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M-I-18-3
(Supplement 1)

March 23, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Correction To The Answer Provided for Question 11.a.) From M-I-18-3 (Answers To Questions Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During Fiscal Year 2016), Issued January 19, 2018

It has been brought to our attention that the answer provided to Question 11.a.) from M-I-18-3 is in error and in direct conflict with a previously cleared and issued answer addressing the same subject. M-I-09-3 (Questions and Answers Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During Fiscal Year 2008), issued May 29, 2009, Question 88 provided the following answer:

88. PMO-Appendix J, Section C

If a sample container set of four (4) containers is tested using the rinse test, how many "SPC positive" containers are needed to declare the sample set is "violative"?

If two (2) or more of the four (4) containers tested in the sample set indicate results greater than fifty (50) SPC, then the sample set is considered violative.

NOTE: *All single-service containers and closures shall be free of coliform organisms to be considered non-violative.*

Prior to this answer being cleared and issued, FDA was asked to explain how this answer was arrived at and does the answer conflict with the text in Section C-Bacterial Standards and Examination of Single-Service Containers and/or Closures within Appendix J-Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the PMO?

Section C states: “2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per fifty (50) cm² (1 per square centimeter) of product-contact surface in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.”

*It is somewhat poorly worded but paragraph 2. above refers that a “good” sample set is a sample set that three (3) out of four (4) containers/closures in the sample set **SHALL NOT** exceed (50) per container. Therefore, if two (2) out of four (4) containers/closures in a sample set (four (4) containers/closures) exceed the residual microbial (bacterial) count standard it is considered a violative sample. Therefore, the above answer and the PMO are not in conflict.*

Based on the above answer that was cleared and issued in M-I-09-3 and to clearly eliminate any error, conflicting answer or confusion, the answer to Question 11.a) is changed to the following to provide a uniform and consistent answer for all stakeholders involved in the Grade “A” Milk Safety Program. The only change to the answers provide in M-I-18-3 (Question 11) is to the answer provided to 11.a.

11. PMO-Sections 3, 5, 6 and 7, Items 11p and 12p; and Appendix J, Section C; and MMSR-Section D; and Appendix A

The following questions relate to **BOTH** IMS listed single-service containers and/or closures manufacturing facilities and single-service containers and/or closures manufacturing facilities that operate in conjunction with a milk plant that are not IMS listed for single-service containers and/or closures and the single-service containers and/or closures are only used for in-milk plant use.

a) What criteria is utilized to determine if a sample set of single-service containers and/or closures exceeds the microbial (bacterial) count or coliform standards cited in Item 12p-Cleaning and Sanitizing Containers and Equipment of the PMO and which are referenced to Section C-Bacterial Standard and Examinations of Single-Service Containers and/or Closures, Appendix J of the PMO?

A sample set from each manufacturing line, as defined in Appendix J of the PMO, shall consist of a minimum of four (4) containers and/or closures, when the rinse test is used, or a minimum of four (4) 250 cm² areas of surface, when the swab test is used.

To determine compliance of the individual sample sets, where a rinse test can be used, the residual microbial (bacterial) count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the microbial (bacterial) count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per fifty (50) cm² (1 per square centimeter) of product-contact surface in

three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.

Therefore, the single-service containers and/or closures sample set would not be considered to be in violation for residual microbial (bacterial) count when only one (1) ~~or two (2)~~ of the four (4) containers and/or closures of the sample set exceeded the residual microbial (bacterial) standards. The single-service containers and/or closures sample set would be considered to be in violation of the residual microbial (bacterial) limit if the sample results indicated that ~~three (3)~~ two (2) or more of the single-service containers and/or closures of the required sample set of four (4) taken on a given day exceeded the residual microbial (bacterial) standard as cited above for the rinse test or swab test. Also, if any single-service container and/or closure within the sample set of four (4) has one (1) or more coliform organisms detected, the sample set would be considered to be in violation of the coliform standard.

b) If a single-service containers and/or closures manufacturer has two (2) out of the last four (4) consecutive microbial (bacterial) counts and/or coliform determinations for the individual sampling sets exceeding the standard(s) is the Regulatory Agency required to issue a written notice/warning letter and collect an additional sample set within twenty-one (21) days of the sending of the written notice/warning letter, but not before the lapse of three (3) days similar to what is required for milk and milk product samples addressed in Section 6-The Examination of Milk and Milk Products of the PMO?

No. There currently is not a specific enforcement procedure, based on sample set results, for single-service containers and/or closures addressed in the PMO, as there is for milk and/or milk products as cited in Section 6-The Examination of Milk and/or Milk Products of the PMO. However, Section D-Certification/Listing Methods for Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 1.b.2) of the MMSR states: "Compliance with bacterial and coliform requirements is based on whether, at the time of the certification, a single-service manufacturer's containers and/or closures meet the standards of Appendix J. of the Grade "A" PMO. Each manufacturing line of containers and/or closures for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample sets results exceed the limit(s), and the last sample set result is in violation..."

c) If a single-service container and/or closure manufacturer has three (3) out of the last five (5) consecutive microbial (bacterial) counts and/or coliform determinations for the individual sampling sets exceeding the standard(s) is the Regulatory Agency required to suspend the permit or stop the sale of single-service containers and/or closures similar to what is required for milk and milk product samples addressed in Section 6 of the PMO?

No. There currently is not a specific enforcement procedure, based on sample set results, for single-service containers and/or closures addressed in the PMO, as there is for milk and/or milk products as cited in Section 6 of the PMO.

The following questions relate **ONLY** to single-service containers and/or closures manufacturing facilities that operate in conjunction with a milk plant that are not IMS listed for single-service containers and/or closures and the single-service containers and/or closures are only used for in-milk plant use.

d) Where in the PMO is it required that enforcement action be taken on single-service containers and/or closures not meeting microbial (bacteria) and/or coliform standards for an IMS listed milk plant that only makes single-service containers and/or closures for in-milk plant use and the single-service container and/or closures manufacturing facility is not IMS listed?

With the in-milk plant single-service containers and/or closures manufacturing facility not being IMS listed for single-service containers and/or closures, the routine inspection of the in-milk plant single-service containers and/or closures manufacturing facility would be under the milk plant's permit and included in the routine three (3) month regulatory inspection of the IMS listed milk plant. Any violations identified within the single-service container and/or closures manufacturing facility would be debited against the milk plant and would be debited on FORM FDA 2359. For single-service containers and/or closures not complying with the microbial (bacteria) and/or coliform standards they would be debited on FORM FDA 2359 under Item 11-Construction and Repair of Containers and Equipment (c)-Approved single-service articles; not reused. This would also apply for ratings and check ratings conducted of this IMS listed milk plant.

Continued violations of the single-service containers and/or closures microbial (bacteria) and/or coliform standard would warrant the repeat consecutive debiting of Item 11(c) on FORM FDA 2359, which would trigger the required PMO enforcement action to suspend the IMS listed milk plant's permit in accordance with Section 3 of the PMO.

It is recommended that the Regulatory Agency address all single-service containers and/or closures violations of microbial (bacteria) and coliform standards by promptly following up with an inspection to determine and correct the cause. It is also recommended that the Regulatory Agency resample and test the single-service containers and/or closures for compliance with the microbial (bacteria) and coliform standards cited in Item 12p and referenced to Section C within Appendix J of the PMO.

e) While conducting a rating or check rating where in the MMSR does it require that the IMS listed milk plant be debited under the ER for single-service containers in violation of the microbial (bacteria) and coliform standards and the required PMO enforcement action not being taken?

Appendix A-Guidelines for Computing Enforcement Ratings (FORM FDA 2359j-Milk Sanitation Rating Report, Section B-Report of Enforcement Methods (Page 2)), PART II-Milk Plants, Item 9-Permit issuance, suspension, revocation, reinstatement, hearing and/or court action taken as required, Sanitation Requirements, Category II-Permit Suspension of the MMSR would be utilized. Item 2-Category II-Permit Suspension under Milk Plant Enforcement Procedures on FORM FDA 2359j, Section E-Milk Plant Enforcement Action and Record Evaluations (Page 5) would not be given Credit if the repeat consecutive debiting of Item 11(c) on FORM FDA 2359 for violations of the single-service containers and/or closures microbial (bacteria) and/or coliform standards, which would trigger the required PMO enforcement action to suspend the IMS listed milk plant's permit in accordance with Section 3 of the PMO was not taken.

The following question relates **ONLY** to IMS listed single-service containers and/or closures manufacturing facilities.

f) While conducting a rating or check rating where in the MMSR does it require that the IMS listed single-service containers and/or closures manufacturing facility be debited under the ER for single-service containers in violation of the *microbial (bacteria) and coliform standards and enforcement action not being taken?*

The MMSR does not address or require Enforcement Ratings to be conducted and calculated for the IMS certification/listing of single-service containers and/or closures for milk and/or milk products manufacturers.

NOTE: *Section D-Certification/Listing Methods for Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 1-Collection of Data, b-Recording of Laboratory and Other Test Data of the MMSR does address points that would be debited against the SCR of a single-service containers and/or closures for milk and/or milk products manufacturers during ratings and check ratings. Compliance with bacterial and coliform requirements is based on whether, at the time of the certification, a single-service manufacturer's containers and/or closures meet the standards of Section C within Appendix J of the PMO. Each manufacturing line of containers and/or closures for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample set results exceed the limit(s), and the last sample set result is in violation. A debit shall be given when less than the required number of sample sets has been examined during the preceding six (6) months. For certification purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the certification is made and the preceding six (6) months. Single-service containers and/or closures manufacturers which have had a permit, if applicable, for less than six (6) months at the time of the certification or which do not operate on a year-round basis and for which the Regulatory Agency, single-service consultants (SSCs) and/or single-service containers and/or closures manufacturer, as*

applicable, has not yet examined the required number of sample sets shall not be debited, provided that the last sample set result is within the limit(s).

We wish to apologize for our oversight in not properly researching this answer prior to it being issued and providing an answer that was in error, conflicted with a previously cleared and issued answer and created confusion throughout the entire Grade "A" Milk Safety Program by providing and issuing two (2) different conflicting answers addressing the same subject.

NOTE: FDA continues to receive questions related to this issue as indicated in FY 2008 and FY 2016. Because similar text, with the exception that "or, 50 colonies per 8 square inches (1 per square centimeter)" was changed to "not over fifty (5) colonies per fifty (50) cm² (1 per square centimeter)" in the 2015 PMO, has been in the PMO since 1999 when the stand alone published *Standards for the Manufacture of Single-Service Containers and Closures for Milk and Milk Products* was incorporated into the PMO, FDA is proposing to submit a Proposal to the 2019 NCIMS Conference to make this issue clear once and for all. Proposed text changes will be submitted to Section C of Appendix J and to similar text cited in Item 12p, Administrative Procedures, 6.a. and 6.b. of the PMO.

Again, we wish to apologize for this error and any confusion that this has generated within the Grade "A" Milk Safety Program.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to robert.hennes@fda.hhs.gov.



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