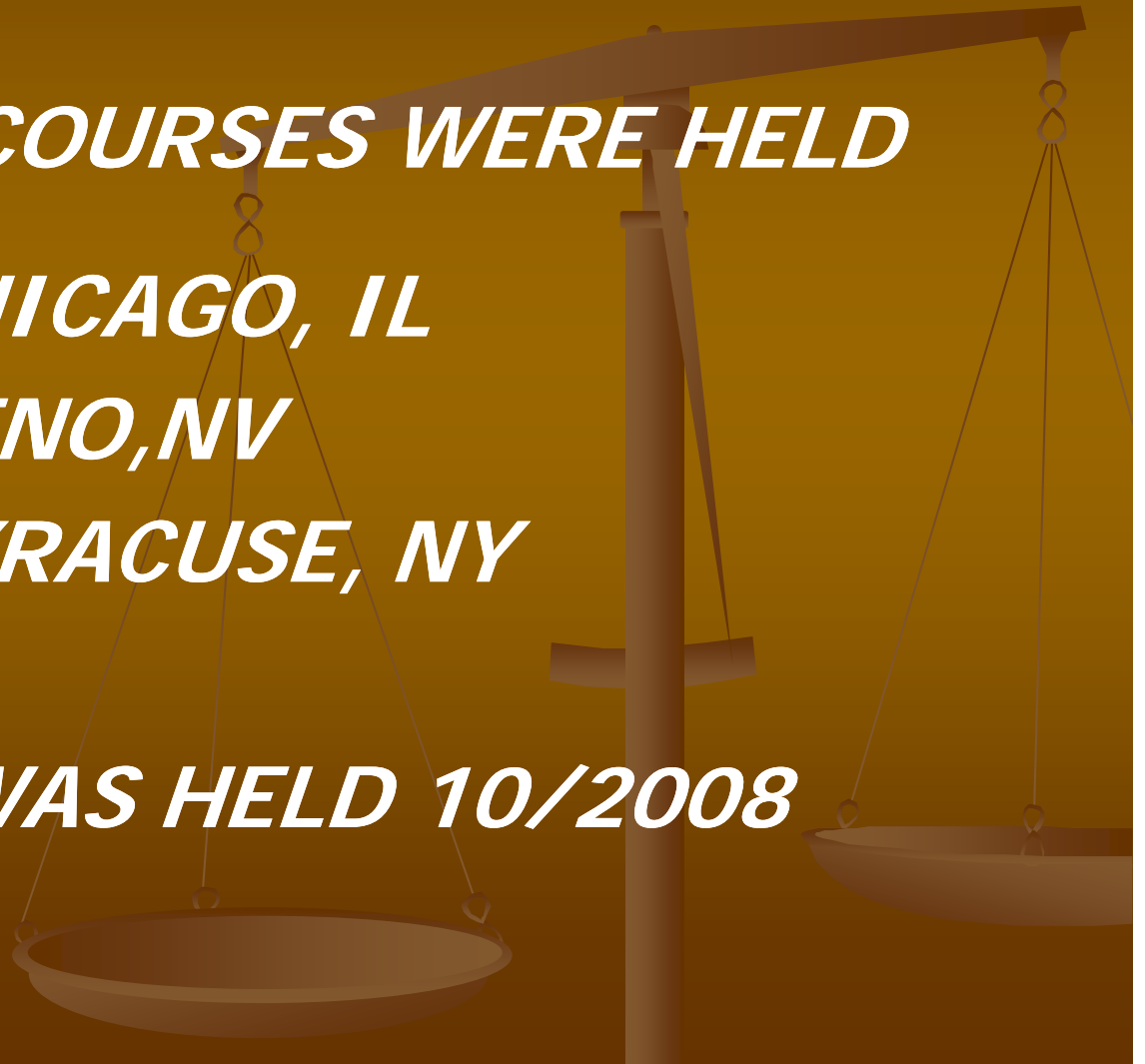
***3 TRAINING COURSES WERE HELD***

***3/2008-CHICAGO, IL***

***4/2008-RENO, NV***

***5/2008-SYRACUSE, NY***

***1 WEBINAR WAS HELD 10/2008***



# **NCIMS ASEPTIC PILOT PROGRAM**

***19 STATES + PUERTO RICO HAVE BEEN TRAINED***

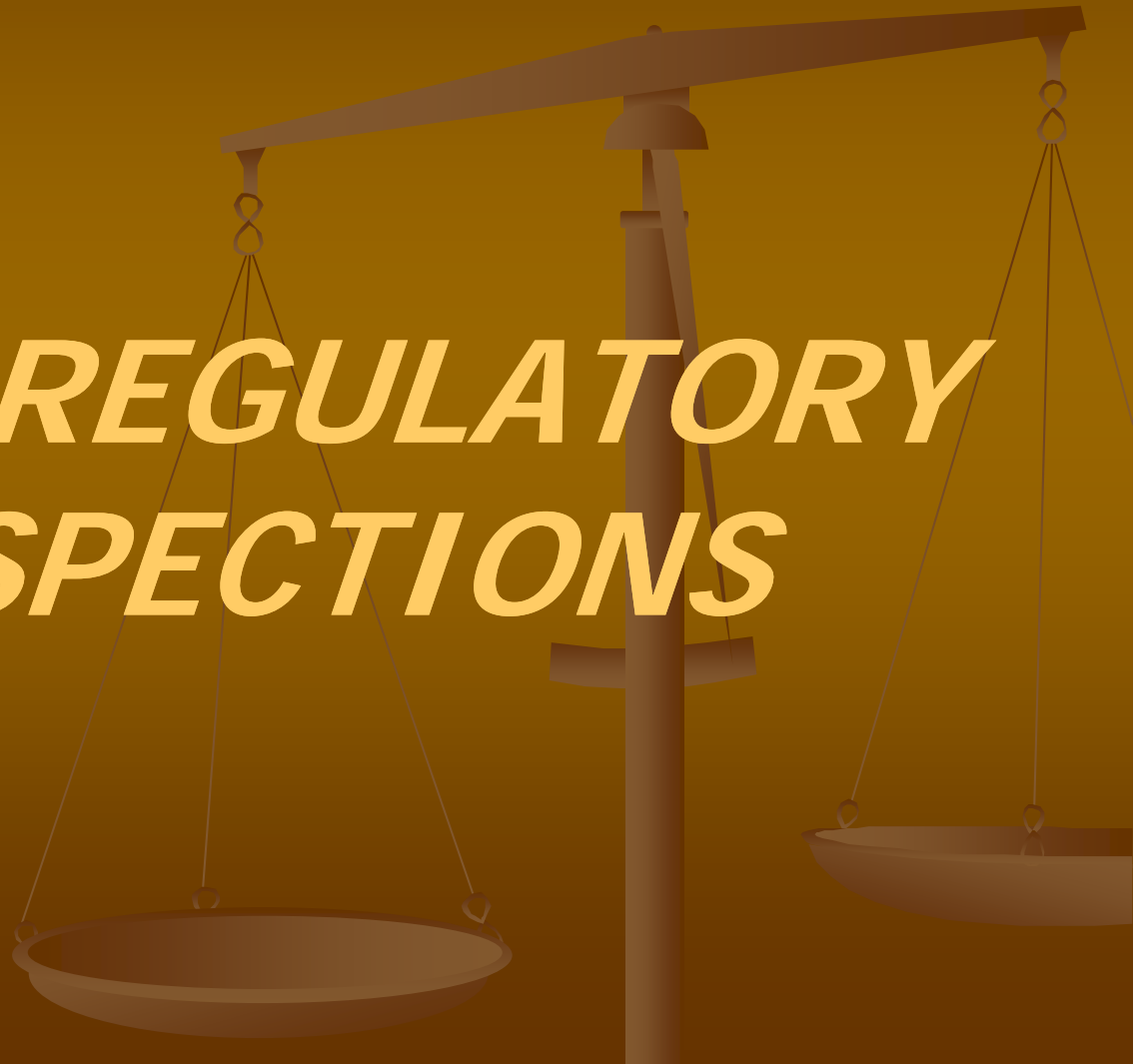
***ALL 3 THIRD PARTY CERTIFIERS UNDER THE NCIMS INTERNATIONAL CERTIFICATION PILOT PROGRAM***

***18 FDA PERSONNEL***



**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***STATE REGULATORY  
INSPECTIONS***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE REGULATORY INSPECTIONS:***

***MILK PLANT IS IMS LISTED TO ONLY PRODUCE GRADE "A" DEFINED ASEPTICALLY PROCESSED/PACKAGED MILK AND/OR MILK PRODUCTS.***

***INSPECTED IN ACCORDANCE TO THE PMO AT LEAST ONCE EVERY 6 MONTHS.***

# NCIMS ASEPTIC PILOT PROGRAM

- *STATE REGULATORY INSPECTIONS:*

*WOULD INSPECT ALL AREAS OF THE ASEPTIC PLANT IN A SIMILIAR MANNER TO HOW THEY CONDUCT THEIR ROUTINE INSPECTIONS,*

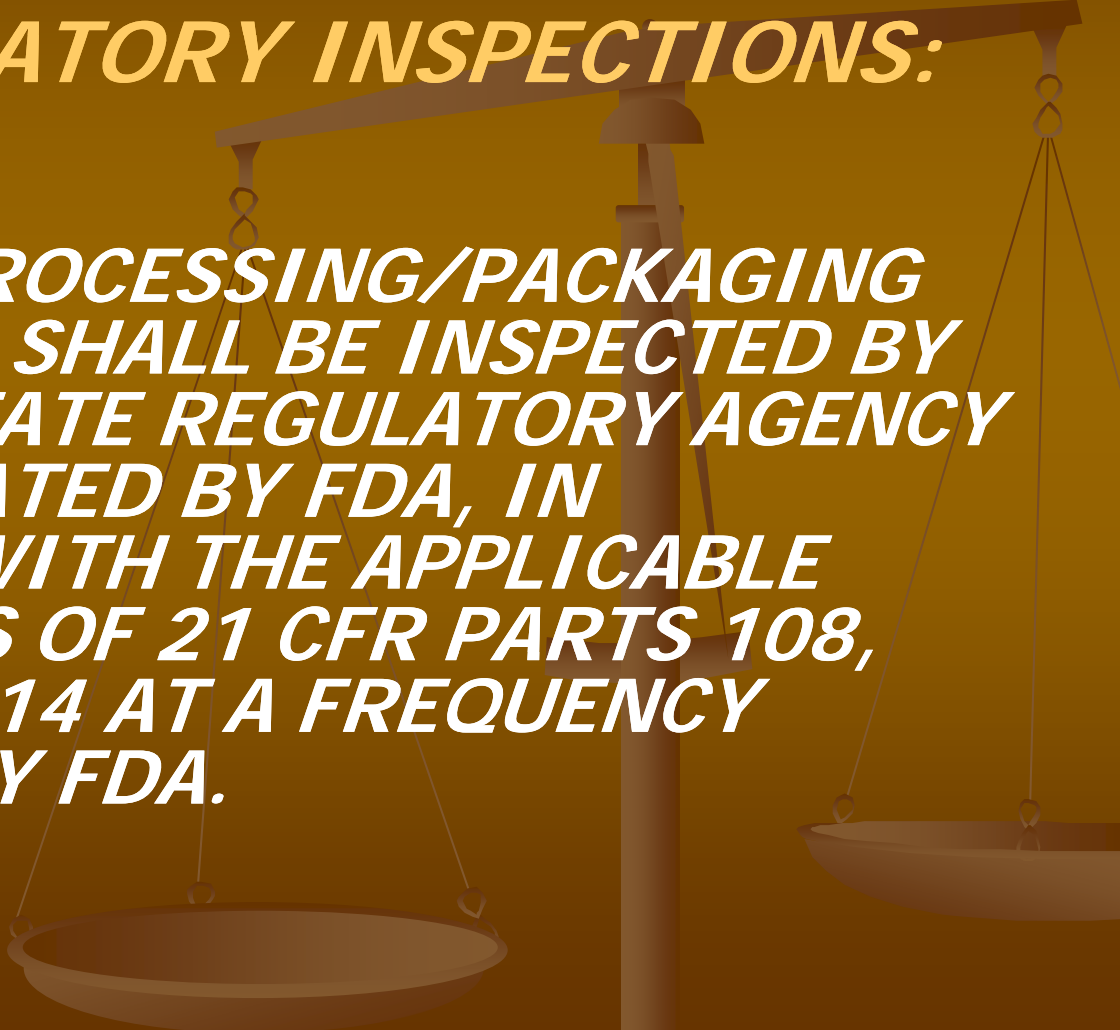
**EXCEPT**



# **NCIMS ASEPTIC PILOT** **PROGRAM**

## ■ ***STATE REGULATORY INSPECTIONS:***

***THE ASEPTIC PROCESSING/PACKAGING SYSTEM (APPS) SHALL BE INSPECTED BY FDA, OR THE STATE REGULATORY AGENCY WHEN DESIGNATED BY FDA, IN ACCORDANCE WITH THE APPLICABLE REQUIREMENTS OF 21 CFR PARTS 108, 110, 113 AND 114 AT A FREQUENCY DETERMINED BY FDA.***





# NCIMS ASEPTIC PILOT PROGRAM

- *Aseptic Processing and Packaging System (APPS)*

*For the purposes of this Ordinance, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110, 113 and 114.*

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***Aseptic Processing and Packaging System (APPS)***

***As a default, the APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.***

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE REGULATORY INSPECTIONS:***

***ADDITIONAL EXCEPTIONS:***

***WITHIN THE APPS THE STATE REGULATORY AGENCY WILL NOT BE REQUIRED TO CONDUCT QUARTERLY EQUIPMENT TESTING AND SEALING OF THE ASEPTIC PROCESSING EQUIPMENT.***

***ASEPTIC PROCESSING/PACKAGING RECORDS AND RECORDING CHARTS WILL NOT BE REQUIRED TO BE REVIEWED DURING ROUTINE STATE REGULATORY INSPECTIONS. (LOW-ACID)***

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE REGULATORY INSPECTIONS:***

***ADDITIONAL EXCEPTIONS:***

***THE STATE REGULATORY AGENCY WILL NOT BE REQUIRED TO COLLECT ASEPTIC PROCESSED/PACKAGED PRODUCT SAMPLES IN ACCORDANCE TO THE PMO.***

***RAW COMMINGLED MILK SAMPLES WILL BE REQUIRED TO BE COLLECTED IN ACCORDANCE TO THE PMO.***

# NCIMS ASEPTIC PILOT PROGRAM

- *STATE REGULATORY INSPECTIONS:*

*MILK PLANT IS IMS LISTED TO PRODUCE BOTH GRADE "A" DEFINED ASEPTICALLY PROCESSED/PACKAGED AND ESL OR PASTEURIZED MILK AND/OR MILK PRODUCTS.*

*INSPECTED IN ACCORDANCE TO THE PMO AT LEAST ONCE EVERY 3 MONTHS.*

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE REGULATORY INSPECTIONS:***

**EXCEPTION:**

***IF THE ASEPTIC OPERATION OF THE MILK PLANT IS A DEDICATED AND SEPARATE AREA FROM THE ESL OR PASTEURIZATION PORTION OF THE MILK PLANT THEN THAT AREA WOULD BE INSPECTED IN ACCORDANCE TO THE PMO AT LEAST ONCE EVERY 6 MONTHS.***

# NCIMS ASEPTIC PILOT PROGRAM

- *STATE REGULATORY INSPECTIONS:*

*EXCEPTION:*

*THE APPS IS EXCLUDED FROM ROUTINE STATE REGULATORY INSPECTION.*



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE REGULATORY INSPECTIONS:***

**EXCEPTION:**

***WITHIN THE APPS THE STATE REGULATORY AGENCY WILL NOT BE REQUIRED TO CONDUCT QUARTERLY EQUIPMENT TESTING AND SEALING OF THE ASEPTIC PROCESSING EQUIPMENT.***

***ASEPTIC PROCESSING/PACKAGING RECORDS AND RECORDING CHARTS WILL NOT BE REQUIRED TO BE REVIEWED DURING ROUTINE STATE REGULATORY INSPECTIONS. (LOW-ACID)***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE REGULATORY INSPECTIONS:***

**NOTE:**

***IF EQUIPMENT IN THE APPS IS ALSO BEING USED TO PRODUCE ESL OR PASTEURIZED GRADE "A" DEFINED MILK OR MILK PRODUCTS , THEN THE PROCESSING/PACKAGING EQUIPMENT WOULD BE REGULATED UNDER BOTH THE PMO AND THE CFR.***

**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***STATE IMS RATINGS***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***CONDUCTED AT A MINIMUM OF ONCE EVERY 24 MONTHS.***

***THIS IS THE CURRENT REQUIRED FREQUENCY FOR IMS LISTING.***



# **NCIMS ASEPTIC PILOT PROGRAM**

## ■ ***STATE IMS RATINGS:***

***CONDUCTED IN A SIMILAR MANNER TO THAT CONDUCTED BY THE STATE REGULATORY PERSONNEL DURING THEIR MANDATORY ROUTINE REGULATORY INSPECTIONS.***

***APPENDIX N RECORDS WILL BE REVIEWED***


***IMS LISTED SOURCES OF MILK AND DAIRY INGREDIENTS WILL BE DETERMINED***



# NCIMS ASEPTIC PILOT PROGRAM

## ■ *STATE IMS RATINGS:*

*THE APPS IS EXCLUDED FROM A STATE IMS RATING, EXCEPT IF USED TO PRODUCE BOTH GRADE "A" ASEPTIC AND ESL AND/OR PASTEURIZED MILK AND MILK PRODUCTS.*



# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

*ASEPTIC PROCESSING/PACKAGING RECORDS AND RECORDING CHARTS WILL NOT BE REQUIRED TO BE REVIEWED DURING A STATE IMS RATING. (LOW-ACID)*



# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

*MILK PLANT IS IMS LISTED TO ONLY PRODUCE GRADE "A" DEFINED ASEPTICALLY PROCESSED/ PACKAGED MILK AND/OR MILK PRODUCTS.*

*GENERALLY WILL ONLY HAVE 1 IMS LISTING.*

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***OF THE CURRENT 26 ASEPTIC MILK PLANT LISTINGS:***

***12 (46%) ARE LISTED ONLY FOR ASEPTIC MILK AND MILK PRODUCTS (PRODUCT CODE #6).***





# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

*MILK PLANT IS IMS LISTED TO PRODUCE BOTH GRADE "A" DEFINED ASEPTICALLY PROCESSED/PACKAGED AND ESL AND/OR PASTEURIZED MILK AND/OR MILK PRODUCTS .*

*REQUIRED TO HAVE AT LEAST 2 SEPARATE IMS LISTINGS.*

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***OF THE CURRENT 26 ASEPTIC MILK PLANT LISTINGS:***

***14 (54%) ARE LISTED FOR BOTH ASEPTIC AND ESL OR PASTEURIZED MILK AND MILK PRODUCTS.***

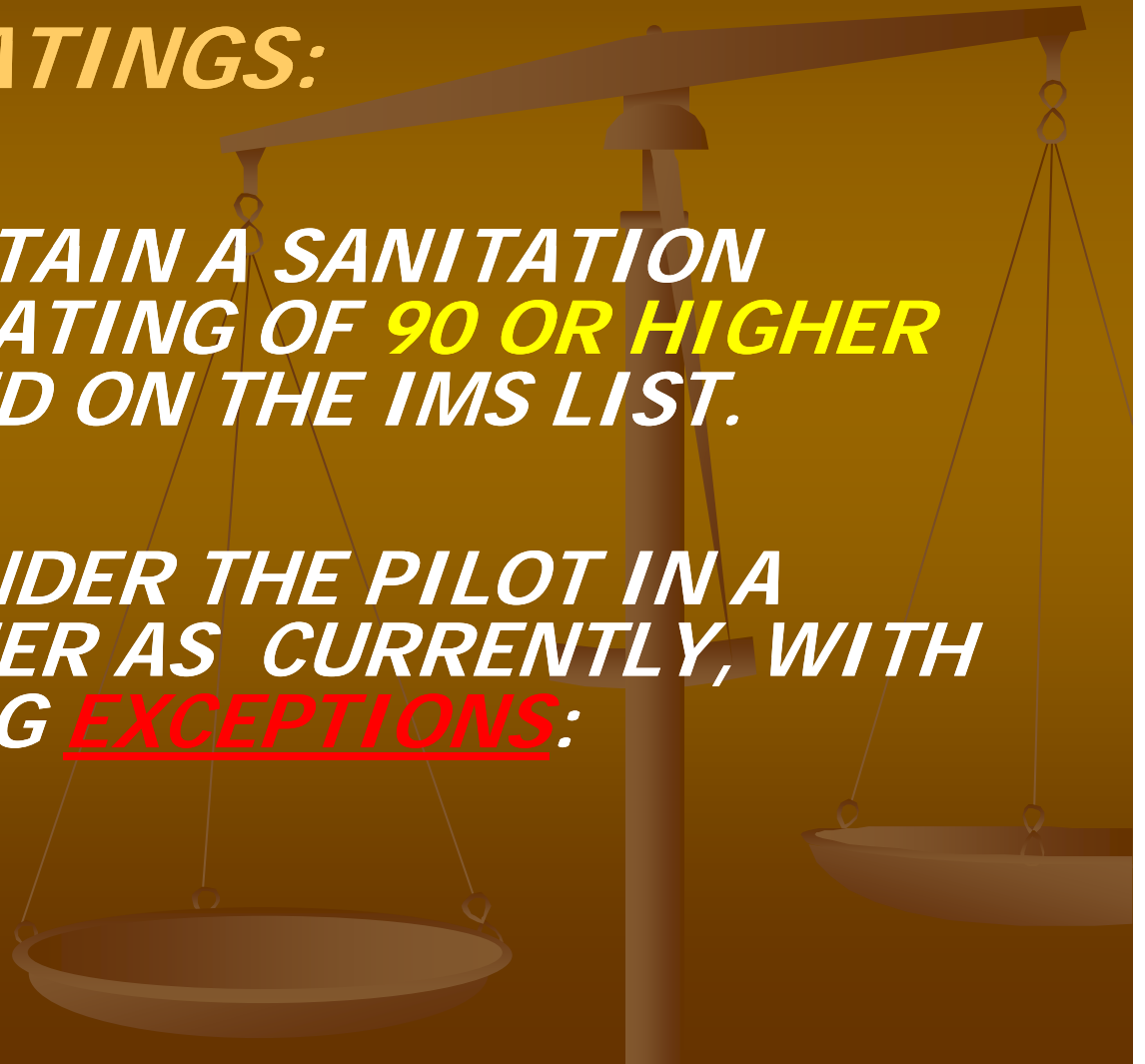


# NCIMS ASEPTIC PILOT PROGRAM

## ■ *STATE IMS RATINGS:*

*MUST STILL OBTAIN A SANITATION COMPLIANCE RATING OF **90 OR HIGHER** TO BE INCLUDED ON THE IMS LIST.*

*CONDUCTED UNDER THE PILOT IN A SIMILAR MANNER AS CURRENTLY, WITH THE FOLLOWING **EXCEPTIONS:***

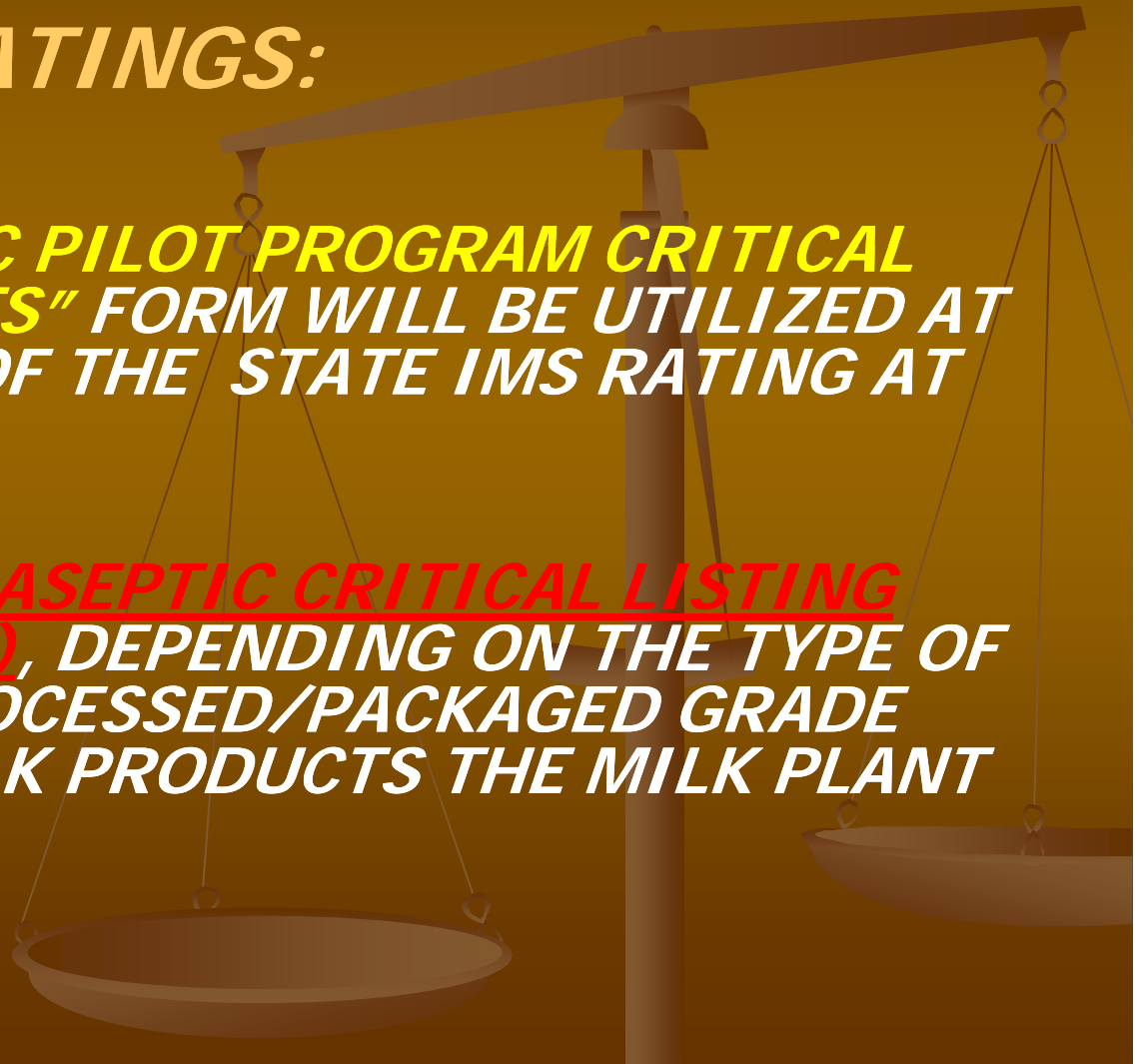


# NCIMS ASEPTIC PILOT PROGRAM

## ■ *STATE IMS RATINGS:*

**A "NCIMS ASEPTIC PILOT PROGRAM CRITICAL LISTING ELEMENTS" FORM WILL BE UTILIZED AT THE BEGINNING OF THE STATE IMS RATING AT THE MILK PLANT.**

**CONTAINS 4 OR 6 ASEPTIC CRITICAL LISTING ELEMENTS (ACLEs), DEPENDING ON THE TYPE OF ASEPTICALLY PROCESSED/PACKAGED GRADE "A" MILK AND MILK PRODUCTS THE MILK PLANT IS PRODUCING.**

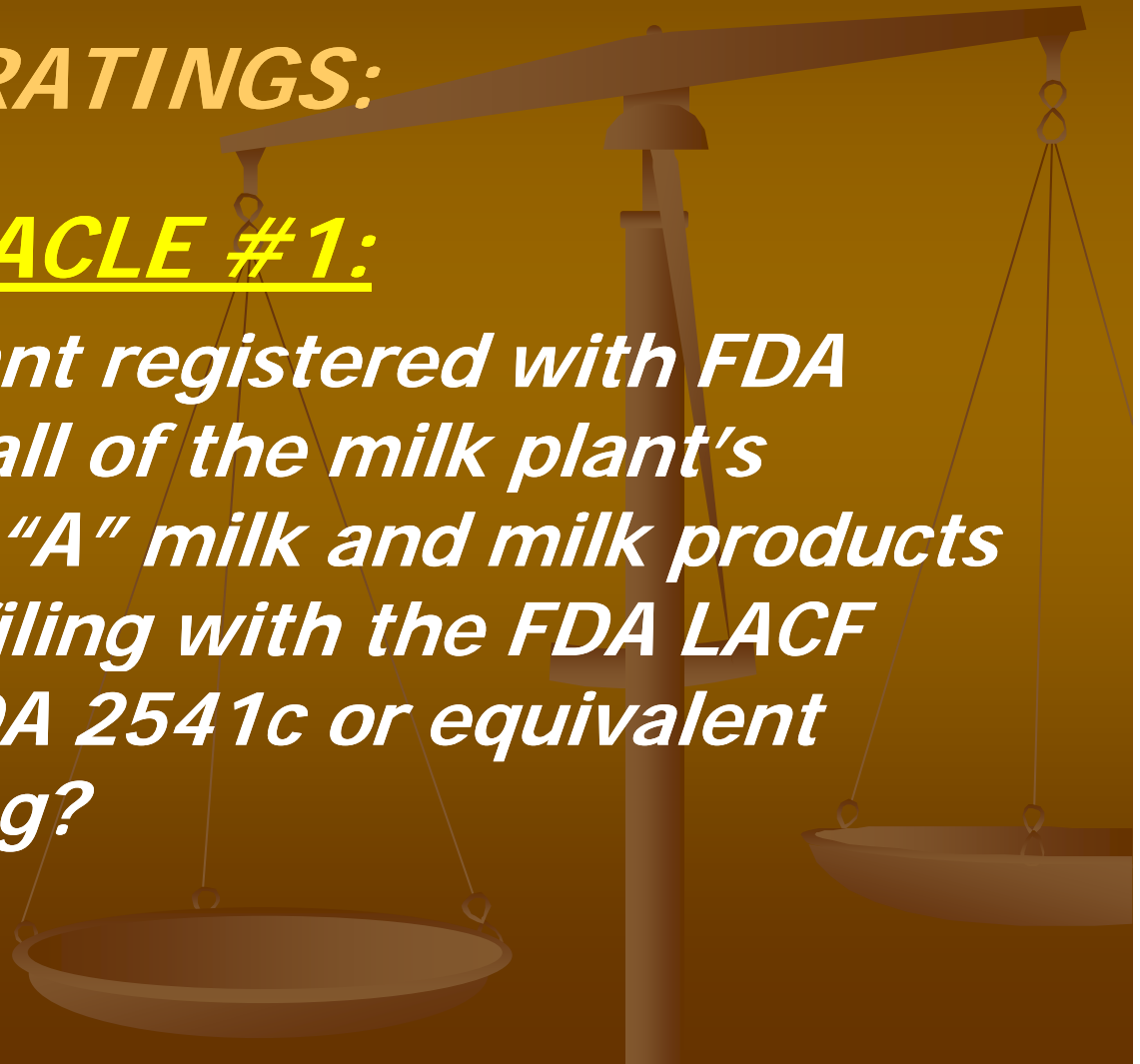


# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

- ACLE #1:**

- Is the milk plant registered with FDA LACF and are all of the milk plant's aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?*



# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

- ACLE #2:*

- Are the milk plant's filed scheduled processes for all of its aseptic Grade "A" milk and milk products developed by a recognized process authority qualified as having expert knowledge of thermal processing requirements?*

# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

- ACLE #3:*

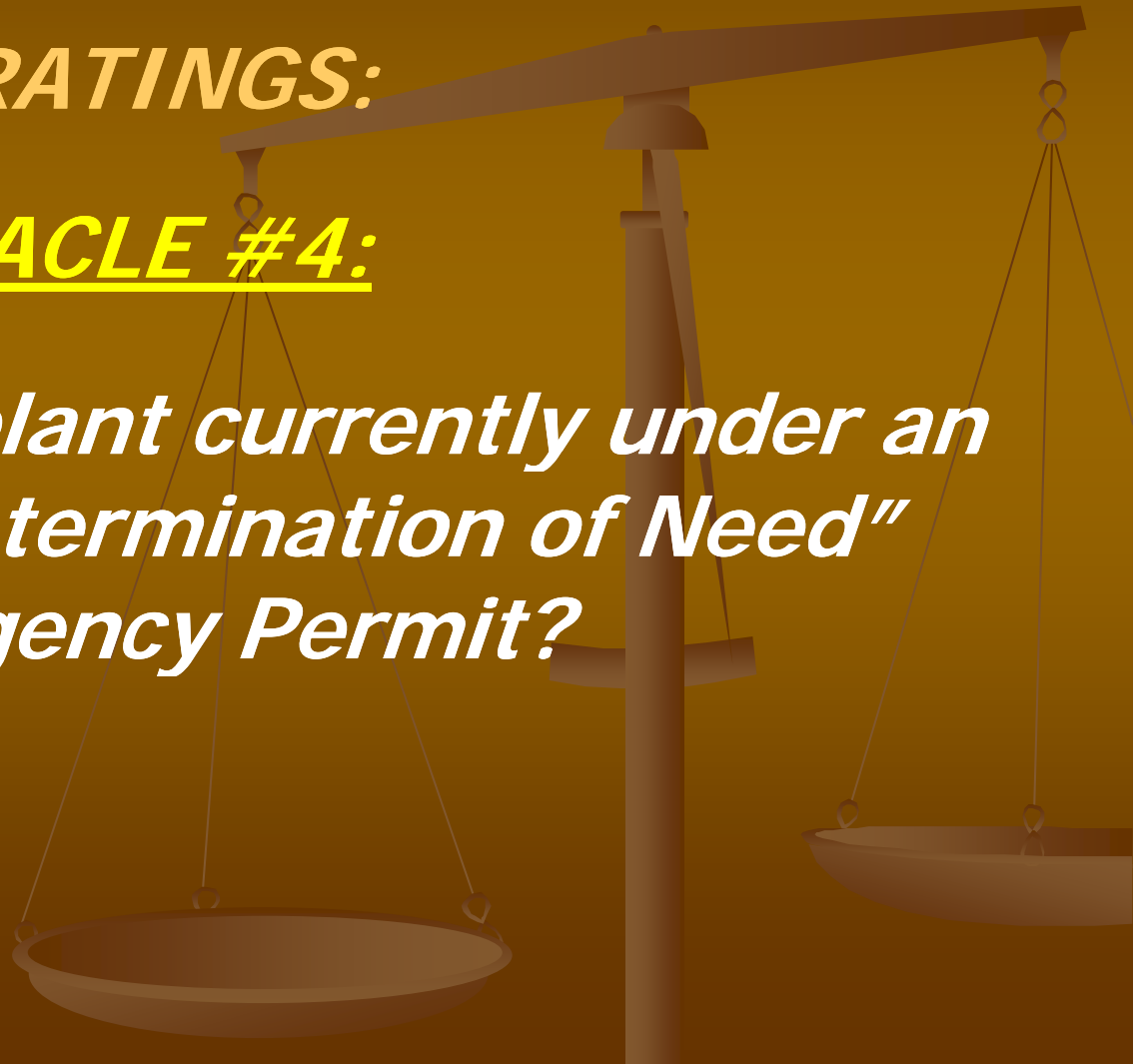
- Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?*

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

**ACLE #4:**

***Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?***





# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

*NOTE:*

*ALL 4 TO 6 ACLEs MUST BE DETERMINED TO BE IN COMPLIANCE ("PASS") WHEN EVALUATED AT THE BEGINNING OF THE RATING.*

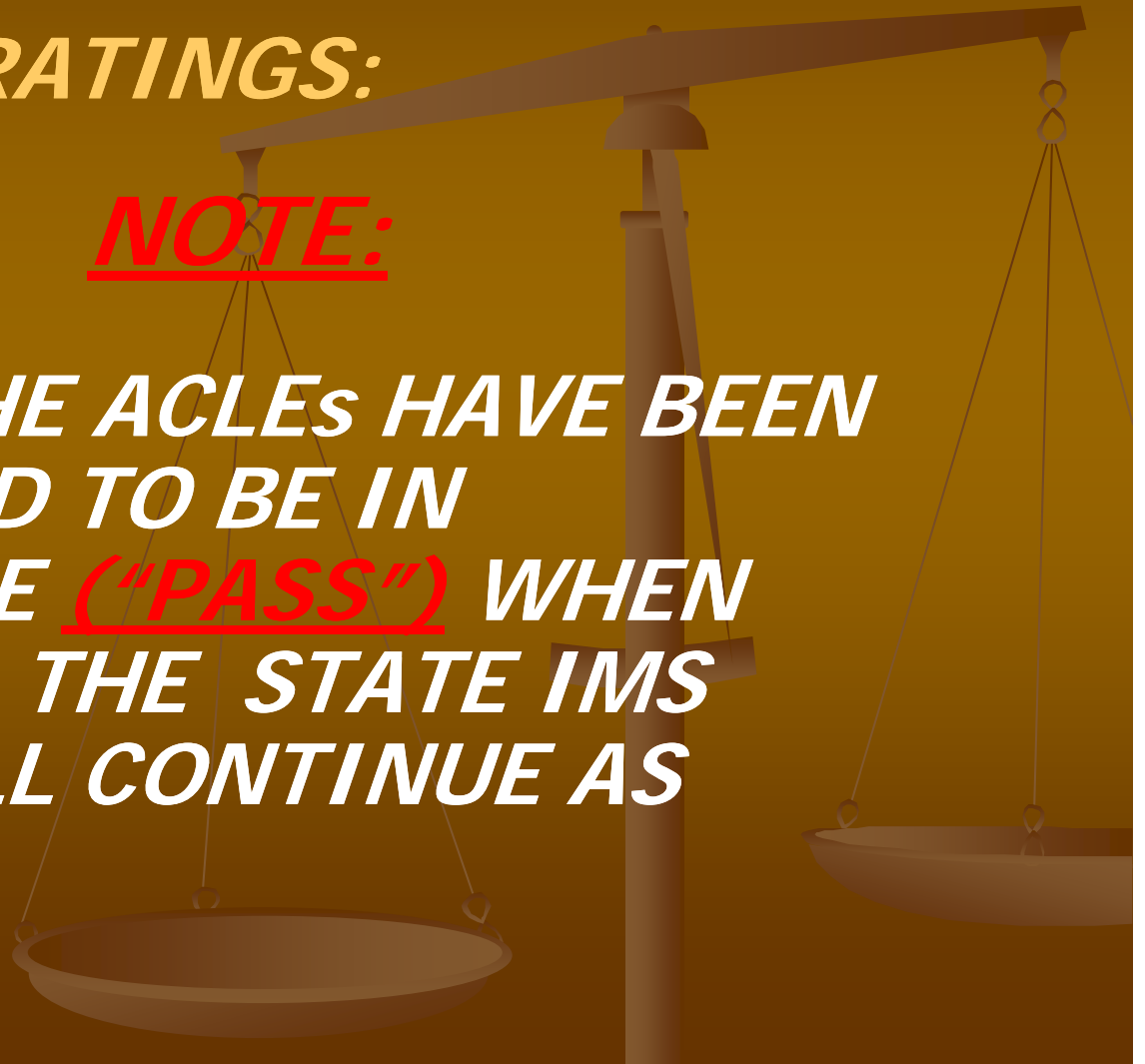
*IF 1 OF THE ACLEs HAS BEEN DETERMINED TO NOT BE IN COMPLIANCE ("FAIL") WHEN EVALUATED, THE STATE IMS RATING WILL STOP AND THE MILK PLANT'S IMS LISTING WILL BE DENIED OR IMMEDIATELY WITHDRAWN.*

# NCIMS ASEPTIC PILOT PROGRAM

- *STATE IMS RATINGS:*

**NOTE:**

***IF ALL OF THE ACLEs HAVE BEEN DETERMINED TO BE IN COMPLIANCE ("PASS") WHEN EVALUATED, THE STATE IMS RATING WILL CONTINUE AS NORMAL.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***A "NCIMS ASEPTIC PILOT PROGRAM MILK PLANT REGULATORY AGENCY REVIEW REPORT" WILL BE UTILIZED INSTEAD OF THE SCORED ENFORCEMENT RATING.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***THE "NCIMS ASEPTIC PILOT PROGRAM MILK PLANT REGULATORY AGENCY REVIEW REPORT" CURRENTLY CONSISTS OF 8 ELEMENTS RELATING TO REGULATORY AGENCY RESPONSIBILITIES ADDRESSED IN THE PMO AND THE IMS PROGRAM.***

***THEY ARE REVIEWED AND ANSWERED BY THE STATE RATING OFFICER AND SUBMITTED WITH THE FINAL REPORT.***

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***AN ENFORCEMENT RATING WILL NOT BE CALCULATED AND A RATING SCORE WILL NOT BE REPORTED OR INCLUDED ON THE IMS LIST.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***STATE IMS RATINGS:***

***24 OF THE 26 (92%) CURRENT ASEPTIC MILK PLANT IMS LISTINGS HAVE HAD AN INITIAL ASEPTIC PILOT PROGRAM STATE IMS RATING CONDUCTED.***

***NO ADVERSE ACTION HAS BEEN WARRANTED FROM ANY OF THE STATE IMS RATINGS CONDUCTED.***

**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***FDA CHECK RATINGS***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CHECK RATINGS:***

***CONDUCTED AT THE SAME FREQUENCY AS INDICATED IN THE FDA COMPLIANCE PROGRAM.***

***(ONCE EVERY 3-4 YEARS)***

***THIS IS THE CURRENT REQUIRED FREQUENCY FOR ALL MILK PLANT IMS LISTINGS.***



# NCIMS ASEPTIC PILOT PROGRAM

- *FDA CHECK RATINGS:*

*CONDUCTED IN A SIMILAR MANNER TO THAT CONDUCTED DURING A STATE RATING.*


*THE APPS IS EXCLUDED FROM A CHECK RATING, EXCEPT IF USED TO PRODUCE BOTH GRADE "A" ASEPTIC AND ESL OR PASTEURIZED MILK AND MILK PRODUCTS.*



# NCIMS ASEPTIC PILOT PROGRAM

- *FDA CHECK RATINGS:*

*ASEPTIC PROCESSING/  
PACKAGING RECORDS AND  
RECORDING CHARTS WILL NOT BE  
REQUIRED TO BE REVIEWED  
DURING FDA CHECK RATINGS.  
(LOW-ACID)*



# NCIMS ASEPTIC PILOT PROGRAM

- *FDA CHECK RATINGS:*

*A SANITATION COMPLIANCE RATING OF 80 WILL REQUIRE A REINSPECTION BY THE STATE RATING AGENCY WITHIN 30 DAYS OF THE FDA CHECK RATING.*

*A SANITATION COMPLIANCE RATING OF <80 WILL REQUIRE AN IMMEDIATE WITHDRAWAL FROM THE IMS LIST.*

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CHECK RATINGS:***

***WILL ALSO USE THE FOLLOWING:***

***"NCIMS ASEPTIC PILOT PROGRAM CRITICAL LISTING ELEMENTS"***


***"NCIMS ASEPTIC PILOT PROGRAM MILK PLANT REGULATORY AGENCY REVIEW REPORT"***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CHECK RATINGS:***

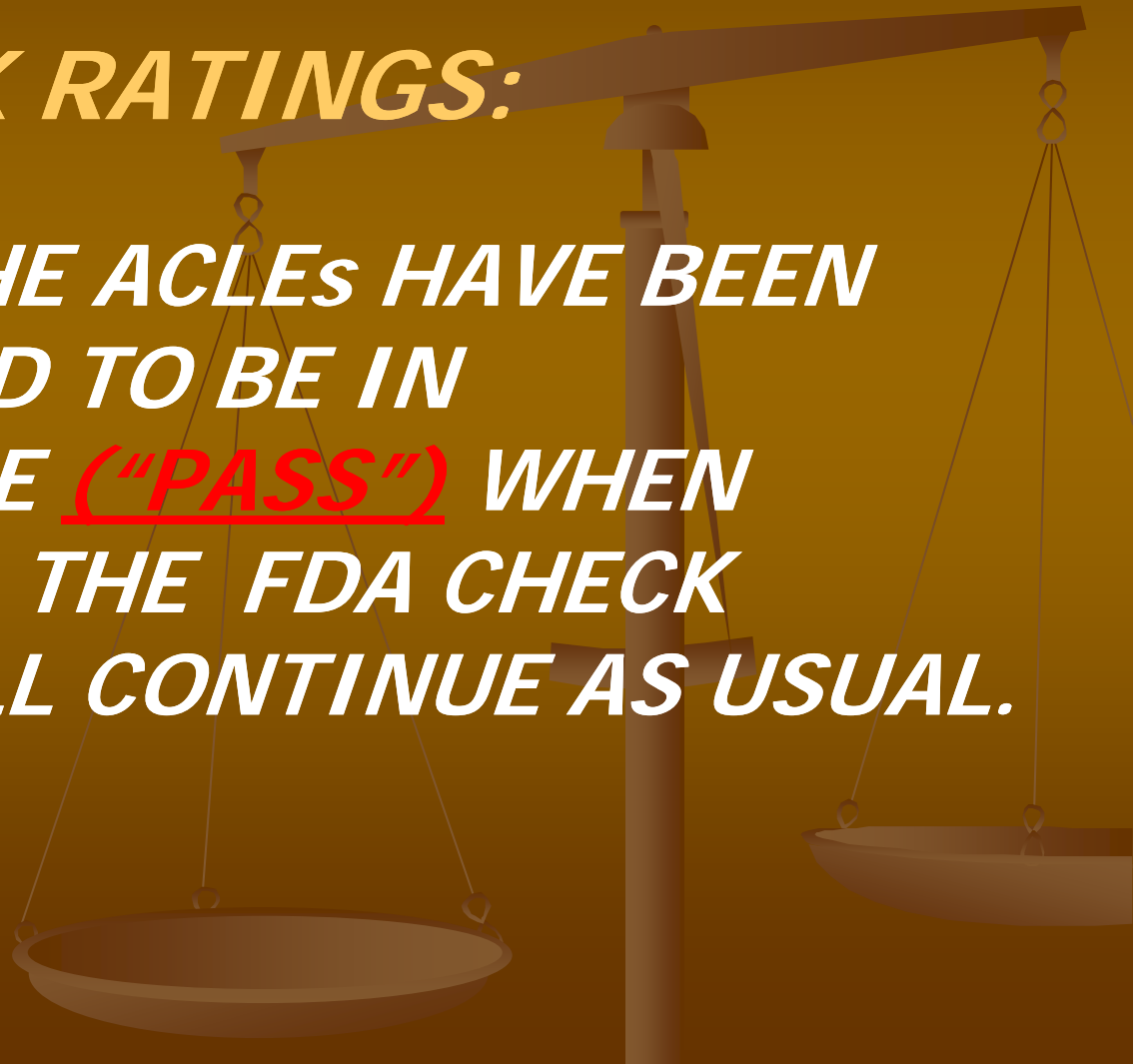
***IF 1 OF THE ACLEs HAS BEEN DETERMINED TO NOT BE IN COMPLIANCE ("FAIL") WHEN EVALUATED, THE MILK PLANT'S IMS LISTING WITH BE IMMEDIATELY WITHDRAWN.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CHECK RATINGS:***

***IF ALL OF THE ACLEs HAVE BEEN DETERMINED TO BE IN COMPLIANCE ("PASS") WHEN EVALUATED, THE FDA CHECK RATING WILL CONTINUE AS USUAL.***

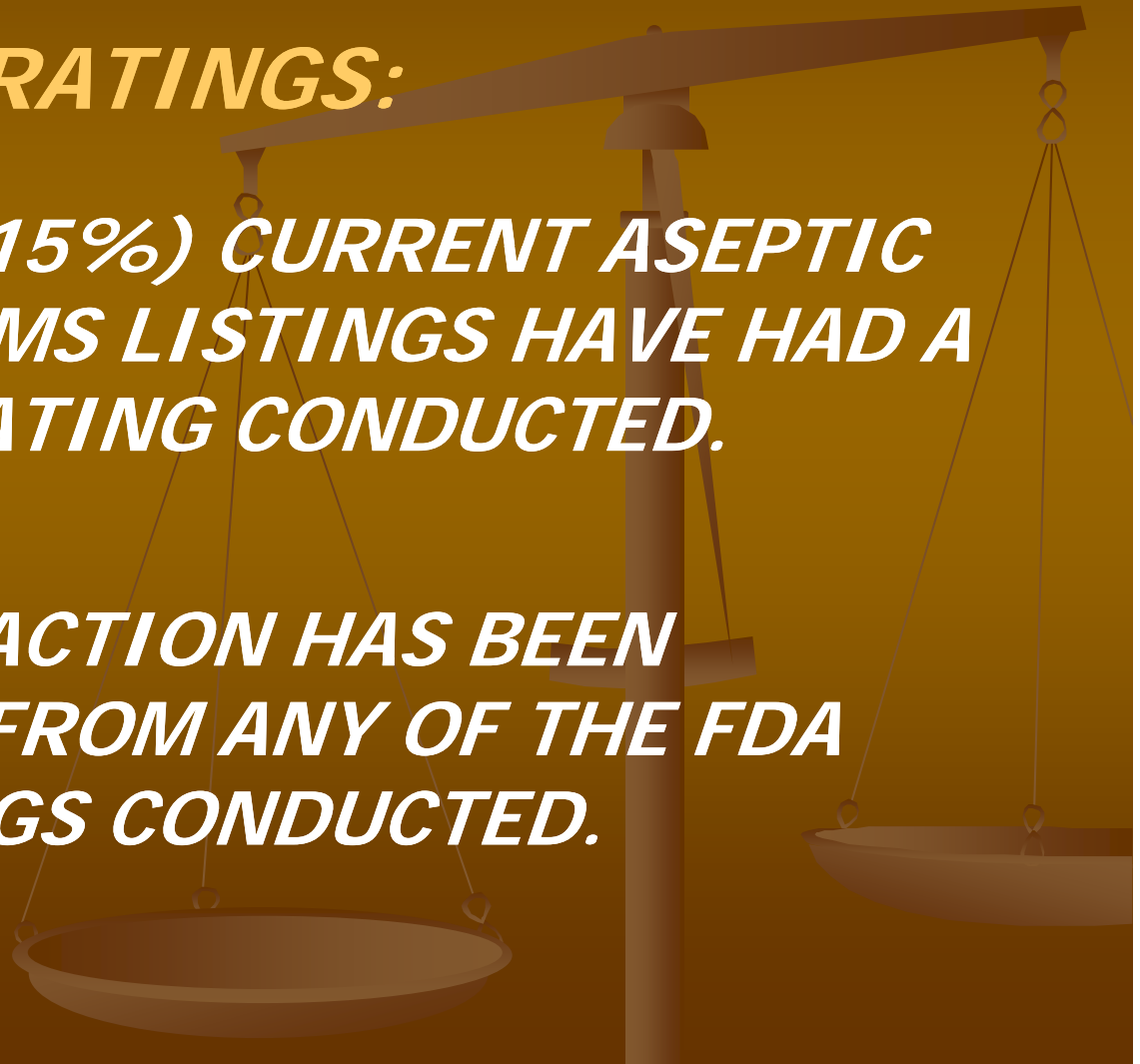


# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CHECK RATINGS:***

***4 OF THE 26 (15%) CURRENT ASEPTIC MILK PLANT IMS LISTINGS HAVE HAD A FDA CHECK RATING CONDUCTED.***

***NO ADVERSE ACTION HAS BEEN WARRANTED FROM ANY OF THE FDA CHECK RATINGS CONDUCTED.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CHECK RATINGS:***

**NOTE:**

***AN ASSIGNMENT HAS BEEN ISSUED THAT ALL CURRENT IMS LISTED ASEPTIC MILK PLANTS HAVE A FDA CHECK RATING CONDUCTED DURING FY 2010 TO BE USED WHEN EVALUATING THE PILOT.***



**NCIMS ASEPTIC PILOT**  
**PROGRAM**

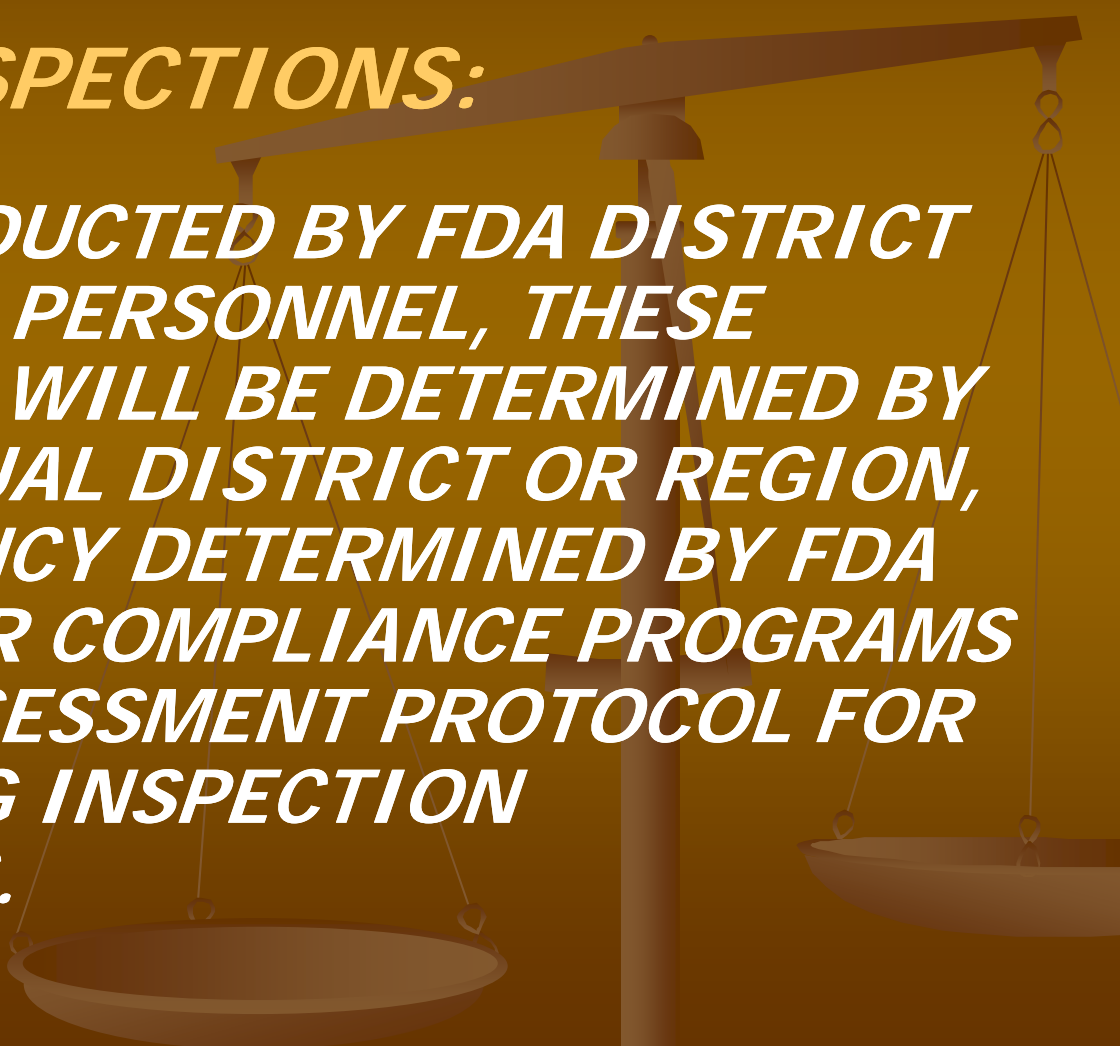
***FDA CFR INSPECTIONS***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CFR INSPECTIONS:***


***WILL BE CONDUCTED BY FDA DISTRICT OR REGIONAL PERSONNEL, THESE INDIVIDUALS WILL BE DETERMINED BY THE INDIVIDUAL DISTRICT OR REGION, AT A FREQUENCY DETERMINED BY FDA WITHIN THEIR COMPLIANCE PROGRAMS AND RISK ASSESSMENT PROTOCOL FOR DETERMINING INSPECTION FREQUENCIES.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CFR INSPECTIONS:***

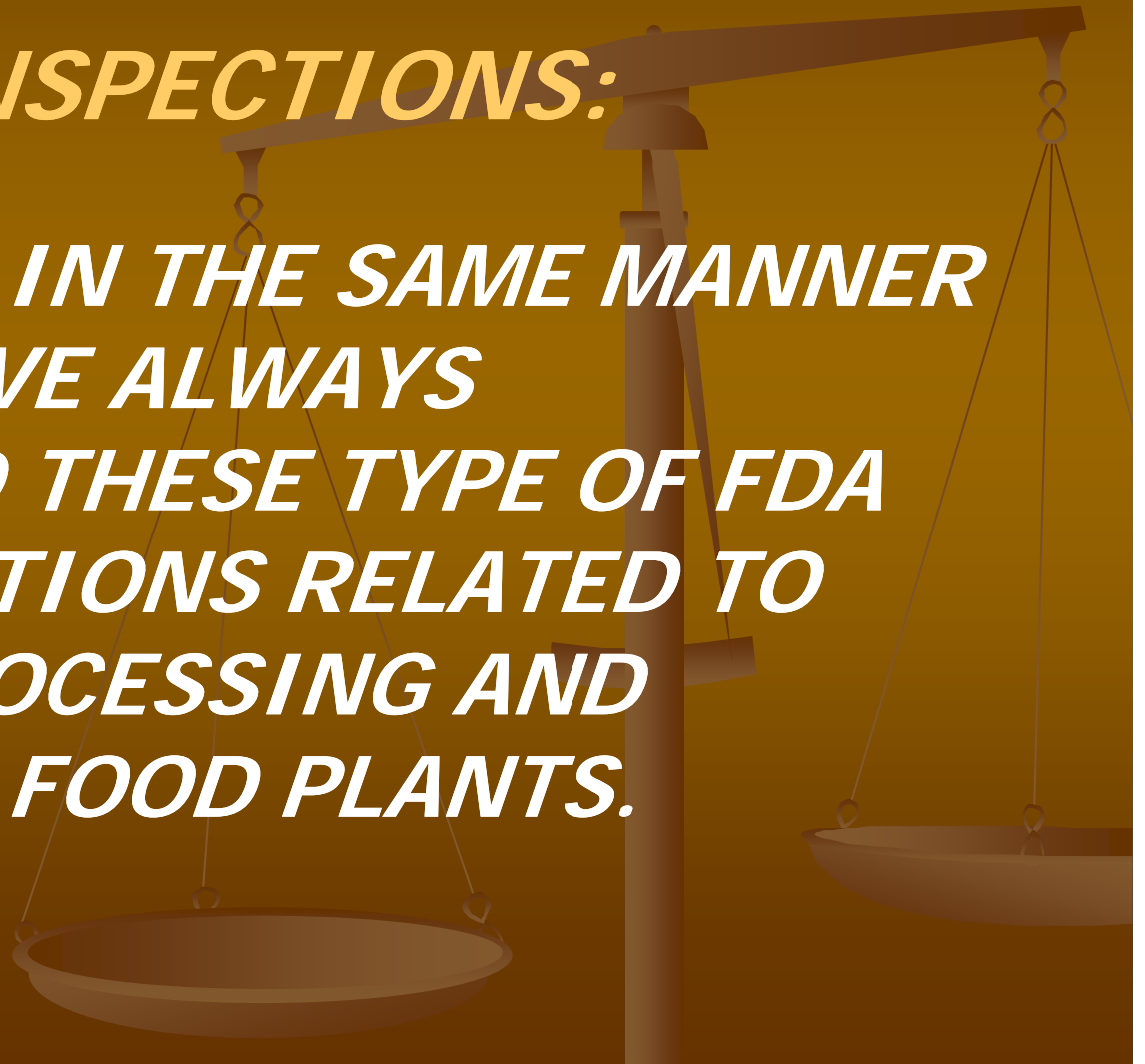
***CONDUCTED IN A MANNER  
DICTATED BY FDA COMPLIANCE  
PROGRAMS, COMPLIANCE POLICY  
GUIDES AND THE FDA  
INVESTIGATIONS OPERATIONS  
MANUAL (IOM).***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CFR INSPECTIONS:***

***IN ESSENCE IN THE SAME MANNER AS THEY HAVE ALWAYS CONDUCTED THESE TYPE OF FDA CFR INSPECTIONS RELATED TO ASEPTIC PROCESSING AND PACKAGING FOOD PLANTS.***



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CFR INSPECTIONS:***

**NOTE:**

***FDA ISSUED A COMPLIANCE PROGRAM ASEPTIC PROCESSING INSPECTION WITHIN IMS GRADE "A" MILK PLANTS ASSIGNMENT TO THE FIELD ON 6/27/2008.***

# **NCIMS ASEPTIC PILOT PROGRAM**

- ***FDA CFR INSPECTIONS:***

**NOTE:**

***THE ASSIGNMENT REQUESTED THE DISTRICTS/REGIONS TO CONDUCT ANNUAL INSPECTIONS FROM THE IMPLEMENTATION OF THIS ASSIGNMENT THROUGH THE END OF FY 2010.***

**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***THANK YOU!!***

**QUESTIONS**

**???**



# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 1p-FLOORS - CONSTRUCTION:*

*Floor drains are not required in storage rooms for aseptic processed and packaged milk or milk products.*



# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## ITEM 2p-WALLS AND CEILING - CONSTRUCTION:

*Ceilings requirements are exempt in aseptically processed and packaged milk or milk products dry storage rooms.  
(Same as for dry milk or milk products.)*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 5p-SEPARATE ROOMS:*

*Fabrication of containers and closures for aseptic processed and packaged milk and milk products within the APPS is exempt.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 7p-WATER SUPPLY:*

*The APPS is exempt, but shall comply with the CFR.*

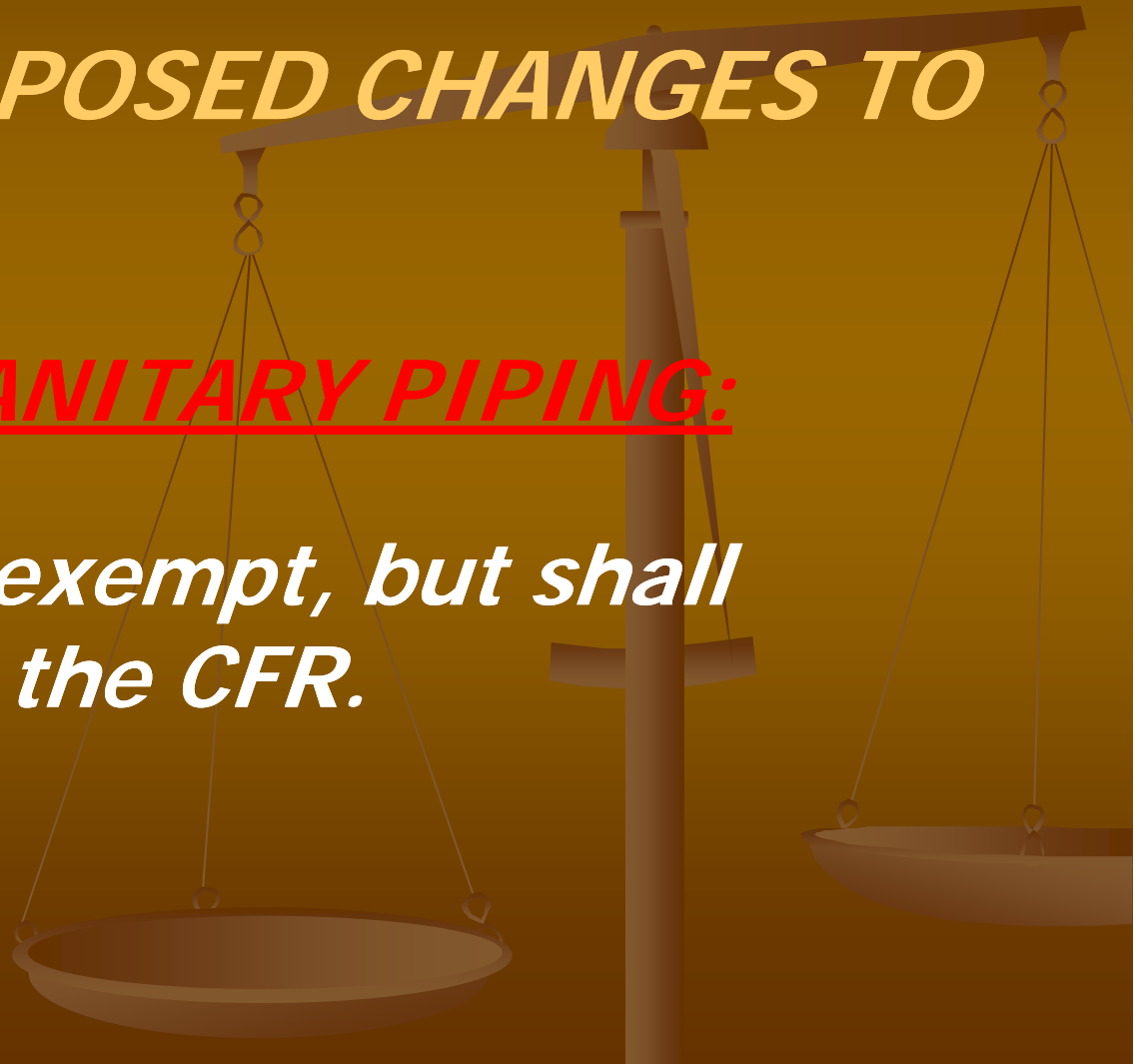
*NOTE:* *APPLIES ONLY IF THE WATER IS USED EXCLUSIVELY WITHIN THE APPS AND NOT IN OTHER PLANT LOCATIONS.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 10p-SANITARY PIPING:*

*The APPS is exempt, but shall comply with the CFR.*



# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

*ITEM 11p-CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT:*

*The APPS is exempt, but shall comply with the CFR.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 11p-CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT:*

*Paper, plastics, foil, adhesives and other components of containers and closures used in the packaging of milk or milk products that have been aseptically processed and packaged are not required to comply with Appendix J of the PMO; originate from an IMS Listed Source; and are subject to the requirements of the CFR.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

*ITEM 12p-CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT:*

*The APPS is exempt, but shall comply with the CFR.*



# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 13p-STORAGE OF CLEANED CONTAINERS AND EQUIPMENT:*

*The APPS is exempt, but shall comply with the CFR.*

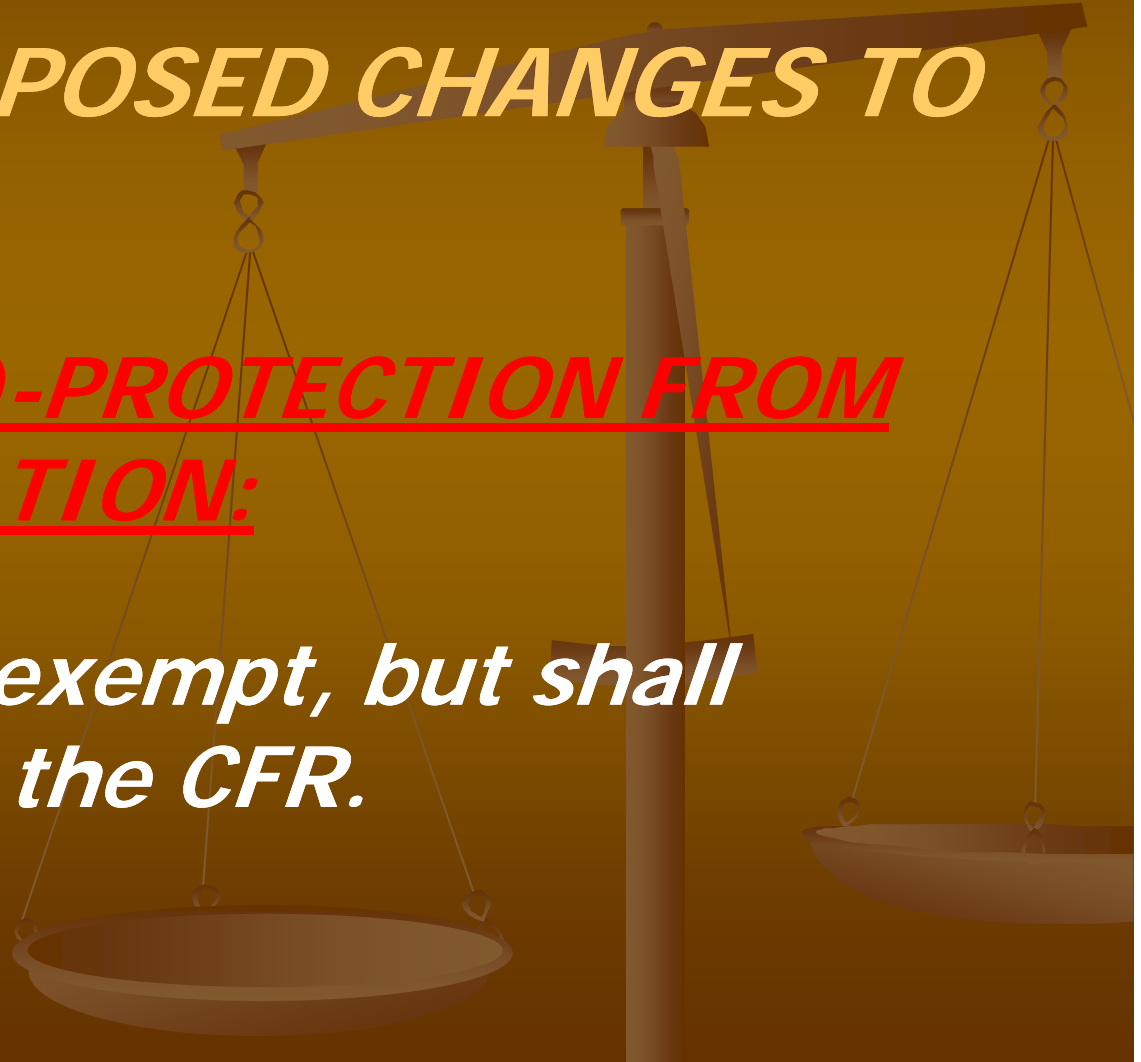


# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 15p(A)-PROTECTION FROM CONTAMINATION:*

*The APPS is exempt, but shall comply with the CFR.*

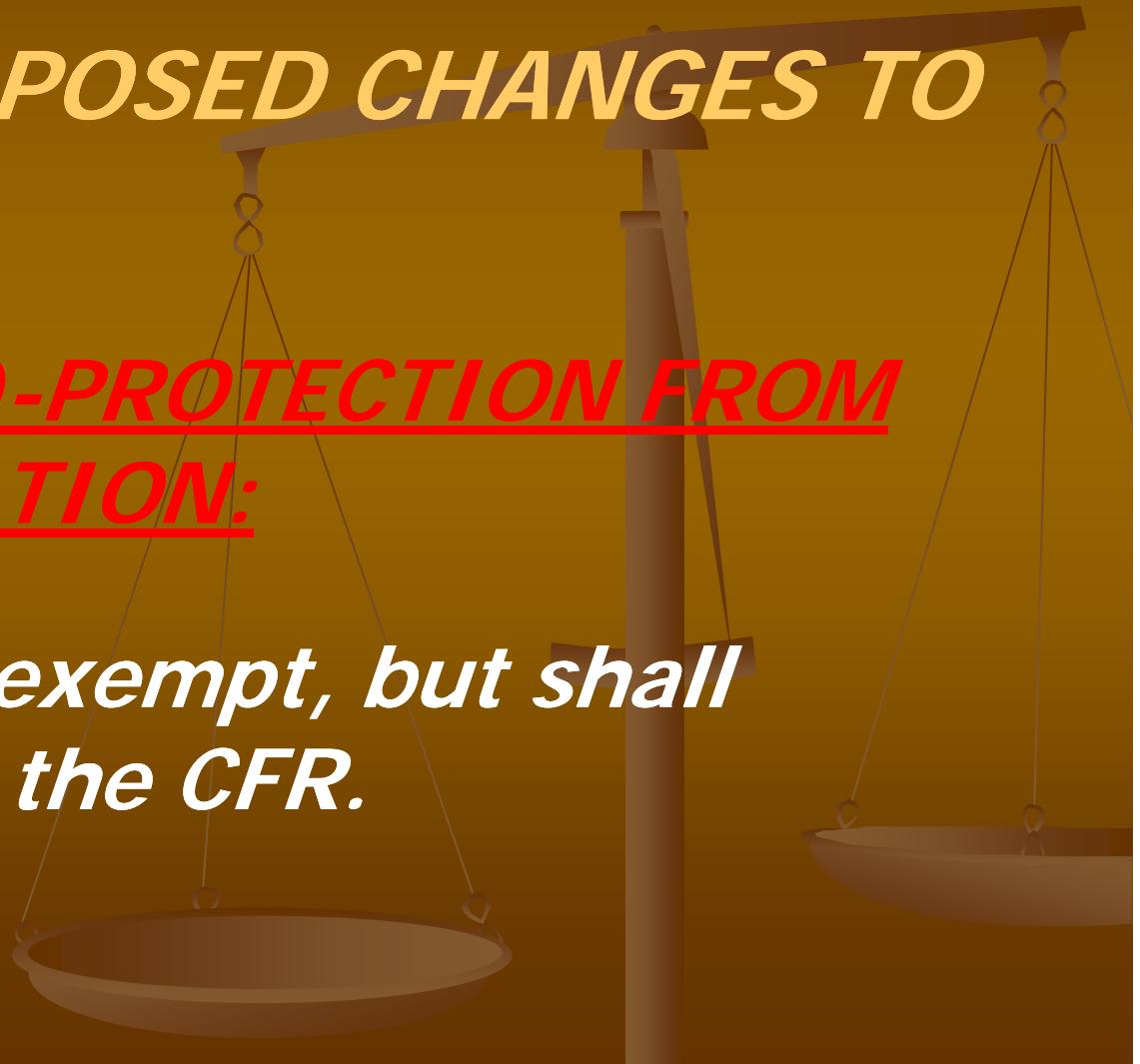


# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 15p(B)-PROTECTION FROM CONTAMINATION:*

*The APPS is exempt, but shall comply with the CFR.*



# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## *ITEM 15p(B)-PROTECTION FROM CONTAMINATION:*

*APPS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

*ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING AND PACKAGING:*

*The APPS is exempt, but shall comply with the CFR. The State Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic processing equipment. Records and recording charts are not required to be reviewed during routine State inspections, State Ratings or Check Ratings.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

## ITEM 17p-COOLING OF MILK AND MILK PRODUCTS:

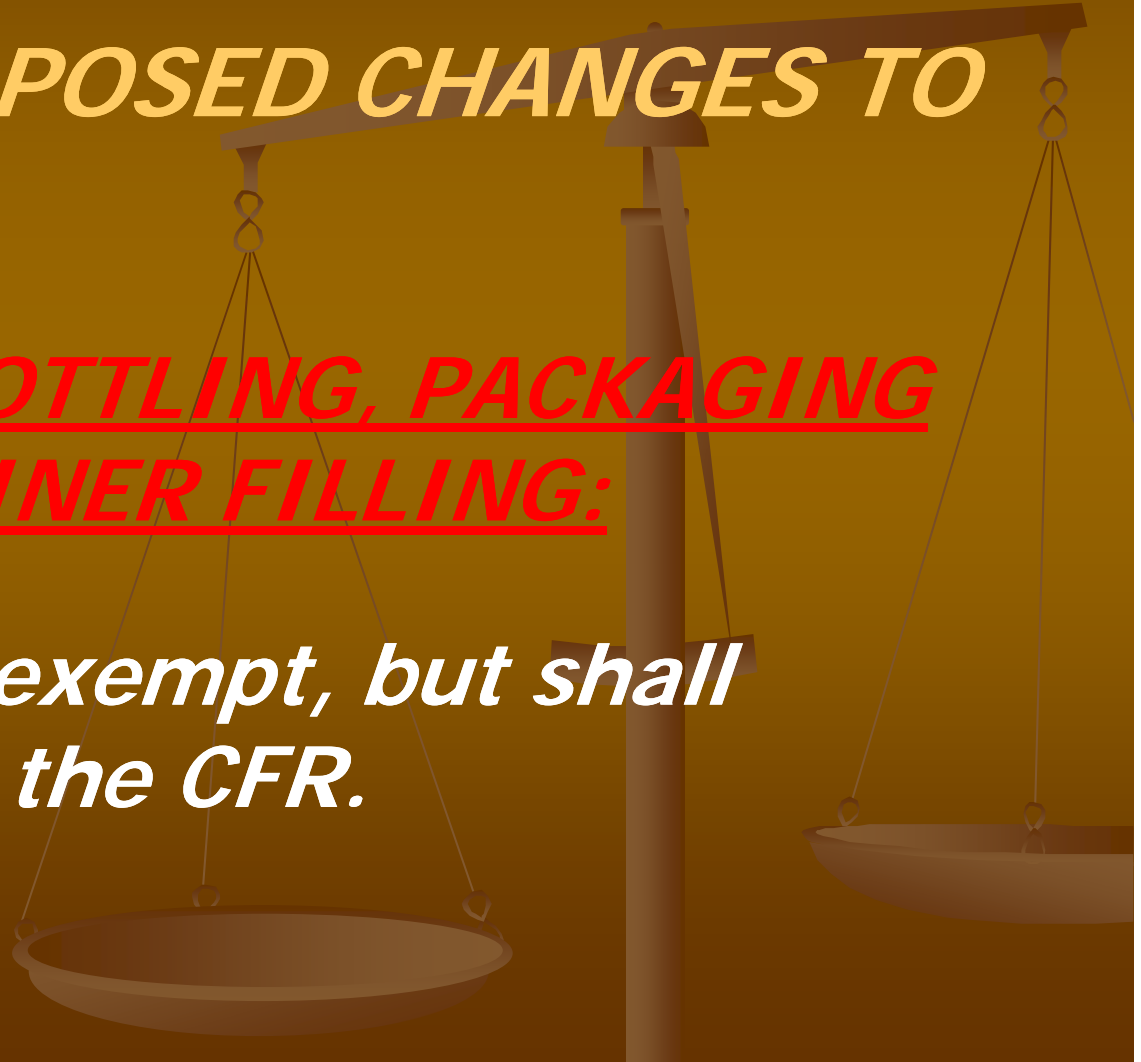
*The APPS is exempt, but shall comply with the CFR.*

# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

*ITEM 18p-BOTTLING, PACKAGING AND CONTAINER FILLING:*

*The APPS is exempt, but shall comply with the CFR.*

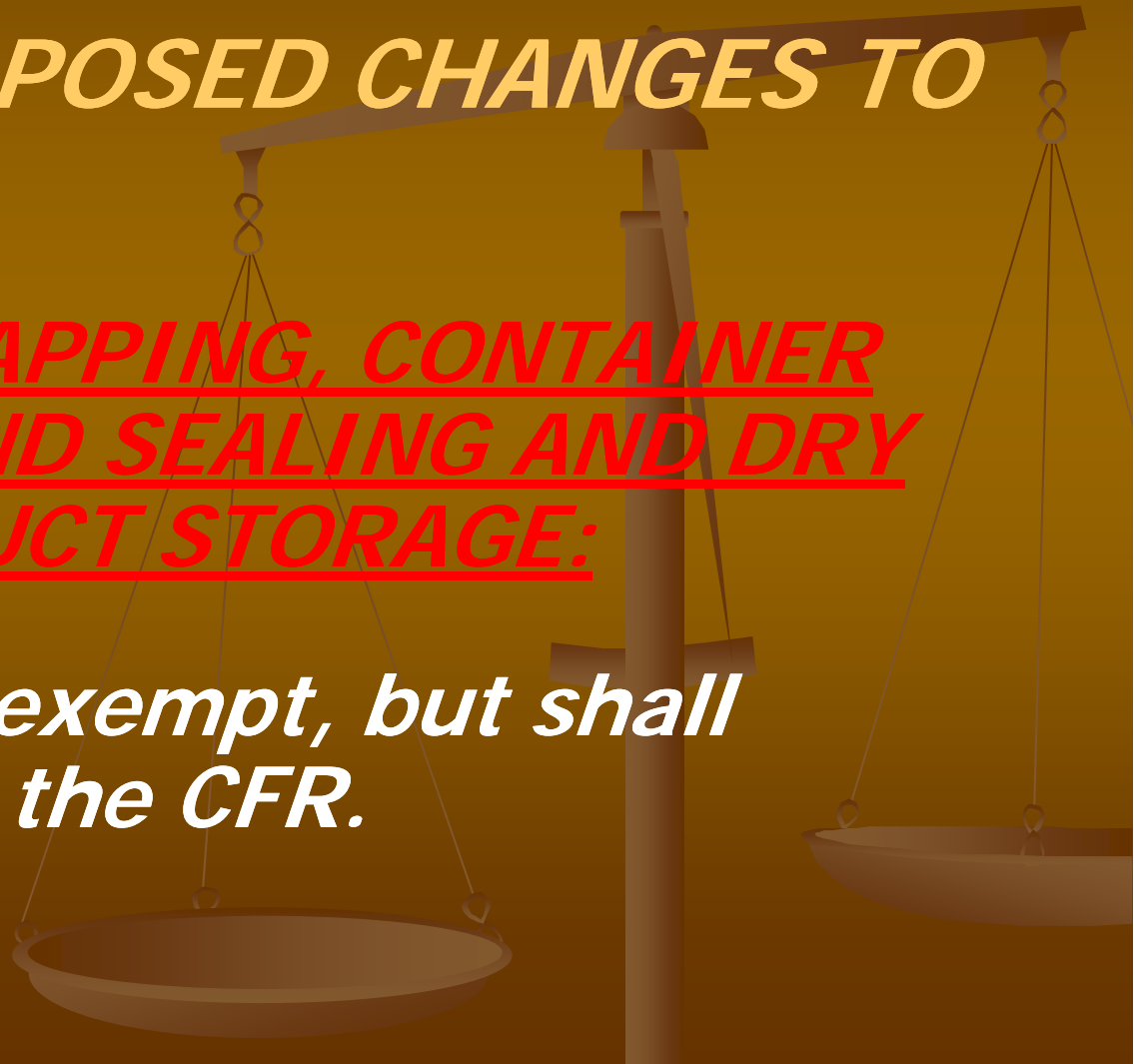


# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

*ITEM 19p-CAPPING, CONTAINER CLOSURE AND SEALING AND DRY MILK PRODUCT STORAGE:*

*The APPS is exempt, but shall comply with the CFR.*



# NCIMS ASEPTIC PILOT PROGRAM

- *PILOT PROPOSED CHANGES TO THE PMO:*

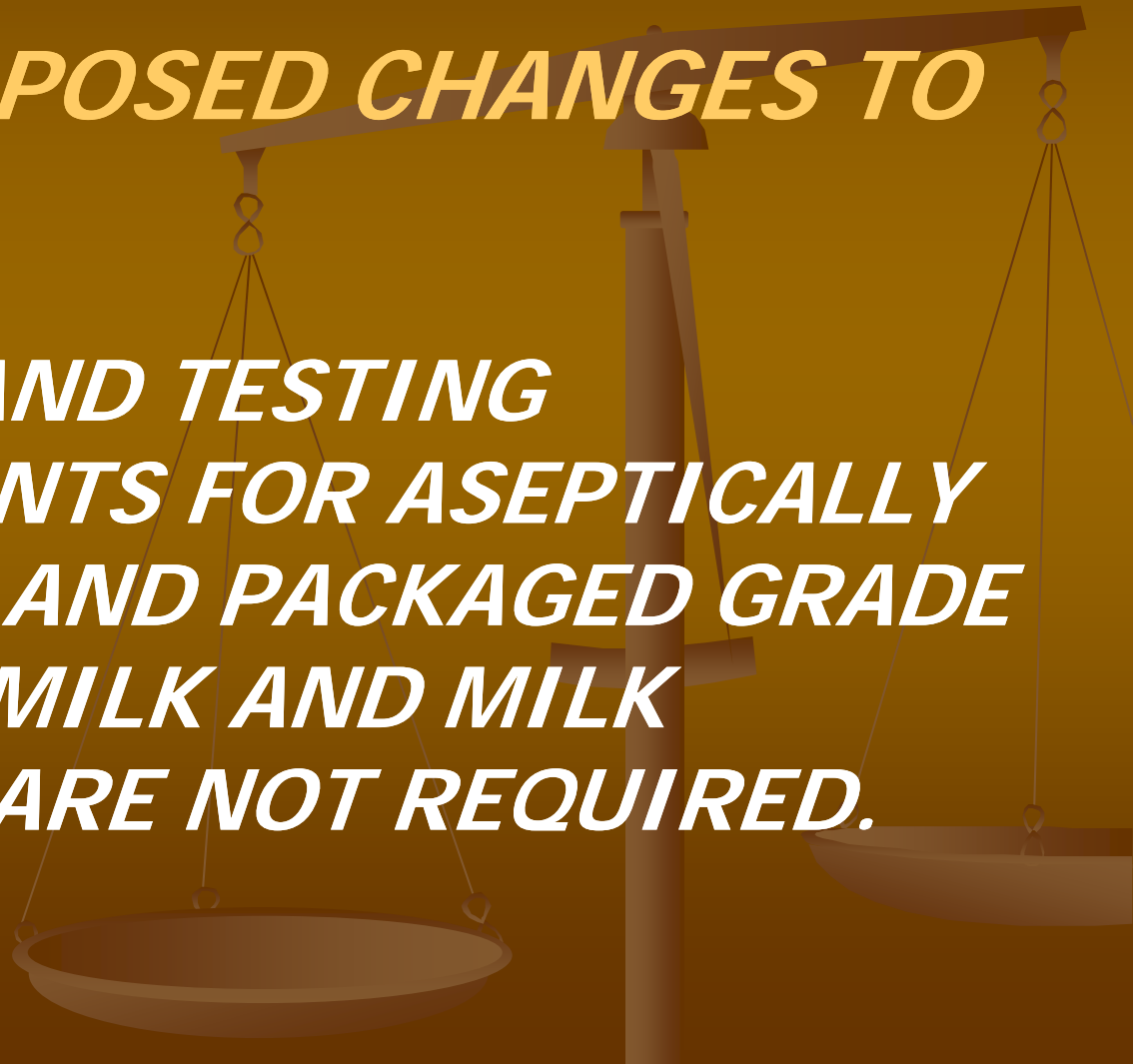
*\* NOTE: In areas of the milk plant where these Items are directly related to the APPS, as defined by the PMO, they shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 110, 113, and 114).*



# **NCIMS ASEPTIC PILOT PROGRAM**

- ***PILOT PROPOSED CHANGES TO THE PMO:***

***SAMPLING AND TESTING REQUIREMENTS FOR ASEPTICALLY PROCESSED AND PACKAGED GRADE "A" DEFINE MILK AND MILK PRODUCTS ARE NOT REQUIRED.***



**NCIMS ASEPTIC PILOT**  
**PROGRAM**

***THANK YOU!!***

**QUESTIONS**

**???**

