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CIAA Bulletin

An Exclusive CIAA Member Update

FDA Releases Final Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

To Be Formally Published in the Federal Register on September 17

The Food and Drug Administration (FDA) has released an advance copy of the final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. This more than 900 page rule will be formally published in the Federal Register on September 17, and will be implemented over the next two years. Most businesses (other than small businesses, very small businesses, and businesses subject to the Pasteurized Milk Ordinance) will have 1 year after the date of publication to come into compliance (i.e., September 17, 2016). Businesses may have more time to comply with the supply chain control requirements.

According to FDA, this rule, required by the Food Safety Modernization Act (FSMA), (1) creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food; (2) modernizes FDA's long-standing current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food; and, (3) clarifies the scope of the exemption for "farms" in FDA's current food facility registration regulations and makes corresponding revisions to FDA's current regulations for the establishment, maintenance, and availability of records. The rule establishes requirements for s written food safety plan; hazard analysis; preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records.

With respect to imported product, the advance copy at page 753-754 states that FDA "...intend(s) to publish a final FSVP rule in the near future. There, we intend to establish modified requirements for food imported from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as "comparable" to that of the United States."

Our preliminary review has found that cheeses are discussed at several places:

- Comment 455 regarding flexibility in the oversight and management of preventive controls beginning at page 475 and referencing cream cheese at 476;
- Comment 516 regarding verification activities beginning at page 532 and referencing soft cheeses in the response on 534, saying they are "among the products for which manufacturing operations would need to have an environmental monitoring program when such foods are exposed to the environment." and continuing through 535;
- Comment 546 regarding requirements for written procedures for environmental monitoring beginning at page 564 with the concern that frequent swabbing and frequent testing could cause cheeses to be held past their optimum ripeness if they are fresh or soft ripened;
- Response 679 at page 700 regarding the supplier's food safety history and the specific example - "...if the receiving facility is obtaining a cheese product from a supplier that is controlling pathogens such as L. monocytogenes and Salmonella, and becomes aware that cheeses from this supplier have been associated with an undeclared allergen due to improper labeling, the receiving facility would determine that it should implement verification activities related to label control to prevent undeclared allergens."; and
- Comment 726 regarding standards of identity for cheese beginning at page 765 with specific references to the 60 day rule, and the following response and the specific statement that "It is premature to determine what role, if any, an aging process could play in a food safety plan for the manufacture of cheese from unpasteurized milk."

FDA has scheduled a webinar for Wednesday, September 16, 2015 to review the Significant Provisions of the Final Rule for Preventive Controls for Human Food. The webinar will be held from 2:00 p.m. - 3:00 p.m. ET, with callers being asked to connect by 1:45 p.m. To hear the presentation and ask questions: Dial: 800-988-0215, passcode: FSMA. To view the slide presentation during the webinar: https://www.mymeetings.com/emeet/join/index.jsp?customHeader=mymeetings&netId=PW5138279&netPass=FSMA&netType=conference&acceptTerms=on

FDA also plans to hold a public meeting to review the rule on October 20, 2015 - 8:30 am to 5:30 pm at the Chicago Marriott Downtown Magnificent Mile, 540 North Michigan Ave., Chicago, IL. More meeting specifics including information on how to register for the meeting will be made available in September through a Federal Register Notice.

If you have any questions, please contact Roger Szemraj at rszemraj@theciaa.org or (202) 789-1212.

DATES TO REMEMBER

September 15, 2015
Last transmission date for licensees applying for reallocated license amounts for calendar year 2015.

October 1, 2015
Last transmission date for licensees to surrender the unused portion for the 2015 calendar year.

October 15, 2015
Last transmission date for all applications for 2016 calendar year licenses.

November 5, 2015
CIAA Member Meeting
9:30 am-11:30 am
Location: Saddle Brook Marriott, Saddle Brook, NJ

December 22, 2015 (approximately)
FAS issues first notice of calendar year 2016 licenses to licensees.

December 31, 2015
Last day for licensees to make entries to fulfill the requirement to use 85% of their calendar year 2015 license amount. Last day for which calendar year 2015 licenses are valid.

January 17, 2016
CIAA Fancy Food Show Reception
5:00 pm-7:30 pm
Thirsty Bear Brewery
San Francisco, CA

* If a deadline date falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next
business day (Section 6.36(a) of the Dairy Tariff-Rate Import Quota Licensing Regulation). This does
not apply to dates of entry for eligibility

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