



September 10, 2015

Re: Final Rules: (1) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and (2) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is releasing the Final Rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food and the Final Rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals on September 10, 2015. These rules were proposed in January, 2013.

These two final rules are part of FDA's implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to problems when they do occur.

Over a two-year period, FDA consulted with tribal officials on the proposed FSMA implementing regulations in order to permit the tribes to have meaningful and timely input into the development of these final regulations. The dialogue between FDA and the tribes began in 2013 when FDA notified all federally-recognized tribes by mail that FDA intended to consult with any interested tribes on the FSMA regulations.

During our consultation and dialogue with the tribes on the proposed FSMA regulations, we had discussions about the important relationship between the FDA and federally-recognized tribes. These tribes are sovereign and federal agencies have an obligation to consult them in certain matters of importance.

A Tribal Summary Impact Statement has been prepared that includes a summary of tribal officials' concerns related to each of the two final rulemakings and how FDA has addressed or will address them. Copies of the tribal summary impact statement specific to each rule may be obtained on the Regulations.gov website that contains the docket for each of these rules.

The compliance dates for these two final rules and for the other five proposed FSMA rules that FDA intends to finalize and publish continuing into 2016 vary, in part, according to the size of the business. Outreach, technical assistance, and industry training are critical components of the successful implementation of FSMA, and FDA will continue to join with public and private partners in tribal, state, federal, and international governments, industry, and academia in the development and delivery of training. We will work with tribes to provide education and technical assistance toward the implementation of the relevant FSMA rulemakings on tribal lands to help ensure that everyone who seeks to comply with these rules, whether legally required to or not, understands the new standards.

The final rules have been posted on our FSMA website at www.fda.gov/FSMA. We plan to hold follow-up webinars on the rules as well as a public meeting. The recordings and slides from these webinars and the public meeting will be available on our website. The public meeting will also be live webcast. The details on the webinars and the public meeting are posted below:

Tuesday, September 15, 2015, 2:00 p.m. – 3:00 p.m. ET

Webinar: Final Rules for Preventive Controls for Human and Animal Food: Who is Covered? What is the Definition of a Farm?

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=PW5137727&netPass=FSMA&netType=conference&acceptTerms=on>

Wednesday, September 16, 2015, 2:00 p.m. – 3:00 p.m. ET

Webinar: Final Rule for Preventive Controls for Human Food: Significant Provisions of the Rule

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>

Thursday, September 17, 2015, 2:00 p.m. – 3:00 p.m. ET

Webinar: Final Rule for Preventive Controls for Animal Food: Significant Provisions of the Rule

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=PW5138284&netPass=FSMA&netType=conference&acceptTerms=on>

Tuesday, October 20, 2015, 8:30 a.m. – 5:30 p.m. CT

Public Meeting on FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human and Animal Food Final Rules

Chicago Marriott Downtown Magnificent Mile

540 North Michigan Ave

Chicago, IL 60611

More meeting specifics, including information on how to register for the meeting will be made available in September through a Federal Register Notice, and on the FSMA website at www.fda.gov/FSMA.

If you have any questions, please contact:

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We look forward to our continued dialogue with the tribal community to achieve food safety goals and ensure thriving food systems.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine