

# FDA FACT SHEET

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## FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP) – UNIQUE FACILITY IDENTIFIER (UFI) REQUIREMENT

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### *Section 1.509 - How must the importer be identified at entry?*

The [Foreign Supplier Verification Programs for Food Importers](#) (FSVP) regulation requires importers to perform certain risk-based activities for food they import into the United States (U.S.). The FSVP regulation defines importer as:

The U.S. owner or consignee of the food offered for import (i.e., owns the food, has purchased it, or has agreed in writing to purchase it at the time of U.S. entry). If there is no U.S. owner or consignee at time of entry, the FSVP importer is the U.S. agent or representative of the foreign owner/consignee, as confirmed in a signed statement of consent. There must be a designated FSVP importer in the U.S. to take responsibility for meeting the FSVP requirements.

Per 21 CFR [1.509\(a\)](#), for *each line entry of food* offered for entry into the U.S., the importer must provide their name, email address, and Unique Facility Identifier (UFI) recognized as acceptable by FDA are provided electronically when filing entry with U.S. Customs and Border Protection (CBP). The DUNS (Data Universal Numbering System) number is the UFI currently recognized as acceptable by the FDA.

### **FSVP Unique Facility Identifier Updates**

Transmission of the FSVP importer's name, email address, and UFI became mandatory on May 30, 2017. The Food and Drug Administration (FDA) expects the transmission of the FSVP importer's DUNS number to be submitted in the PG19 field when filing electronically in the Automated Commercial Environment (ACE). Permission to transmit UNK was intended to be temporary to give importers time to obtain their DUNS number.

In April 2021, the FDA began sending letters via email to importers and customs brokers that were using "UNK" in lieu of the DUNS number to identify the FSVP importer at the time of entry. In April 2022, the FDA issued updated guidance documents titled, [Recognition of Acceptable Unique Facility Identifier \(UFI\) for the Foreign Supplier Verification Programs Regulation](#) and the [Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation](#), to reinforce the UFI FSVP requirement.

As of July 24, 2022, UNK is no longer an acceptable UFI and importers of food(s) subject to the FSVP regulation are required to have a DUNS number. After July 24, 2022, customs brokers must transmit an importer's DUNS number

when electronically filing entry for each line of food subject to the FSVP regulation. Electronic entries containing UNK in the **Entity Number** field will be rejected by CBP's electronic import system.

## Frequently Asked Questions

### Q1. What is a DUNS number?

**A1.** DUNS numbers are assigned and managed by Dun & Bradstreet (D&B). The D&B DUNS number is a unique nine-digit identifier for businesses.

### Q2. How do I get a DUNS number?

**A2.** The DUNS number is available free of charge to all importers, and can be obtained by contacting D&B by telephone at 866-705-5711 or 800-234-3867, sending an email to [govt@dnb.com](mailto:govt@dnb.com), or by visiting D&B's website at <https://www.dnb.com/duns-number.html> or <https://importregistration.dnb.com/>.

### Q3. After placing a request, how long does it take until I receive my DUNS number?

**A3.** Although a DUNS number may be obtained within a few business days, in some circumstances it could take up to 45 days or more (charges may apply for expedited delivery).

### Q4. What is a customs broker?

**A4.** All brokers are regulated and empowered by CBP to assist importers and exporters in meeting Federal requirements governing imports and exports. Brokers submit necessary information and appropriate payments to CBP on behalf of their clients and charge them a fee for this service.

Brokers must have expertise in the entry procedures, admissibility requirements, classification, valuation, and the rates of duty and applicable taxes and fees for imported merchandise. There are approximately 16,170 active licensed Customs brokers in the U.S.

### Q5. How can I determine if I already have a DUNS number?

**A5.** To determine if you already have a DUNS number, visit the D&B website using the DUNS Number Lookup feature at <https://www.dnb.com/duns-number/lookup.html>. If you do not find your DUNS number, you can request one through the D&B Import Registration website at <https://importregistration.dnb.com/>

### Q6. If I already have a DUNS number, how do I provide it to the FDA?

**A6.** On behalf of the importer, a customs broker is responsible for transmitting the DUNS number when electronically filing entries using CBP's ACE Import System. Alternatively, if the importer is filing a manual, paper entry, the DUNS number should be identified in the entry documents for each line of food subject to the FSVP regulation.

### Q7. After I obtain my DUNS number, how do I provide my FSVP records to FDA?

**A7.** The FSVP regulation does not require the importer to send FSVP records to the FDA unless we request the records in writing. Section [1.510\(b\)\(1\)](#) of the FSVP regulation requires the importer to promptly make FSVP records available to an authorized FDA representative for inspection and copying (e.g., promptly make records available to an FDA investigator during an onsite inspection). If we request the importer to send FSVP records to the Agency, the importer must send the records electronically, or through other means that delivers the records

promptly, to the address indicated in the request (21 CFR [1.510\(b\)\(3\)](#)). Prior to inspection, an FDA investigator will email or initiate a telephone call to the person or entity identified at the time of entry as the FSVP importer. For more information, please access the fact sheet titled, [“What to Expect During a Foreign Supplier Verification Programs Inspection”](#).

**Q8. How do I register my DUNS number with FDA? Do I need to include my DUNS number on the entry documents?**

**A8.** The FSVP regulation does not require the importer to send their DUNS number directly to FDA prior to filing entry. However, for each line entry of food subject to the FSVP regulation that is offered for entry into the United States, the importer must provide their name, email address, and unique facility identifier recognized as acceptable by FDA when filing entry with CBP (21 CFR [1.509\(a\)](#)). If the entry data is filed electronically, your customs broker should transmit your DUNS number using the “FSV” entity role code in ACE for all lines of food subject to the FSVP regulation. If you are filing physical paperwork, you can include the DUNS number on the documentation you provide to CBP. Refer to the [FDA Supplemental Guide](#) for more information.

**Q9. Do I input my DUNS number under Prior Notice?**

**A9.** No. The DUNS number should only be provided in the FDA entry data. The DUNS number can be transmitted through ACE for each line of food subject to the FSVP regulation if filing electronically with CBP or must be included in the entry documentation if filing an entry manually.

**Q10. I have a DUNS number and already provided it to my customs broker. Why do I continue to receive email notifications from FDA about the requirement to transmit a DUNS number?**

**A10.** If you or your firm were identified as the FSVP importer on an entry line of food subject to the FSVP regulation and “UNK” was transmitted in lieu of your DUNS number, you may be receiving email notifications from FDA. Please continue to advise your customs broker to transmit your DUNS number using the “FSV” entity role code in ACE for all lines of food subject to the FSVP regulation. Refer to the [FDA Supplemental Guide](#) for more information. If additional information about an entry for which your name or your firm’s name appears on the [FSVP Importer List of Participants](#) or List, you may submit a [Freedom of Information Act \(FOIA\) request](#) to FDA.

**Q11. I am not an importer and I do not intend to import foods that are subject to the FSVP regulation. How do I identify the entries for which I was identified as the FSVP importer?**

**A11.** If you are not an importer or are not importing foods subject to the FSVP regulation, you should advise your customs broker that the products you are importing are not subject to the FSVP regulation and therefore they should not transmit the “FSV” entity role code for products not subject to the FSVP regulation. If the product is exempt from FSVP regulation, the customs broker should use the appropriate exemption code in the PG23 Affirmations of Compliance section of the electronic entry data. Refer to the [FDA Supplemental Guide](#) for more information. If additional information about an entry for which your name or your firm’s name appears on the List, you may submit a [FOIA request](#) to FDA.

**Q12. Do I need to obtain a DUNS number from all my foreign suppliers or is obtaining a DUNS number only required for importers of food subject to the FSVP regulation?**

**A12.** The FSVP regulation does not require foreign suppliers to obtain a DUNS number. For the purpose of

FSVP, the importer of the food located in the U.S. is required to obtain and transmit a DUNS number when electronically filing entry with CBP.

**Q13. If I only plan to import foods subject to the FSVP regulation either one time or on an infrequent basis, do I still need to obtain a DUNS number?**

**A13.** Regardless of the frequency you intend to import, all importers of food subject to the FSVP regulation are required to obtain and transmit a DUNS number, including the importer's name and email address for each line entry of food offered for import into the U.S. when electronically filing entry with CBP.

**Q14. I only import foods that are exempt from the FSVP regulation. How does my customs broker indicate that the foods are exempt when electronically filing entries with CBP?**

**A14.** Unless an exemption in 21 CFR [1.501](#) applies, the FSVP regulation applies to importers of human and animal food and the food they offer for importation into the United States. The FSVP exemptions include:

- Fish and fishery products (in compliance with part 123), or certain ingredients for use in fish and fishery products in compliance with part 123
- Juice (in compliance with part 120), or certain ingredients for use in juice products in compliance with part 123
- Food for research or evaluation
- Certain alcoholic beverages, or certain ingredients for use in alcoholic beverages
- Certain meat, poultry, and egg products regulated by USDA
- Food imported for personal consumption
- Food that is transshipped
- Food that is imported for processing and export
- U.S. food that is exported and returned without further manufacturing/ processing in a foreign country

If the imported food is exempt from the FSVP regulation, the customs broker should submit the appropriate Affirmations of Compliance code when electronically filing entry with CBP.

- The Affirmation of Compliance code, RNE, should be used if the human or animal food offered for import is exempt from the regulation requirements because the food is intended to be used for research or evaluation. This exemption applies if the food is not intended for retail sale and is not sold or distributed to the public; the food is labeled with the statement, "Food for research or evaluation use"; and the food is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of.
- The Affirmation of Compliance code, FSX, should be transmitted for all other human or animal food offered for import that are exempt from the FSVP regulation requirements.

Refer to the [FDA Supplemental Guide](#) for more information.

**Q15. Can I provide my customs broker with my Food Facility Registration (FFR) number instead of my DUNS number?**

**A15.** No. Currently, the only acceptable UFI for the FSVP importer is the DUNS number. The DUNS requirement for the FSVP regulation and Food Facility Registration (FFR) are two separate, independent regulations for which one or both may apply. The DUNS number is used for facility verification under the FSVP regulation and is not a substitute for an FDA FFR number which is required under the Bioterrorism Act (BTA).

The BTA requires domestic and foreign food facilities, that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their establishment with the FDA. If your facility is engaged in one of these activities and imports food subject to the FSVP regulation, both requirements apply.

**Q16. Can my customs broker transmit my CBP Employers Identification Number (EIN) instead of my DUNS number when electronically filing entry with CBP?**

**A16.** No. Currently, the only acceptable UFI for the FSVP importer is a DUNS number. The DUNS number is different from your federal tax Employers Identification Number (EIN). The FDA does not currently use EINs for entity identification purposes.

**Q17. I have tried to contact D&B multiple times via telephone and email, but I am unable to reach anyone and have not received a response from D&B. Is there someone else I can contact to obtain a DUNS number or receive further assistance?**

**A17.** Dun and Bradstreet is a third-party company not managed by the FDA. However, if you are not able to contact D&B by telephone or email, you may consider reaching out to FDA's Imports Inquiry Team at [FDAImportsInquiry@fda.hhs.gov](mailto:FDAImportsInquiry@fda.hhs.gov) for further assistance.

**For more information:**

- [FSMA Final Rule on Foreign Supplier Verification Programs \(FSVP\) for Importers of Food for Humans and Animals](#)
- [FDA Supplemental Guide](#)
- [How to Make a FOIA Request](#)
- [What to Expect During a Foreign Supplier Verification Programs Inspection](#)
- [FSVP Importer List of Participants](#)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.