

Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals:

Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-0721 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, contact the Office of Foods and Veterinary Medicine (OFVM), at 301-796-4500.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

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This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, or we) 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. To discuss an alternative approach, contact the Office of Foods and Veterinary Medicine as listed on the title page.

I. Introduction

The purpose of this document is to state the Food and Drug Administration's (FDA's or the Agency's) intent to exercise enforcement discretion regarding application of the regulation on foreign supplier verification programs (FSVPs) 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 standards).

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

This guidance provides information to facilitate understanding of the applicability of the FSVP requirements to the importation of live animals. The pronouns "I," "me," and "you" are used in this guidance to refer to the importer. "Agency" and the pronouns "we" and "our" are used to refer to FDA.

II. Background

Many live animals are imported into the United States for consumption as food. Most imported live animals (e.g., cattle, poultry, 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 HACCP requirements.¹ The slaughter and processing of other live animals (e.g., farmed bison, farmed wild boar, and elk) is under FDA's jurisdiction and is subject to FDA's current good manufacturing practice (CGMP) 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. Note that establishments that slaughter animals under mandatory FSIS inspection must have HACCP plans that address hazards associated with the animals. Further, an FSIS inspector must be present during these slaughter operations. In contrast, establishments that slaughter animals under voluntary FSIS inspection must comply with some, but not all, FSIS regulations; for example, such establishments are not required to comply with FSIS HACCP requirements. See FSIS Directive 12,600.1, Revision 1, Amendment 2 (July 2007).

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 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)). Among other things, in many cases, the FSVP regulation (21 CFR 1.500-1.514) requires food importers to do the following:

- Analyze the hazards for the foods they import (21 CFR 1.504);
- Evaluate the performance of their potential foreign suppliers and the risk posed by the foods to be imported (21 CFR 1.505); and
- Determine and conduct appropriate foreign supplier verification activities, such as onsite auditing of foreign suppliers, sampling and testing, and review of supplier food safety records (21 CFR 1.506).

¹ USDA-regulated establishments have the option to apply for Federal or for state inspection under an inspection program that a State operates under a cooperative agreement with FSIS. State programs must enforce requirements "at least equal to" those imposed under the Federal Meat Inspection Act, Poultry Products Inspection Act, and Humane Methods of Slaughter Act of 1978 (see 21 U.S.C. 661 and 21 U.S.C. 454). However, products produced under such equivalent state requirements are limited to intrastate commerce, unless a state opts into an additional cooperative program, the Cooperative Interstate Shipment Program. (See <https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs>.)

The FSVP regulation applies (with certain exceptions²) to the importation of food as defined in section 201(f) of the FD&C Act (except that “food” for FSVP purposes does not include pesticides as defined in 7 U.S.C. 136(u)) (see 21 CFR 1.500). Live animals that are not reasonably likely to be directed to food use (e.g., animals imported for showing or breeding) are not subject to FSVP. Although the FSVP regulation explicitly exempts food regulated by USDA at the time of importation (i.e., certain meat, poultry, and egg products), this exemption does not include live animals that are for use as food.

FSIS and USDA’s Animal and Plant Health Inspection Service (APHIS) have comprehensive regulatory requirements, including HACCP requirements, that control food safety hazards in live animals that must be slaughtered and processed in official USDA establishments (those requiring a grant of inspection to operate). Such establishments are required to conduct a hazard analysis and consider the food safety hazards that might be expected to arise from, for example, drug residues, and are also required to develop systems to guard against these hazards. In addition, FSIS oversees the requirements related to the identification and control of hazards, collects samples of meat, poultry, and egg products, and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, among other contaminants. Thus, when slaughter and process establishments are subject to USDA-administered HACCP and other requirements, the hazards associated with the live animals processed at such establishments ordinarily would be identified and controlled and the food resulting from the slaughter and processing of those live animals could not be consumed without such controls. The same would be true for establishments that slaughter and process subject to equivalent requirements but under state inspection.

III. Discussion

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.³ 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.

This intent to exercise this enforcement discretion is consistent with the exemption from the FSVP requirements for foods that are under USDA jurisdiction, as imported live animals heading to slaughter and processing at USDA-regulated establishments subject to USDA-administered

² For example, note that importation of live seafood (e.g., mussels, lobsters) is covered by the importer provisions of FDA’s seafood HACCP regulation (21 CFR 123.12) and, therefore, is exempt from FSVP under 21 CFR 1.501(b)(1).

³ By “feeder animals” we mean animals going to feedlots for finishing before slaughter.

HACCP requirements (or slaughter and processing under state requirements that are at least equivalent to the requirements for USDA-regulated establishments) are the predecessor of the meat and poultry products that are already under USDA jurisdiction when they cross the border. This intent to exercise enforcement discretion with respect to the FSVP regulation does not apply to importers of live animals for food use that fall under FDA jurisdiction. These animals are not processed at USDA-regulated slaughter and processing establishments under HACCP requirements (or state-inspected establishments with equivalent requirements). An importer of such animals would be subject to FSVP and would need to conduct foreign supplier verification with respect to such animals if the importer determined there were drug residues or other hazards requiring supplier control. We will consider revising our intent to exercise enforcement discretion if, for example, there are changes to the information upon which our intent to exercise enforcement discretion is based or if new information becomes available regarding safety concerns associated with the importation of these live animals.

Data requirements at entry

When a food product under FDA oversight is offered for entry into the United States, the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) system will prompt the filer to transmit an entity role code or affirmation of compliance code related to FSVP. The entity role code “FSV” indicates that the entry line is subject to the FSVP regulation and currently subject to FSVP enforcement, so the importer must provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA (see 21 CFR 1.509). If the food entry line is exempt from the requirements of the FSVP regulation, not yet subject to the regulation, or FDA has provided guidance that the Agency intends to exercise enforcement discretion for the relevant shipment with respect to the FSVP regulation, the filer should transmit the applicable Affirmation of Compliance code. “FSX” should be used if FDA has provided guidance that the agency intends to exercise enforcement discretion for the relevant shipment with respect to the FSVP regulation.

Therefore, importers of live animals for food use and imported for slaughter and processing at USDA-regulated establishments subject to USDA-administered HACCP requirements (or for slaughter and processing at state-inspected establishments with equivalent requirements), including designated feeder animals, should transmit the affirmation of compliance code “FSX” when making entry in the United States. Importers of all other live animals for food use subject to the FSVP regulation should transmit the entity role code “FSV.” For more information on importer identification, consult FDA’s guidance on “Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation,” available at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm>.