

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-a-96

November 21, 2006

Implementation Date: January 1, 2007

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Evaluation of Milk Laboratories (2005 Revision)

Proposal 246 of the 2005 National Conference on Interstate Milk Shipments (NCIMS) Conference directed the Food and Drug Administration (FDA) and the NCIMS Laboratory Committee to update the Evaluation of Milk Laboratories (EML) document. The 2005 Revision of the EML reflects approved changes made to the laboratory program since the 1995 NCIMS Conference and recommended changes proposed by the NCIMS Laboratory Committee. Final approval of the 2005 Revision of the EML has been granted based on a majority vote of the submitted votes by the NCIMS State voting delegates.

Background Information:

1. Following the 1995 NCIMS Conference, the EML that had been in force since 1985 was revised.
2. At the 2003 NCIMS Conference, Proposal 258 was passed directing the FDA to update the 1995 EML with changes that had occurred since the 1995 EML was adopted.
3. March 4, 2005 the revised 2003 EML was issued through M-I-05-2.
4. At the 2005 NCIMS Conference, Proposal 246 sought to further update the 2003 EML and included changes suggested by the NCIMS Laboratory Committee. A draft copy of the proposed 2005 Revision of the EML was provided to the delegates at the Conference. During the debate it was decided that the delegates did not have enough time to review the new revision and the Proposal was tabled. The Proposal was removed from the table and a substitute motion made. In the discussion it was

decided that there had not been sufficient time for the delegates to review the proposed 2005 Revision of the EML in order to make an informed vote. Discussion also indicated that the 2003 EML had also not been sufficiently reviewed and it was decided that this revision should be set aside and the 1995 Revision of the EML put back in place. The substitute motion directed the NCIMS Laboratory Committee, along with the FDA, to revisit the proposed revision of the 2005 EML and re-submit the document through the memorandum review process in October 2005. Final approval of the 2005 Revision of the EML would be by a majority vote of the submitted votes of the NCIMS State voting delegates.

5. The 2005 Revision of the EML was reviewed again and submitted through the memorandum review process in November 2005.
6. The 2005 Revision of the EML was reviewed through the memorandum review process and comments provided in June 2006.
7. FDA reviewed the comments and provided their response to the NCIMS Executive Board for their acceptance of the proposed modifications to the EML per the comments received.
8. At the September 25, 2006 NCIMS Executive Board's Conference Call, approval was granted for FDA's modifications identified in the 2005 Revision of the EML.
9. Final approval of the 2005 Revision of the EML has been obtained by a majority vote of the submitted votes by the NCIMS voting delegates.

The 2005 Revision of the Evaluation of Milk Laboratories document has been completed and an electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the CFSAN Web Site at <http://www.cfsan.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov or Larry.Maturin@fda.hhs.gov.



Larry Maturin, PhD, Chief
Laboratory Quality Assurance Team



CAPT Robert F. Hennes, RS, MPH, Chief
Milk Safety Team