THE NATIONAL MILK DRUG RESIDUE DATABASE (NMDRD)

A Review: Focus on Reporting

May 11, 2021

Presented by:
NCIMS Appendix N Modification Committee
GLH, Incorporated

WELCOME AND INTRODUCTIONS

- Appendix N Modification Committee / Moderator

  Frank Barcellos
- FDA/ App N Modification Committee

  Roger Hooi, Chairperson

  Dr. Thomas Graham, FDA/CFSAN/ LPET

  Laurie Bucher Kurtz, FDA/CFSAN/ MMPB
- GLH, Inc.

  Kris Enzor, System Tech., NMDRD

  Paul M. Hoge, Technical Director, NMDRD

TODAY'S AGENDA

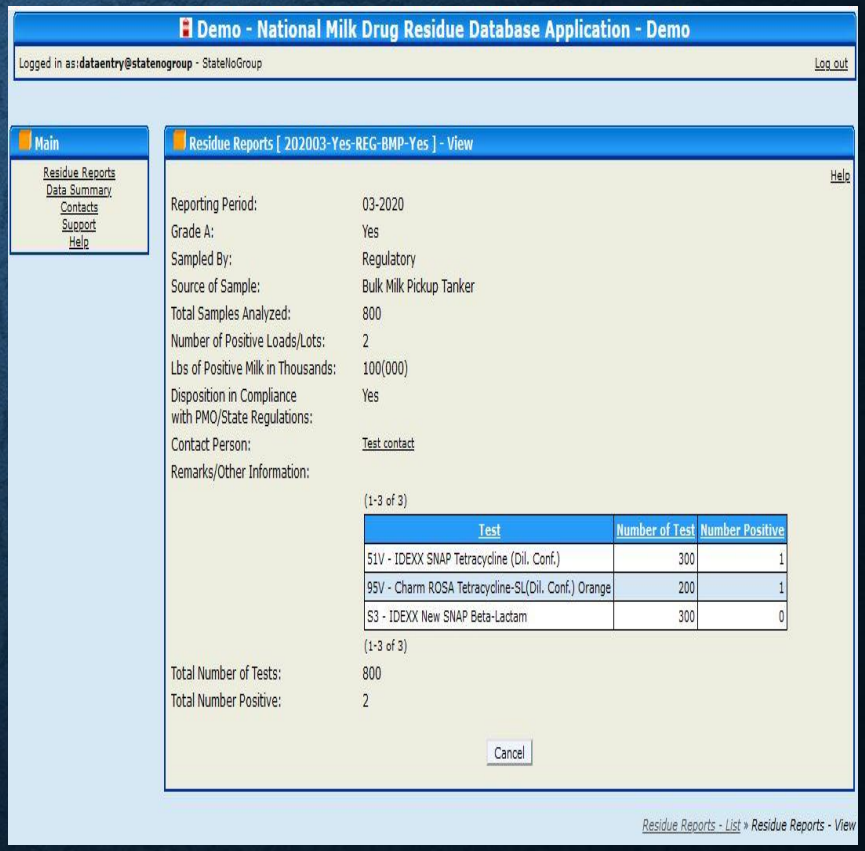
- Importance of Reporting Drug Residue Testing to NMDRD
- Requirements for Reporting
- NMDRD Database Input, Processing, Output
- Q & A

IMPORTANCE OF REPORTING DRUG RESIDUE TESTING

- An old adage comes to mind – "Garbage In = Garbage Out"
- The NMDRD is a tool needed by the dairy industry
- This national database provides the U.S. dairy industry credit where credit is due!
- Documentation of drug residue testing for the milk supply must be *accurate, timely, and complete*

IMPORTANCE OF REPORTING DRUG RESIDUE TESTING

- NMDRD – Let's review the essentials!
- Most Frequent Reporting Questions
- Common errors in reporting
- Database operations/ getting help
- Database outputs
- GOAL – Assure uniform and accurate reporting by all State and 3rd party reporters!



DATABASE MANAGEMENT AND REPORTING

Paul M. Hoge, Technical Director, NMDRD

West Alexander, PA

GLH, Inc.

Lynchburg, VA

NATIONAL MILK DRUG RESIDUE DATABASE (NMDRD)

- Background
- Management of Data (Input from Reporters)
- Processing of Data
- NMDRD Products (Output)

NMDRD – BACKGROUND

- 2021 marks ***30 Years*** since Appendix N was added to the PMO and the Database was established!
- PMO Appendix N entitled Drug Residue Monitoring and Farm Surveillance
- But why?
- Appendix N was developed to respond to the issue of drug residues in the nation's milk supply – i.e., sulfonamides and beta-lactams

WHY MAINTAIN A DRUG RESIDUE TESTING DATABASE?

- FDA was required to testify before Congress however officials were hard pressed to account for drug residue test numbers

- The data resided with the individual state programs…..

- *Only a centralized database of testing would credit the testing completed by state regulatory agencies and the dairy industry*

WHY MAINTAIN A DRUG RESIDUE TESTING DATABASE?

- The database framework developed by the NCIMS envisioned mandatory reporting by states/ optional reporting by industry.
- Additionally, a 3rd party under contract with FDA should develop the database as an **informational**, **non-regulatory** tool.
- NCIMS Conference Procedures Section IV. Oversight and Responsibilities

B. State and TPC Responsibilities

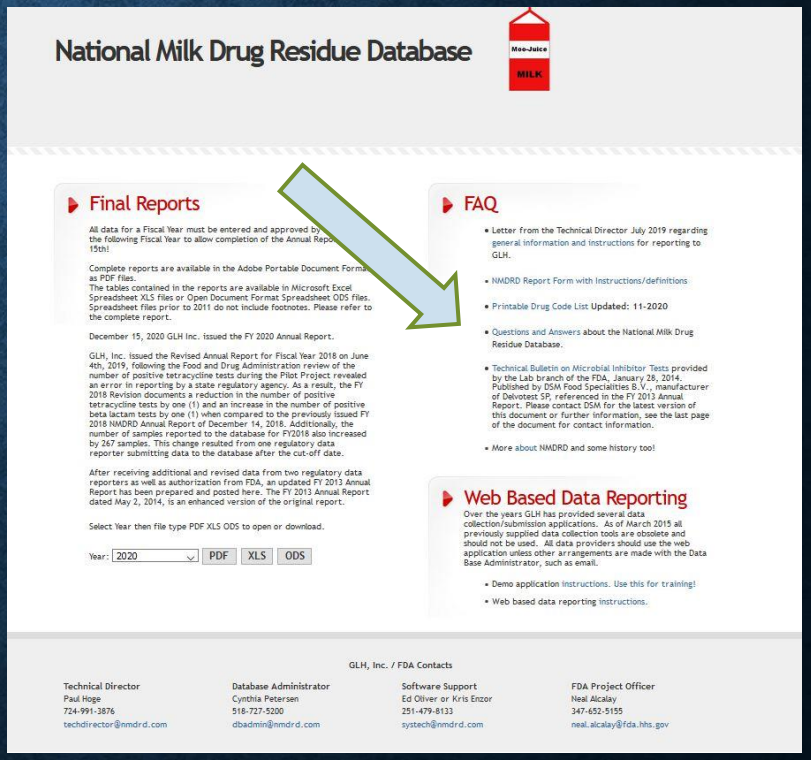
6. <u>Reports to Database:</u> *State Regulatory or Rating Agencies shall submit drug residue summary to a third-party database.*

WHY MAINTAIN A DRUG RESIDUE TESTING DATABASE?

- Data received by the 3rd Party Contractor is only specific regarding the:
  - state
  - type and number of samples
  - test numbers and methods
  - results
  - milk (pounds) that must be properly disposed of…
- **Names of dairy processors, producer cooperatives, receiving stations, etc. are not reported**

MANAGEMENT OF DATA (INPUT BY REPORTERS)

- 'Input' related questions - common to multiple reporters (states or third-party certifiers)
- NMDRD website may help
- Questions and Answers may help
- https://www.nmdrd.com



MANAGEMENT OF DATA (INPUT BY REPORTERS)

- *Q: Who is required to submit data to GLH?*
- A: All state regulatory agencies and third-party certifiers responsible for milk and milk product safety.

- *Q: What about a small non-Grade "A" milk plant that manufactures cheese products in my state?*
- A: Any drug testing that is completed per manufacturing regulations must be reported.
  - Additionally, testing that may be done by the plant in NCIMS certified lab facilities is requested to be reported, however industry reporting is optional.

MANAGEMENT OF DATA (INPUT BY REPORTERS)

- *Q: What data are required to be submitted to GLH?*
- A: For Regulatory agencies - All drug residue test results from samples collected under their regulatory programs.
  - Includes Appendix N testing and PMO Section 6 samples (raw commingled, producer samples, and pasteurized finished milk and milk products)
- *CONCERN: Some state reporters are reporting only limited testing, i.e., Industry Bulk Milk Pickup (IND BMP) samples only.*
  - ***This prevents the NMDRD from being complete.***

SUMMARY OF TESTING DATA REQUIRED TO BE SUBMITTED TO NMDRD

- Bulk Milk Tanker Testing (BMP)
- Includes Milk Not Hauled in Bulk Tankers
- Pasteurized Fluid Milk and Milk Products*
- Producer Samples*
- Other Samples (i.e., raw, commingled silo samples)*
- *(*PMO Section 6)*

NATIONAL MILK DRUG RESIDUE DATA BASE REPORTING FORM

1. State: _____ 2. Grade A: ___ (Yes/No) 3. Sampled By: _____

4. Source of Samples: _____ 5. Reporting Period: _____

6. Total Samples Analyzed: _____

7. Number of Positive Loads or Lots: _____

8. Pounds of Positive Milk (000's) _____

9. Disposition in Compliance with PMO/State Regulations: (Yes/No) _____

10. Contact Person and Organization: _____

11. Telephone Number: _____

12. Remarks: _____

_____

Test Results (enter as many rows as needed)

Test Code	Number of Tests	Number Positive

Information from the NMDRD Report Form with Instructions Document found at https://nmdrd.com/

Form Item	Field description/definition/options
4. Source of Samples	Report the source of the samples by entering the appropriate code from the following four categories: *Source Code* **BMP** Bulk Milk Pickup Tanker and/or Raw Milk Supply that has not been transported in a Bulk Milk Pickup Tanker – bulk raw milk from a dairy farm. **PFM** Pasteurized Fluid Milk and Milk Products – after pasteurization; finished product in package form or bulk. This includes milk products such as milk and cream. **PS** Producer - raw milk obtained from the bulk tank/silo from a dairy farm. **OTH** Other - Milk from milk plant tank/silos, milk transport tankers, etc. Note: Producer Samples should be reported by the permitting State, rather than by the analyzing State.

NMDRD REPORTERS SHOULD ENCOURAGE INDUSTRY TO REPORT ADDITIONAL TESTING

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MANAGEMENT OF DATA (INPUT BY REPORTERS)

- *Q: When are data to be submitted?*
- A: Web application reports are requested within sixty (60) days after the end of the month in which the testing was completed.
  - Allows two (2) month leeway following end of each month before data is considered overdue.
  - REMINDER: All FY data to be submitted by <u>December 1st to enable Annual Report</u> to be released by December 15.

- Concern: Some reporters allow data to become long overdue!
  - Leads to more errors as reporters attempt to ‘catch up’ with ‘last minute’ data reporting…..

MANAGEMENT OF DATA (INPUT BY REPORTERS)

- Q: What about samples collected by certified industry representatives?
- A: Samples collected to meet regulatory requirements = regulatory samples
  - Example: Producer samples collected by certified samplers for Section 6 are Reg PS (regulatory producer samples)
  - *Uniformly classifying producer testing makes the NMDRD a more accurate resource.*

MANAGEMENT OF DATA (INPUT BY REPORTERS)

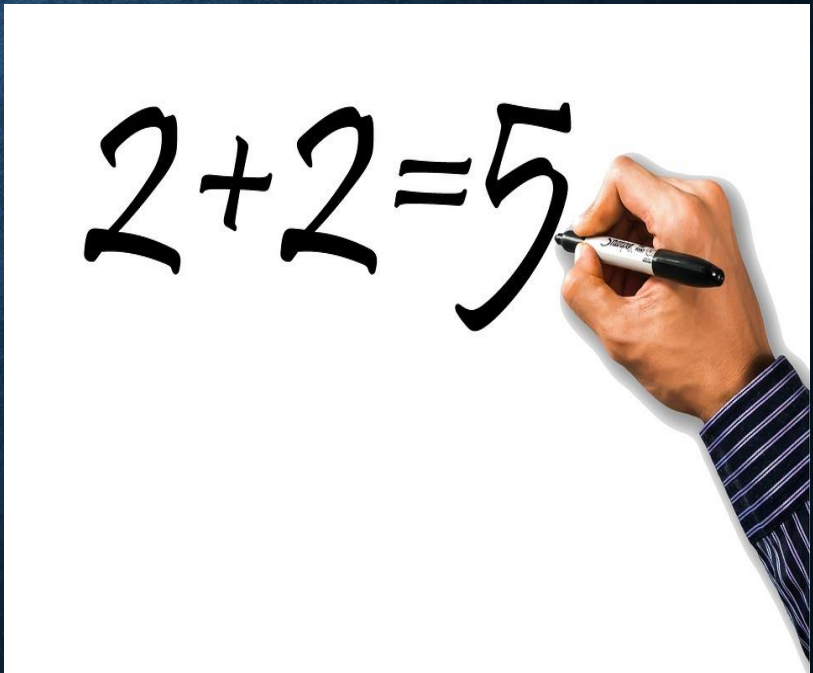
- *Q: When we test producer samples as part of the farm trace back (following an Appendix N positive test), should these be reported as producer samples (PS)?*
- A: No - considered part of the follow-up required under Appendix N to a positive sample that will be reported
  - *<u>Also do not report cow and/or tank samples requested by dairy producers.</u>*

MANAGEMENT OF DATA (INPUT BY REPORTERS)

- *Q: For out-of-state milk loads, who reports?*
- A: Testing – including a positive load - is reported by reporter <u>whose plant receives the load</u>
  - Includes volume of milk disposed for positives
- Concern: Must avoid duplicative reporting…
  - If in doubt, contact Technical Director with questions

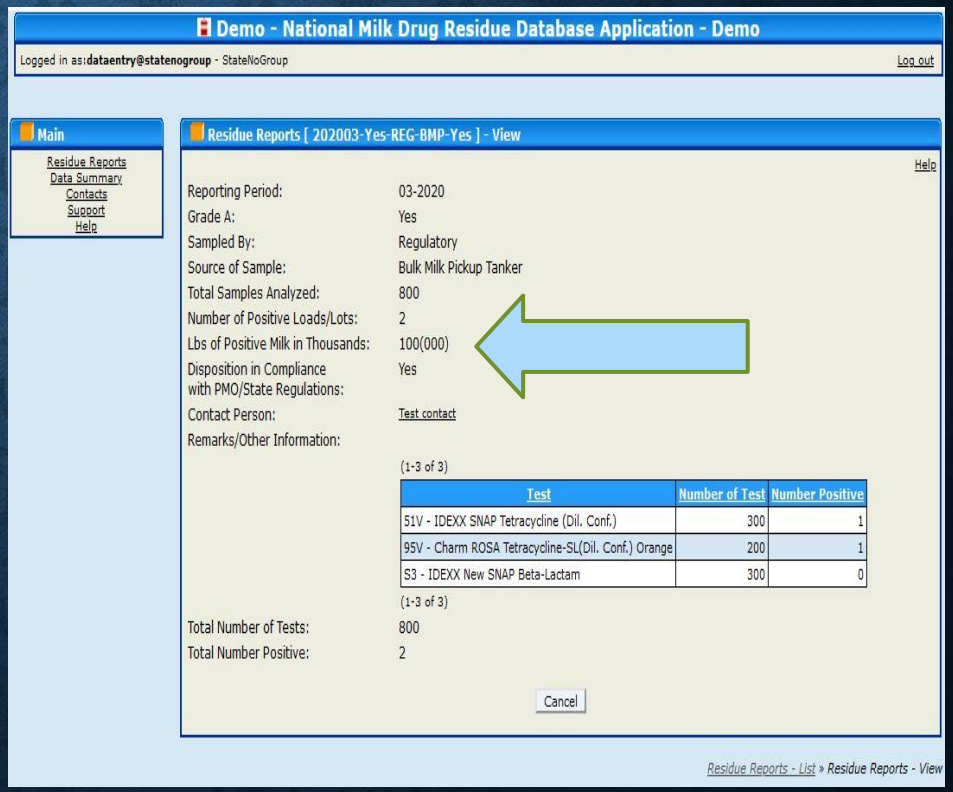
COMMON REPORTING ERRORS

1. Reporting Extra Zeros
2. Not distinguishing Samples from Tests
3. Incorrect coding of test methods



1. REPORTING EXTRA ZEROS…

- Database already assumes numbers in the Thousands…. 0(000)
- Entering 100,000 pounds - the database will report as 100,000,000 pounds!
- For a positive volume of 100,000 lbs., report 100 as positive milk in thousands



2. NOT DISTINGUISHING SAMPLES FROM TESTS…

- Most methods provide <u>one</u> test result for <u>one</u> sample analyzed
- Several methods provide <u>multiple test results</u> for <u>one</u> sample analyzed.
- Example: Charm TRIO method: One (1) sample produces three (3) test results:
  - F2, Beta-lactams;
  - F3, Sulfonamides;
  - F4, Tetracyclines
- **Report three (3) tests for each Charm TRIO sample**

3. INCORRECT CODING OF TEST METHODS

- Reporters sometimes enter incorrect test codes
- Outdated quick reference sheet
- NMDRD Test Code List updated regularly and posted to nmdrd.com immediately

NMDRD 11/2020 Drug Test Kit List Revision

DRUG FAMILY
Aminoglycosides

TEST CODE	TEST NAME		
67	CHARM II Tablet Competitive Aminoglycosides	Active	Non-Validated
98	Charm ROSA Gentamicin	Active	Non-Validated
A10	IDEXX SNAP Gentamicin	Active	Non-Validated

DRUG FAMILY
Amphenicols

TEST CODE	TEST NAME		
E5V	Charm II Amphenicol	Active	Validated
69	Charm II Chloramphenicol	Active	Non-Validated
A6	Charm ROSA Amphenicol	Active	Non-Validated
20	GC Chloramphenicol - FDA Method	Active	Validated
33	HPLC Florfenicol - FDA/CVM Method	Active	Validated

DRUG FAMILY
Beta lactams

TEST CODE	TEST NAME		
93	Charm 3 SL-3 Beta lactams	Active	Validated
96	Charm BL30SEC	Active	Validated
13	Charm BsDA	Active	Validated
97	Charm Cowside II Inhibition	Active	Non-Validated
68	Charm II Tablet Competitive - Beta lactams	Active	Validated
80	Charm II Tablet Quantitative - Beta lactams	Active	Validated
83	Charm II Tablet Sequential Beta lactams	Active	Validated
86	Charm SL Beta lactams	Active	Validated
F2	Charm TRIO - Beta lactams	Active	Validated
48	Delvotest P 5 Pack	Active	Validated
28	Delvotest P Mini - Beta lactams	Active	Validated
31	Green Book Micro - Beta lactams	Active	Validated
S3	IDEXX New SNAP Beta-Lactam	Active	Validated
N3	Neogen BetaStar Advanced for Beta-lactams	Active	Validated

NMDRD

Welcome to NMDRD.
Please select from the menu on your left.

The National Milk Drug Residue Database is a voluntary industry reporting program. Mandatory reporting is required by State regulatory agencies under the National Conference on Interstate Milk Shipments (NCIMS). Data are reported on the extent of the national testing activities, the analytical methods used, the kind and extent of the animal drug residues identified, and the amount of contaminated milk, including whether it was disposed of properly for non-human use. The system includes all milk, Grade A and non-Grade A, commonly known as manufacturing grade. Data reported to the National Milk Drug Residue Database are for educational and analytical purposes and are not intended or suitable for regulatory follow-up.

Printable Drug Code List **Updated: 11-2020**

3. INCORRECT CODING OF TEST METHODS

- Significant issue during 2015 NCIMS Proposal 211 Pilot Project
- Confusion arose during changeover from Charm SL – Tetracyclines (Code 89) to Charm ROSA Tetracycline – SL (Dil Conf.) Orange Strip (Code 95V)
- Resulted in potential inaccuracy in NMDRD Code 95V and 89 test method numbers…
- Details in NMDRD FY 2018 REVISED Annual Report

3. INCORRECT CODING OF TEST METHODS

- A more recent example…..Charm II Tablet Sequential – Sulfonamides
- An issue during drafting of FY 2020 Annual Report
- The Non-Validated test (Code 85) used 1972 times
- Upon follow-up with our state reporters, actual usage was 0 times!

3. INCORRECT CODING OF TEST METHODS

The 11/2020 Drug Test Kit List Revision includes approximately 28 changes…

- Seven test kit methods were added to the list
- Very important that laboratory personnel consult test method labeling <u>and</u> most current NMDRD test kit list for correct coding of test methods

NMDRD – *PROCESSING* OF WEB BASED REPORTS

- Following correct and complete data input, sample and test data are processed into the database

- Processing web based reports – four steps
  - Data administrator (State) – ONE per reporting entity
  - Technical director – review, follow-up, final acceptance of data submitted
  - Database Administrator (GLH) – download & import
  - IT support – Server support and data security

NMDRD – *PROCESSING* OF WEB BASED REPORTS

- State NMDRD Administrator presses "Submit"

- Submitted data to Technical Director Inbox

- Technical Director reviews each report checking for the kind of errors discussed…
  - May result in emails/ phone calls with reporters
  - Tech Director authorized to re-open reports for editing by NMDRD reporters

NMDRD – *PROCESSING* OF WEB BASED REPORTS

- With Review and Acceptance by Technical Director…

- Data is submitted to Database Administrator, Cynthia Petersen
  - Data is downloaded from the data entry application and imported to a separate off-line NMDRD database
  - Database is backed up to multiple servers and backups sent to GLH, Inc. staff members

NMDRD – ***AND WHEN HELP IS NEEDED***

- NMDRD Administrative Issues - Contact Cynthia at:
  - dbadmin@nmdrd.com
  - (518) 727-5200 mobile and text
- Access requirements – new usernames and passwords
- Changes to administrator and data entry personnel
- General data entry questions….

NMDRD – *PROCESSING* OF WEB BASED REPORTS

- Backup files are automatically sent to servers maintained by IT group Kris Enzor and Ed Oliver
- Maintain web-based application (reporting tool), including backups to your submitted reports
- Assist users with access issues, e.g., firewalls
- Adjust report templates and assure 508 Compliance
- Maintain and update the informational website https: www.nmdrd.com

National Milk Drug Residue Database

Final Reports

All data for a Fiscal Year must be entered and approved by Dec first of the following Fiscal Year to allow completion of the Annual Report by Dec 15th!

Complete reports are available in the Adobe Portable Document Format as PDF files.
The tables contained in the reports are available in Microsoft Excel Spreadsheet XLS files or Open Document Format Spreadsheet ODS files. Spreadsheet files prior to 2011 do not include footnotes. Please refer to the complete report.

December 15, 2020 GLH Inc. issued the FY 2020 Annual Report.

GLH, Inc. issued the Revised Annual Report for Fiscal Year 2018 on June 4th, 2019, following the Food and Drug Administration review of the number of positive tetracycline tests during the Pilot Project revealed an error in reporting by a state regulatory agency. As a result, the FY 2018 Revision documents a reduction in the number of positive tetracycline tests by one (1) and an increase in the number of positive beta lactam tests by one (1) when compared to the previously issued FY 2018 NMDRD Annual Report of December 14, 2018. Additionally, the number of samples reported to the database for FY2018 also increased by 267 samples. This change resulted from one regulatory data reporter submitting data to the database after the cut-off date.

After receiving additional and revised data from two regulatory data reporters as well as authorization from FDA, an updated FY 2013 Annual Report has been prepared and posted here. The FY 2013 Annual Report dated May 2, 2014, is an enhanced version of the original report.

Select Year then file type PDF XLS ODS to open or download.

Year: 2020 PDF XLS ODS

FAQ

- Letter from the Technical Director July 2019 regardin general information and instructions for reporting to GLH.
- NMDRD Report Form with Instructions/definition
- Printable Drug Code List Updated: 11-2020
- Questions and Answers about the National Milk Drug Residue Database.
- Technical Bulletin on Microbial Inhibitor Tests provided by the Lab branch of the FDA, January 28, 2014. Published by DSM Food Specialities B.V., manufacturer of Delvotest SP, referenced in the FY 2013 Annual Report. Please contact DSM for the latest version of this document or further information, see the last page of the document for contact information.
- More about NMDRD and some history too!

Test Kit Codes

Web Based Data Reporting

Over the years GLH has provided several data collection/submission applications. As of March 2015 all previously supplied data collection tools are obsolete and should not be used. All data providers should use the web application unless other arrangements are made with the Data Base Administrator, such as email.

- Demo application instructions. Use this for training!
- Web based data reporting instructions.

Annual Reports

Data Reporting Instructions

Technical Director
Hoge
724-991-3876
techdirector@nmdrd.com

Datab
Cynthi
518-72
dbadmi d.com

Software Support
Ed Oliver or Kris Enzor
251-479-8133
systech@nmdrd.com

FDA Project Officer
Neal Alcalay
347-652-5155
neal.alcalay@fda.hhs.gov

NMDRD – OUTPUT (REPORTS)

Intermittent Reports

NATIONAL MILK DRUG RESIDUE DATA BASE

Pilot Project for Tetracyclines

July 1, 2017 - December 31, 2018

Submitted by:

GLH, Incorporated

501 V.E.S. Road, Suite W225

Lynchburg, VA 24503

434-386-3702

Contract Number: HHSF 223 201810028C

March 20, 2019

Annual Reports

NATIONAL MILK DRUG RESIDUE DATABASE

FISCAL YEAR 2020 ANNUAL REPORT

October 1, 2019 - September 30, 2020

Submitted to:

Office of Regulatory Affairs

U. S. Food and Drug Administration

5630 Fishers Lane, Room 2129

Rockville, MD 20857

Submitted by:

GLH, Incorporated

501 V.E.S. Road, Suite W225
Lynchburg, VA 24503
434-386-3702

Contract Number: HHSF 223 201810028C

December 15, 2020

TYPICAL TABLE FROM THE ANNUAL REPORT

Table 2 -- Industry and Regulatory Samples

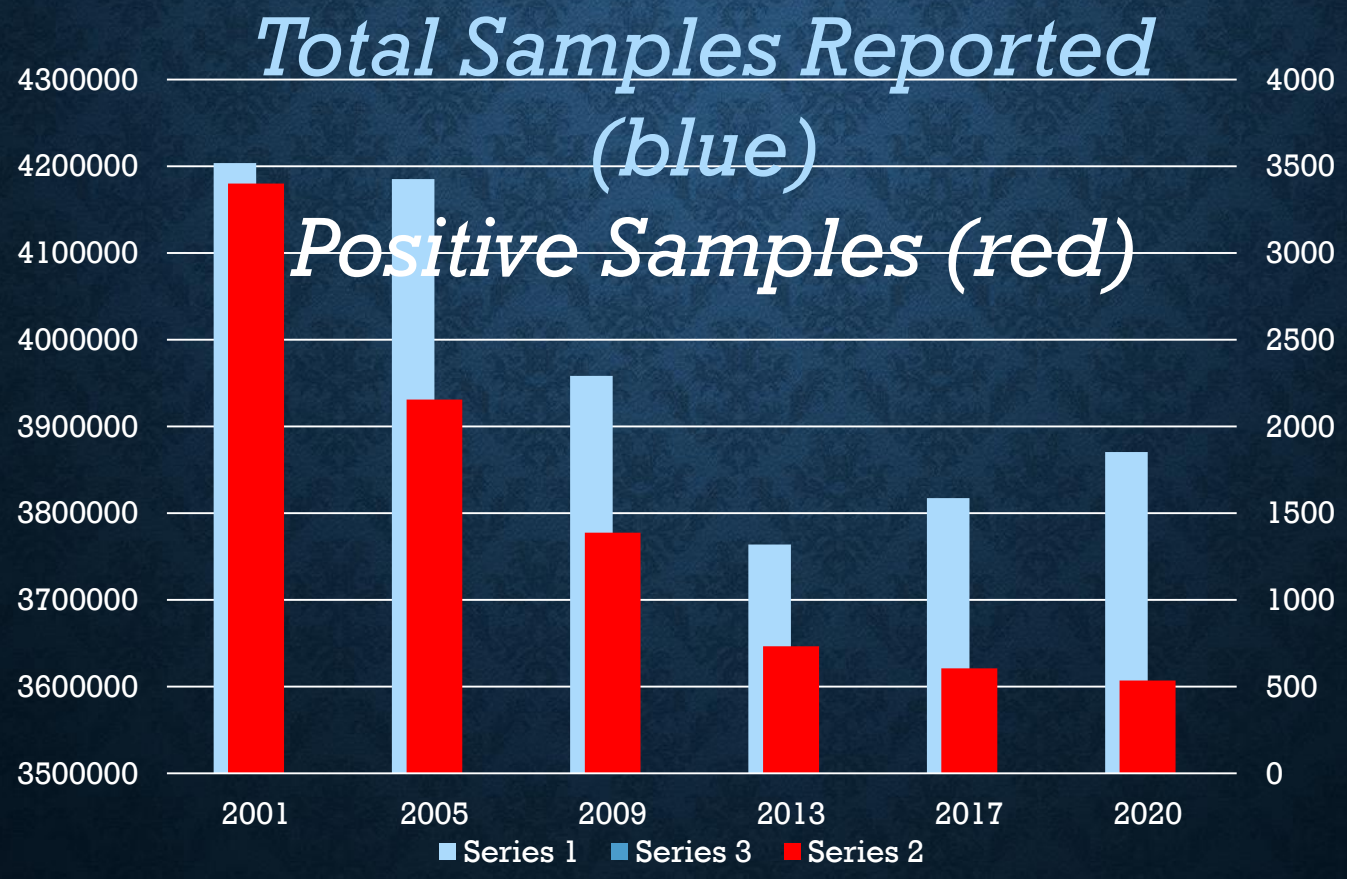
Source of Sample	Number of Industry Samples	Number of Positive Industry Samples	Number of Regulatory Samples	Number of Positive Regulatory Samples	Total Samples	Total Positive Samples	Total Percent Positive	Disposition Per PMO (Pounds)
GRADE "A"								
Bulk Milk Pickup Tanker	3,247,033	307	28,266	1	3,275,299	308	0.009%	14,441,000
Pasteurized Fluid Milk and Milk Products	1,869	0	24,069	0	25,938	0	0.000%	0
Producer	198,121	146	100,545	38	298,666	184	0.062%	433,000
Other	43,869	0	9,676	0	53,545	0	0.000%	0
NON-GRADE "A"								
Bulk Milk Pickup Tanker[1]	184,974	24	13,614	2	198,588	26	0.013%	929,000
Pasteurized Fluid Milk and Milk Products	291	0	385	0	676	0	0.000%	0
Producer	15,730	18	283	0	16,013	18	0.112%	64,000
Other	1,509	0	461	0	1,970	0	0.000%	0
TOTALS	3,693,396	495	177,299	41	3,870,695	536	*	15,867,000[2]

[1] It is a common practice in some states, including two large milk producing states, that bulk milk pickup tankers collect milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

[2] Note that this represents 0.007% of the total milk supply of the United States with an annual production of 218 billion pounds.

* See Table 1 for explanation

ANNUAL REPORT DATA-LONGITUDINAL DATASET



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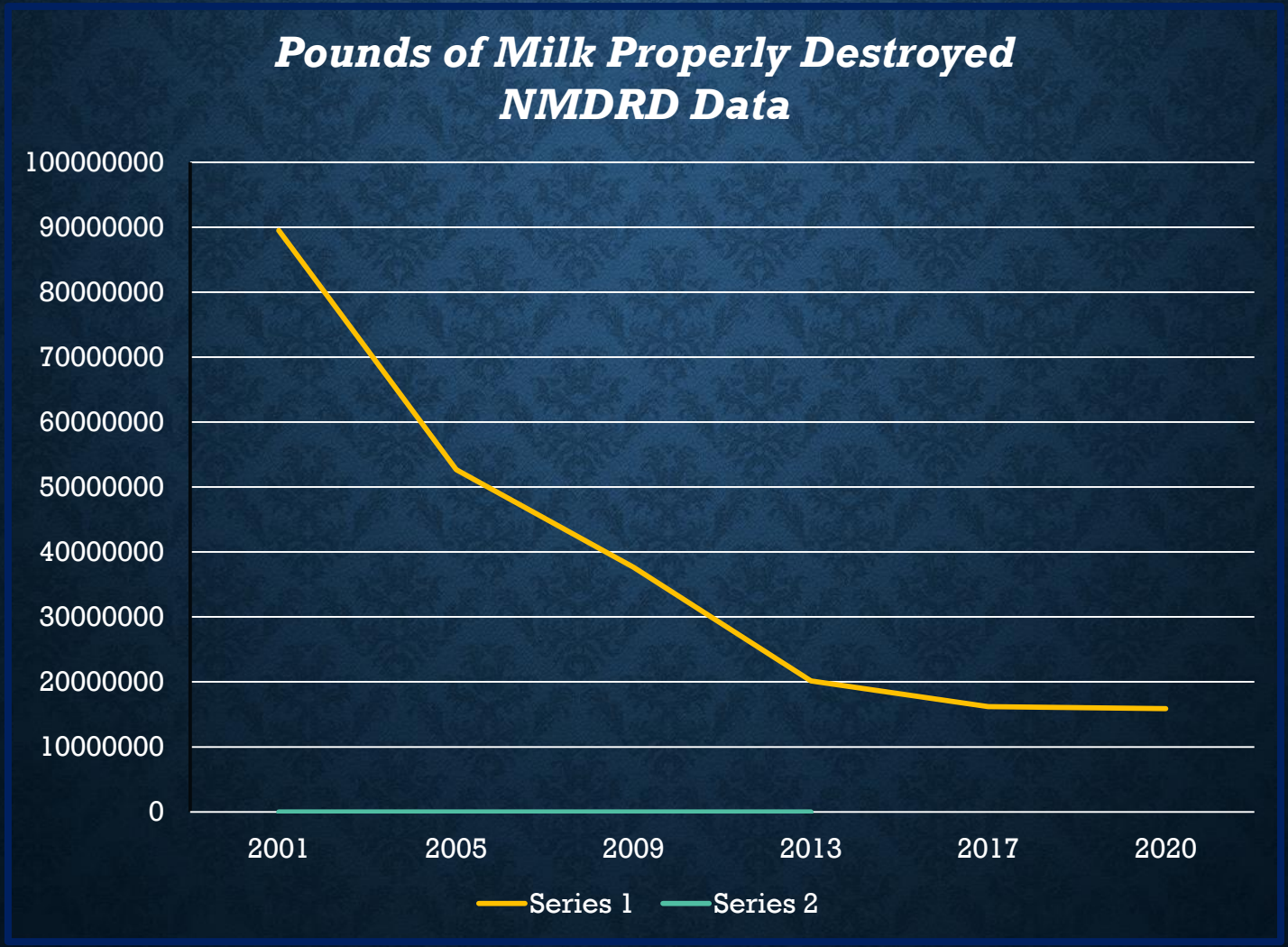
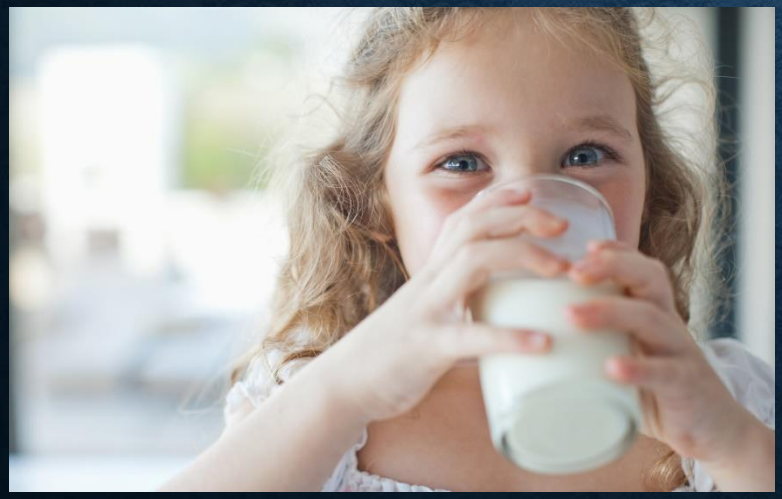


NMDRD – A VALUABLE RESOURCE!



- The National Milk Drug Residue Database is truly a cooperative effort……
- A non-regulatory tool that credits the commitment of the American dairy industry to producing safe, high quality dairy products!

QUESTIONS AND ANSWERS

- Should your questions not be answered today, please reach out to us !
  - Frank Barcellos: frank.barcellos.fb@gmail.com
  - Roger Hooi: roger.hooi@dfamilk.com
  - Dr. Thomas Graham: Thomas.Graham@fda.hhs.gov
  - Laurie Bucher Kurtz: Laurie.Kurtz@fda.hhs.gov
  - Kris Enzor: systech@nmdrd.com
  - Cynthia Petersen: dbadmin@nmdrd.com
  - Paul M. Hoge: techdirector@nmdrd.com