

# NYS ASSOCIATION FOR FOOD PROTECTION ANNUAL CONFERENCE 2019 FARM PRESENTATION

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19 SEPTEMBER 2019

FARM Q & A'S  
M-I-18-3  
DATED 19 JAN 2018

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# M-I-18-3, Q19, PMO SECTION 6

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- A dairy producer's raw milk is sampled and tested in accordance with Section 6 of the PMO, including when sampled and tested within twenty-one (21) days of the sending of written notice, but not before the lapse of three (3) days, whenever two (2) of the last four (4) consecutive samples exceed the PMO standard for Standard Plate Count (SPC). Is the drug (inhibitor) test result required to be recorded on the official laboratory report form that is provided to the Regulatory Agency and the results which are subsequently recorded on the dairy producer's official Regulatory Agency sampling ledger/record, or **is it enough to be able to verify that the laboratory runs inhibitor testing with all SPC testing as part of their Standard Operating Procedures (SOP), and be able to produce records to verify if requested by FDA?**

## ANSWER, M-I-18-3, Q19

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- *The drug/inhibitor test result, along with the SPC result, are required to be recorded on the official laboratory report form that is provided to the Regulatory Agency and which is subsequently recorded on the dairy producer's official Regulatory Agency sampling ledger/record.*

# M-I-18-3, Q25, PMO SECTION 7, ITEM 6R

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- a) On a dairy farm may air be drawn from a utility room into the milkhouse?
  - Yes.
- b) Would it be a debit if the utility room is unclean?
  - *Yes. If it is determined to be significant it would be considered a violation of Item 6r-Milkhouse – Cleanliness of the PMO.*

# M-I-18-3, Q26, PMO SECTION 7, ITEM 6R

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- If a two (2) compartment wash vat or vertical CIP tank, which is not a combination receiving vessel/CIP tank, is found to be dirty with milk solids build-up on a dairy farm would this be considered a violation of Item 6r-Milkhouse-Cleanliness or Item 10r-Utensils and Equipment-Cleanliness?

- *Item 6r.*

## M-I-18-3, Q19, PMO SECTION 7, ITEM 8R

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- Does the PMO require that dairy farm individual water system samples be collected directly from the well, before a pressure tank and/or any treatment application, such as a water softener or iron filter?
- **No.** *A dairy farm's individual water system supply may be sampled at any location provided the sample can be aseptically collected and is representative of the water being used in the milkhouse and the milking operation.*

# M-I-18-3, Q30, PMO SECTION 7, ITEM 8R AND MMSR- SECTIONS B AND E

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- While conducting a BTU rating or check rating with an industry field representative or a regulatory inspector, and the dairy producer is not available, if the well cannot be located, is it still FDA's position that this would be considered a violation of Item 8r of the PMO and be debited against the dairy farm since it cannot be inspected?



## ANSWER, M-I-18-3, Q30

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- **Yes.** *It would be debited under Item 8-Water Supply (a)-Constructed and operated according to Ordinance on FORM FDA 2359a and would be a five (5) point debit.*
- **NOTE:** *This dairy farm would also be debited on FORM FDA 2359j, Section B (Page 2), Item #4-Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections.*

# M-I-18-3, Q3 I, PMO SECTION 7, ITEMS 8R AND 13R; AND APPENDICES D AND G

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- A dairy farm is capturing the water that exits a plate heat exchanger in a properly constructed and protected storage vessel and this reclaimed water is not being sampled. The reclaimed water collected in this storage vessel is then utilized in their sprinkler pens, **using rainbird type sprinklers directed at the underside of the cows to clean the teats prior to milking.** At the time of milking, the **teats, flanks and bellies are still damp** from the non-potable reclaimed water that was sprayed on the cow's teats. The milker does not clean the cow's teats with potable water but just manually wipes the teats dry, sanitizes and dries the teats and the milking unit is attached.

# ANSWER, M-I-18-3, Q3 I

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- a) Is the reclaimed water from this properly constructed and protected storage vessel for this use as described above required to be “potable” from a supply properly located, protected, operated and of a safe, sanitary supply?
- *Yes. In order for this reclaimed water to be considered “potable” and utilized in the manner described above to clean the cow’s teats, it shall meet all the criteria cited in Appendix D- Standards for Water Sources, Section VI-Water Reclaimed from Heat Exchanger Processes or Compressors on Grade “A” Dairy Farms of the PMO.*

# ANSWER, M-I-18-3, Q3 I, CONTINUED

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- b) What bacteriological standards is this reclaimed water that is utilized in the sprinkler pens using rainbird type sprinklers as described above required to meet?
- *Appendix D, Section VI of the PMO requires this reclaimed water to comply with the Bacteriological Standards of Appendix G-Chemical and Bacteriological Tests, Section II-Reclaimed Water and Recirculated Water – Bacteriological of the PMO.*

## M-I-18-3, Q32, PMO SECTION 7, ITEMS 8R AND 14R

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- May non-potable water be sprayed on the outside of milking claws and inflations between individual dairy animals that are being milked? This is being observed as a more common practice with rotary milking installations.
- **No.** *Only potable water is allowed for this milking operation practice.*

## Q37, PMO-SECTION 7, ITEM 15R

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- On dairy farms, a human over-the-counter (OTC) **enema (phosphorous in a saline solution)** is being observed for use in the milking herd as an IV treatment for reproductive disorders that may be due to hypophosphatemia. What are the PMO labeling requirements or would this human OTC product be exempt from the labeling requirements of Item 15r of the PMO?
- *It would be exempt from the labeling requirements of Item 15r of the PMO.*

## Q38, PMO-SECTION 7, ITEM 15R

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- On dairy farms, the ready-to-use (RTU) drug **Utresept**, labeled as an intrauterine flush, is being observed. Would this drug be considered to be in violation of Item 15r of the PMO?
- **Yes.** *FDA's Center for Veterinary Medicine (CVM) has stated that this is an unapproved new animal drug and should not be used or stored on the dairy farm. This unapproved new animal drug would be debited on FORM FDA 2359a under Item 15(d) and would be a five (5) point debit.*

## Q39, PMO-SECTION 7, ITEM 15R

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- On dairy farms, the drug **UtterFlush** labeled for reproductive care for beef and dairy cattle is being observed. Would this drug be considered to be in violation of Item 15r of the PMO?
- **Yes.** *CVM has stated that this intrauterine product is labeled with a structure/function claim and the product is not the subject of a New Animal Drug Application (NADA) approval. It is an unapproved new animal drug and should not be used or stored on the dairy farm. This unapproved new animal drug would be debited on FORM FDA 2359a under Item 15(d) and would be a five (5) point debit.*



## Q40, PMO-SECTION 7, ITEM 15R

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- On dairy farms, the drug **Uterine Capsules** labeled for use by administering two (2) to three (3) capsules intrauterine during post-partum to help maintain normal uterine environment is being observed. Would this drug be considered to be in violation of Item 15r of the PMO?
- **Yes.** *CVM has stated that this is an unapproved new animal drug and should not be used or stored on the dairy farm. This unapproved new animal drug would be debited on FORM FDA 2359a under Item 15(d) and would be a five (5) point debit).*

## Q41, PMO-SECTION 7, ITEM 15R

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- On dairy farms, the drug **Dura-Pen** labeled for use in beef cattle **only** is being observed. Can it be stored on the dairy farm?
- **Yes.** *It shall be stored with the **non-lactating dairy** animal drugs.*

## Q43, PMO-SECTION 7, ITEM 15R

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- If the human Rx drug **Sulfamethoxazole-Trimethoprim** is ELU for calf scours, does Item 15r of the PMO require the ELU label on the drug to include the Caution statement: “Not to be used in female dairy animals twenty (20) months of age or older”?
- **No.**

# QUESTIONS

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