4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Clarification of Compliance Date for Certain Food Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; clarification of compliance date for certain food establishments.

SUMMARY: The Food and Drug Administration (FDA or we) is clarifying the compliance date that we provided for certain food establishments subject to a final rule that published in the Federal Register of September 17, 2015. Among other things, that final rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. We are taking this action in response to requests for clarification of the compliance date for facilities that manufacture, process, pack, or hold grade "A" milk or milk products and that are regulated under the National Conference on Interstate Milk Shipments (NCIMS) system.

DATES: The compliance date under the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (published on September 17, 2015 at

80 FR 55908) for grade "A" milk and milk products covered by NCIMS under the PMO is September 17, 2018.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 17, 2015 (80 FR 55908), we published a final rule entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (the final human preventive controls rule). Among other things, the final human preventive controls rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for human food. In the preamble to the final human preventive controls rule (80 FR 55908), we stated that the rule is effective November 16, 2015, and provided for compliance dates of 1 to 3 years in most cases.

In Comment 214 in the final human preventive controls final rule (80 FR 55908 at 55986 to 55987), we described comments that discuss facilities that comply with the Grade "A" PMO and are regulated under the NCIMS system, and we used the term "PMO facilities" as an abbreviation for these facilities. As previously discussed (78 FR 3646 at 3662; January 16, 2013), the PMO is a model regulation published and recommended by the U.S. Public Health Service/FDA for voluntary adoption by State dairy regulatory agencies to regulate the

production, processing, storage and distribution of Grade "A" milk and milk products to help prevent milk-borne disease. Some comments recommended that we make full use of the existing milk safety system of State regulatory oversight for Grade "A" milk and milk products provided through the NCIMS and the food safety requirements of the PMO. Some comments asked us to exempt PMO-regulated facilities (or the PMO-regulated part of a PMO facility that also produces food products not covered by the PMO) from the requirements of the rule for hazard analysis and risk-based preventive controls, or to otherwise determine that facilities operating in compliance with the PMO are also in compliance with those requirements. These comments suggested we could, as an interim step if we find it necessary, stay the application of these requirements to PMO-regulated facilities and work with the NCIMS cooperative program to enact any modifications to the PMO as may be needed to warrant an exemption or comparability determination. In response to these comments, we established a compliance date of September 17, 2018, for "PMO facilities" (see Response 214, 80 FR 55908 at 55987 to 55988).

II. Clarification of the Compliance Date for Facilities Regulated Under the NCIMS System

On September 10, 2015, the Office of the Federal Register made a pre-publication copy of the final human preventive controls rule available to the public through its procedures for advance display (Ref. 1). Since September 10, 2015, we have provided opportunities for stakeholders to ask questions about the rule, through webinars and through a Web portal for submission of questions (Refs. 2 and 3). Some PMO facilities, in addition to manufacturing, processing, packing, or holding grade "A" milk or milk products, manufacture, process, pack, or hold other food subject to the final human preventive controls rule. Some of these facilities have asked us to clarify whether the extended compliance date for "PMO facilities" applies only to grade "A" milk and milk products covered by NCIMS under the PMO, or whether the extended

compliance date applies broadly to all activities conducted by the facility (e.g., activities related to other food produced at the facility).

In this document, we are clarifying that the extended compliance date of September 17, 2018, for "PMO facilities" applies only to grade "A" milk and milk products covered by NCIMS under the PMO, and not to the manufacturing, processing, packing, or holding of other food. As we discussed in Response 214 (80 FR 55908 at 55987 to 55988), we agreed that we should make use of the existing system of State regulatory oversight for Grade "A" milk and milk products provided through the NCIMS and the food safety requirements of the PMO. We described our reasons for deciding to extend the compliance date for "PMO-regulated facilities" to comply with the requirements of subparts C and G to September 17, 2018. Those reasons related to the current provisions of the PMO, the work already begun by NCIMS to modify the PMO to include all of the requirements established in the final human preventive controls rule, and complex implementation issues concerning the interstate movement of milk and milk products and imported milk. We explained that in establishing a compliance date of September 17, 2018, for PMO facilities, we considered: (1) The extent of revisions that must be made to incorporate the requirements of this rule for hazard analysis and risk-based preventive controls into the PMO; (2) the process to revise the PMO; and (3) the date at which the necessary revisions to the PMO could begin to be made. All of these discussions in the human preventive controls final rule related to the activities regulated by NCIMS under the PMO.

III. Economic Analysis of Impacts

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all

costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of this final rule (Ref. 4). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule is making no change to the compliance date announced for facilities regulated under the NCIMS system in the human preventive controls rule published on September 17, 2105, we have determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

IV. Environmental Impact, No Significant Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Office of the Federal Register, "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food," September 10, 2015. Available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-21920.pdf.

2. FDA, "FSMA Webinar Series: Preventive Controls for Human and Animal Food Final Rules," 2015. Available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461512.htm.

3. FDA, "Contact FDA About FSMA," 2015. Available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

4. FDA, "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Clarification of Compliance Date for Certain Food Establishments," 2015. Available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

Dated: November 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-29340 Filed: 11/17/2015 8:45 am; Publication Date: 11/18/2015]