

Congress intended to preclude: the adoption of standards that would achieve higher efficiency by eliminating currently available “performance characteristics” (including “features”) that are important to many purchasers.

Conclusion

DOE’s rulemaking proceedings concerning standards for residential furnaces and commercial water heaters have been fatally undermined by their failure to recognize that EPCA precludes the adoption of standards that would effectively eliminate fuel gas products that do not use condensing combustion technology. Petitioners believe that prompt action to correct that failure is both warranted and necessary to facilitate any reasonably efficient path forward in those rulemaking proceedings. Accordingly, Petitioners respectfully request that DOE—after soliciting and appropriately considering public comment on this Petition—promptly take final action by:

- Issuing an interpretive rule confirming that energy conservation standards limiting the market for natural gas and/or propane gas furnaces or water heaters to products using condensing combustion technology would result in the unavailability of “performance characteristics” within the meaning of 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), and
- Withdrawing its proposed standards for residential furnaces and commercial water heaters on the grounds of appropriate written findings as specified by 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), respectively.

Further deliberation in the two pending rulemaking proceedings can then occur, with appropriate consideration—as EPCA requires—of any need for separate standards (and separate product classes) for products that use condensing combustion technology and those that do not.²⁶ Respectfully submitted,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2018-D-3631]

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing four public meetings to discuss “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry.” The purpose of the public meetings is to discuss the draft guidance for compliance and implementation of the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule, which was issued under the FDA Food Safety Modernization Act.

DATES: Submit either electronic or written comments on the notice by April 22, 2019. See “How to Participate in the Public Meetings” in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, and other information regarding meeting participation.

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 April 22, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 22, 2019. 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-2018-D-3631 for “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket

²⁶ See 42 U.S.C. § 6295(q)(1).

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.

- **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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meetings or to register by phone: Melissa Schroeder, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, 240-393-2901, EventSupport@Sidemgroup.com.

For general questions about the public meetings or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug

Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

“The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (the produce safety rule, published in the **Federal Register** of November 27, 2015 (80 FR 74354) (<https://www.fda.gov/fsma>)) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The rule is part of the Agency’s ongoing efforts to implement the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). FSMA also requires FDA to issue guidance for the safe production and harvesting of fresh produce (section 419(e)(1) of the FD&C Act (21 U.S.C. 350h(e)(1))) and to also conduct at least three public meetings in diverse geographical areas of the United States as part of an effort to conduct education and outreach regarding the guidance for interested stakeholders (section 419(e)(2) of the FD&C Act).

In the **Federal Register** of October 22, 2018 (83 FR 53196), we announced the availability of the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry” (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf>). The draft guidance provides information on and recommendations for compliance with the requirements of the produce safety rule, which produce and farms are covered by the rule, and whether certain produce or farms may be eligible for exemptions.

FDA is announcing a series of public meetings entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry” so that stakeholders can better evaluate and comment on the draft guidance. These meetings will be held during the formal comment period on the draft guidance.¹ All four public meetings will cover the same agenda items and are intended to facilitate and

¹ Under FDA’s Good Guidance Practices regulation, anyone may comment on an FDA guidance document at any time (see 21 CFR 10.115(g)(5)).

support the public’s evaluation and commenting process.

While oral presentations² from specific individuals and organizations will be necessarily limited due to time constraints during the public meetings, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the draft guidance (Docket No. FDA-2018-D-3631).

II. Purpose and Format of the Public Meetings

The purpose of the public meetings is to provide information and facilitate comment so that stakeholders can better evaluate and provide input on the draft guidance. We invite interested parties to provide information and offer comments related to the produce safety rule draft guidance. During the public meetings we will present information on the various chapters of the draft guidance: General provisions; personnel qualifications and training; health and hygiene; biological soil amendments of animal origin; domesticated and wild animals; growing, harvesting, packing, and holding activities on a farm; equipment, tools, buildings, and sanitation; records; and variances.³ Stakeholder panels will provide discussion on the various issues. There will be an opportunity for questions, as well as an opportunity for open public comment.

III. How To Participate in the Public Meetings

There will be a total of four public meetings held in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment on the draft guidance.

Table 1 provides information on participation in the public meetings.

² Requests to make oral presentations must be made in advance. Please see table 1 for deadlines to request making an oral presentation for each meeting.

³ We have proposed to extend the compliance dates related to the requirements of subpart E of the produce safety rule, which addresses agricultural water, and have provided enforcement discretion until the finalization of that rulemaking (82 FR 42963, 42965; September 13, 2017). Accordingly, the draft guidance does not contain any recommendations related to subpart E, and agricultural water is not on the agenda for these public meetings. Also not on the agenda for these public meetings is the draft guidance issued in January 2017 entitled “Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.”

TABLE 1—INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PRODUCE SAFETY RULE DRAFT GUIDANCE DOCKET

Activity	Date	Electronic address	Address	Other information
First public meeting	November 27, 2018; 8:30 a.m.–5 p.m.	Hilton Portland Downtown, 921 SW Sixth Ave., Portland, OR 97204.	
View webcast	November 27, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	The webcast will have closed captioning.
Advance registration.	by November 16, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	We encourage you to use electronic registration if possible ¹ .	There is no registration fee for the public meetings. Early registration is recommended because seating is limited. ¹
Request to make an oral presentation.	by November 9, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	https://www.regulations.gov	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability.	by November 9, 2018.	See FOR FURTHER INFORMATION CONTACT .	
Second Public Meeting.	November 29, 2018; 8:30 a.m.–5 p.m..	DoubleTree Suites by Hilton Anaheim Resort-Convention Center, 2085 S Harbor Blvd., Anaheim, CA 92802.	
View webcast	November 29, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	The webcast will have closed captioning.
Advance registration.	by November 16, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	We encourage you to use electronic registration if possible ¹ .	There is no registration fee for the public meetings. Early registration is recommended because seating is limited. ¹
Request to make an oral presentation.	by November 9, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	https://www.regulations.gov	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability.	by November 9, 2018.	See FOR FURTHER INFORMATION CONTACT .	
Third Public Meeting.	December 11, 2018; 8:30 a.m.–5 p.m.	Hilton Albany, 40 Lodge St., Albany, NY 12207.	
View webcast	December 11, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	The webcast will have closed captioning.
Advance registration.	by November 23, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	We encourage you to use electronic registration if possible ¹ .	There is no registration fee for the public meetings. Early registration is recommended because seating is limited. ¹
Request to make an oral presentation.	by November 16, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	https://www.regulations.gov	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability.	by November 16, 2018.	See FOR FURTHER INFORMATION CONTACT .	
Fourth Public Meeting.	December 13, 2018; 8:30 a.m.–5 p.m.	Embassy Suites Atlanta at Centennial Olympic Park, 267 Marietta St., Atlanta, GA 30313.	

TABLE 1—INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PRODUCE SAFETY RULE DRAFT GUIDANCE DOCKET—Continued

Activity	Date	Electronic address	Address	Other information
View webcast	December 13, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	The webcast will have closed captioning.
Advance registration.	by November 23, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	We encourage you to use electronic registration if possible ¹ .	There is no registration fee for the public meetings. Early registration is recommended because seating is limited. ¹
Request to make an oral presentation.	by November 16, 2018.	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	https://www.regulations.gov	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability.	by November 16, 2018.	See FOR FURTHER INFORMATION CONTACT .	

¹ You may also register via email, mail, or Fax. Please include your name, title, firm name, address, and phone and Fax numbers in your registration information and send to: Melissa Schroeder, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, 240–393–4496, Fax: 202–495–2901, EventSupport@Sidemgroup.com. Onsite registration will be available at all four meetings, however, please note that if we have reached capacity, we will not be able to accommodate those who have not pre-registered.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <https://www.regulations.gov>. You may also view the transcript at the Dockets Management Staff (see **ADDRESSES**).

Dated: October 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23868 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–2018–F–3932]

Bonamar Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Bonamar Corp., proposing that we amend our food additive regulations to provide for the safe use of sources of ionizing radiation to control food-borne pathogens in finfish and flatfish.

DATES: The food additive petition was filed on September 27, 2018.

ADDRESSES: For access to the docket to read background documents or 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: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1075.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 8M4822), submitted by Bonamar Corp., c/o Robert P. Smith, Department of Biological Sciences, Nova Southeastern University, 3301 College Ave., Fort Lauderdale, FL 33314. The petition proposes to amend the food additive regulations in § 179.26 (21 CFR 179.26) *Ionizing radiation for the treatment of food* to provide for the safe use of sources of ionizing radiation to control food-borne pathogens in: (1) Chilled or frozen raw finfish and flatfish; and (2) frozen, raw vacuum-packed finfish and flatfish.

The petitioner has claimed that this action is categorically excluded from the need to prepare an environmental assessment or an environmental impact statement under 21 CFR 25.32(j), because the petition requests approval for a source of irradiation which is a piece of permanent equipment intended

for repeated use. In addition, the petitioner has stated that, to the petitioner’s knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23946 Filed 10–31–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 1002, 1010, and 1040

[Docket Nos. FDA–2011–N–0070 and FDA–2016–N–2491]

RIN 0910–AG79 and 0910–AF87

Withdrawal of the Laser Products; Proposed Amendment to Performance Standard and the Electronic Submission of Labeling for Certain Home-Use Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is