

NCIMS LIAISON COMMITTEE PERSPECTIVE ON GRADE A & NON- GRADE A PILOT

63RD NADRO ANNUAL
CONFERENCE

FRANKLIN, TN

JULY 2022

NCIMS LIAISON COMMITTEE

- MEMBERS:
- CHAIR- CASEY McCUE (NY)
- VICE CHAIR- DUSTIN COX (NM)
- JOHN ALLAN, IDFA
- STEVE BEAM, NCIMS CHAIR (CA)
- CLAY DETLEFSEN, NMPF
- ROGER HOOI, DFA DAIRY BRANDS
- ANTONE MICKELSON, NW DAIRY ASSN.
- REBECCA PISTON, HP HOOD
- SOFIA STIFFLEMIRE (TX)
- BRIAN WISE (OH)
- * OPEN SEAT WITH T. ANDERSON'S PROMOTION

GRADE A & NON-GRADE A PILOT 1.0

“WHEN IT COMES TO THE FDA’S MILK INSPECTION PROTOCOLS, THE AGENCY IS SEEKING ADDITIONAL WAYS TO MAXIMIZE STATE AND FEDERAL RESOURCES AND CREATE GREATER EFFICIENCY THROUGH ITS OBLIGATIONS UNDER THE FDA FOOD SAFETY MODERNIZATION ACT.”

“WE BELIEVE THERE’S MORE OPPORTUNITY FOR FDA AND STATE REGULATORS TO BETTER COORDINATE OVERSIGHT EFFORTS OF THE DAIRY INDUSTRY, MAKING THE PROCESS MORE EFFICIENT WHILE MAINTAINING THE HIGH SAFETY OF THE U.S. MILK SUPPLY.”

DR. SCOTT GOTTLIEB, FDA COMMISSIONER, NOVEMBER 1, 2017

GRADE A & NON-GRADE A PILOT

- PROPOSAL JC-1 2019 CONFERENCE
- THE LIAISON COMMITTEE REQUESTS THE CHAIR TO ASSIGN THIS PROPOSAL TO AN NCIMS STANDING COMMITTEE, SPECIAL COMMITTEE, OR AD HOC COMMITTEE AS APPROVED BY THE NCIMS EXECUTIVE BOARD.
- THE ASSIGNED COMMITTEE IS CHARGED TO WORK COOPERATIVELY WITH FDA TO DEVELOP A PILOT PROGRAM WHICH WILL ESTABLISH A REGULATORY FRAMEWORK TO FIND EFFICIENCIES IN INSPECTION ACTIVITIES FOR FACILITIES THAT MANUFACTURE BOTH GRADE “A” AND NON-GRADE “A” PRODUCTS AND BE IMPLEMENTED BY FDA AND THE PARTICIPATING STATES.
- IN DEVELOPING THE DETAILS OF THE INSPECTIONAL MODEL(S) TO PILOT, THE ASSIGNED COMMITTEE WILL, AT LEAST, CONSIDER: THE REGULATORY AUTHORITIES OF STATE REGULATORY AGENCIES, THE ELIGIBILITY CRITERIA FOR PILOT CONSIDERATION, THE TYPES OF NON-GRADE “A” PRODUCTS MANUFACTURED IN DUAL-GRADE FACILITIES, THE RESOURCE NEEDS AND POTENTIAL HURDLES LIKELY TO BE ENCOUNTERED, AND THE METRICS FOR EVALUATING SUCCESS.

GRADE A & NON-GRADE A PILOT

- **WHEN IMPLEMENTED, THE PILOT PROGRAM WILL MEET THE AGENCY'S COMMITMENT TO THE NCIMS OF IDENTIFYING ADDITIONAL WAYS TO MAXIMIZE STATE AND FEDERAL RESOURCES AND TO CREATE GREATER EFFICIENCIES THROUGH ITS OBLIGATIONS UNDER THE FDA FOOD SAFETY MODERNIZATION ACT WHILE MAINTAINING THE HIGH SAFETY OF THE U.S. MILK SUPPLY.**
- **FDA SHALL INFORM AND CONFER WITH THE ASSIGNED COMMITTEE TO ANSWER QUESTIONS AND ADDRESS CONCERNS TO PROVIDE CLARITY AND TRANSPARENCY AT A FREQUENCY DETERMINED BY THE NCIMS EXECUTIVE BOARD. A COMPLETE REPORT OF THE PILOT PROGRAM WILL BE SHARED AT THE 2021 CONFERENCE.**
- **IN RECOGNITION THAT FDA IS STRONGLY COMMITTED TO DEVELOPING AND IMPLEMENTING THE DAIRY INSPECTION PILOT PROGRAM AND STANDS READY TO WORK IN A COLLABORATIVE SPIRIT ON THE FRAMEWORK FOR THIS PILOT PROGRAM IMMEDIATELY WITH THE ASSIGNED COMMITTEE, THE LIAISON COMMITTEE REQUESTS AN EFFECTIVE DATE OF THE RECEIPT AND ACCEPTANCE OF FDA CONCURRENCE AT THE NEXT NCIMS EXECUTIVE BOARD MEETING AFTER THE CONFERENCE.**

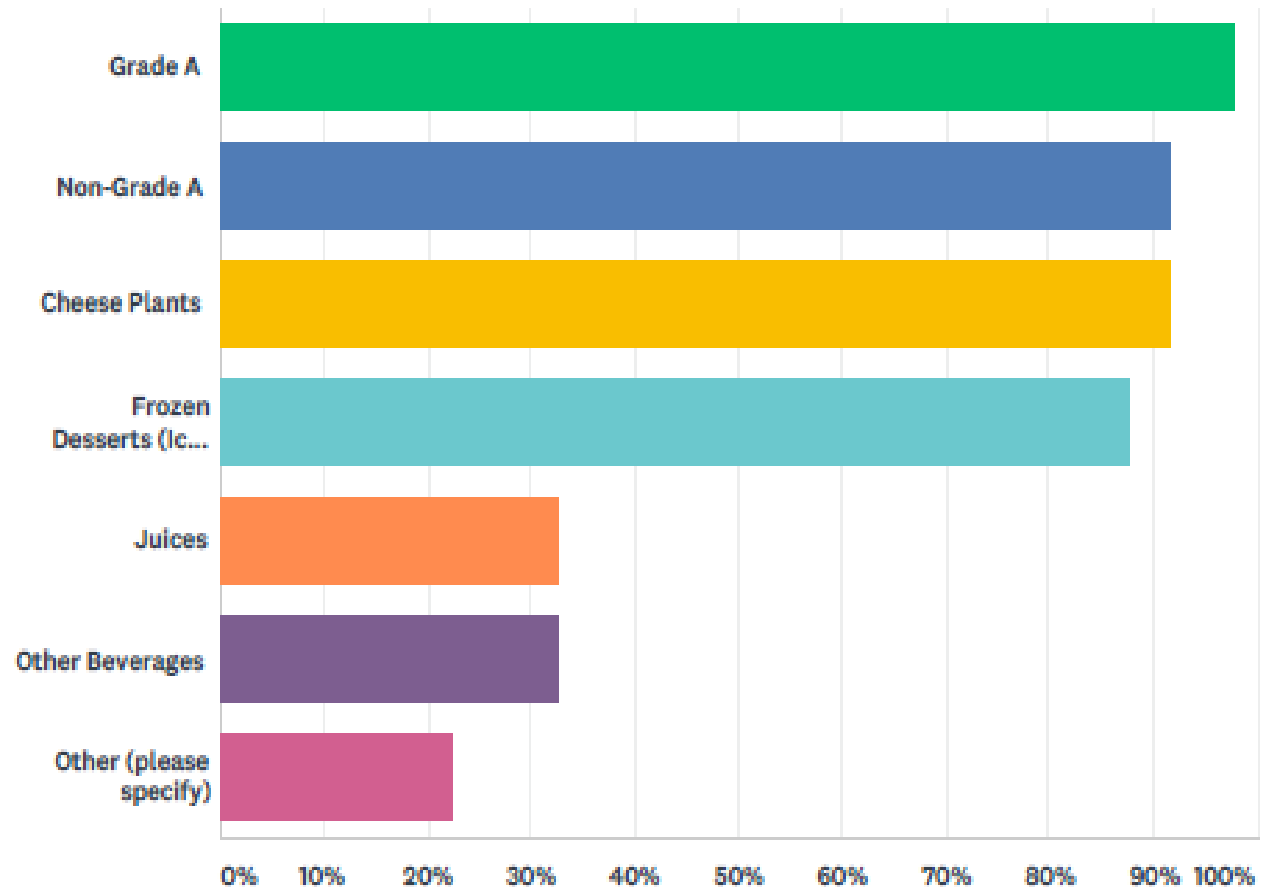
GRADE A & NON- GRADE A PILOT 2.0

STATE SURVEY

- JURISDICTION
- PMO OR STATE RULE
- CONTRACT WORK W/ FDA
- 21CFR 117 ADOPTION
- TRAINING

Q3 Please select all types of processing facilities listed below in which you have jurisdiction.

Answered: 49 Skipped: 0



GRADE A & NON-GRADE A PILOT 2.0

FDA WILL PILOT TWO APPROACHES FOR
DUAL-GRADE FACILITIES:

- FEDERAL-STATE PARTNERSHIP
- APPENDIX T/LIMITED SCOPE PC
COMBINATION

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Option A: Federal-State Partnership

State Regulatory Agency

Grade "A"
Inspection with Non-Grade "A"
PC Inspection

How
often?

What data will
be provided to
FDA?

When/How will the
data be transmitted
to FDA?

How will
noncompliance
be handled?

Option A: Federal-State Partnership

Milk Specialist

Appendix T
Audit

with

Non-Grade "A"
Audit (*new**)

What does the
audit entail?

How will
noncompliance
be handled?

What happens if the audit
does not verify the state's
inspection work?

**GRADE A &
NON-GRADE
A PILOT 2.0**

Option B: Appendix T/Limited Scope PC Combination

Milk Specialist

Appendix T
Audit with Activity to count as
Limited Scope PC

How are the
'gaps' identified?

What data is captured?

How will
noncompliance
be handled?

**GRADE A &
NON-GRADE
A PILOT 2.0**

PILOT STATES

| Participating State | Option |
|---------------------|--------|
| California | A |
| Connecticut | A |
| Oregon | A |
| Texas | A |
| Wisconsin | A |
| Ohio | B |
| Vermont | B |
| Virginia | B |



GRADE A & NGA PILOT 2.0

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GRADE A & NON-GRADE A PILOT 2.0

- TRAINING
 - PCQI
 - FD 8000R (WEBINAR) MODERNIZED GMP/LIMITED SCOPE INSPECTIONS
- LIMITED SCOPE
 - DEFINED IN FDA COMPLIANCE PROGRAM GUIDANCE MANUAL 7303.040
 - REFERENCES TERM “BROAD ASSESSMENT”
 - CONDUCTED FACILITY WIDE

GRADE A & NON-GRADE A PILOT 2.0

- KEY ISSUES:
 - LIMITED SCOPE
 - FIELD INSPECTION STAFF SHOULD NOT CONDUCT THEIR OWN HAZARD ANALYSIS OR REVIEW WRITTEN FOOD SAFETY PLANS, INCLUDING THE FACILITY'S HAZARD ANALYSIS, PREVENTIVE CONTROL PROGRAMS, SUPPLY-CHAIN PROGRAMS, OR RECALL PLAN, AS PART OF THEIR BROAD ASSESSMENT.
 - FIELD INSPECTION STAFF SHOULD NOTIFY DIVISION MANAGEMENT WHEN EGREGIOUS CONDITIONS ARE OBSERVED PERTAINING TO THE CONTROL OF SIGNIFICANT HAZARDS TO DETERMINE WHETHER A FULL SCOPE PCHF INSPECTION IS WARRANTED. DO NOT CONDUCT A LIMITED SCOPE PCHF INSPECTION WHEN ENVIRONMENTAL SAMPLING IS BEING CONDUCTED DURING THE INSPECTION. ENVIRONMENTAL INSPECTIONS COVERING PROCESSES SUBJECT TO SUBPART C MUST BE EITHER FULL SCOPE PCHF OR PCHF FOLLOW-UP INSPECTIONS.

GRADE A & NON-GRADE A PILOT 2.0



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MARCH 16, 2022-LIAISON SENDS 5-PAGE LETTER TO FDA OUTLINING:

- **NO OTHER COMMODITY CREATED A FSMA CARVE OUT BASED UPON GRADE.**
- **REQUESTS LIMITED SCOPE BE INCORPORATED DAIRY PROGRAM WIDE (ALL GRADES) TO SEEK EQUITY IN THE COMMODITY.**
- **APPENDIX T AS WRITTEN (w/ FDA AT THE TABLE) HAS BEEN DEEMED TO BE EQUIVALENT TO 21CFR117 PCHF (FULL-SCOPE).**
- **APPENDIX T IS MASSIVELY OVERBUILT WITH FDA'S "GAME CHANGING" LIMITED SCOPE APPROACH.**



GRADE A AND NGA PILOT 2.0

APRIL 4, 2022-FDA RESPONDS TO LIAISON LETTER OUTLINING:

- AGREES TO A 2-SCOPE APPROACH FOR APPENDIX T AUDITS.
- RESPONDED THAT JC-1 PILOT BELONGS TO THE LIAISON COMMITTEE AND IF THE LC WISHES TO PILOT A DUAL GRADE PILOT UTILIZING LIMITED SCOPE, IT CAN DO SO. (REQUEST SUBMITTED 5/11/22)
- CURRENTLY WORKING TO GET A TIMELINE ON FDA'S APPENDIX T ALIGNMENT TO THE AGENCY'S CURRENT POLICY USING THE LIMITED SCOPE INSPECTION SCHEME.
- NEW PHASE OF EXPLORATION IS CAUSING A REVISIT AND RECREATION OF THE SELECTED PILOT STATES AND APPROACHES.
- STAY TUNED FOR MORE.





**GRADE A & NON-GRADE A
PILOT**

2.000001

OR

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