

the intentional adulteration draft guidance that we announced on June 20, 2018 (83 FR 28651). This multi-chapter draft guidance for industry is intended to help food facilities required to comply develop and implement some of the components of a food defense plan, including conducting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 We intend to announce the availability for public comment of the final portion of the draft guidance once it is complete.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This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on food defense measures against intentional adulteration for the regulation “Mitigation Strategies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This draft guidance refers to previously approved collections of information found in FDA regulations.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Persons with access to the internet may obtain the draft guidance at either 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.

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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; facsimile 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

species are listed in Appendices to CITES, which are available on the CITES Secretariat's website at <http://www.cites.org/eng/app/index.php>.

Currently 182 countries and the European Union have ratified, accepted, approved, or acceded to CITES; these 183 entities are known as Parties. The Convention calls for regular biennial meetings of the Conference of the Parties, unless the Conference of the Parties decides otherwise. At these meetings, the Parties review the implementation of CITES, make provisions enabling the CITES Secretariat in Switzerland to carry out its functions, consider amendments to the lists of species in Appendices I and II, consider reports presented by the Secretariat and the permanent CITES committees (Standing, Animals, and Plants Committees), and make recommendations for the improved effectiveness of CITES. Any country that is a Party to CITES may propose amendments to Appendices I and II, resolutions, decisions, and other agenda items for consideration by all of the Parties at the meetings.

This is our fourth in a series of **Federal Register** notices that, together with the announced public meeting, provides you with an opportunity to participate in the development of U.S. negotiating positions for the eighteenth regular meeting of the Conference of the Parties to CITES (CoP18). We published our first CoP18-related **Federal Register** notice on January 23, 2018 (83 FR 3179), in which we requested information and recommendations on species proposals for the United States to consider submitting for consideration at CoP18. In that notice, we also described the U.S. approach to preparations for CoP18. We published our second such **Federal Register** notice on March 12, 2018 (83 FR 10736), in which we requested information and recommendations on proposed resolutions, decisions, and other agenda items for the United States to consider submitting for consideration at CoP18, and provided preliminary information on how to request approved observer status for non-governmental organizations that wish to attend the meeting. In our third CoP18-related **Federal Register** notice, published on October 1, 2018 (83 FR 49421), we requested public comments and information on species proposals that the United States was considering submitting for consideration at CoP18. We also requested public comments and information on proposed resolutions, decisions, and other agenda items that the United States was considering submitting for consideration at CoP18,

and provided more information on how to request approved observer status for non-governmental organizations that wish to attend the meeting.

The three prior CoP18 **Federal Register** notices are in the docket (FWS-HQ-IA-2017-0079) at <http://www.regulations.gov>. A link to these notices, along with information on U.S. preparations for CoP18, can also be found at <https://www.fws.gov/international/cites/cop18/index.html>. For further information on proposed resolutions, decisions, and other agenda items, contact the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, MS-IA, Falls Church, VA 22041; and for information on species proposals, contact the Division of Scientific Authority, 5275 Leesburg Pike, MS-IA, Falls Church, VA 22041. Our regulations governing this public process are found in title 50 of the Code of Federal Regulations at 50 CFR 23.87.

On December 21, 2018, the United States submitted to the CITES Secretariat, for consideration at CoP18, its species proposals, proposed resolutions, proposed decisions, and other agenda items. These documents are available on our website at <https://www.fws.gov/international/cites/cop18/index.html>.

Announcement of Provisional Agenda for CoP18

The provisional agenda for CoP18 is currently available on the CITES Secretariat's website at <https://cites.org/eng/cop/18/doc/index.php>. The working documents associated with the items on the provisional agenda, including proposed resolutions, proposed decisions, and discussion documents, are also available on the Secretariat's website. To view the working document associated with a particular agenda item, access the provisional agenda at the above website, locate the particular agenda item, and click on the document link for that agenda item in the column entitled "Document." The species proposals that will be considered at CoP18 are also available on the Secretariat's website. Proposals for amendment of Appendices I and II can be accessed at <https://cites.org/eng/cop/18/prop/index.php>. We look forward to receiving your comments on the items on the provisional agenda.

Announcement of Public Meeting

We will hold a public meeting to discuss the items on the provisional agenda for CoP18. The public meeting will be held on the date specified in **DATES** and at the address specified in

ADDRESSES. Directions to the building are available on our website at <https://www.fws.gov/international/cites/cop18/index.html>. Please note that the Sidney Yates Auditorium is wheelchair accessible and all persons planning to attend the meeting will be required to present photo identification when entering the building. The U.S. Fish and Wildlife Service is committed to providing access to this meeting for all participants. Please direct all requests for sign language interpreting services, close captioning, or other accommodation needs to Frank Kohn, 703-358-2408 (voice), frank_kohn@fws.gov, TTY 800-877-8339 by close of business March 1, 2019. For those who cannot attend the public meeting but are interested in watching via live stream please go to our website: <https://www.fws.gov/international/cites/cop18/index.html>, and look for the link to the live feed.

Public Comments

We will not consider comments sent by email or fax or to an address not listed in **ADDRESSES**. If you submit a comment via <http://www.regulations.gov>, your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on <http://www.regulations.gov>.

Future Actions

Through an additional notice and website posting in advance of CoP18, we will inform you about tentative U.S. negotiating positions on species proposals, proposed resolutions, proposed decisions, and agenda items that were submitted by other Parties, the permanent CITES committees, and the CITES Secretariat for consideration at CoP18.

Author

The primary author of this notice is Frank B. Kohn, Division of Management Authority; under the authority of the U.S. Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: February 27, 2019.

Margaret E. Everson,

Principal Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

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