National
Conference on
Interstate
Milk
Shipments

Appendix N Modification Committee DRAFT DOCUMENT

2015 NCIMS Proposal 211

Raw Milk Testing Pilot for Non-Beta Lactam Drugs

Version 3 November 14 2016

The presentation covers current committee actions and are subject to further changes.

Appendix N Committee Members

Appendix N Modification Committee

(14 members, 7 State Regulatory, 6 Industry, and 1 Academia – VOTING MEMBERS)

Roger Hooi	**Dean Foods/Chair**
Roger Tedrick	**Ohio/Vice Chair**
Tom Angstadt	DFA
Frank Barcellos	Oregon
Beth Briczinski	NMPF
Laurie Bucher	Maryland
Steve Divincenzo	Illinois
Don Falls	Missouri
Pat Gorden	Iowa State
Bob Hagberg	LOL
Rebecca Piston	HP Hood
Lewis Ramsey	Kentucky
John Sanford	Dean Foods
Bill Thompson	Tennessee

Appendix N Modification

Committee – FDA Advisors

Dennis Gaalswyk
Amber McCoig
Phil Kijak
Tom Graham
Tim Roddy
Jeff Hamer
Christina Megalis

Appendix N Modification

Committee – Technical Advisors

- Charm Science
- DSM
- IDEXX
- Neogen

Appendix N Modification Committee

- Busy!
- Since 2007 >85 conference calls.
- 2013-2016 current >50 conference calls (not including subcommittee calls)
- 1-2 hour Conference calls
- 5 "Physical" Meetings (1 - 2013, 2- 2014, 1-2015, 1-2016 July 25th - 27th)

Appendix N – Proposal 211 Committee Assignment

Review of Proposal 211

Appendix N - Proposal 211 Committee Assignment

- The Appendix N Modification Committee is charged to develop a pilot program, establishing a regulatory framework by which **testing raw milk** for veterinary drugs would be *required for drugs other than beta-lactams*
- No Packaged/Finished product testing
- The pilot program, when finalized, would include, but is not limited to, consideration of the following criteria (8 deliverables)

Appendix N - Proposal 211 Committee Assignment

- **Veterinary drugs required to be tested**
  - FDA's recommendation from the output of the risk ranking model: Beta lactams, Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, and Avermectins
- **Testing methodology**
- **Availability of suitable test methods**
- **Number of samples to be collected and assayed**
- **Reduction of required Beta-Lactam testing**
- **National Milk Drug Residue Database**
- **Report of challenges of program implementation**
- **A complete report of the pilot program in 2017**

Appendix N – Proposal 211

Committee Actions

Committee Actions
Possible Timeline

- March -October 2016 – Drug tests for targeted drug identified
- July 2016 – Committee meeting in Kentucky
- August 2016 – Committee Documents and Report to NCIMS Board
- October 2016 - January 2017 – ramp up, 2400 Pilot Program Forms, Lab certification, and communications
- 2017 – Implementation (TBD) – Effective date still to be determined (covered later in slides)

Committee Actions

- **NCIMS Board direction relative to participation**
  - Board direction is that all 50 states plus Puerto Rico participate in the pilot
  - NCIMS Executive Board looks at participation by member states of the conference, as well as Grade "A" Milk facilities, to be expected
  - Should any state or US territory have difficulties in implementing the program such hurdles should be brought to the attention of the Board for consideration

Committee Actions

- Drug Residue:
  - Tetracycline class of drugs (oxytetracycline, tetracycline, chlortetracycline)
  - **Tetracyclines** (as a class of drugs) are proposed as the first drug to pilot for implementation of expanded testing through the pilot program, largely based on the fact that a tolerance has been established (300 ppb), usage, and rapid test methods can be developed and approved in a timely manner

Committee Actions

- The pilot is initially for COW raw milk only
- Frequency:
  - One out of every 15 loads (~6.7%) per quarter (based on 6.7% of loads received per quarter) to be determined (by the user of the test method) with the Regulatory Agency
  - However, this would not prohibit industry voluntarily testing at a greater frequency
  - For example: 1500 Bulk Milk Pickup Tankers was received in a quarter. 1500 x 1/15 = 100 Bulk Milk Pickup Tankers to be tested in a quarter.
  - May be accomplished all in a week, over a month or over the entire 3 months quarter to be determined by the lab performing the test

Committee Actions

- Duration:
  - Minimum of 18 months with a start date TBD (To Be Determined) for 2017
- Who:
  - IMS listed Grade A Milk plants will be screening and reporting tetracycline results to the Regulatory Agency (refer to Q&A latest release)
- Test Methods:
  - CVM reviewed, Appendix N Modification, and Laboratory Committee accepted for the pilot tests
  - IDEXX Current Equipment use (Currently pending CVM review)
  - Charm SL Current Equipment Used (Currently pending CVM review)
  - Charm II (already an NCIMS accepted method with 2400 forms – does not require further acceptance)

Committee Actions

- 2400 Forms:
  - 2400 Forms will be available specifically for the pilot program (will be titled as such). “Tetracycline Testing for Pilot Program” laboratory forms based on FDA CVM acceptance
  - Will not require LEO to revisit or recertify certified labs that will be using the same equipment for beta-lactams for tetracyclines testing (To be communicated by LPET)
  - NCIMS Lab Committee and LPET will be providing directions to LEOs. (TBD)

Committee Actions

- Industry Reporting:
  - Industry will be reporting completed test results to the Regulatory Agency (monthly)
- State Reporting:
  - Reported to the National Drug Residue Monitoring Database (monthly)
- 2015 NCIMS Proposal 211 Pilot Program Funding for small producer-processor:
  - FDA Office of Partnership funding was not achieved
  - Small producer-processors experiencing difficulty implementing the Pilot Program should discuss concerns with their State Regulatory Agency.

Committee Actions
Available Documents

- 2015 NCIMS Proposal 211 Pilot Program on NCIMS Website
- Q&A Release 3.0 TBD
- Test Flowchart
- Power Point Presentation (TBD)
- Appendix N Modification LEO Responsibilities Appendix N Committee DRAFT

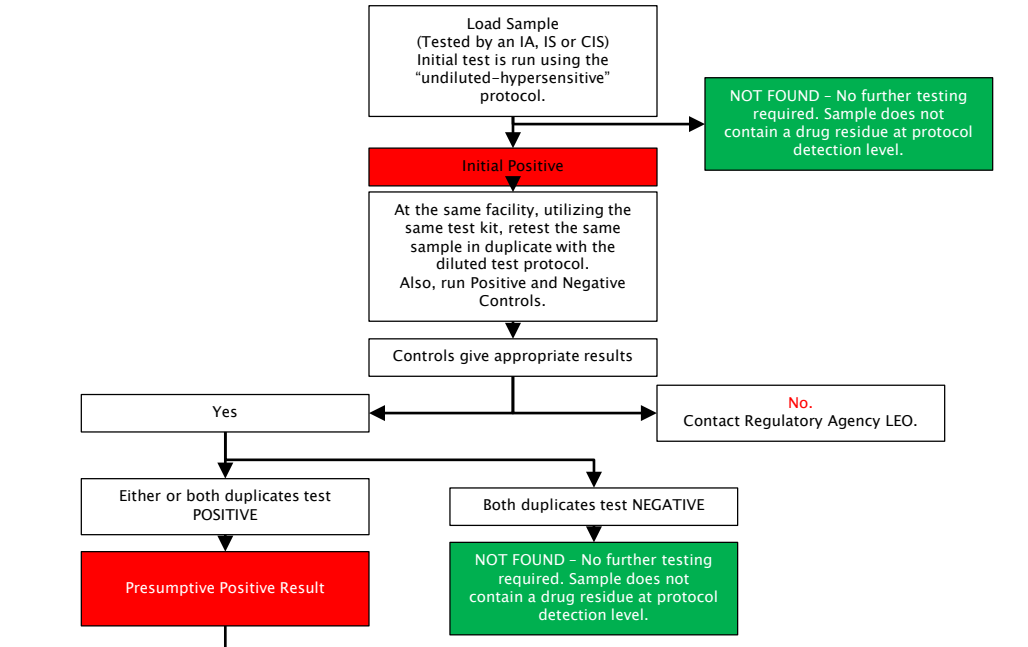
Committee Actions

Key Elements of method

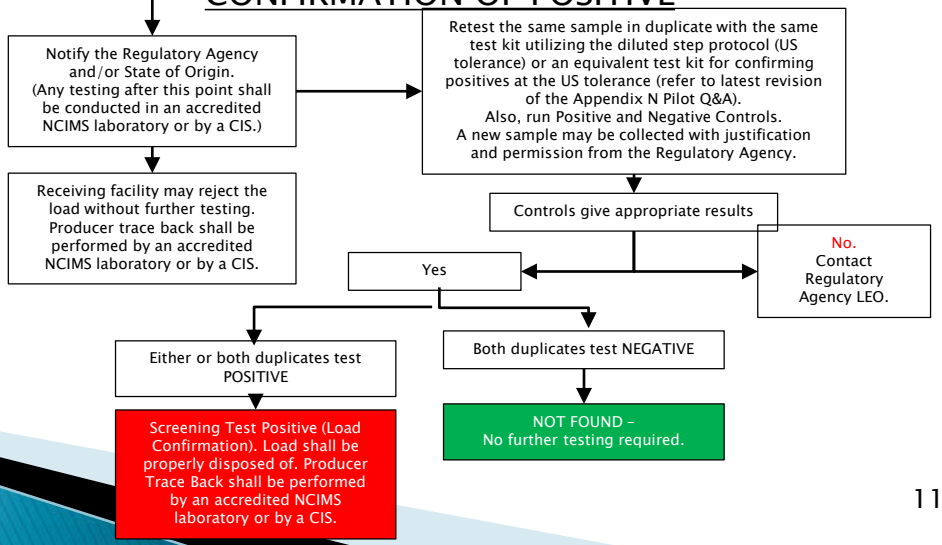
- Initial testing on undiluted sample
- Initial positive repeated 2X with Positive and Negative Controls but with diluted samples (diluent either from supplier or previously tested negative tested sample depending on test method used) to bring the test method closer to the testing limit (old Tolerance levels). Any Positive = Positive (Inform State)
- Confirmation will be performed at a certified lab 2X with Positive and Negative Controls with diluted samples. Any positive = Positive
- Producer trace back, each producer, on diluted sample, 1st test negative = negative, 1st test positive = Repeat 2x with controls. Any positive = Positive
- Producer Reinstatement on same test of first test, or with Charm II accepted test on diluted sample.
- Producer Reinstatement utilizing same test method as first test utilizing diluted sample or with the Charm II accepted test."

2015 NCIMS Proposal 211
Pilot Program Accepted Tetracycline Test Kit Using Both Undiluted and Diluted Steps

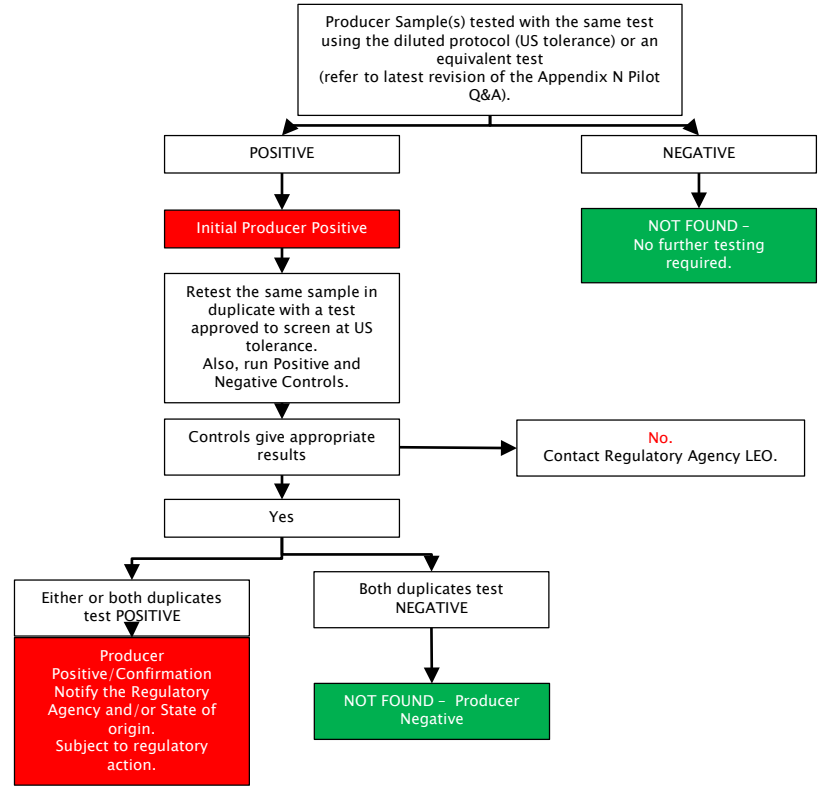
PRESUMPTIVE POSITIVE DETERMINATION



CONFIRMATION OF POSITIVE



TETRACYCLINE PRODUCER TRACE BACK



Note: Suspension of permit or equally effective measures shall immediately be taken to prevent the sale of milk containing drug residues and further pickup or use of milk shall be immediately discontinued.

PRODUCER REINSTATEMENT

Producers that test Positive shall have a Negative sample using the diluted protocol (US tolerance) or an equivalent test
(refer to latest revision of the Appendix N Pilot Q&A).

Note: CVM will allow a kit for use in the NCIMS Proposal 211 Pilot testing for tetracyclines to test for oxytetracycline and either chlortetracycline or tetracycline at the published tolerance (300 ppb). However, for the drug (tetracycline or chlortetracycline) that is not detected at the tolerance, the 90/95 must be within twice the tolerance (600 ppb).

Committee Actions
Communications

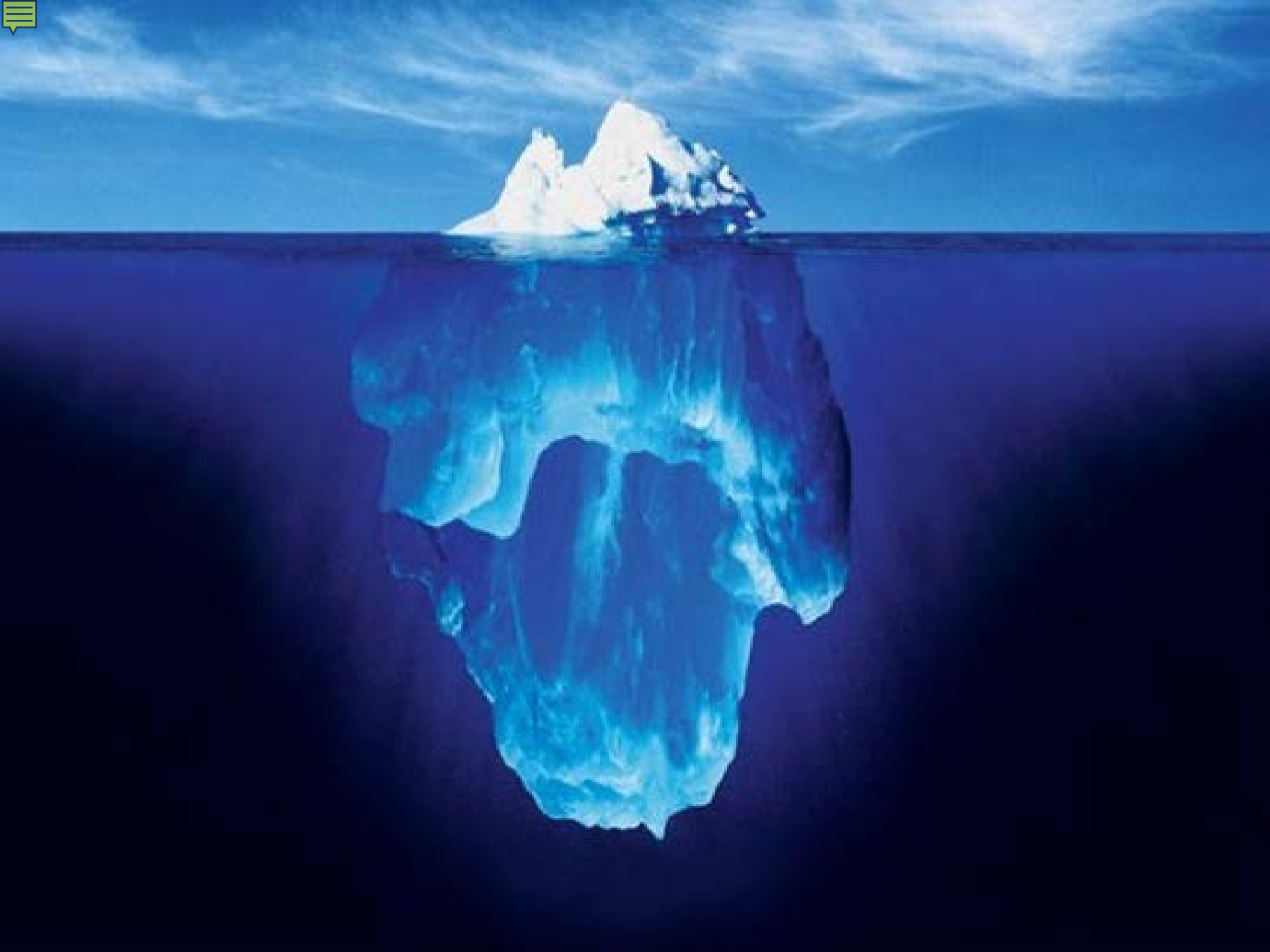
- 2015
  - Regional Milk Seminars: early version of update was provided at two RMS in 2015 (John Sanford)
- 2016
  - Pacific Southwest RMS (Roger Hooi)
  - Central States RMS (Roger Hooi)
  - IDFA – Cultured Products Meeting (Roger Tedrick)
  - Associated Illinois Milk, Food and Environmental Sanitarians (Steve DiVincenzo)
  - NADRO (Roger Tedrick)
  - IAFP (Roger Hooi)
  - Kentucky Dairy Meeting (Roger Hooi)
  - NY State association for Food Protection Meeting (Roger Hooi)
  - Dairy Practices DPC Roger Hooi, Scheduled)

Final Tasks

- Finalize evaluation of test methods for acceptance in the Pilot – FDA CVM
- Finalize Laboratory Forms for “Tetracycline Pilot Program” - NCIMS Lab Committee
- Exemption –LPET; “Appendix N Modification LEO Responsibilities Appendix N Committee DRAFT”

Implementation Date

- The effective date for the implementation of the 2015 NCIMS Proposal 211, Pilot Program has not been finalized and it is dependent on
- FDA CVM evaluation of test methods for acceptance in the Pilot, and the
- completion of the "Tetracycline Testing for Pilot Program" laboratory forms based on FDA CVM acceptance.
- The Appendix N committee best estimate of the effective date pending the completion of tasks mentioned would still be in 2017 and probably be in the second quarter of 2017.
- Communication on implementation on NCIMS website and Appendix N Committee



Questions?