



May 26, 2016

Re: Mitigation Strategies to Protect Food Against Intentional Adulteration

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is releasing the Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration on May 26, 2016.

This final rule is 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. The FSMA rules are 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. The rule on Mitigation Strategies to Protect Food Against Intentional Adulteration was proposed on December 24, 2013.

Over a two-year period, FDA consulted with tribal officials on the suite of seven proposed FSMA implementing regulations 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 specific to this rule has been prepared and may be obtained on the Regulations.gov website that contains the docket for this rule, (<https://www.regulations.gov/#!/home>)

The compliance date for this rule varies, in part, according to the size of the business. Outreach, technical assistance, and industry training are critical components of the successful implementation of FSMA. FDA will join with public and private partners in tribal, state, federal, and international governments, industry, and academia to deliver training and to provide education and technical assistance related to FSMA rules.

The final rule has been posted on our FSMA website at www.fda.gov/FSMA. We plan to hold a follow-up webinar on the rule. The recording and slides from this webinar will be available on our website. The details on the webinar are posted below:

Tuesday, June 21, 2016, 11:00 a.m. – 12:00 p.m. ET

Webinar: Final Rule Mitigation Strategies to Protect Food Against Intentional Adulteration

Dial: 888-946-6302, passcode: 3811136

To view the slide presentation during the webinar:

<https://www.mymeetings.com/emeet/join/index.jsp?customHeader=mymeetings&netId=PW8496974&netPass=3811136&netType=conference&acceptTerms=on>

If you have any questions, please contact:

Jeff Farrar, DVM, MPH, PhD
Director of Intergovernmental Relations and Partnerships
Office of Foods and Veterinary Medicine
U.S. Food and Drug Administration
WO1-3241
10903 New Hampshire Avenue
Silver Spring, MD 20993
240-401-4926

We look forward to our continued dialogue with the tribal community to achieve food safety goals and ensure thriving food systems. More information related to FDA engagement with tribal governments is available at <http://www.fda.gov/tribal>.

Sincerely,

Stephen M. Ostroff, M.D.
Incoming Deputy Commissioner for Foods
and Veterinary Medicine