2/21/18

United Fresh highlights of Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry (DRAFT)

This 108 p draft guidance is open for comment until May 25. It has a companion draft guidance related to the Supply Chain program of the Preventive Controls Rule. They main elements of the programs are very similar. While long, this draft guidance is put together in an easy to read Q&A format covering 14 main topical areas. Here are some highlights.

General Information

B.2 explains that your FSVP must be specific to *each supplier of a food.*

F.4 suggests that if you need to use an unapproved supplier on a "temporary" basis, the timeframe is situation specific, but is typically expected to be a few weeks to a few months.

Remember that when you are verifying the supplier, what you actually need to verify is *their control of the hazard you identified in your hazard analysis* (for produce RACs this means verifying that they are following the Produce Safety Rule). The relationship to the hazard is what drives your selection of appropriate verification activities (which default to an annual onsite audit for fresh produce because it is assumed to have a SAHCODHA hazard). This is covered in F.9, which also provides a detailed example on the need to separately verify growers, harvesters and packers if these are different entities.

Who is responsible?

There are modified requirements for "very small importers" which are defined as those with less than $1M annual food sales (includes all food sales, not just imports, and not just in the US; L.2). Note: according to L.7, an affiliate or subsidiary can *not* meet the definition of a very small importer if the parent company does not meet that definition.

A.8 asks: Would a retailer that places a purchase order with a U.S.-based food distributor be considered the "U.S. owner or consignee," *where the retailer does not specify the source* of the food and the distributor purchases the food directly from a foreign supplier?
A: No. If the retailer does not direct the distributor to purchase the food from a particular source or sources, the retailer would not be the "U.S. owner or consignee." For example, if a retailer places a purchase order for bell peppers from a U.S.-based distributor without specifying the source of the peppers, the retailer would not own the food, have purchased the food, or have agreed in writing to purchase the food at the time of entry. The retailer would have only placed an order directing the distributor to obtain peppers, leaving the decision about the source of the peppers to the distributor. At the time of entry, the distributor is the entity that purchased the peppers. Therefore, the distributor would meet the "U.S. owner or consignee" definition in 21 CFR 1.500.

A.16, A.17, and other information in the draft guidance confirm that the "supplier" is the GROWER, even if there is a packing operation between you (the FSVP importer) and the grower.

E.9 specifies that only YOU can approve your suppliers. This obligation cannot be delegated. Obviously, this requires you to know who your suppliers actually are (remembering that the "supplier" is defined as the one who grew the food or manufactured/ processed the food, and may not be the one you purchased the food from).

If your supplier is exempt from the produce safety rule (because they have less than $25K sales/ yr), you as the importer still need to get a written assurance from them at least every two years stating that they understand that they may not export adulterated food into the US (L.16). L.19 goes over all the things you need to do if you are importing from a small foreign supplier.

Relationship with the Preventive Controls Rule

Questions B.9- B. 11 explain the relationship between FSVP and the Supply Chain Program under Preventive Controls. Many UFPA members are covered by the PC Rule and required to have a Food Safety Plan. If that is the case, then whether you need a supply chain program or are covered under FSVP depends on whether or not you meet the PC Rule's definition of a "receiving facility" (that does manufacturing/processing, which includes packaging). The bottom line is if you're importing fresh produce you still need to manage your supply chain. Whether it's technically done to comply with FSVP or done as part of your food safety plan doesn't really change the nature of the program.

Hazard Analysis

D.12 ad D.13 provide somewhat confusing explanations to the questions "What hazard analysis must I conduct for a RAC that is a fruit or vegetable?" and "How must I evaluate the risk posed by a RAC that is a fruit or vegetable?" The bottom line is that you don't need to spend a lot of time thinking about all the microbiological hazards associated with fresh produce because FDA assumes you are there. The most useful line in the response is "Therefore, even though you are not required to conduct a hazard analysis regarding the biological hazards in fruits and vegetables, you must take into account the risks posed by these hazards (as addressed under the produce safety regulation) in approving foreign suppliers of such produce and determining appropriate supplier verification activities." This is reiterated in D.19, which states "However, this [a hazard analysis that finds no hazards that require a preventive control] does not apply if the food is a RAC that is a fruit or vegetable that is "covered produce" (as defined in 21 CFR 112.3) subject to the requirements of the produce safety regulation *(because FDA has determined that there are biological hazards associated with "covered produce" that require controls).* Thus, such fruit and vegetables are subject to the FSVP requirements to conduct an evaluation for foreign supplier approval and verification and to conduct foreign supplier verification activities."

In D.5 FDA calls out "Examples of known or reasonably foreseeable biological hazards include bacterial pathogens, such as *Salmonella* …[and] *Listeria monocytogenes* in ready-to-eat produce". In F.25 FDA identifies "Examples of foods for which a hazard needs to be controlled during transportation include the following:

• Produce shipped in open or porous containers or crates: A pathogen (e.g., *Salmonella*, *Listeria monocytogenes*) may be introduced into the produce if the transportation vehicle is not properly cleaned and sanitized before loading."

F. 25 goes on to talk about transportation and states "if your foreign supplier is subject to the requirements of the sanitary transportation regulation (because it meets the definition of shipper in the rule), you should consider your foreign supplier's compliance with the regulation as part of your evaluation for foreign supplier approval and verification"

Audits and auditors:

E.2 explains that if there is a SAHCODHA hazard (which is automatic for fresh produce), "the default verification activity is to conduct an annual onsite audit before initially importing the food from the supplier and at least annually thereafter".

F.9 discusses audits. FDA states: "You could rely on the results of audits conducted in accordance with such [private] schemes *provided that the audits consider the farm or facility's compliance with applicable FDA regulations, review the supplier's food safety pla*n (if any) and its implementation,…" F. 18 states "We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit because HACCP requirements are not identical to preventive controls requirements, …" and "inspection by the USDA to determine whether a farm satisfies the requirements of the produce safety regulation could constitute an appropriate inspection that could substitute for an audit, …" F.10 notes that an "annual" audit means once every 365 days.

Question C.11 discusses what is meant by "qualified auditor", notably, that this person has "the knowledge and experience to assess the applicable FDA regulations." Therefore, if you are relying on 3rd party audits, especially from other countries, be sure to verify (and document!) that the auditor has a firm grasp of the FDA regulations that apply to the audited establishment (e.g., Produce Safety or Preventive Control Rule).

F.29 suggests that "To ensure that a qualified auditor or qualified individual who conducts a supplier verification activity on your behalf does not have a financial conflict of interest with your foreign supplier, you may want to request that the person provide you with a written, signed, no-conflict-of-interest statement."

Other forms of verification (or not)

In G.6 FDA notes "We do not recommend use of documents such as contractual agreements, letters of guarantee, specifications, and terms and conditions to communicate the information required in the disclosure statement. Such documents generally are not specific to a particular shipment and some of these documents may not be available to the customer's food safety manager or other appropriate employees."

DUNS Number

I.6 states "you might choose to provide the DUNS number that applies to the location at which you maintain your FSVP records, because FDA investigators will conduct records reviews at the location identified by your DUNS number." I.7 suggests "you should provide the email address that will ensure that you receive FSVP-related communications from FDA."

Records and enforcement

J.5 cautions "When an FDA representative makes this request at your place of business, we expect you to provide the requested onsite records *while FDA is at your place of business*. We consider electronic records to be available onsite if they are accessible from your onsite location. You must provide records stored offsite within 24 hours of FDA's request for the records". My read is that the 24 hour timeframe to provide records does not apply when records are available onsite (including electronically). FDA has the right to request that you send records electronically and states that must be done within 72 hours. (this can be done through the FURLS portal system on FDA's website. See the question/answer for more details).

N.10 states that "If you are on an import alert because of your FSVP violations, this will not directly affect importation of the same food by other importers." In other words, you don't need to be concerned that another importer's noncompliance will interrupt your imports from the same foreign supplier.

Importing from a country whose food safety system is comparable or equivalent to the US (as officially determined by FDA)

M.3 goes over how you can demonstrate the supplier is in "good standing" with their regulatory authority.

Miscellaneous

Some members have asked about the interplay with PACA if a shipment is rejected. This is addressed in A.10 Q: Would a U.S.-based distributor be the "U.S. owner or consignee" of a shipment of food if the distributor has a written agreement with the foreign producer to purchase the food, but the agreement allows for the distributor to reject the food if certain quality standards are not met?
A: Yes. In this situation, the distributor has a written agreement to purchase the food at the time of U.S. entry. The distributor therefore meets the "U.S. owner or consignee" definition, even if the condition regarding quality standards means that the distributor does not own the food unless the quality standards are satisfied.

A.20 provides the most up to date information on FSVP requirements pertaining to food contact substances (e.g., the rationale behind exercising enforcement discretion even though technically food contact substances are covered by this regulation).

A.24 explains when food meets the criteria that it's being used for "research and evaluation" and A.26 states that food imported for distribution or consumption at a trade show is generally *not* exempt and would still be covered under FSVP.