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)

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

**Committee – FDA Advisors**

<table>
<thead>
<tr>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dennis Gaalswyk</td>
</tr>
<tr>
<td>Amber McCoig</td>
</tr>
<tr>
<td>Phil Kijak</td>
</tr>
<tr>
<td>Tom Graham</td>
</tr>
<tr>
<td>Tim Roddy</td>
</tr>
<tr>
<td>Jeff Hamer</td>
</tr>
<tr>
<td>Christina Megalis</td>
</tr>
</tbody>
</table>

Appendix N Modification
Committee – Technical Advisors

- Charm Science
- DSM
- IDEXX
- Neogen
Busy!
Since 2007 >85 conference calls.
2013–2016 current >50 conference calls (not including subcommittee calls)
1–2 hour Conference calls
Appendix N – Proposal 211
Committee Assignment

Review of Proposal 211
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)
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 × 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

Load Sample
(Tested by an IA, IS or CIS)
Initial test is run using the
“undiluted-hypersensitive” protocol.

Initial Positive
At the same facility, utilizing the
same test kit, retest the same
sample in duplicate with the
dilated test protocol.
Also, run Positive and Negative
Controls.

Controls give appropriate results

Yes

Either or both duplicates test
POSITIVE

Presumptive Positive Result

No.
Contact Regulatory Agency LEO.

Both duplicates test NEGATIVE

NOT FOUND - No further testing
required. Sample does not
contain a drug residue at protocol
detection level.

CONFIRMATION OF POSITIVE

Notfify the Regulatory Agency
and/or State of Origin.
(Any testing after this point shall
be conducted in an accredited
NCIMS laboratory or by a CIS.)

Receiving facility may reject the
load without further testing.
Producer trace back shall be
performed by an accredited
NCIMS laboratory or by a CIS.

Controls give appropriate results

Yes

Either or both duplicates test
POSITIVE

Screening Test Positive (Load
Confirmation). Load shall be
properly disposed of. Producer
Trace Back shall be performed
by an accredited NCIMS
laboratory or by a CIS.

No.
Contact Regulatory Agency LEO.

Both duplicates test NEGATIVE

NOT FOUND - No further testing required.
TETRACYCLINE PRODUCER TRACE BACK

Producer Sample(s) tested with the same test using the diluted protocol (US tolerance) or an equivalent test (refer to latest revision of the Appendix N Pilot Q&A).

POSITIVE

Initial Producer Positive

Retest the same sample in duplicate with a test approved to screen at US tolerance. Also, run Positive and Negative Controls.

Controls give appropriate results

Yes

Either or both duplicates test POSITIVE

Producer Positive/ Confirmation
Notify the Regulatory Agency and/or State of origin.
Subject to regulatory action.

NOT FOUND - Producer Negative

Both duplicates test NEGATIVE

NOT FOUND - Producer Negative

NEGATIVE

NOT FOUND - No further testing required.

Contact Regulatory Agency LEO.

Either or both duplicates test POSITIVE

Producer Positive/ Confirmation
Notify the Regulatory Agency and/or State of origin.
Subject to regulatory action.

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?