4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2018-D-0721]

Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a guidance for industry entitled "Application of the Foreign Supplier Verification Program Regulations to the Importation of Live Animals: Guidance for Industry." The purpose of this document is to state FDA's intent to exercise enforcement discretion regarding application of the regulation on foreign supplier verification programs (FSVPs) to importers of certain live animals. The enforcement discretion would apply to importers of live animals that are required to be slaughtered and processed at U.S. Department of Agriculture (USDA) regulated establishments subject to USDA-administered Hazard Analysis and Critical Control Point (HACCP) requirements, or at State-inspected establishments subject to requirements equivalent to the Federal standard.

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 Agency 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-0721 for "Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals: 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 Office of Food Safety, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sharon Mayl, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Springs, MD 20993, 301-796-4716.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals: Guidance for Industry." We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because the guidance presents a less burdensome policy consistent with the public health. Although this guidance is immediately in

effect, it remains subject to comment in accordance with FDA's GGP regulation. 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. This guidance is not subject to Executive Order 12866.

Many live animals are imported into the United States for consumption as food. Most imported live animals (e.g., cattle and swine) that are for use as food are slaughtered under mandatory inspection by USDA's Food Safety and Inspection Service (FSIS) and are processed at USDA-regulated establishments subject to USDA-administered Hazard Analysis Critical Control Point (HACCP) requirements. The slaughter and processing of other live animals (e.g., farmed bison, boar, and elk) is under FDA's jurisdiction and is subject to FDA's current good manufacturing practice and, unless an exemption applies, preventive controls requirements (21 CFR part 117). Some animals under FDA jurisdiction ("FDA animals") are slaughtered under voluntary inspection by USDA-FSIS.

The importation into the United States of live animals for food use is subject to certain supplier verification requirements established in the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add, among other food safety requirements, provisions requiring verification of the safety of food imported from foreign suppliers. Section 805(c) of the FD&C Act (21 U.S.C. 384(c)) directs FDA to issue regulations on the content of FSVPs. We issued the FSVP final rule on November 27, 2015 (80 FR 74225).

The FSVP regulation requires food importers to develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier uses processes and procedures that

provide the same level of public health protection as those required under the preventive controls or produce safety provisions of FSMA (if applicable) and regulations implementing those provisions, as well as assurances that the imported food is not adulterated and that human food is not misbranded with respect to allergen labeling (21 CFR 1.502(a)).

The food resulting from the slaughter and processing of certain live animals cannot be consumed without slaughter and processing at establishments subject to USDA-administered HACCP requirements (or equivalent state programs). In light of the role of another Federal agency with regard to these animals, FDA intends to exercise enforcement discretion with respect to the FSVP regulation for importers of live animals that are imported for slaughter and processing at USDA-regulated establishments subject to USDA-administered HACCP requirements, or imported for slaughter and processing under state requirements that are at least equivalent to the requirements for USDA-regulated establishments, including designated feeder animals. This means that we will not expect FSVP importers of live animals that are slaughtered and processed at USDA-inspected establishments subject to USDA-administered HACCP requirements (or State-inspected establishments subject to equivalent requirements) to meet any of the FSVP requirements.

II. Paperwork Reduction Act of 1995

This 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 part 1, subpart L, have been approved under OMB control number 0910-0752.

III. Electronic Access

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

Dated: March 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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