Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1398]

Mitigation Strategies To Protect Food Against Intentional Adulteration; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' The revised draft guidance supersedes the version of the intentional adulteration draft guidance that we announced on June 20, 2018. This draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) comply with the requirements of our regulation entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration.''

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–1398 for ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' 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.

- 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.

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 Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3712, *ryan.newkirk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.

FSMA added to the FD&C Act several new sections that reference intentional adulteration. For example, section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are required to register under section 415 (21 U.S.C. 350d). Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk.

We are announcing the availability of a revised draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This revised draft guidance supersedes the version of

the intentional adulteration draft guidance that we announced on June 20, 2018 (83 FR 28651). This multi-chapter draft guidance for industry is intended to help food facilities required to comply develop and implement some of the components of a food defense plan, including conducting vulnerability assessments, and meet other requirements under 21 CFR part 121. We are announcing the availability of the following chapters:

- Introduction
- Chapter One—The Food Defense Plan
- Chapter Two—Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps
- Chapter Three—Mitigation Strategies for Actionable Process Steps
- Chapter Four—Mitigation Strategies Management Components: Food Defense Monitoring
- Chapter Eight—Education, Training, or Experience
- Appendix 1—Food Defense Plan Worksheets
- Appendix 4— Vulnerability Assessment Examples

We have indicated new content, mostly located in Chapter Two, Chapter Eight, Appendix 1 and Appendix 4, with brackets stating, ''[New March 2019] or [Updated March 2019].'' We have also made minor changes to previously published sections for clarity and consistency with the new content. We intend to announce the availability for public comment of the final portion of the draft guidance once it is complete.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on food defense measures against intentional adulteration for the regulation ''Mitigation Strategies to Protect Food Against Intentional Adulteration.'' 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: February 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04060 Filed 3–5–19; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2017–0079; FF09A30000–190FXIA16710900000]

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); Eighteenth Regular Meeting; Provisional Agenda; Announcement of Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The United States, as a Party to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), will attend the eighteenth regular meeting of the Conference of the Parties to CITES (CoP18) in Colombo, Sri Lanka, May 23 to June 3, 2019. Currently, the United States is developing its negotiating positions on proposed resolutions, decisions, and amendments to the CITES Appendices (species proposals), as well as other agenda items that have been submitted by other Parties, the permanent CITES committees, and the CITES Secretariat for consideration at CoP18. With this notice we announce the provisional agenda for CoP18, solicit your comments on the items on the provisional agenda, and announce a public meeting to discuss the items on the provisional agenda.

DATES: *Public meeting:* The public meeting will be held on March 13, 2019, at 1 p.m.

Comment submission: In developing the U.S. negotiating positions on species proposals and proposed resolutions, decisions, and other agenda items submitted by other Parties, the permanent CITES committees, and the CITES Secretariat for consideration at CoP18, we will consider written information and comments you submit if we receive them by April 22, 2019.

ADDRESSES: *Public meeting:* The public meeting will be held in the Sidney Yates Auditorium at the Main Interior Building at 18th and C Streets NW, Washington, DC. Directions to the building are available on our website at *https://www.fws.gov/international/cites/cop18/index.html.* For more information about the meeting, see ''Announcement of Public Meeting'' under **SUPPLEMENTARY INFORMATION**.

Comment submission: You may submit comments pertaining to items on the provisional agenda for discussion at CoP18 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2017–0079 (the docket number for this notice).
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–HQ–IA–2017–0079; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS BPHC; Falls Church, VA 22041.

Comments and materials we receive, as well as supporting documentation, will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at: U.S. Fish and Wildlife Service Headquarters, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: For information pertaining to resolutions, decisions, and other agenda items, contact: Pamela Scruggs, Chief, Division of Management Authority; telephone 703–358–2095; facsimile 703–358–2298. For information pertaining to species proposals, contact: Rosemarie Gnam, Chief, Division of Scientific Authority; telephone 703–358–1708; fascsimile 703–358–2276.

SUPPLEMENTARY INFORMATION:

Background

The Convention on International Trade in Endangered Species of Wild Fauna and Flora, hereinafter referred to as CITES or the Convention, is an international treaty designed to control and regulate international trade in certain animal and plant species that are now or potentially may become threatened with extinction. These