



October 21, 2020

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA or the Agency) is initiating written consultation with federally recognized Indian Tribes on the proposed rule “[Requirements for Additional Traceability Records for Certain Foods](#).”<sup>i</sup> The proposed rule published in the *Federal Register* on September 23, 2020. The FDA also published a draft “[Food Traceability List](#),”<sup>ii</sup> (FTL) which describes the foods that would be subject to the proposed requirements. The list includes leafy greens, fresh cut fruits and vegetables, some types of fish, shell eggs, nut butters, and more.

This proposed rule is a key component of the FDA’s New Era of Smarter Food Safety [Blueprint](#)<sup>iii</sup> and would implement Section 204(d) of the [FDA Food Safety Modernization Act \(FSMA\)](#).<sup>iv</sup> If finalized, the proposal would facilitate rapid and accurate traceability by standardizing the data elements and information that certain traceability records would need to contain, and the information that firms would need to send to the next entity in the supply chain. While limited to only certain foods, this proposal lays the foundation for a standardized approach to traceability recordkeeping, paving the way for industry to adopt, harmonize, and leverage more digital traceability systems in the future. Where possible, FDA has drawn on existing consensus standards that industry members may already be using.

All written comments on this proposed rule submitted in the docket by January 21, 2021, will be considered before the final rule is published. The FDA will also be holding three virtual meetings with the general public during the public comment period. The dates for the virtual public meetings are as follows:

- First Virtual Public Meeting – November 6, 2020, 8:30 a.m. – 4:30 p.m. EST
- Second Virtual Public Meeting – November 18, 2020, 9:30 a.m. – 5:30 p.m. EST
- Third Virtual Public Meeting – December 2, 2020, 11:30 a.m. – 7:30 p.m. EST

Additional information about the general public meetings, including registration information, is provided on the [webpage](#).<sup>v</sup>

Comments on the proposed rule may be submitted to FDA using either of the following methods:

- Electronic Submissions: Please follow the instructions for submitting comments on the Federal eRulmaking Portal at: <http://www.regulations.gov>. You can submit comments directly there.
- Written submissions via Mail/Hand Delivery/Courier: Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

All comments must include the docket number for the proposed rule: Docket No. FDA-2014-N-0053. Received comments will be placed in the docket and publicly viewable<sup>vi</sup> at <http://www.regulations.gov>.

If you have any questions regarding the proposed rule, please contact the FDA Intergovernmental Affairs (IGA) team at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
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The FDA Intergovernmental Affairs Staff is available to assist tribal officials. For more information regarding FDA's activities with federally recognized tribal governments, please visit [www.fda.gov/tribal](http://www.fda.gov/tribal).<sup>vii</sup> We look forward to continuing to strengthen the relationship between FDA and tribal governments as the Agency fulfills its mission to protect and promote public health.

Sincerely,

--/s/--

Frank Yiannas  
Deputy Commissioner for Food Policy and  
Response

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<sup>i</sup> Proposed Rule Federal Register link: <https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods>

<sup>ii</sup> Food Traceability List link: <https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>

<sup>iii</sup> New Era Blueprint link: <https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint>

<sup>iv</sup> FSMA link: <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>

<sup>v</sup> Public Meeting Information and Registration: <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meetings-discuss-fsma-proposed-rule-requirements-additional-traceability-records-certain>

<sup>vi</sup> Confidentials submission are not publicly viewable and directions for such submissions can be found in the Proposed Rule Federal Register notice here: <https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods>

<sup>vii</sup> FDA IGA website link: <http://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs>