



April 5, 2016

Re: Sanitary Transportation of Human and Animal Food

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is releasing the Final Rule on Sanitary Transportation of Human and Animal Food on April 5, 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, and builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act (SFTA) (Pub. L. 109-59). 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 Sanitary Transportation of Human and Animal Food rule was proposed on February 5, 2014.

Over a two-year period, FDA consulted with tribal officials on the suite of seven 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 this final rulemaking and how FDA has addressed or will address them. The tribal summary impact statement specific to this rule may be obtained on the Regulations.gov website that contains the docket for this rule:

[\(https://www.regulations.gov/\)](https://www.regulations.gov/)

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 the 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:

Monday, April 25, 2016, 11:00 a.m. – 12:00 p.m. ET

Webinar: Final Rule on Sanitary Transportation of Human and Animal Food

Dial: 888-946-8408, passcode: FSMA

To view the slide presentation during the webinar:

<https://www.mymeetings.com/emeet/join/index.jsp?customHeader=mymeetings&netId=PW7654409&netPass=FSMA&netType=conference&acceptTerms=on>

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

Sincerely,

Jeff Farrar
Director of Intergovernmental Relations &
Partnerships