GUIDANCE DOCUMENT

Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

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Final

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Center for Veterinary Medicine
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition

The purpose of this document is to provide guidance for industry on the requirements for a foreign supplier verification program (FSVP) in 21 CFR part 1, subpart L, that importers of human or animal food must establish and follow to ensure that each food they import into the United States meets applicable U.S. requirements and is not adulterated or (for human food) misbranded with respect to allergen labeling.

In general, FDA's guidance documents 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 questions and answers to facilitate importers' understanding of the FSVP requirements.[1] 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. The term "food" includes food for humans and animals and has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(f)), except that, for the purposes of FSVP, "food" does not include pesticides as defined in 7 U.S.C. 136(u) (21 CFR 1.500). "Food" includes:

- Articles used for food or drink for man or other animals,
- Chewing gum, and
- Articles used for components of any such article.

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[1] Because FDA's FSVP regulations pertain to the importation of human and animal food, they contain several terms that are similar or similar-sounding to those also used by U.S. Customs and Border Protection (CBP) relating to the importation of all merchandise. However, due to the different authorities implemented by FDA and CBP, these terms may have different meanings. Where relevant, this guidance clarifies these differences in certain Questions and Answers. For guidance from CBP on basic importing and exporting, see Basic Importing and Exporting | U.S. Customs and Border Protection (cbp.gov) (https://www.cbp.gov/trade/basic-import-export).

Related Information

- FSMA Rule on FSVP for Importers of Food for Humans and Animals (/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals)
- Additional FSMA Guidance (/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#guidance)
- Constituent Update: FDA Issues the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals Final Guidance (/food/cfsan-constituent-updates/fda-issues-foreign-supplier-verification-programs-importers-food-humans-and-animals-final-guidance) (January 10, 2023)

Questions?

For questions regarding this document, you may contact the FSMA Technical Assistance Network online (/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan), by mail at

Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD, 20740

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