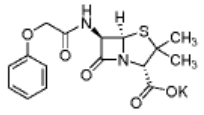
Appendix N Updates

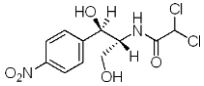
2021 Update

DPC

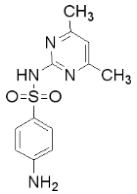
Appendix N Modification Committee Overview



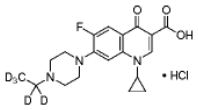
Beta-lactams



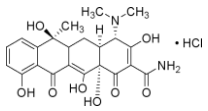
Amphenicols/Chloramphenicol



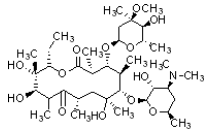
Sulfonamides



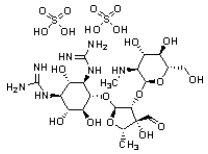
Quinolones



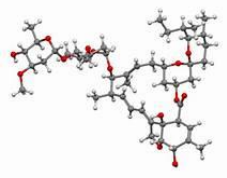
Tetracyclines



Macrolides



Aminoglycosides



Ivermectin

Appendix N Modification Committee 2020 – 2021 Activities

- Committee Changes
- NMDRD Report
- Exploring – discussions on a new approach
- Considerations into updating/clarifying Appendix N in the PMO

Appendix N 2021

Effect of COVID-19

- Physical Meeting in Chicago was postponed indefinitely due to COVID-19 in 2020
- Committee continues to meet via conference calls

Added New Committee Members:

- Heather Torino, NY
- Anne Quilter, CA
- Kristopher Welch, OH (to be confirmed by NCIMS Board)

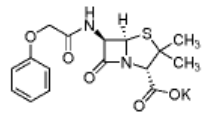
Latest on Appendix N

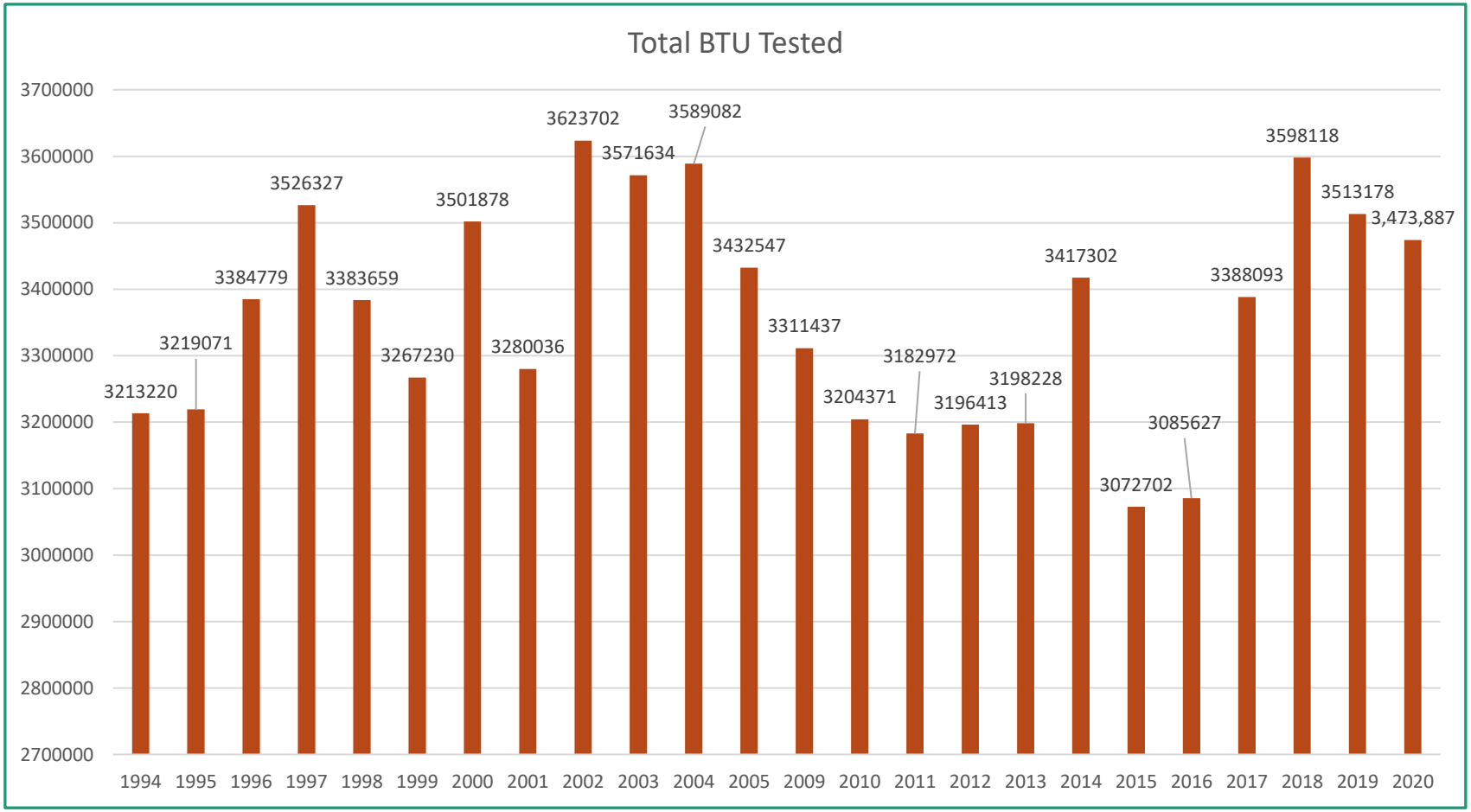
- Conference calls
- Review some current data from NMDRD
- Exploring “A New Approach”
- Appendix N Clarification Proposal

NMDRD Drug Residue Testing – Brief Overview

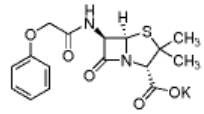
2020

Beta-lactams
Bulk Milk Pick Up Tanker

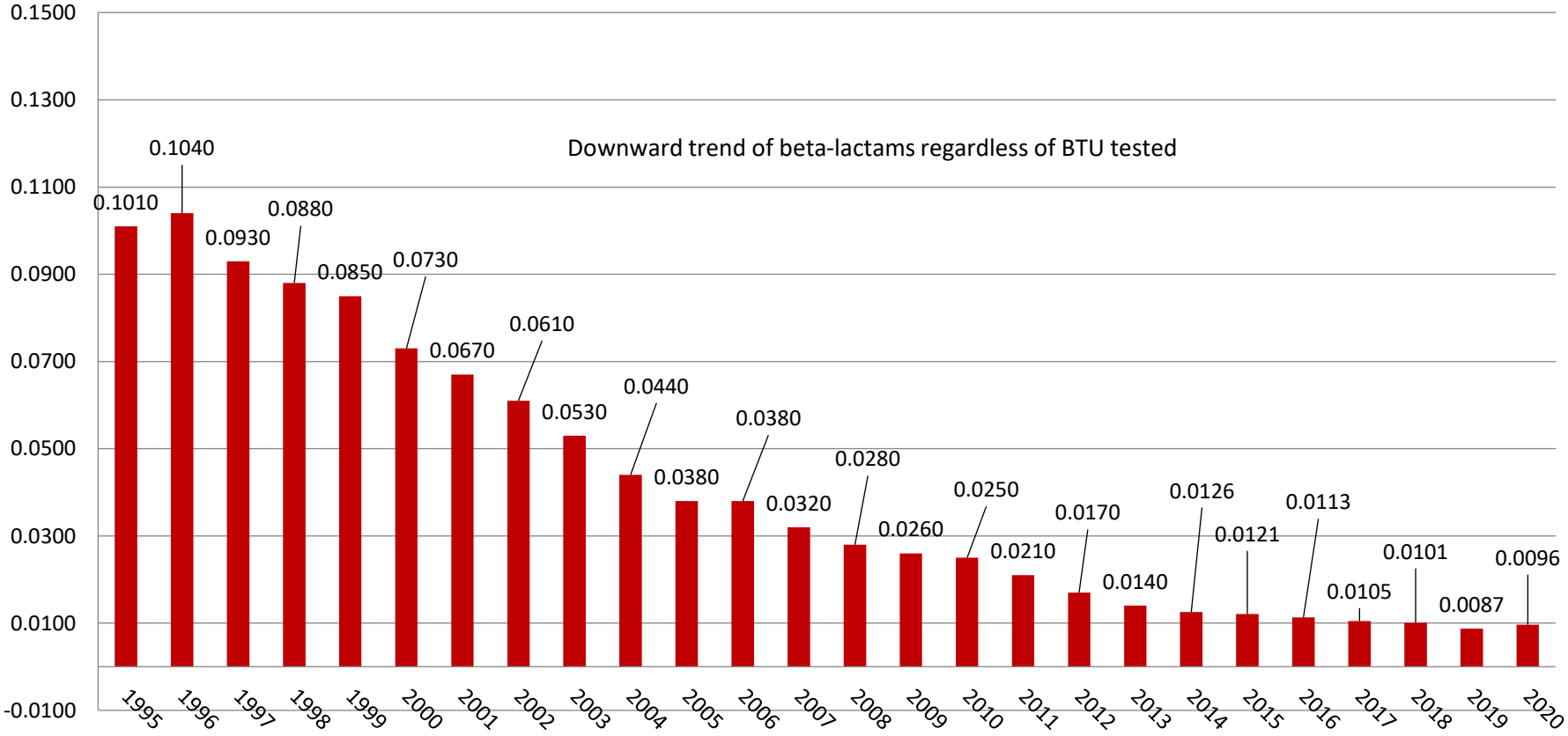




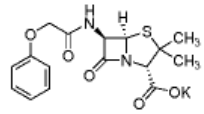
Beta Lactams



Bulk Milk Pick Up Tanker Appendix N Beta-lactam % Positive



Beta Lactams

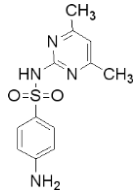


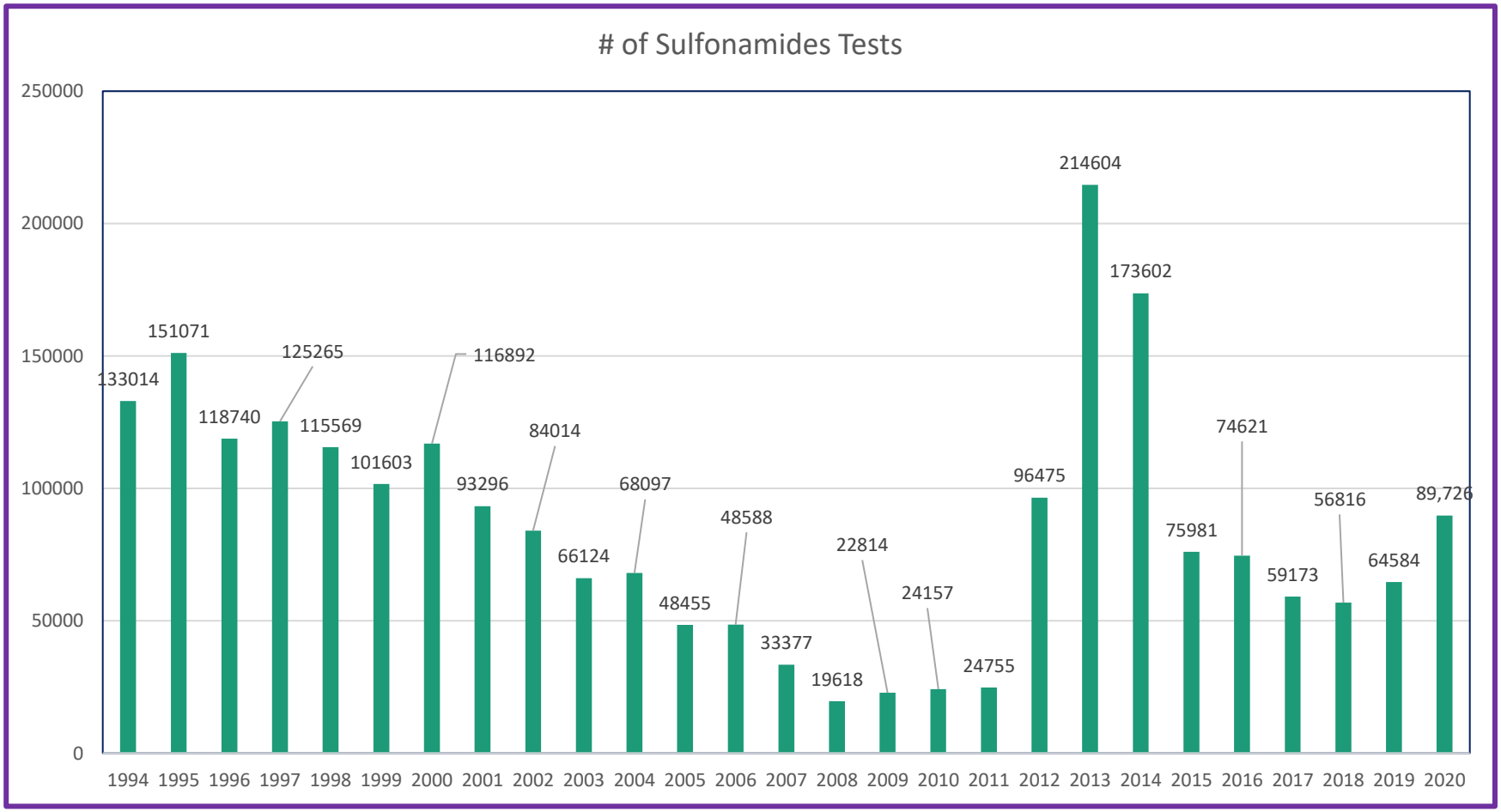
Pasteurized Milk and Milk Products
% Positive

1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
0.0110	0.0030	0.0050	0.0050	0.0040	0.0070	0.0030	0.0050	0.0150	0.0070	0.0150	0.0020	0.0050	0.0070	0.0000	0.0020	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0122	0.0032	0.0000

Sulfonamides

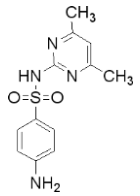
Tested

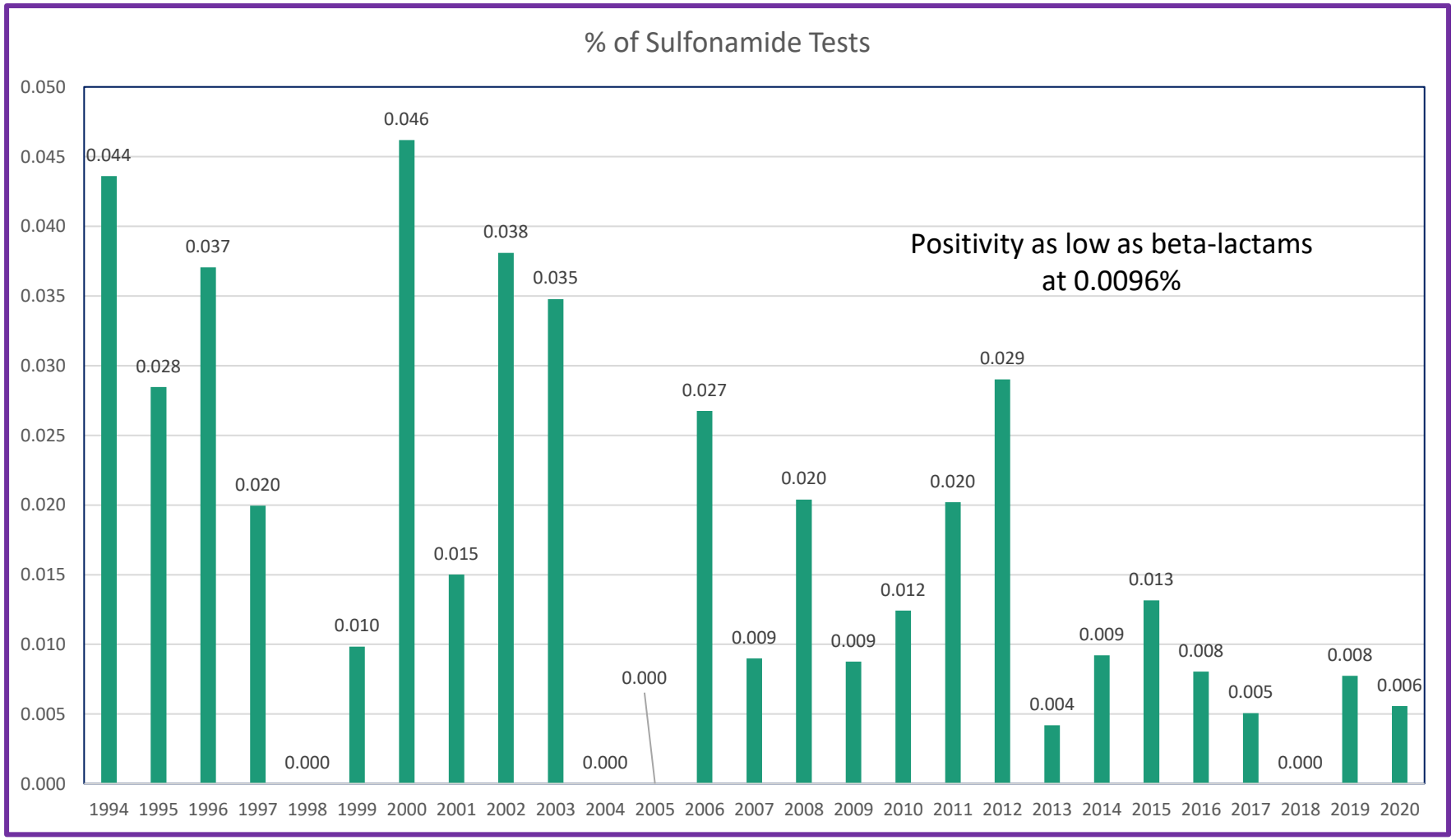




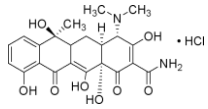
Sulfonamides

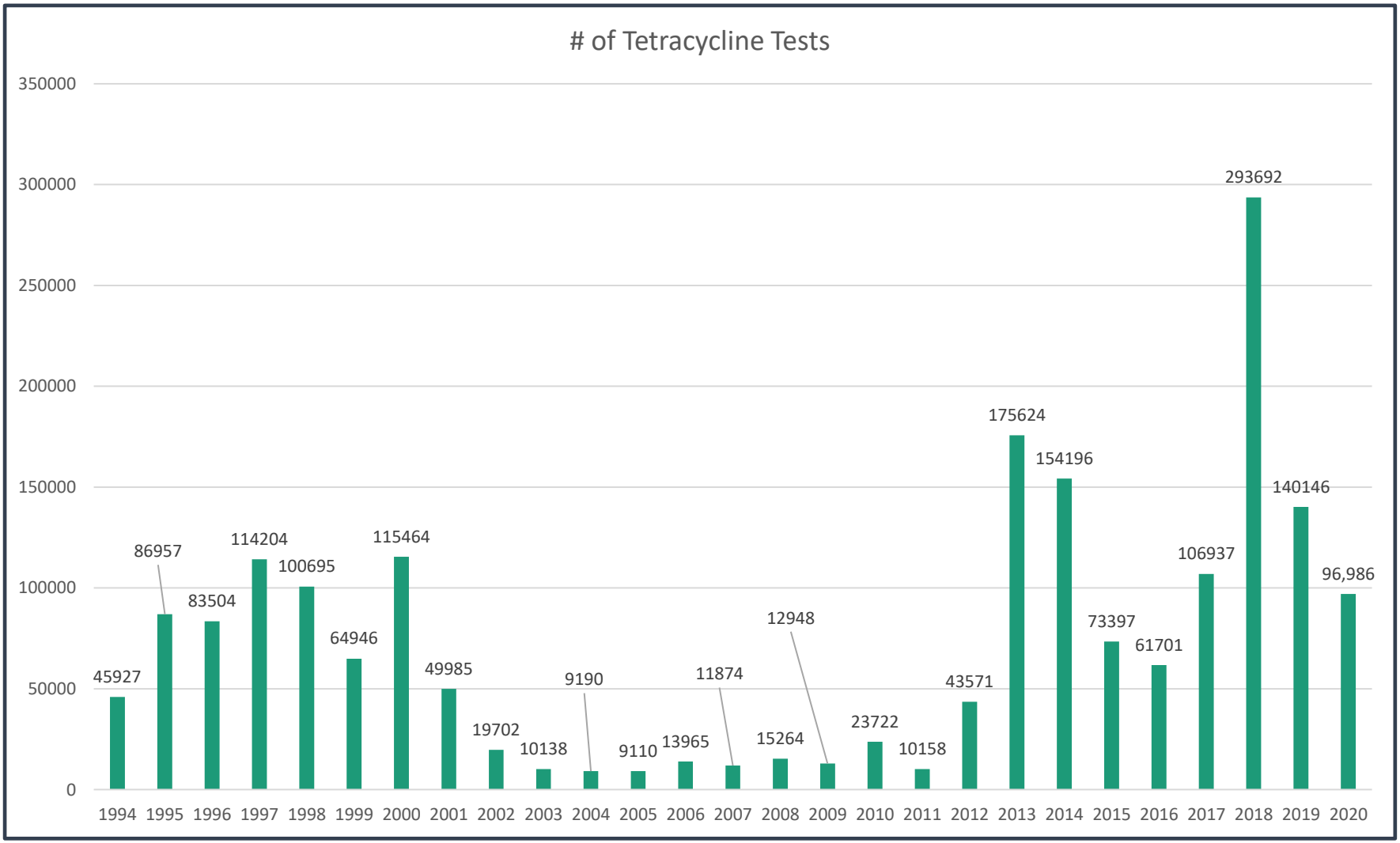
% Positive



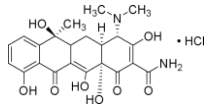


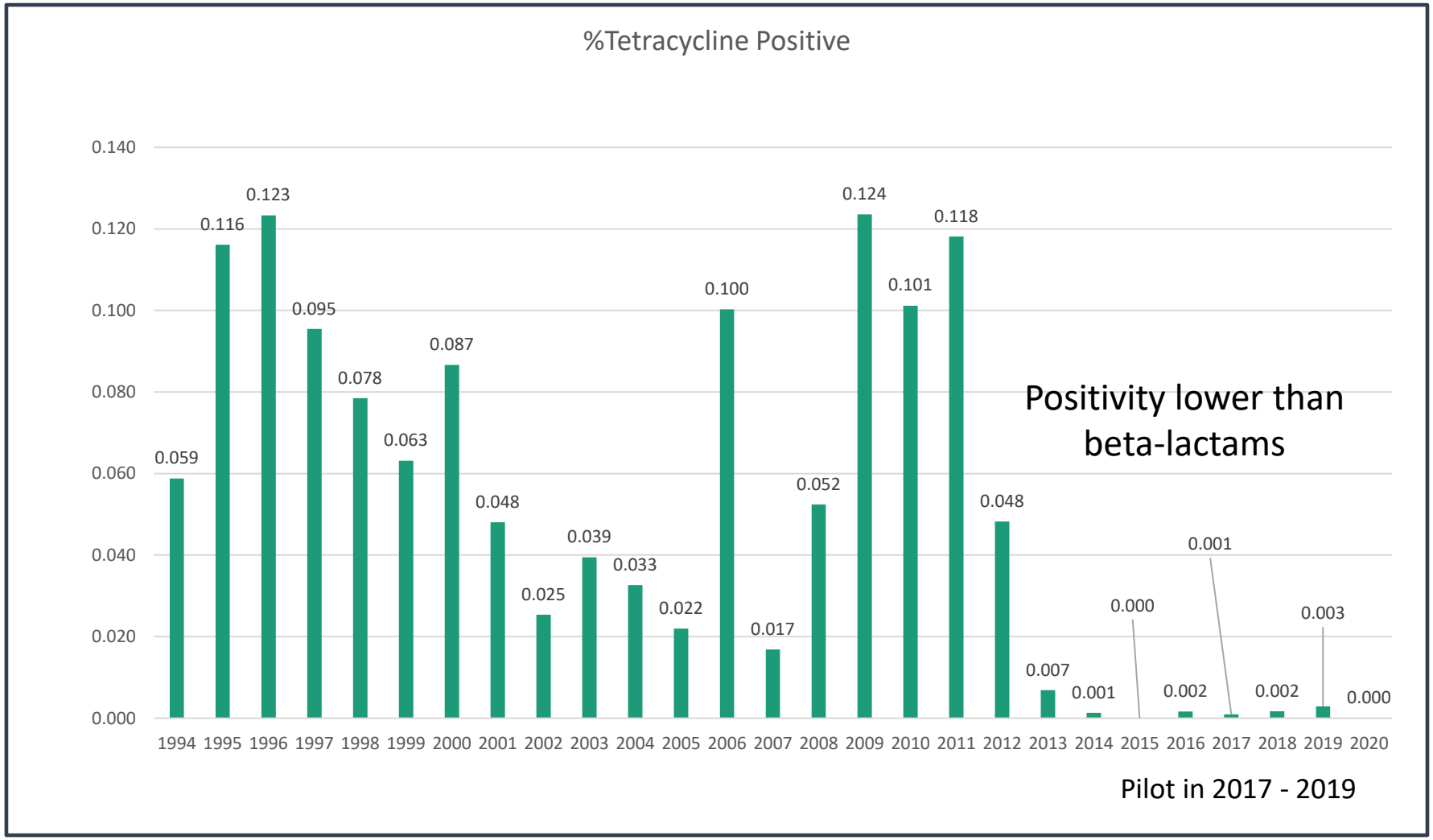
Tetracyclines





Tetracyclines





To Explore A New Approach

- 10/24/19 NCIMS Board Meeting Chicago, Illinois
- “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.”

To Explore A New Approach

- FDA
  - Recommendation by FDA
- NCIMS Board
  - Assigned to the Appendix N Modification Committee
- Partnership:
  - Explore a new approach for drug residue testing in a partnership between the NCIMS and FDA
- Strengthen and Minimize:
  - Strengthen our system to minimize the risk of drug residues in milk
- Verification
  - Verification to ensure the system is being effectively implemented

A New Approach

Identified – 4 areas to explore

1. Discovery: Improvement on reporting to the NMDRD
   - Ongoing before assignment
   - 5/11/21, GLH webinar, 1 ½ Hours, ~31 States

Registered	Attended	% Attendance
76	54	71%

2. Preventive/Mitigation Steps – Consider:
   - Education at the NCIMS Conference
   - Continued support for development of dairy farmer education materials

3. FDA Responsibility - Consider
   - FDA /PMO Changes needed for the PMO?
   - No changes recommended to the PMO for Appendix N to meet new approach

4. Explore – Consider the possibility of a Surveillance Program

Re-write of Appendix N for the purpose of clarification

Potential Proposal for 2022 Conference

Indianapolis, Indiana

Consideration in clarifying Appendix N in the PMO

Re-write of Appendix N for the purpose of clarification

- Clarify but not change language or intent
- Standardize nomenclature (i.e., NCIMS Accepted Drug Test Methods)
- Correct grammatical errors
- Based on NCIMS actions, M-a documentation
- Provide for a chart of testing procedures
- Significant changes or additions will be directed to a proposal at the 2022 conference.

Re-write of Appendix N for the purpose of clarification
6 Sections, I Introduction and 1 Definitions

- Introduction
  - Provide for explanation of the Appendix N program
- Definitions
- Section I. Industry Responsibilities
- Section II. Regulatory Agency Responsibilities
- Section III. Testing Program for Drug Residues Established –Section
- IV. Established Tolerances and/or Target Testing Levels of Drug Residues
- Section V. Approved Test Methods
- Section VI. Test Methods for Non-Beta-lactams

Some Highlights - Appendix N Clarification

- **Bulk milk storage** means a farm or plant bulk milk tank, silo, or any other approved vessel for storing raw milk intended for further processing or for shipment to another facility.
- **All Grade "A" Raw Milk Supplies (**AGARMS): "all Grade "A" raw milk supplies transported in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers."
- **NCIMS Accepted Drug Test Methods**: Test methods evaluated by FDA and accepted by NCIMS as cited in M-a-85, latest revision, and M-I-92-11 for the purposes of Appendix N testing for drug residues in all Grade "A" raw milk supplies transported in bulk milk pickup tankers and/or raw milk supplies that have not been transported in bulk milk pickup tankers (AGARMS).

Some Highlights
Appendix N Clarification [providing clear(er) directions]

- **Confirmed Positive**
- A Confirmed Positive result is obtained when:
  - 1. A Presumptive Positive sample (Section III. or Section VI. Option 2) is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test method as that was used for the presumptive positive with a positive (+) and negative (-) control that give the proper results, and either or both of the duplicates are positive., or
  - 2. A Verified Screening Positive sample (Section VI. Option 1) is tested in duplicate, using a NCIMS accepted drug test method with a positive (+) and negative (-) control that gives the proper results, and either or both of the duplicates are positive.

- Confirmation testing shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Prior to confirmation, the presumptive positive or verified screening positive milk may be resampled, at the direction of the Regulatory Agency (refer to Section III of this Appendix).