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Date: November 30, 2003

To: State Regulators and Drug Residue Database Providers

From: Ginger Levin, Project Manager, National Milk Drug Residue Database Project (NMDRD)

During the 1991 meeting of the National Conference on Interstate Milk Shipments (NCIMS) the voting delegates authorized a national program for compiling the results of drug residue testing by industry and state regulatory agencies. We are rapidly approaching the 10th anniversary of the NMDRD. In addition to the substantial changes to the milk industry, which have occurred over the past 10 years, there have also been the inevitable changes in personnel especially at the state regulatory level.

Our experience suggested it might be advisable to reissue and reinforce the reporting requirements because of the above changes. The need to do so was confirmed by audits we made of state programs last summer at the request of FDA.

The audit project was helpful in assessing the strengths and weaknesses of the program. We were pleasantly surprised with how well the respective states were doing. While there were some deficiencies, corrective action was taken promptly. We also found some excellent procedures to be in place, which we can use as recommendations when the need arises.

The audits included discussions of a number of reporting issues with industry and state regulatory officials, which lend themselves to a Question and Answer (Q and A) format that is being appended to the instructions. By combining the instructions and Q and A, we hope to more fully meet the goal of the project, which was to capture and report all the drug residue testing being performed by the milk industry and state regulatory officials.

As a final note it is the end of the reporting year, and participants are reminded that all data up to and including September 2003, are due now for inclusion in the FY 03 Summary Report. These data should be sent to Mrs. Cynthia M. Petersen, GLH, Inc., 30 Ahl Avenue, Albany, NY 12205; e-mail cpetersen@nycap.rr.com. This is the most important reporting date of the

year because we need to analyze all the data and begin preparation of the annual report.

Thanks again for your cooperation in the program. Please feel free to call me at 954-783-9819 or send me an e-mail to ginlevin@aol.com should you have any questions. You may also contact our Technical Director, Dennis Tidwell, at 609-890-0375; e-mail Dwtidwell@aol.com.

Sincerely,

Ginger Levin, D.P.A.
Project Manager

Attachments:

1. Instructions for Submitting Data for the NMDRD

2. Reporting Form

3. Definitions

4. Question and Answer Sheet

Revised ~~May 25, 1995~~ November 30, 2003

INSTRUCTIONS FOR SUBMITTING DATA

FOR THE NATIONAL MILK DRUG RESIDUE DATABASE PROGRAM

The following are revised instructions for industry participants and State Regulatory agencies use in submitting data for the National Milk Drug Residue Database Program.

Item 1. State. This field will be used by the State regulatory agency. It will contain the standard Numerical Code for each State.

Item 2. Grade A. If the sample was Grade A, enter Y. If it was not Grade A, enter N.

Item 3. Sampled By. If the sample was taken by Industry, enter **IND**. If it was taken by the regulatory Agency, enter **REG**.

Item 4. Source of Samples. Report the source of the samples by entering the appropriate code from the following four categories:

Source	*Code*
Bulk Milk Pickup Tanker	BMP
Pasteurized Fluid Milk and Milk Products	PFM
Producer Sample	PS
Other (Silo, Over-the Road Tanker)	OTH

Note: Producer Samples should be reported by the permitting State, rather than by the analyzing State.

Item 5. Reporting Period. Enter the data (month and year) in which the testing was done.

Item 6. Total Samples Analyzed. Enter the Total number of samples that were analyzed

Note 1: *Duplicate reporting is to be avoided. Report only one positive per incident. For example, if a bulk milk pickup tanker is positive and trace back to the farm identifies one or more positives, report only the bulk milk pickup sample positive to the database program. Individual producer sample results are to be reported when they reflect the regular sampling program for producers and when they are taken as follow-up to a tanker found to contain residues below the tolerance or safe levels.*

Note 2: *If additional analyses are done after a positive result has been reported, report these under the remarks section. Do not add these results to the total number of samples analyzed because the positive result already has been counted.*

Note 3: *The total number of samples analyzed often will be lower than the number of tests reflected in the tables because some samples are tested for more than one residue. It is important that the number you report represents the number of samples as that term is defined, that is, the number of loads, lots, silos, producers, etc., rather than the number of tests performed.*

Item 7. Number of Positive Loads of Lots.	Enter the number of tankers or lots of milk reported as positive.
Item 8. Pounds of Positive Milk (000)	Enter the pounds of milk positive in the tankers reported in item 7. Round this number to the nearest thousand and ***exclude the last three zeros***. For example, enter 50 for a 50,000 pound tanker load. Pounds of producer milk disposed prior to acceptance or delivery need not be entered.
Item 9. Disposition in Compliance with PMO State Regulations?	Enter **Y** for **Y**es if the milk was disposed of in compliance with the PMO or State Regulations. Enter **N** for **N**o if the milk is disposed of in any other way and explain why in the Remarks Section.
Item 10. Contact Person and Organization	Enter the name of a contact person and your organization should there be any questions when your form is received.
Item 11. Telephone Number	Enter the telephone number of the contact person.
Item 12. Remarks	Enter any necessary information here that has not been reported.

~~May 23, 1995~~ **November 30, 2003**

NATIONAL MILK DRUG RESIDUE DATA BASE REPORTING FORM

1. State: _____2. Grade A: _____ (Yes/No) 3. Analyzed 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: _____

_____

_____

TESTS		
Test Code	**Number of Tests**	**Number Positive**
TOTALS		

Test Code — Enter the Test Code. Note. If you enter a test code, you must enter data for the number of tests and the number positive.

Number of Tests — Enter the number of tests.

Number of Positive — Enter the number of tests which were positive.

REVISED DEFINITIONS ~~**May 25, 1995**~~ **November 30, 2003**

1. **State -** State where milk sampled identified by a numeric code.

2. **Grade A** - Y(es) is used for milk meeting the requirements of the PMO. Manufacturing grade is to be coded N(o).

3. Sampled By:

- **Regulatory** - The sample is taken by the regulatory agency or to meet the regulatory agency's requirements under the PMO.

- **Industry** - The sample is taken by industry. The sample may be for quality control purposes or to meet the industry requirement of Appendix N.

4. **Source of Sample** -

- ***Bulk Milk Pickup Tanker (BMP)*** bulk raw milk from the dairy farm.

- ***Pasteurized Fluid Milk and Milk Products (PFM)*** - after pasteurization; finished product in package form or bulk. Includes milk products such as milk, cream, condensed milk, and dry milk products, and condensed and dry whey products.

- ***Producer Sample (PS)*** - raw milk obtained from a dairy farm. Report these samples by the permitting State, rather than by the analyzing state.

- ***Other (OTH)*** - milk from silos, over -the-road tankers, etc.

5. **Sample** - Load or lot of milk sampled and analyzed, e.g. a bulk milk pickup tanker, one producer, an over the road tanker, a silo, etc.

6. **Reporting Period** - The period of time of sampling: report starting (month and year) and ending (month and year) dates of the sampling.

7. **Total Samples Analyzed** - All samples analyzed.

8. **Positive Result** - The sample was found to be positive for a drug residue by a test acceptable for taking regulatory action in a certified laboratory by a certified analyst, or the milk was rejected on the basis of an initial test by the milk processor.

9. **Number of Positive Loads or Lots** - The number of positive tanker loads, or positive lots of milk from a producer, silo or finished product.

10. **Pounds of Positive Milk** - The amount of milk contained in the tank or lot found to be positive.

11. **Disposition in Compliance with PMO or Applicable State Regulations** - Report Y(es) or N(o) to indicate whether the positive milk was disposed of in accordance with the PMO and/or applicable State regulations. The PMO requirement usually will govern Grade A milk. If no, report the details in the Remarks section of the reporting form.

12. **Contact Person/Organization** - The name of a person and organization to contact if there are questions about the data on the form.

13. **Test Code** - A two digit code to identify the test used and specific drug or drug/family.

Questions and Answers **November 30, 2003**

Q: Who is required to submit data to GLH?

A: All state or territorial regulatory agencies responsible for the safety of milk and milk products. The goal of the project is to capture the results of all testing performed for the detection of animal drug residues in milk. The Procedures of the NCIMS require such reporting by these agencies. The states are responsible for enlisting the support of the dairy industry for full and complete reporting of the tests they perform. Appendix N requires all milk receivers to report each positive result to their regulatory agency. It is therefore important that the results of all testing be reported so as not to unfavorably skew the results.

Q: What data are required to be submitted to GLH?

A: State regulatory agencies are required to submit all drug residue test results from samples collected under their regulatory program. This includes samples under Section 6 of the PMO (raw commingled, producer samples, and pasteurized finished milk) as well as tanker monitoring samples under Appendix N. Industry is required to notify state regulatory agencies of any positive results under Appendix N. This is to be reported to the database. In addition, industry is requested to submit any of their own sampling results on raw commingled, producer samples and pasteurized finished product.

Q: When are data to be submitted?

A: Sixty days after the end of the month in which the testing was done. The program allows for two months from the close of data collection before we contact states that are late. For example, data of January's testing should be in GLH's hands by the end of March.

Q: Where and how are data to be submitted?

A: Data can be downloaded, using the export utility included in the software, to a floppy disk and mailed to Mrs. Cynthia M. Petersen, GLH, Inc., 30 Ahl Avenue, Albany, NY 12205; or the downloaded data can be attached to an e-mail message to Cynthia and sent to: mccindyc@aol.com. In addition, hard copy reports can be "snail mailed" to Cynthia at the above address, and she will input the data into the database. The preferred methods are floppy disk or e-mail attachment.

Q: Our state uses certified industry representatives to collect some of the Section 6 samples for the agency. How should these samples be reported?

A: Samples collected to satisfy a state's regulatory program are regulatory samples and should be reported as such. For example, producer samples collected by certified samplers should be reported as regulatory samples, not industry samples.

Q: Our state regulatory agency conducts all confirmations on positive tanker loads sampled initially by industry at the plant. Should these results be reported as regulatory or industry?

A: These results should be reported as industry. Confirmation by the state regulatory agency does not make the sample regulatory. The positive sample should only be reported once, unless the sample was positive for more than one class of drugs (beta lactams and sulfonamides, etc.)

Q: I'm having a problem with the software we were given to track and report samples. Whom should I contact for help?

A: Initially, get in touch with the Technical Director for GHL, Dennis Tidwell, at 609-890-0375 or send e-mail to: dwtidwell@aol.com. If he is unable to provide you with assistance, he will contact our software wizard, Ed Oliver, or he will refer you directly to Ed at ed@K&C-sbcc.com or 251-479-8133.

Q: We receive most of our milk from out of state sources and the shipping state monitors the disposal of positive loads. Who should report the pounds of positive milk destroyed?

A: If your state has established special arrangements with the shipping state, the shipping state can report the pounds destroyed; otherwise, the receiving state should be reporting the pounds that were disposed.

Q: Our milk plant has a number of sources from which we routinely receive milk, but we occasionally receive milk from other BTU's and co-ops. How should these samples be reported?

A: In the same manner as that received from regular supplies in accordance with the definitions for the Source of Sample.

Q: When we test producer samples as part of the farm trace back, should these be reported as producer samples (PS)?

A: No. This is all considered as part of the follow-up required under Appendix N (see Note 1 of The Instructions For Submitting Data For The National Milk Drug Residue Data Base Program. Similarly, the testing of cow samples and herd samples are not to be reported to the program. Such testing is done by some receivers for the convenience of their patrons and is not a part of the reporting program.