



November 13, 2015

Re: (1) Final Rules:

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
  - Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications; and
- (2) Final Environmental Impact Statement for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is releasing the Final Rules on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; and Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications. In addition, FDA is making available its Final Environmental Impact Statement (EIS) for the Proposed Rule: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.

These three 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. FSMA is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply and 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.

FDA has prepared a Tribal Summary Impact Statement which includes a summary of tribal officials' concerns related to each of the three final rulemakings and the EIS and how FDA has

addressed or will address these concerns. 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. A discussion of tribal concerns regarding the EIS can be found in the Tribal Summary Impact Statement for the Produce Safety rule. For access to the Final EIS document or other background documents and comments received on the Draft EIS, go to <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm396564.htm>.

The compliance dates for these three final rules 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](http://www.fda.gov/FSMA). We plan to hold follow-up webinars on the rules and recordings and slides from these webinars will be available on our website. The details on the webinars are posted below:

**Tuesday, November 17, 2015, 2:00 p.m. – 3:00 p.m. ET**

*Webinar: Final Rule for Produce Safety: Significant Provisions of the Rule*

Dial: 800-857-5012, passcode: FSMA

To view the slide presentation during the webinar:

<https://www.mymeetings.com/emeet/join/index.jsp?customHeader=mymeetings&netId=PW5836210&netPass=FSMA&netType=conference&acceptTerms=on>

**Monday, November 23, 2015, 10:00 a.m. – 11:30 a.m. ET**

*Webinar: Final Rules for Foreign Supplier Verification Program (FSVP) & Third Party Auditors*

Dial: 800-857-5012, passcode: FSMA

To view the slide presentation during the webinar:

<https://www.mymeetings.com/emeet/join/index.jsp?customHeader=mymeetings&netId=PW5836233&netPass=FSMA&netType=conference&acceptTerms=on>

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