

Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs for Food Importers Regulation: Guidance for Industry

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For questions regarding this document, you may contact the FSMA Technical Assistance Network online at <https://www.fda.gov/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, or by phone at 1-888-SAFEFOOD (1-888-723-3366).

**U.S. Department of Health and Human Services
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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 FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides information on the requirement under the Foreign Supplier Verification Programs for Food Importers (FSVP) regulation for the importer of a food to ensure that for each entry line of food offered for importation into the United States the unique facility identifier (UFI) recognized as acceptable by FDA for importer identification² is provided electronically when filing entry with U.S. Customs and Border Protection (CBP). The UFI initially recognized as acceptable by FDA for importer identification is a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number. The pronoun “you” is used in this guidance to refer to the FSVP importer as defined in the FSVP regulation (21 CFR [1.500](#)).

This guidance replaces FDA’s “Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation: Guidance for Industry” issued March 2018.

The March 2018 guidance provided for the temporary use of the entity role code “UNK” (to represent “unknown”) in lieu of a DUNS number, to be provided in the Entity Number field for

¹ This guidance was jointly prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Division of Import Operations in the Office of Regulatory Affairs at the U.S. Food and Drug Administration.

² The FSVP regulation requires the submission of a UFI recognized as acceptable by FDA and does not specify DUNS numbers in the regulation to give FDA the flexibility to recognize alternative UFIs as appropriate in the future through guidance. We stated in the final FSVP rule that we anticipated issuing guidance specifying which UFI(s) we recognized as acceptable and that we expected to recognize DUNS numbers as being acceptable (80 FR 74226 at 74301). FDA subsequently issued guidance recognizing DUNS numbers as acceptable UFIs for purposes of 21 CFR 1.509(a).

importer identification when filing entry with CBP for a food subject to FSVP. FDA explained that while the agency expected all importers to provide their UFI in accordance with 21 CFR 1.509(a), the agency recognized that this was a new requirement and some factors may have prevented importers from doing so. Therefore, FDA provided that for FSVP importers temporarily unable to obtain a DUNS number, FDA intended to allow filers to transmit the value “UNK” in the UFI field for the FSVP importers.

This guidance updates the March 2018 guidance by removing the temporary policy of permitting the use of the entity role code “UNK” in lieu of a DUNS number. Needs and circumstances have changed since FDA announced its temporary policy, as FSVP importers have now had ample time to familiarize themselves with the requirements in 21 CFR 1.509(a). Accordingly, beginning on July 24, 2022, FSVP importers must comply with the requirement in 21 CFR 1.509(a) of providing a unique facility identifier recognized as acceptable by FDA when filing entry with CBP. This guidance also provides additional information for what importers should do when they have multiple DUNS numbers.

Beginning July 24, 2022, the use of the entity identification code “UNK” will no longer be an option. Consistent with 21 CFR 1.509(a), the FSVP importer will be required to ensure that their valid, 9-digit DUNS number is provided in the Entity Number field. CBP will reject an entry line of a food subject to the FSVP regulation when the importer’s DUNS number is not provided in the Entity Number field.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA’s guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The FSVP regulation was established in Title 21 of the Code of Federal Regulations, part 1, subpart L, as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). FDA issued the final rule on FSVP for importers of food for humans and animals on November 27, 2015 (80 FR 74225). The FSVP regulation, codified in 21 CFR 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and establishes various requirements. Among other requirements, section 1.509(a) of the FSVP regulation requires that, for each entry line of food subject to FSVP, offered for importation into the United States, you must ensure that your name, electronic mail address, and UFI recognized as acceptable by FDA are provided electronically when filing entry with CBP.

On March 31, 2017, FDA issued guidance recognizing the DUNS number as the acceptable UFI for the FSVP regulation (see FDA’s guidance “[Recognition of Acceptable Unique Facility Identifier \(UFI\) for the Foreign Supplier Verification Programs Regulation](#)”). A DUNS number is a nine-digit unique number assigned by Dun and Bradstreet (D&B), a commercial company. This guidance provides additional information on the requirement for you to ensure that your DUNS number is provided when filing an entry line with CBP for a food subject to the FSVP

regulation.

III. Discussion

When a food under FDA oversight subject to FSVP regulation is offered for entry into the United States, CBP's Automated Commercial Environment (ACE) system will require the filer to transmit either the FSVP Importer information or an appropriate Affirmation of Compliance code (A of C Code):

- (1) Entity role code "FSV" indicating the entry line is subject to the FSVP regulation; or
- (2) One of two Affirmation of Compliance codes (FSX, RNE) indicating the importer is exempt from the FSVP regulation at the time of entry.

For line entries that use the entity role code "FSV," the following information must be provided: the FSVP importer's name, email address, and DUNS number. (See 21 CFR 1.509(a)).

If the food entry line is exempt from the requirements of the FSVP regulation or FDA has provided guidance that the Agency intends to exercise enforcement discretion for the food offered for entry with respect to the FSVP regulation, the filer should transmit the A of C code "FSX," instead of the entity role code "FSV."

If the food is exempt from the FSVP regulation in accordance with 21 CFR 1.501(c) because it will be used for research or evaluation, the filer should transmit the A of C code "RNE" instead of the entity role code "FSV." FDA requires a specific "RNE" A of C code for food imported for research or evaluation because the final FSVP regulation specifically requires that a food be accompanied, when filing entry with CBP, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public to qualify for this exemption (21 CFR 1.501(c)(4)). By entering the "RNE" A of C code, filers would be providing such a declaration.

If one of these three codes (FSV, FSX, or RNE) is not transmitted for an imported food under FDA oversight, the ACE system will reject the entry line. Similar to all rejections in the ACE system, the rejection will generate an error message to the filer. After the filer receives an error message, they can make the appropriate adjustments to the entry submission and retransmit the entry line.

The ACE system will reject a food entry if the filer does not transmit the importer's UFI (i.e., DUNS number), along with the other data elements required for products that require entity role code "FSV." Thus, for the Entity Number field, your valid, nine-digit DUNS number must be provided. The ACE system will reject an entry line for which the filer enters "UNK" or an inappropriate syntax combination in the Entity Number field (e.g., not 9 digits or non-numeric characters).

You may obtain a DUNS number from D&B free of charge within 30 business days or longer. D&B also provides for expedited delivery of a DUNS number for a one-time charge. To obtain a DUNS number, please contact D&B directly by phone at 866-705-5711 or at

<https://www.dnb.com/duns-number/get-a-duns.html>. If you already have a DUNS number, you should use that DUNS number as your importer identification UFI. You do not need to obtain a separate DUNS number for FSVP.

The DUNS number, which is location specific, must correspond to your U.S. location. If you have multiple U.S. locations and, thus, multiple DUNS numbers, you may choose to provide the DUNS number that applies to the location at which you maintain your FSVP records. FDA investigators may conduct FSVP records reviews at the location associated with the DUNS number you provide to CBP at entry. For example, if you maintain your FSVP records at your corporate headquarters, you may choose to provide the DUNS number of your headquarters when you identify yourself at entry as the FSVP importer. However, because the FSVP regulation permits importers to store records offsite if they can be retrieved and provided to us within 24 hours of request (see 21 CFR 1.510(b)(2)), you may instead provide the DUNS number for another of your locations. Once chosen, the same DUNS number should be used for all of the importer’s FSVP entries, to the extent the DUNS number is applicable to an entry line.

If you have questions about the FSVP requirement to provide a DUNS number, you may contact FDA’s Division of Import Operations via email at FDAImportsInquiry@fda.hhs.gov.

We will issue updated guidance to announce any changes, including if FDA recognizes additional UFIs as acceptable.

IV. Guidance History

Status of Guidance	Date	Type of Revisions	Description of Changes
Final guidance	May 2017	Level 2	First version
Final guidance	March 2018	Level 2	Edits made to reflect additional use of entity role code “FSX” for products which FDA has announced its intent to exercise enforcement discretion
Final guidance	April 2022	Level 2	Edits made to reflect removal of the option to use the entity role code “UNK” in lieu of providing a DUNS number and to provide information for when an FSVP importer has multiple DUNS numbers.