4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA-2018-D-3583]

Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled "Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce." This guidance supersedes a previous guidance, entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables," issued in 2008, and is a final guidance to the draft guidance for industry entitled "Guide to Minimize Food Safety Hazards of Fresh-Cut Produce" issued in 2018. The guidance is intended to help manufacturers or processors of ready-to-eat fresh-cut produce that is not a low-moisture food comply with applicable requirements in our regulations on current good manufacturing practices for hazard analysis and risk-based preventive controls for human food.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

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-2018-D-3583 for "Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce." Received comments 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." We 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Microbiological Food Safety's Office of Produce Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Adam Baker, Office of Microbiological Food Safety, Office of Produce Safety, or Marla Hallacy, Office of Policy and International Engagement, Office of Policy Initiatives and Projects, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-5528.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the *Federal Register* of October 22, 2018 (83 FR 53197), we made available a draft guidance for industry entitled "Guide to Minimize Food Safety Hazards of Fresh-Cut Produce" and gave interested parties an opportunity to submit comments by April 22, 2019, for us to consider before beginning work on a final guidance. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include clarifying that the guidance applies only to ready-to-eat fresh-cut produce with a water activity above 0.85; adding another example of an antimicrobial substance that can be used as a process control in the production of fresh-cut produce; providing additional examples of a supply chain program to control pathogens in a fresh-cut processing facility; and providing additional recommendations on time/temperature controls. To further improve clarity, we made editorial and organizational changes throughout the guidance. The guidance announced in this notice finalizes the draft guidance dated October 2018. This guidance supersedes a previous guidance, entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables," issued in 2008.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 117 have been approved under OMB control number 0910-0751.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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