

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell

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Re: Action Required: FSVP Implementation Triggers New Data Entry Requirements for All Imported FDA-Regulated Foods on May 30, 2017

There will be significant changes at the U.S. border starting May 30, 2017, that will affect all imported FDA-regulated foods—even if they are exempt from the Foreign Supplier Verification Programs (FSVP) regulation under the FDA Food Safety Modernization Act (FSMA). **All food imports will be rejected at entry unless certain new information is provided to FDA.** This memorandum summarizes these new data requirements.

For foods that fall under FSVP, including imported foods for which the importer is conducting supplier verification under the Preventive Controls regulation and foods with modified FSVP requirements such as dietary supplements the FSVP importer must electronically provide their name, email address, and unique facility identifier recognized as acceptable by FDA when filing entry with U.S. Customs and Border Protection. ^{1/} FDA has affirmed the use of Dun & Bradstreet Data Universal Numbering System (DUNS) numbers as the acceptable unique facility identifiers for this purpose. ^{2/}

FDA recently issued guidance explaining operational aspects of the FSVP rollout at the border. As FDA explains in its *Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation* ^{3/}:

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

^{1/} 21 C.F.R. § 1.509. We understand that FDA also is requiring submission of the FSVP importer’s address, though that information is not required to be submitted under the regulation.

^{2/} See Hogan Lovells memorandum dated April 4, 2017, *FDA Guidance Affirms Use of DUNS Numbers to Identify FSVP Importer*.

^{3/} Available at: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm>.

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.

FDA advises that if the food entry line is exempt from FSVP, or not yet subject to the regulation based on the applicable compliance date, the filer should transmit the applicable Affirmation of Compliance code. There are two such codes:

- FSX: This code designates that the food is exempt from the FSVP regulation or that compliance with the FSVP regulation is not yet required.
- RNE: This code designates 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). ^{4/}

An Affirmation of Compliance code must be submitted for food that is exempt from FSVP – including food under juice HACCP, food under seafood HACCP, food imported for processing and export, and food that will be transshipped.

FDA also is temporarily allowing filers to submit the value “UNK” (to represent “unknown”) in the UFI field for the FSVP importer in the event that the nine-digit, site-specific DUNS number is not available at the time the entry is transmitted. FDA intends to contact those FSVP importers for whom “UNK” was transmitted in place of the DUNS number and “will provide additional information to help ensure that FSVP importers understand this FSVP regulation requirement and take the appropriate steps to obtain a UFI.” FDA will provide a communication to importers at a future date when use of the “UNK” value is discontinued.

In summary, is important for everyone who imports FDA-regulated food to the U.S. to recognize that as of May 30, 2017, their imports will be rejected unless:

1. The code FSV is submitted at entry for food subject to the FSVP regulation;
 - a. For these foods, the FSVP importer name, email address, and a DUNS number (or the “UNK” code, as discussed above) also must be provided;

OR

^{4/} FDA explains that they 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. Also note that to be exempt from FSVP, the food must be labeled “for research and evaluation.” Other requirements are outlined in 21 CFR § 1.501(c)(4).

2. The code FSX is submitted at entry for food exempt from FSVP (e.g., food under juice HACCP; food under seafood HACCP) or food for which the FSVP compliance date has not yet occurred;

OR

3. The code RNE is submitted at entry for food for research and evaluation.

Keep in mind that the FSVP importer identified at entry is the entity that FDA will hold responsible for FSVP compliance. Therefore, it is important for all companies (including brokers, distributors, traders, food manufacturers, retailers, and restaurants) that receive imported food (either finished products or ingredients) to determine those circumstances in which they meet the definition of FSVP importer (i.e., they either own, have purchased, or have a written agreement to purchase the food at the time of entry). When more than one entity meets the definition of FSVP importer, companies will need to work with their supply chain to determine who will assume FSVP responsibility and therefore be identified as the FSVP importer to FDA through the CBP ACE system.

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We will continue to monitor these and other developments related to FSMA implementation. Please contact us if you have any questions or if we can help you with development of your FSVP.