



APPENDIX N MODIFICATION COMMITTEE UPDATE

NOVEMBER 2019 UPDATE



National
Conference on
Interstate
Milk
Shipments

COMMITTEE



Balanced with 6 Regulatory,
6 Industry (including
academia)



Committee members: Roger
Hooi (Chair), Steve DiVincenzo
(Vice Chair), Tom Angstadt,
Frank Barcellos, Zach Conlin,
Ellen Fitzgibbons, Pat Gorden,
Harris Hollingsworth, Jaime
Jonker, Rebecca Piston, Lewis
Ramsey, John Sanford



FDA: Laurie Bucher, Phil Kijak,
Jeff Hamer, Tom Graham, Tim
Roddy, Amber McCoig, Hui Li



Supplier stakeholders: Charm,
IDEXX, Neogen, others

Committee is Balanced

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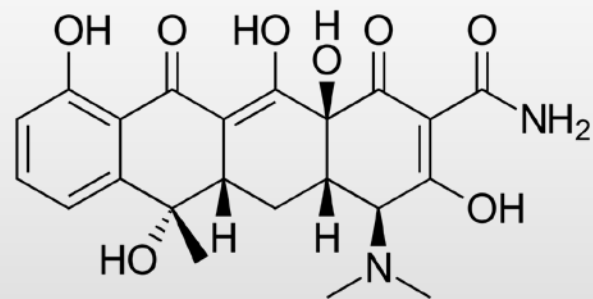


2019 NCIMS REPORT (2015 NCIMS PROPOSAL 211)

- 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*.
- **VETERINARY DRUGS REQUIRED TO BE TESTED**
- **TESTING METHODOLOGY REQUIRED TO BE USED**
- **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**

TETRACYCLINE PILOT

- BULK MILK TANKERS
- 1/15 (6.7%) LOADS PER QUARTER
- NCIMS APPENDIX N ACCEPTED TESTS
- APPENDIX N BETA-LACTAM APPROVED LABS
- LAUNCHED JULY 1, 2017
- ENDED DECEMBER 31, 2018



WHAT ARE THE LATEST UPDATES?



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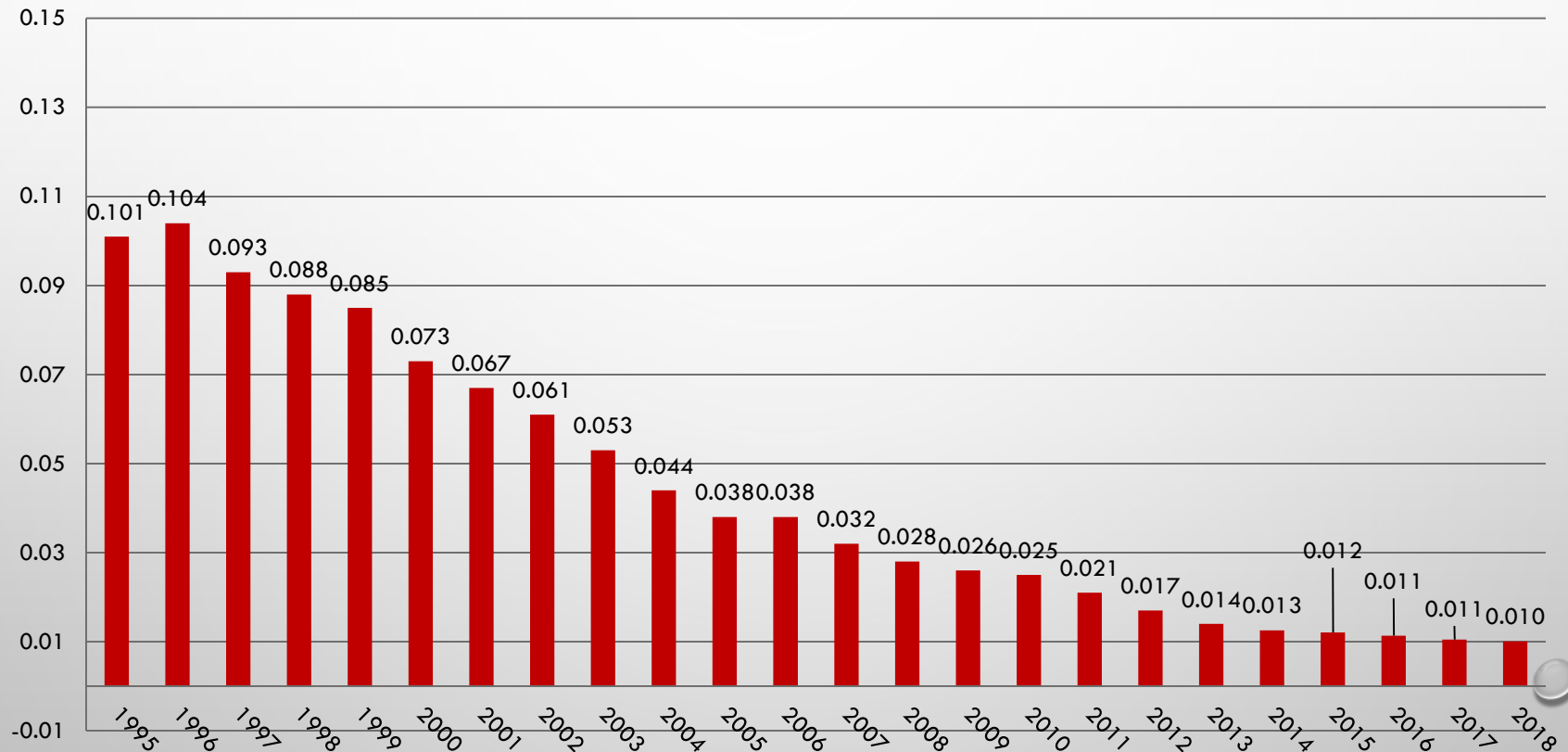
ANIMAL DRUGS

1994 – 2018 SUM OF ALL TEST

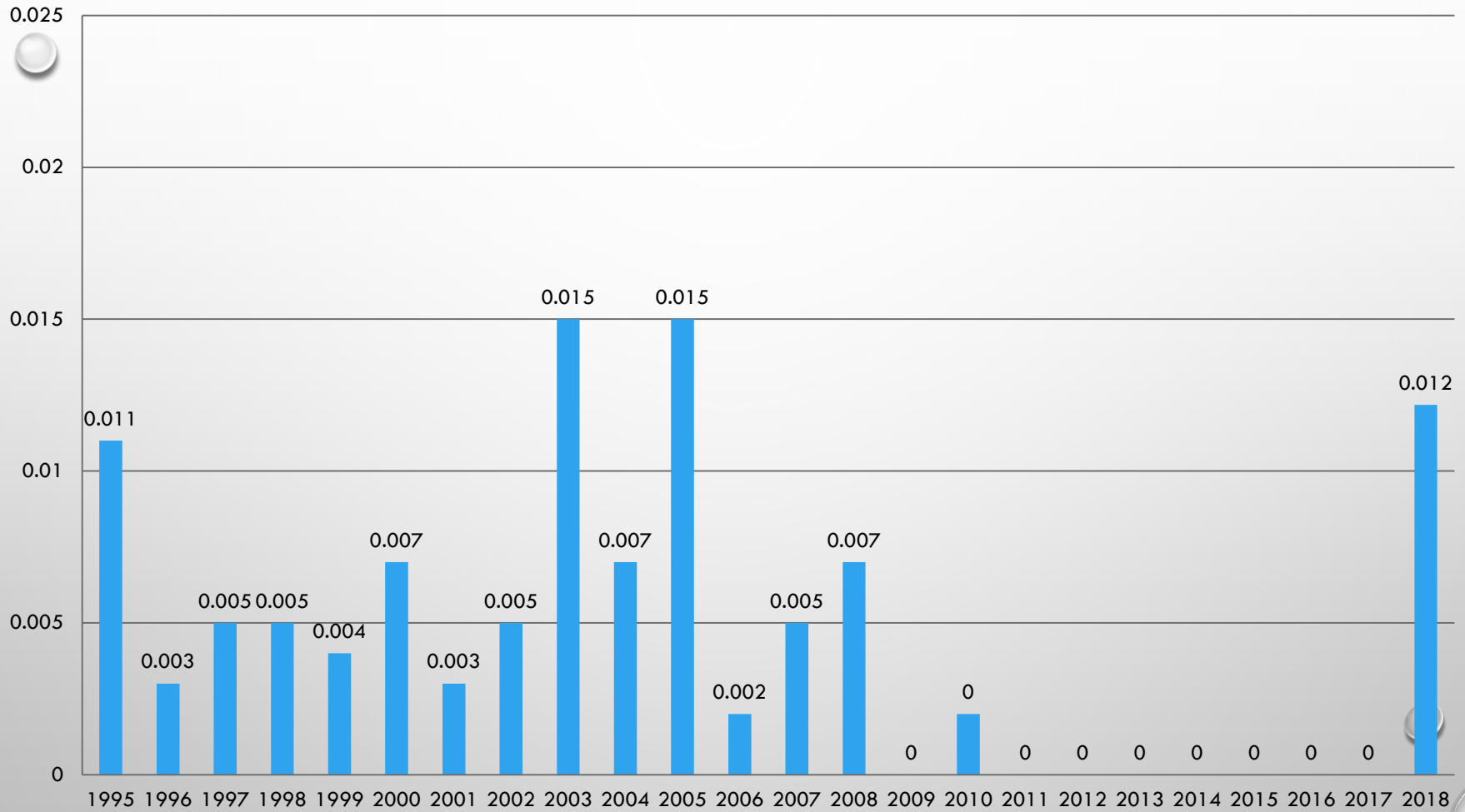
Drug Family	Total Tests	Total Positive	%
Aminoglycosides (Gentamicin)	25691	20	0.08
Amphenicol (Florfenicol, Chloramphenicol)	270	0	0.00
Avermectins (antiparasitics)			
Beta-lactams	76936306	35673	0.05
Fluoroquinolone - Enrofloxacin (Baytril)	50693	10	0.02
Macrolides	12457	3	0.02
NSAID (Flunixin)	2054*	0*	
Sulfonamides	2089905	405	0.02
Tetracyclines	1413179	711	0.05

* Internal data, 1 unconfirmed positive

Bulk Milk Pick Up Tanker Appendix N Beta-lactam % Positive National Milk Drug Residue Database (NMDRD)



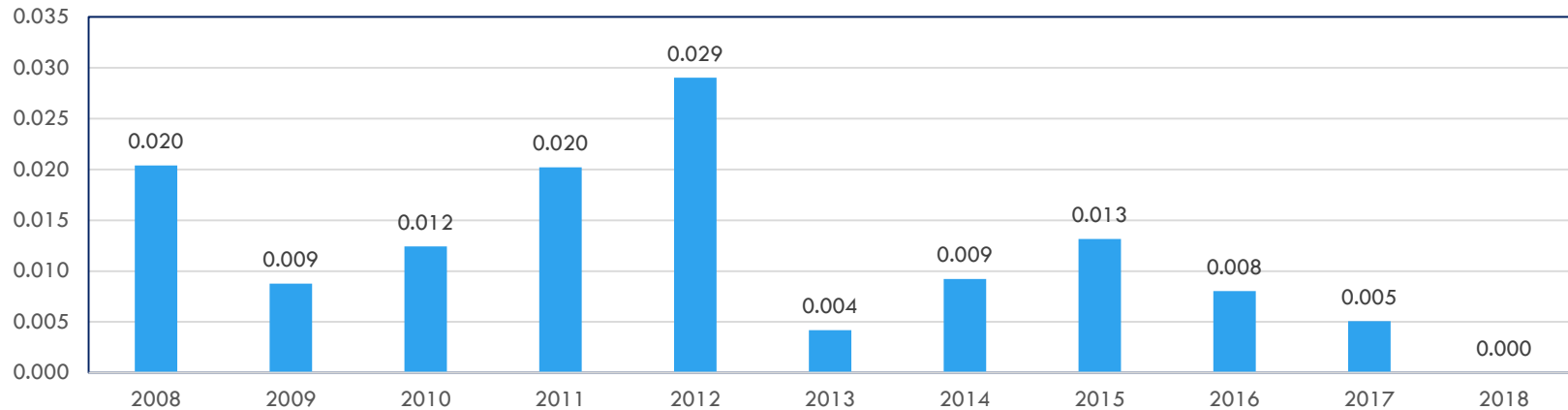
Pasteurized Milk and Milk Products Beta-lactam % Positive National Milk Drug Residue Database (NMDRD)



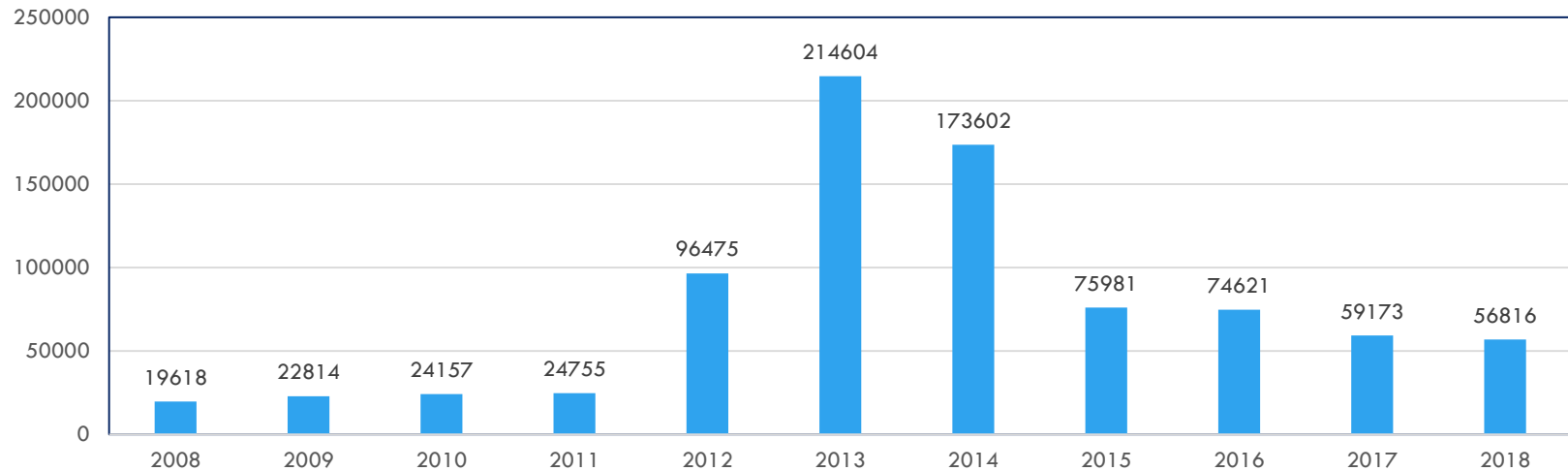
SULFONAMIDES

NATIONAL MILK DRUG RESIDUE DATABASE (NMDRD)

% + of Sulfonamide Tests

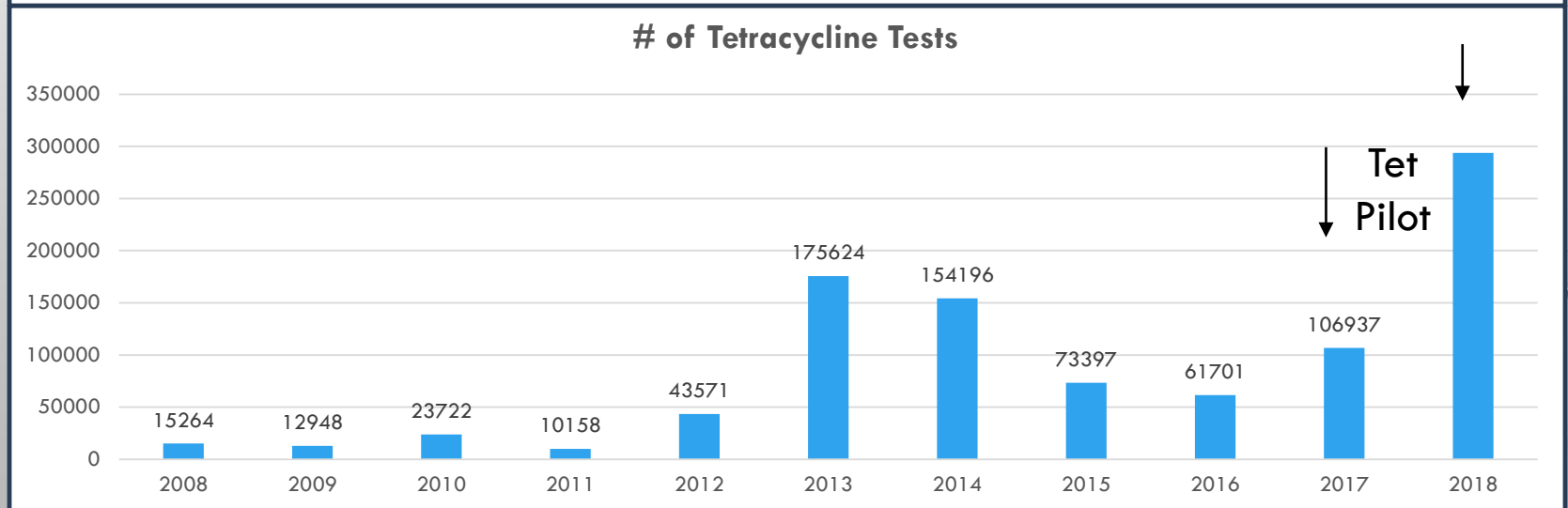
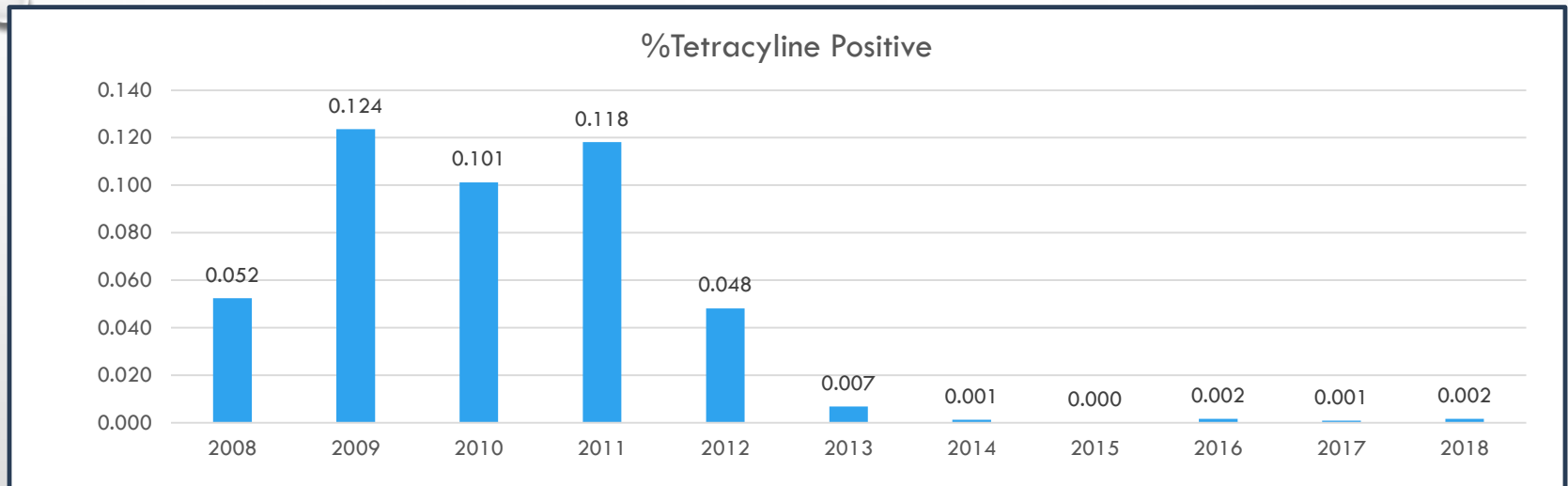


of Sulfonamides Tests



TETRACYCLINES OVER 10 YEARS

NATIONAL MILK DRUG RESIDUE DATABASE (NMDRD)



TETRACYCLINE PILOT

DATA

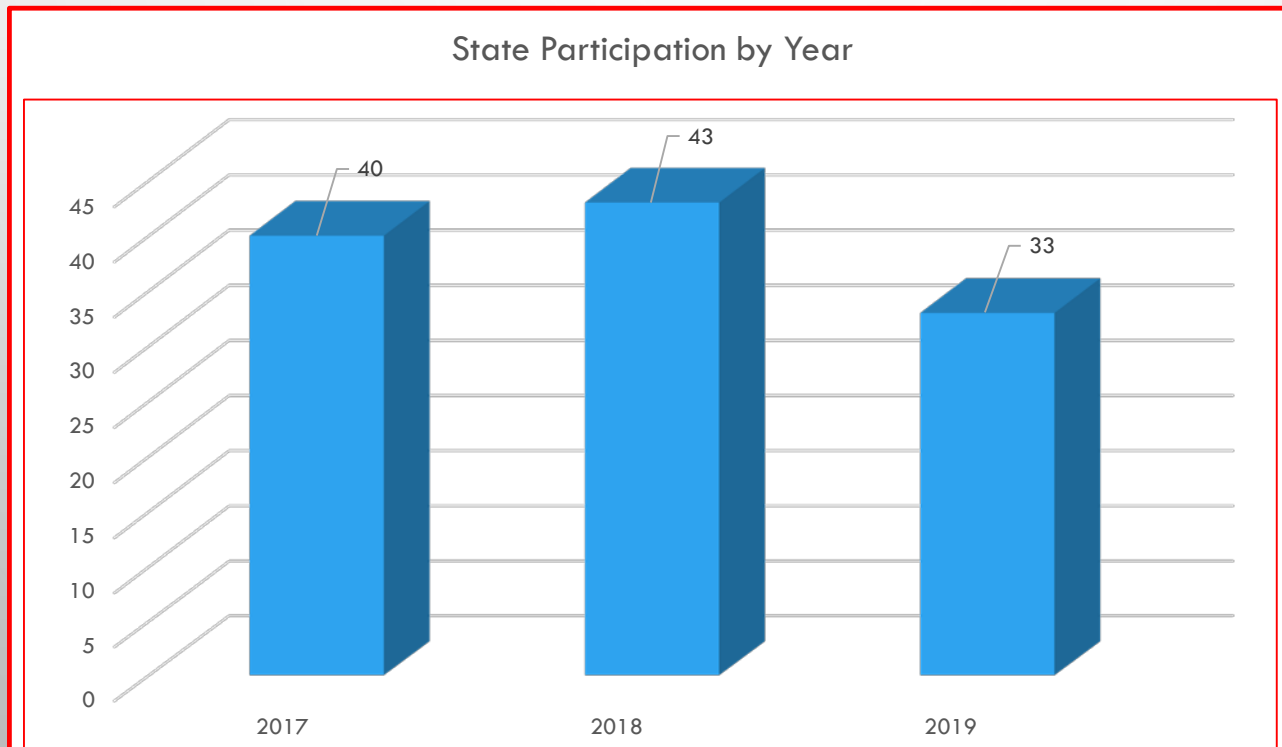
PILOT RESULTS

- STATE PARTICIPATION
- INDUSTRY PARTICIPATION
- OVERALL TETRACYCLINE RESULTS
- TEST METHODS AVAILABLE
- HURDLES

PILOT RESULTS

STATE PARTICIPATION

- STATE: 81% PARTICIPATION (43/53)
- STATES PERFORMED ~ 6,500 OWN TESTING



PILOT RESULTS

INDUSTRY PARTICIPATION

- **INDUSTRY TESTED AT A 399,900 TESTS**
- **POTENTIAL SPEND OF \$1.8 MILLION OVER THE 18-MONTH PERIOD**
- **OVER A 12 MONTH COMPARISON INDUSTRY TESTED AT A 9.27% (1/11) VERSUS A REQUESTED 6.7% (1/15) RATE (2.5% MORE, >80K TESTS)**
- **~409,534 TESTS INDUSTRY AND STATE COMBINED (ANOTHER 3,119 SUBMITTED SINCE MARCH 2019)**

PILOT RESULTS

OVERALL TETRACYCLINE PILOT RESULTS

- 11
- 10
- 9
- 7
- **7/409,534 OR 0.0017% / 18 MONTHS**
- **0/6,500 OR 0%**
- **~ 0.0017% V 0.01%**

PILOT RESULTS TEST METHODS

- **SUPPLIERS PARTICIPATION**
- **CHARM, IDEXX, NEOGEN**
- **PROVIDED METHODS ACCEPTED BY NCIMS**

HURDLES

- **COMPLIANCE OR TESTING PROGRAM OR FOOD SAFETY**
- **DRUG RESIDUE, SAMPLING RATE**
- **DEVELOPMENT, VALIDATING TEST METHOD(S), APPROVING METHODS**
- **2400 FORMS**
- **NMDRDB REPORTING – REPORTING ACCURACY**
- **EQUIVALENT METHODS**
- **REGULATORY ACTION**
- **COMMUNICATION**
- **RESOURCES, TRAINING**

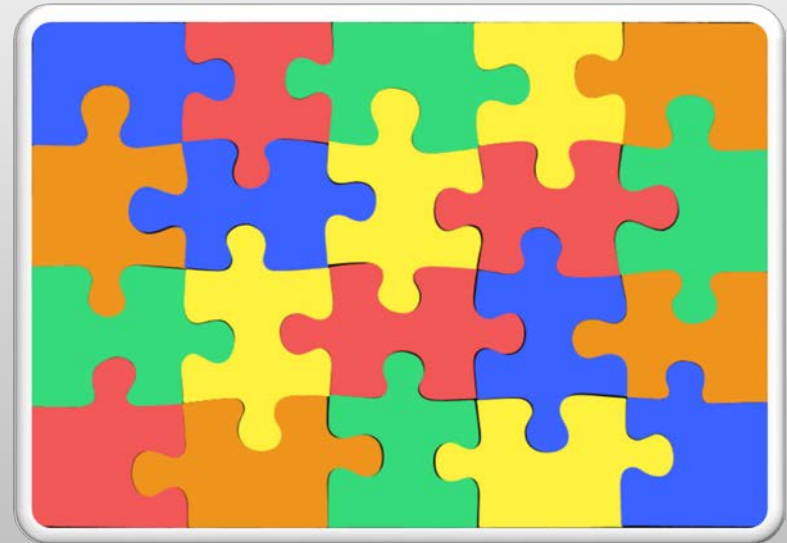


A REGULATORY FRAMEWORK

- A FOUNDATION OF UNDERSTANDING THE USE AND IMPLICATION OF AN ANIMAL DRUG RESIDUE TO BE FOUND IN MILK
- DETERMINATION OF A FREQUENCY OF TESTING.
- SETTING OF REGULATORY TOLERANCE AND/OR TESTING LIMITS.
- DESIGNING A TESTING PATH THAT INVOLVES METHODS, AND NCIMS VALIDATION
- NATIONAL MILK DRUG RESIDUE DATABASE (NDMDRD) REPORTING
- DEFINING REGULATORY ACTIONS
- COMMUNICATION, IMPLEMENTATION

SUMMARY

- PILOT TO DEVELOP A REGULATORY FRAMEWORK
- TETRACYCLINE DATA
- 81% (43/53) OF STATE PARTICIPATED
- POSITIVE LEVELS LOWER THAN BETA-LACTAMS
0.0017% V 0.01%
- ACCURATE DATA



SO WHAT?

APPENDIX N
MODIFICATION
COMMITTEE

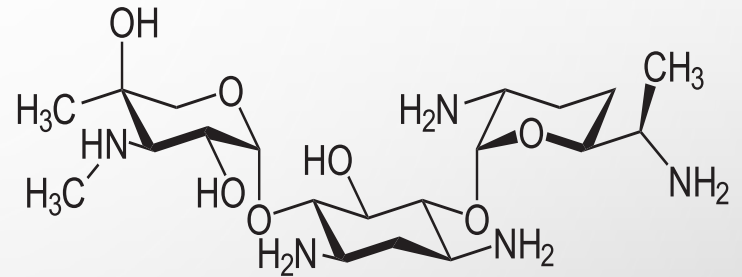


CURRENT ACTIONS OF THE APPENDIX N MODIFICATION COMMITTEE

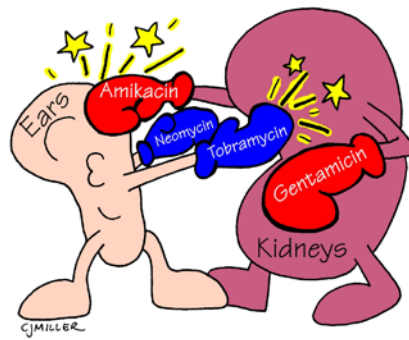
- 2019 NCIMS AD HOC TO STANDING COMMITTEE
- STEVE DIVINCENZO – VICE CHAIR OF THE COMMITTEE
- REVIEW OF APPENDIX N DOCUMENTS FOR CLARITY 2021 NCIMS
- 2019 NCIMS APPENDIX N MODIFICATION “STUDY” COMMITTEE PROGRESS REPORT, TESTING FOR DRUGS OTHER THAN BETA-LACTAMS TETRACYCLINE PILOT PROGRAM (OCTOBER 23, RECEIVED BY NCIMS BOARD)

ACTIONS OF THE APPENDIX N MODIFICATION COMMITTEE

- NEXT DRUG – GENTAMICIN?
- A NEW APPROACH GIVEN...



AMINOGLYCOSIDE TOXICITY



Major toxic effects of Aminoglycosides are Ototoxicity & Nephrotoxicity

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ACTIONS OF THE APPENDIX N MODIFICATION COMMITTEE OCTOBER 2019 NCIMS EXECUTIVE BOARD

- “THE NCIMS EXECUTIVE BOARD SUPPORTS THE RECOMMENDATION BY FDA THAT THE CURRENT DRUG RESIDUE TESTING PILOT PROTOCOL OF TESTING FOR INDIVIDUAL DRUGS, INITIATED BY PROPOSAL #15-211, BE DISCONTINUED BY THE APPENDIX N MODIFICATION COMMITTEE AND THAT THE COMMITTEE EXPLORE A NEW APPROACH IN PARTNERSHIP WITH THE NCIMS AND FDA – TO STRENGTHEN OUR SYSTEM TO MINIMIZE THE RISK OF DRUG RESIDUES IN MILK, INCLUDING MEANS OF VERIFICATION TO ENSURE THE SYSTEM IS BEING EFFECTIVELY IMPLEMENTED.”

ACTIONS OF THE APPENDIX N MODIFICATION COMMITTEE

WHAT DOES IT MEAN?

- NCIMS BOARD SUPPORTS A NEW APPROACH
- FDA
 - RECOMMENDATION OF TESTING FOR INDIVIDUAL DRUGS DISCONTINUED, 2015 NCIMS PROPOSAL 211
- A NEW APPROACH
 - TO STRENGTHEN OUR SYSTEM TO MINIMIZE THE RISK OF DRUG RESIDUES IN MILK
 - INCLUDING MEANS OF VERIFICATION TO ENSURE THE SYSTEM IS BEING EFFECTIVELY IMPLEMENTED

A NEW APPROACH

- **SUBCOMMITTEE TO PROVIDE FOR A DRAFT ROADMAP**
 - **ROGER HOOI, STEVE DIVINCENZO, PAT GORDEN, FRANK BARCELLOS, LAURIE BUCHER TO PROVIDE FOR A DRAFT CONCEPT TO START DISCUSSIONS**
- **FULL COMMITTEE DISCUSSIONS**

THANK YOU

STATES, INDUSTRY, FDA, SUPPLIERS – COOPERATIVE NCIMS
PARTICIPANTS

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