WORLD TRADE ORGANIZATION

G/SPS/N/USA/3203

25 September 2020

(20-6528)

Page: 1/3

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	**Notifying Member:** UNITED STATES OF AMERICA **If applicable, name of local government involved:**
2.	**Agency responsible:** US Food and Drug Administration (FDA)
3.	**Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** HS Code(s): 1211, 2008, 07, 0406, 0407, 08, 0302, 0303, 0306, 0304, 0305, 0307; ICS Code(s): 67
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** **[X] All trading partners** **[ ] Specific regions or countries:**
5.	**Title of the notified document:** Requirements for Additional Traceability Records for Certain Foods; Proposed Rule. **Language(s):** English. **Number of pages:** 55 https://www.govinfo.gov/content/pkg/FR-2020-09-23/pdf/2020-20100.pdf https://members.wto.org/crnattachments/2020/SPS/USA/20_5730_00_e.pdf
6.	**Description of content:** The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish additional traceability recordkeeping requirements for persons that manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed rule would require these entities to establish and maintain records containing information on critical tracking events in the supply chain for these designated foods, such as growing, shipping, receiving, creating, and transforming the foods. The proposed requirements are intended to help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this proposed rule in accordance with the FDA Food Safety Modernization Act (FSMA).
7.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests.**

8. **Is there a relevant international standard? If so, identify the standard:**

[ ] **Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:**

[ ] **World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:**

[ ] **International Plant Protection Convention *(e.g. ISPM number)*:**

[X] **None**

Does this proposed regulation conform to the relevant international standard?

[ ] Yes [ ] No

If no, describe, whenever possible, how and why it deviates from the international standard:

9. **Other relevant documents and language(s) in which these are available:** Food Traceability List: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list (available in English)

10. **Proposed date of adoption *(dd/mm/yy)*:**

Proposed date of publication *(dd/mm/yy)*:

11. **Proposed date of entry into force: [ ] Six months from date of publication, and/or *(dd/mm/yy)*:**

[ ] **Trade facilitating measure**

12. **Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 21 January 2021 - Submit either electronic or written comments on the proposed rule by 21 January 2021. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of 21 January 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Agency or authority designated to handle comments: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Submit electronic comments in the following way:
Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.
Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in ''Instructions.''
Instructions: All submissions received must include the Docket No. FDA-2014-N-0053 for ''Requirements for Additional Traceability Records for Certain Foods.'' Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket

	and, except for those submitted as ''Confidential Submissions,'' publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. *Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. FOR FURTHER INFORMATION CONTACT: *Regarding the proposed rule:* Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4614, Brian.Pendleton@fda.hhs.gov.
13.	**Text(s) available from: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** Text can be found in the Federal Register, Vol. 85, No. 185, page 59984 or on the internet at https://www.govinfo.gov/content/pkg/FR-2020-09-23/pdf/2020-20100.pdf United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: us.spsenquirypoint@fas.usda.gov