



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2020-N-1119]

Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is opening a docket to receive information and comments related to certain produce commodities with no or low reported consumption in the database relied on to create the list of rarely consumed raw commodities that are exempt from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation. FDA intends to use the information to consider whether any of these commodities should be added to the rarely consumed raw list.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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.

Electronic Submissions

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>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- 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-2020-N-1119 for “Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States.” 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, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1636.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of November 27, 2015, we issued the final rule, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (80 FR 74354), which established at 21 CFR Part 112 science-based minimum standards for fruits and vegetables grown for human consumption (produce safety regulation). The produce safety regulation is one of the seven foundational regulations that we issued as part of our implementation of the FDA Food Safety Modernization Act (Pub. L. 111-353), which directs FDA to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety.

Produce is subject to the produce safety regulation (i.e., is “covered produce”) unless it is “not covered” because it is: (1) rarely consumed raw (RCR) (§ 112.2(a)(1) (21 CFR 112.2(a)(1))) (the RCR exemption); (2) produced for personal or on-farm consumption

(§ 112.2(a)(2)); or (3) not a raw agricultural commodity (§ 112.2(a)(3)). This request for information pertains to certain commodities that were not categorized as RCR.

The RCR list is a list of produce commodities that we determined are almost always consumed in the United States only after being cooked. Cooking is a kill step that can be expected to adequately reduce the presence of microorganisms of public health significance in most cases. FDA concluded that it is not reasonably necessary to subject RCR commodities to the produce safety regulation.

FDA's classification of produce as RCR was based on food consumption patterns reported in a robust dataset: The National Health and Nutritional Examination Survey/What We Eat in America (NHANES/WWEIA) dataset (Ref. 1), which is the most comprehensive, robust, and nationally representative dataset currently available on dietary intake in the United States. We also used the U.S. Environmental Protection Agency's Food Commodity Intake Database (Ref. 2), which is a recipe database that identifies proportions of commodity ingredients in NHANES/WWEIA codes, and also identifies the cooking status (uncooked or cooked) and the food forms (e.g., fresh, frozen, canned) associated with each commodity ingredient. We provided background information and data analyses informing the inclusion of produce commodities in the RCR list in a memorandum (the Produce RCR memorandum) that we made available in the administrative record of the produce safety rulemaking (Ref. 3).

Note that the identification of a commodity on the RCR list does not mean the produce is never eaten raw or that it is not eaten raw, typically or occasionally, in specific regions of the United States (or among specific ethnic communities in the United States). The RCR list also does not reflect the form in which these commodities are consumed by populations in other countries.

Consumption patterns for a commodity had to meet three criteria that were used to determine if a commodity qualified as rarely consumed raw. First, the commodity had to be consumed uncooked by less than 0.1 percent of the United States population. Second, the commodity had to be consumed uncooked on less than 0.1 percent of eating occasions. Third, at least 1 percent of the weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers. The purpose of the third criteria was to ensure that we had sufficient data to provide a reasonable representation of how the commodity is consumed in the United States for the purpose of exempting commodities from the coverage of the produce safety regulation (80 FR 74354 at 74388). For commodities not reported as consumed by at least 1 percent of the weighted number of respondents, we consider the overall reported rate to be too low to justify relying on these data as a reasonable representation of consumption among all U.S. consumers.

Commodities that failed to satisfy all three NHANES/WWEIA food consumption criteria were not included in the RCR list. Several produce commodities satisfied the first two NHANES/WWEIA food consumption criteria for demonstrating that the commodities are almost always eaten only after being cooked, but are covered by the produce safety regulation because the 2003-2010 NHANES/WWEIA dataset did not demonstrate consumption of the commodities in any form by at least 1 percent of survey respondents. (See Response to Comments 68 and 69, 80 FR 74354 at 74392 to 74394.) In the remainder of this document, we refer to these commodities as “produce commodities with low reported consumption.” The following is an

exhaustive list¹ of these produce commodities with low reported consumption according to the methodology used in developing the RCR list: artichoke, globe-type; artichoke, Jerusalem; arugula; balsam pear; boysenberry; Brazil nut; breadfruit; broccoli, Chinese; brussels sprouts; burdock; cabbage, Chinese, bok choy; cabbage, Chinese, mustard; cabbage, Chinese, Napa; cactus; celeriac; chayote fruit; chestnut; Chinese waxgourd; chrysanthemum garland; citron; cress, garden; currant; dandelion leaves; dasheen (taro) (leaves and corm); fennel, Florence; genip; gooseberry; grape, leaves; guava; huckleberry; jicama; kale; kohlrabi; kumquat; leek; lime; lotus root; lychee; macadamia nut; mulberry; mustard greens; palm heart, leaves; parsnip; passion fruit; persimmon; pine nut; plantain; pomegranate; quince; radish, oriental, roots; rhubarb; rutabaga; shallot; soursop; soybean, sprouts; starfruit; swamp cabbage; sweetsop; Swiss chard; turnip (roots and greens); and yam.

Some produce commodities did not appear in the NHANES/WWEIA at all; a commodity is added to NHANES/WWEIA partly based on the number of times the new food is reported and partly based on whether a new reported food has nutrient contents that are very different from the nutrient contents of a food that already exists in the database. In the remainder of this document we refer to these commodities as “produce commodities with no reported consumption.”

Arrowroot and fiddleheads are examples of produce commodities with no reported consumption.

As we stated when we issued the produce safety final rule, we will consider updating the list of RCR commodities if new data become available (80 FR 74354 at 74390). We therefore

¹ The original analysis included amaranth, which we have not included here because it is a grain, and grains are not “produce” as that term is defined by the produce safety regulation. See 21 CFR 112.3(c). We have also omitted from this list several pulse commodities (e.g., dry pea) because that group of commodities is under separate consideration. See the discussion related to pulses in our guidance entitled “Guidance for Industry: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-enforcement-policy-entities-growing-harvesting-packing-or-holding-hops-wine-grapes>.

invite interested persons to submit data, information, and/or comment to support whether particular commodities with either no or low reported consumption in NHANES/WWEIA should be categorized as RCR. We seek commodity-specific data that would indicate whether that particular fruit or vegetable is consumed cooked by almost all consumers across the United States at this time. To be most useful, newly submitted data should be quantitative data of U.S. consumption patterns that are sufficiently robust such that we could draw from them scientifically valid conclusions. The data should clearly indicate what proportion of the population consumes the commodity in the uncooked form and/or how often the commodity is consumed uncooked compared to the cooked form. Results of a well-designed consumer survey would be one possible type of data that may be submitted. Market data that closely parallels consumer consumption data may also be helpful. Another type of data that could be useful is data indicating that a commodity cannot safely be consumed uncooked, e.g., because in its uncooked state it contains toxic properties. We also request information on any kill steps other than cooking (e.g., fermentation that adequately reduces microorganisms of public health significance) that are always or almost always applied to produce commodities with no or low reported consumption and data on the extent to which this kill step is applied consistently across the industry.

For this Request for Information, FDA is requesting data, information, and comments from all interested parties, including, but not limited to, academic and government researchers, industry, and any other source. When submitting information, please include details about how the data were collected, including information on the study design and sample population, year(s) of data collection, a detailed summary of the methods and measures used (e.g., any surveys utilized) and if available, the survey results (i.e., raw data).

II. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Center for Disease Control and Prevention, National Center for Health Statistics. “National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA).” Available at <https://www.cdc.gov/nchs/nhanes/wweia.htm>. Last accessed July 23, 2020.
2. Environmental Protection Agency Office of Pesticide Programs and University of Maryland Joint Institute for Food Safety and Applied Nutrition. “What We Eat in America-- Food Commodity Intake Database, 2005-2010 (WWEIA-FCID 2005-10).” Available at <https://fcid.foodrisk.org/>. Last accessed July 23, 2020.
3. Tijerina, M. J., J. Johanson, J. Spungen, and S. Briguglio, “Memorandum to the File-- Produce Rarely Consumed Raw,” October 2015. Available in Docket No. FDA-2011-N-0921 at <https://www.regulations.gov>.

Dated: July 28, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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