Appendix N Modification Committee

2015 NCIMS Proposal 211
Raw Milk Testing Pilot for Non–Beta Lactam Drugs
NADRO – July 2017
John Sanford
# Appendix N Modification Committee

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
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<tr>
<td>Roger Hooi</td>
<td>Dean Foods/Chair</td>
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<td>Roger Tedrick</td>
<td>Ohio/Vice Chair</td>
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<tr>
<td>Tom Angstadt</td>
<td>DFA</td>
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<tr>
<td>Frank Barcellos</td>
<td>Oregon</td>
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<td>Beth Briczinski</td>
<td>NMPF</td>
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<tr>
<td>Connie Caffes</td>
<td>Maryland</td>
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<td>Steve Divincenzo</td>
<td>Illinois</td>
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<td>Don Falls</td>
<td>Missouri</td>
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<td>Pat Gorden</td>
<td>Iowa State</td>
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<td>Bob Hagberg</td>
<td>LOL</td>
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<tr>
<td>Harris Hollingsworth</td>
<td>Texas</td>
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<tr>
<td>Rebecca Piston</td>
<td>HP Hood</td>
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<td>Lewis Ramsey</td>
<td>Kentucky</td>
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<td>John Sanford</td>
<td>Dean Foods</td>
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<tr>
<td>Laurie Bucher- MD- Ret</td>
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<td>Bill Thompson – TN -Ret</td>
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# Appendix N Modification Committee

FDA Advisors

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<tr>
<th>Name</th>
<th>Agency</th>
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<tr>
<td>Dennis Gaalswyk</td>
<td>CFSAN</td>
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<td>Amber McCoig</td>
<td>CVM</td>
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<td>Phil Kijak</td>
<td>CVM</td>
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<tr>
<td>Tom Graham</td>
<td>LPET</td>
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<td>Tim Roddy</td>
<td>ORA</td>
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<tr>
<td>Jeff Hamer</td>
<td>CFSAN</td>
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<tr>
<td>Christina Megalis</td>
<td>LPET</td>
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Appendix N Modification Committee
Technical Advisors

- Charm Sciences
- DSM Food Specialties
- IDEXX Labs
- Neogen
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
- May lessen the testing frequency required for beta lactam drugs in the future
Committee Actions

Initial 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

Timelines

- **October 2016 - January 2017** – ramp up, Pilot Program Forms, Lab certification, and communications
- **July 1, 2017** – Implementation Date for Tetracycline Pilot Programs.

The Pilot Program will continue testing for the tetracycline class of drugs until a minimum of 18 months of data are generated by each Regulatory Agency for the Appendix N Modification Committee to review testing results and make recommendations.
Committee Actions Participation

“Expected to Participate”

- Dairy Facilities
  - All IMS-listed milk plants (as defined in the PMO)
  - No size exemption

Participation NOT Expected

- Transfer Stations and Receiving Stations
- Facilities that receive Grade “A” raw milk but produce NO Grade “A” dairy products
- Facilities that receive Grade “A” raw milk but do not ship out of state
Committee Actions

Particulars:

- The pilot is for Grade “A” COW raw milk only
- The Pilot Program requires no less than 1 out of 15 (~6.7%) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers of Grade “A” raw milk to be tested for tetracyclines calculated on a quarterly basis.
- However, this would not prohibit industry voluntarily testing at a greater frequency
- For example: 1500 Bulk Milk Pickup Tankers were received in a quarter. 1500 x 1/15 = 100 Bulk Milk Pickup Tankers to be tested in a quarter.
- Testing could be accomplished all in a week, over a month, or any other means to meet the requirements by the facility in consultation with the Regulatory Agency.
Committee Actions

Test Methods

- The Pilot Program will utilize FDA evaluated and NCIMS Appendix N Modification Committee accepted tests or NCIMS approved/accepted (M–a–85, latest revision) test methods for screening, confirmation, producer trace back and reinstatement. Currently, the four tetracycline drug test methods that will be used as part of the Pilot Program are:
  - Charm® II Tetracycline Drug Test (Competitive Assay) M–a 85 approved
  - Neogen BetaStar® Advanced for Tetracyclines – M–a 85 status pending
  - Charm® ROSA Tetracycline–SL Test (Dilution Confirmation) M–a 85 status pending
  - IDEXX – SNAP® Tetracycline Test (Dilution Confirmation)
# Committee Actions

## Test Methods

- **Raw Commingled Cow Milk Confirmation Tests**

<table>
<thead>
<tr>
<th>Presumptive Positive Test</th>
<th>Screening Test Positive (Confirmation Test) Options</th>
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<tbody>
<tr>
<td>Charm® II Tetracycline Drug Test (Competitive Assay) M-a–85 test</td>
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Committee Actions
FDA on Laboratory Certification

- “Appendix N Modification LEO Responsibilities For New Tetracycline Test Kits”
- Will not require LEO to revisit or recertify labs that will be using the same equipment for beta-lactams for tetracyclines testing (FDA Appendix N Modification LEO Responsibilities For New Tetracycline Test Kits)
- Tetracycline Pilot Program 2400 Forms have been developed
Committee Actions

Reporting

- Industry Reporting:
  - Industry will be reporting completed test results to the Regulatory Agency (monthly)

- State Reporting:
  - Reported to the National Milk Drug Residue Database (monthly)
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 undiluted (in question at present, 2400 vs chart) sample, 1st test negative = negative, 1st test positive = Repeat 2x with controls. Any positive = Positive
Committee Actions
Available Documents at http://ncims.org/

- 2015 NCIMS Proposal 211 Pilot Program Accepted Tetracycline Test Kit Using Both Undiluted and Diluted Steps
- Appendix N Modification LEO Responsibilities For New Tetracycline Test Kits
- Drug Residue Test Methods for Confirmation Tetracyclines Proposal 211 Pilot
- **Q&A Document: Appendix N Pilot Program Question and Answer Version 5.0**
- PowerPoint 2015 NCIMS Proposal 211 Raw Milk Testing Pilot for Non-Beta Lactam Drugs Version 4 2017
- FDA evaluated and Appendix N Modification Committee accepted Charm ROSA Tetracycline-SL Test (Dilution Confirmation) form, “TETRACYCLINE PILOT PROGRAM, BULK MILK TANKER SCREENING TEST FORM, CHARM® ROSA TETRACYCLINE-SL TEST DILUTION CONFIRMATION), (Raw Commingled Cow Milk)”
http://ncims.org/programs/appendix-n-pilot-program/

Appendix N Pilot Program

2015 NCIMS PROPOSAL 211 APPENDIX N MODIFICATION COMMITTEE PILOT PROGRAM

The implementation of the NCIMS Proposal 211 Pilot Program is July 1, 2017. The Pilot Program will use the FDA evaluated and Appendix N Modification Committee accepted Charm ROSA.
Questions?