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

Resources

- **FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (/Food/GuidanceRegulation/FSMA/ucm361902.htm)**
- **Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm)**

How to Comment

Submit electronic comments on **http://www.regulations.gov (http://www.regulations.gov)** to docket number FDA-2011-N-0143.

Submit written comments to:
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
All comments should be identified with the docket number FDA-2011-N-0143.

Introduction

This guidance provides information on how you may comply with FDA's requirement to identify yourself as the importer of a food at entry into the United States under the Foreign Supplier Verification Programs (FSVP) regulation, including the requirement to provide a unique facility identifier (UFI) recognized as acceptable by FDA. This guidance also provides information on what to do if you are unable to obtain a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number in time for applicable FSVP compliance date. The first FSVP compliance date is May 30, 2017. The pronoun "you" is used in this guidance to refer to the importer as defined in the FSVP regulation.

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.

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 FSVPs 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 line entry of food product offered for importation into the United States, the importer provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA electronically when filing entry with U.S.

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm)).

This guidance provides additional information about how importers may provide and filers may transmit the required information at entry.

Discussion

When a food product under FDA oversight is offered for entry into the United States (U.S.), the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) system will prompt the filer to transmit one of the following codes:

1. An entity role code "FSV," which will send a signal to the ACE system indicating the entry line is subject to the FSVP regulation; or
2. (2) One of two Affirmation of Compliance codes indicating the article of food and importer are not subject to the FSVP regulation at the time of entry.

The transmission of entity role code "FSV" will trigger a request for the FSVP importer's name, email address, and DUNS number as the UFI recognized as acceptable by FDA.

If the food entry line is exempt from the requirements of the FSVP regulation, or not yet subject to the regulation based on the applicable compliance date, the filer should transmit the applicable Affirmation of Compliance code, either "FSX" (designating that the food is exempt from the FSVP regulation or that compliance with the FSVP regulation is not yet required) or "RNE" (designating that 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). Note that we are requiring a specific "RNE" Affirmation of Compliance code for foods that are imported for research or evaluation because the final FSVP regulation specifically requires that a food be accompanied, when filing entry with U.S. Customs and Border Protection, 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 in order to qualify for this exemption. (21 CFR 1.501(c)(4)). By selecting the "RNE" Affirmation of Compliance code, filers would be providing such a declaration.

If one of these codes is not transmitted for an imported food product under FDA oversight, the entry line will be rejected. Similar to all rejections in the ACE system, the rejection will generate an error message to the filer. Once an error message is received, the filer can make the appropriate adjustments to the entry submission and retransmit the entry line.

While FDA expects all FSVP importers to provide their UFI starting on the applicable compliance date, the Agency recognizes that this is a new requirement and there may be factors that prevent importers from doing so. Therefore, for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field for the FSVP importer. FDA will allow this beginning May 30, 2017. This temporary allowance will allow for articles of food offered for import into the United States to be processed through the ACE system even if an importer has not yet provided a DUNS number. We will update the guidance and communicate with importers at such time when we discontinue this use of the "UNK" value.

During the time that FDA and CBP allow the use of the "UNK" value for the UFI field, FDA intends to contact those FSVP importers for whom "UNK" was transmitted in place of the UFI. We will provide additional information to help ensure that FSVP importers understand this FSVP regulation requirement and take the appropriate steps to obtain a UFI.