DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

December 31, 2014

Dear Tribal Leader:

I am writing to invite your participation and feedback in commenting on the Draft Environmental Impact Statement (EIS) for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

On or about Friday, January 9, 2015, the U.S. Food and Drug Administration (FDA) will make public its Draft EIS for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (also known as the Produce Safety Proposed Rule). The following week on Friday, January 13, 2015, FDA expects the Notice of Availability (NOA) for the Draft EIS to be published in the *Federal Register*, which begins a 60-day public comment period likely ending on March 10, 2015 (please see the notice in the Federal Register for the exact date).

FDA prepared the Draft EIS pursuant to the National Environmental Policy Act of 1969 (NEPA); Council for Environmental Quality (CEQ) regulations for Implementing NEPA, 40 CFR Parts 1500-1508; and FDA regulations for Environmental Impact Considerations, 21 CFR Part 25.

FDA initiated an invitation to consultation to all federally recognized Indian Tribes on FDA's intent to prepare an EIS on August 16, 2013, and we have engaged in consultation throughout the NEPA process. Concerns raised by Indian Tribes with respect to the EIS were considered and included in the EIS for analysis, and we look forward to continue working with Tribes as the process moves forward.

Specifically, the EIS assesses the potential environmental and related human health and socioeconomic impacts for those provisions that FDA has determined may significantly affect the quality of the human environment (hereinafter referred to as "potentially significant provisions"), and alternatives to those provisions. For those potentially significant provisions, FDA identified the preferred alternative and other alternatives to the preferred alternative, including a no action alternative. The potentially significant provisions are 1) standards directed to agricultural water, 2) standards directed to biological soil amendments of animal origin and human waste, 3) standards directed to domesticated and wild animals, and 4) general provisions. An overarching "No Action" Alternative was considered for not enacting a final rule.

The EIS conducts an impact analysis on key environmental resource components, which FDA selected based on extensive public and agency scoping and outreach. These environmental resource components include the following: Water Resources; Biological and Ecological Resources; Soils; Waste Generation, Disposal, and Resource Use; Air Quality; Socioeconomics and Environmental Justice, including Tribal Impacts; and Human Health and Safety.

Public Meeting

FDA is hosting a public meeting on February 10, 2015, from 1:00 p.m. until 4:00 p.m. at the Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740, to discuss the Draft EIS for the Produce Safety Proposed Rule. The public meeting will also have webinar and telephone access for all interested parties to attend. The deadline for registration is February 3, 2015.

Beginning on January 9, 2015, you may register for the public meeting on-line at: http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm

Additional instruction will be provided during the registration process.

For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX or e-mail, contact: Rick Williams, c/o FDA EIS, 72 Loveton Circle, Sparks, MD 21152; Phone: (410) 316-2377; Fax: (410) 472-3289; email: RWilliams@jmt.com.

For general questions about the meeting; to request an opportunity to make an oral presentation at the public meeting; to submit the full text, comprehensive outline, or summary of an oral presentation; or for special accommodations due to a disability, contact: Cynthia Wise, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, telephone: 240-402-1357, email: cynthia.wise@fda.hhs.gov.

Submitting Comments

FDA requests your comments on the Draft EIS (Docket Number FDA-2014-N-2244) by the end of the 60 day comment period, which will likely be March 10, 2015 (please see the notice in the Federal Register for the exact date). You may submit your comments, identified by the docket number, by any of the following methods:

- Electronic comment submissions
  - Follow the instructions for submitting comments on the Federal eRulemaking Portal at http://www.regulations.gov.
- Written comment submissions
  - Mail/hand delivery/courier (for paper or CD-ROM submissions) to Division of Dockets Management, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852

All submissions must include the Agency name and relevant docket number. All comments received may be posted without change to http://www.regulations.gov.

For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number referenced above into the "Search" box and follow the prompts. Access can also be provided through the Division of Dockets Management at the address above.

If you have any questions regarding FDA's process for soliciting your input on the Draft EIS, you may also contact FDA's Director of Intergovernmental Affairs, Danielle Grote, at 301-796-8907, or email danielle.grote@fda.hhs.gov.

The FDA is committed to working with federally recognized Tribes on FDA's implementation and enforcement of the FDA Food Safety Modernization Act (FSMA) in Indian Country. I hope you are able to provide feedback on the Draft EIS by joining us for the public meeting and submitting comments to the docket, and I thank you for your interest in food safety issues.

Sincerely,

/s/

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine