Are audits appropriate for FSVP verifications?

Introduction

Custom and historical practices dictate that Foreign Supplier Verification Program (FSVP) verification must be completed by auditing. It is perceived as the most efficient and effective way to maintain compliance with the FSMA FSVP requirement. In 2020 there were 514 violations for FSVP Development. The citations were triggered because receiving facilities did not adhere to the FSVP verification requirements of FSMA.

The citations are based on the FDA visits to companies for enforcement. Suffice it to say, the number of companies with undeveloped FSVP programs is likely to be far more than those identified in audits.

The challenge is

- Completing annual audits of the 100000 plus foreign entities and the 80000 USA food producers in a timely manner.
- Importers who have multiple suppliers and GFSI requirements– must track approved suppliers' inspection/audit dates for compliance
- The auditing method has changed because FSMA is a risk-based regulation for conducting a risk-based audit in organizations. A risk-based audit approach to auditing is addressed in ISO 19011:2018 for a risk-driven organization. Risk-based audits are different from utilizing a clause by clause audit checklist.'

At the time of writing it is unclear how many audits are completed as risk based audits.

Types of Onsite Audits - FSVP

First party – Internal Audits – usually an internal PCQI function.

Second-party – Receiving facilities on Suppliers – it is unclear whether every receiving facility to a supplier conducts an audit

Third-party – External audits – conducted by independent supplier auditors and FDA auditors.

There are three types of external audits of food safety Audit schemes for Foreign Suppliers

- FSMA Voluntary Qualified Importer Program (VQIP),
    - audits are unannounced,
    - the same auditor limited to regulatory audits at the same facility once every 13 months,
    - regulatory audit reports shared with FDA.
    - Expedited entry program
- FSMA FSVP
    - A compliance certificate for foreign suppliers
- GFSI Certification
    - FSMA is still required. Two separate audits are needed, although

the GFSI has included modules for FSMA compliance. Some audit companies offer an integrated audit.

According to 117.435 Onsite Audits. There is no requirement in 117.435 that onsite audits are for conducting the verification. The purpose of the onsite audit is described as follows:

b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (*e.g.,* Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)

There may be a substitution for onsite audits as follows

FSMA 117.435 (c)1 The following may be substituted for an onsite audit, provided that the inspection was conducted within one year that the date onsite audit would have been required to be undertaken. 117.435 speaks to auditing inspections annually by the FDA (c) (i) and(ii). Noting in

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

Seemingly the responsibility for onsite audits is the FDA itself or its agents, and the inspections do not qualify as verifications.

FSPCA defines verification as The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan. In other words – verification is about determining whether controls are operating as intended.

I have not found any clause in FSMA which states verifications are mandated annually. Still, when an audit is conducted as a verification method, the activities include those stated in the onsite audit clause.

The FSVP legal verification requirements

The FDA has provided the following options for FSVP verifications.

- Onsite audit
  - Include audit procedures, audit dates, conclusions, corrective actions, performed by qualified auditor

- If the food is subject to one or more FDA food safety regulations, must consider applicable FDA food safety regulations or, when applicable, may consider relevant laws and regulations of country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States
- Must include review of supplier's written food safety plan, if any, and its implementation, for the hazard being controlled
- Conducted before importing the food and periodically thereafter
- Must be performed by entity other than foreign supplier **(a privately hired auditor, not the FDA auditor – the FDA auditor verifies the verification)**
- Results of inspection can be substituted for onsite audit (inspection within 1 year of date audit would have been conducted)

 Sampling and testing of the food

- Include number of samples tested, type of tests conducted, dates of tests, date of test report, results, any corrective actions, testing laboratory, performed by qualified individual
- Conducted before importing the food and periodically thereafter

 Review foreign supplier's food safety records

- Include dates, general nature of records reviewed, conclusions, any corrective actions taken, conducted by qualified individual
- Cannot be performed by foreign supplier
- Conducted before importing the food and periodically thereafter

 "Other" verification activity - Conduct and document or obtain documentation of other supplier verification activity

- Documentation of each activity, including description of activity, date activity conducted, findings or results, any corrective actions taken, and conducted by qualified individual
- Conducted before importing the food and periodically thereafter – **interpreted to mean prior to each shipment of the food and periodically.**

 Review and assessment of results of supplier verification activity performed by another entity

- Documentation that appropriates supplier verification conducted for each foreign supplier before importing the food and periodically thereafter
- Actions taken if results of verification activity do not provide adequate assurance that hazards requiring a control in the food were significantly minimized or prevented
- Foreign supplier itself or its employees may not perform supplier verification activities, except with respect to sampling and testing of food

- Not required to retain documentation of verification activity conducted by another entity, but must obtain the documentation and make it available to FDA upon request

Verification insights

- Audit Sampling

  An audit is a sampling exercise. A Supplier audit was conducted. Its sample does not include a specific receiving facility's documents because the supplier has many receiving facilities as customers. Does the auditor sample each receiving facility documents separately or is it sample across the population of receiving suppliers? If the sample is across the board – it may mean the verification of controls associated with a receiving facility remains unverified. Is the missed verification unacceptable?

- Auditing multiple food safety plans

  "Sec. 1.504 (d) *Review of another entity's hazard analysis.* If another entity (including your foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in food by reviewing and assessing the hazard analysis conducted by that entity".

  For the same ingredient or formulas at one supplier from different receiving facilities, the auditor sampling retrieves an assortment of food safety plans with various preventive controls that do not match. Is verification what each receiving facility decides on their own or is it consensus?

- Receiving Facility Reevaluation

  Between the annual audits of a supplier – changes to the receiving facility formulations are made. However, it does not appear in the third-party audit because those documents were missed during the audit sample. Verification of revaluation / reanalysis /revalidation is undetermined for the supplier, as the receiving facility is dependent on the supplier audit.

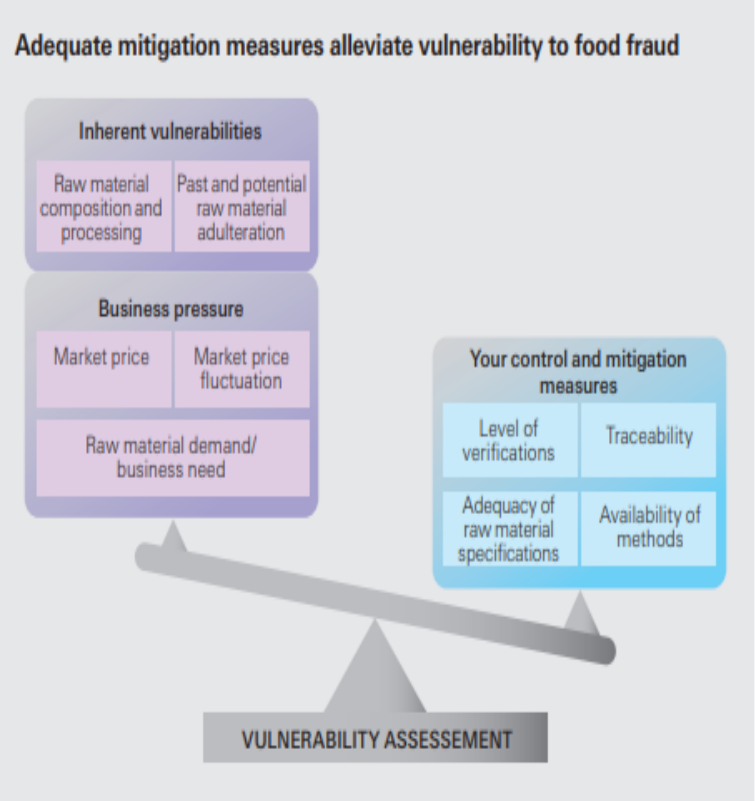
- Expediting

  VQIP is required to conduct an audit at a supplier for a receiving supplier – the auditor samples the documents. Does the auditor riffle through the supplier documents to select only the requesting receiving facility documents? In such a case, it is an inspection not an audit. Alternatively, if an audit is sampled and only the other receiving facility records show up, what happens at customs? If the supplier serves more than one receiving facility, is an expediting

audit required for each receiving facility's product request, beyond the legally required annual onsite audit for the supplier?

- Food Fraud

  Nestles in a food fraud prevention pamphlet presents the following diagram on page 8 related to food fraud



The diagram by Nestles indicate the measures to control and mitigate the inherent vulnerabilities and business pressures, which leads to food fraud. To balance the scale for the receiving facility to be assured of reduced risk the following actions are required.

- increase in verifications,
- enhanced traceability and
- available of **control** methods
- Adequacy of raw material specification

Annual audits for verifications are insufficient. Audits are an expensive way to increase verifications. Fortunately, FSVP rules provides us with more options to increase the level of verifications.

An audit is not an effective verification method because sampling limits the selection of documentation and poses a risk of incomplete verification, which could lead to citations and re-inspections.

Verification by Technology

Nestles recommendation of increased verification for food fraud serves other shortcomings associated with audits.

- The ideal level of verification is for all lots to be verified by the respective receiving facility.
- Enhanced traceability is barcoding from the source by including the supplier's name and quantity for the operation with UPC bar code scan.
- The receiving facility can verify the UPC with the named seller, and the PO # of the raw materials
- The raw material specification is subject to detailed formulation within the food safety plan, which is set in a binary format.

A seamless interface between each receiving facility and the respective suppliers allows the receiving facility to 'see' the supplier's operations and records.

The access to the records offers real-time control because a trend map of efficiency and effectiveness measures also form records with visibility to the receiving facility. Different suppliers can be seen on a receiving facility dashboard. The receiving facility can establish baselines of operations and compare the performance of their suppliers. The intent is to depend less on Nestles' trusted supplier' and use the comparative performances between suppliers for decision making. The supplier knows you can see the results of the operations.

Audits as verification are required periodically. Once a year does not qualify as periodic. An audit is just a sampling with a snapshot in time. An audit cannot give a cross-sectional supplier verification and performance assessment of 100 % for receiving facilities, It is the receiving facility which as FSVP accountability according to the law. Verification is not partial, which is what audit sampling suggests. The citations issued for FSVP development can also be for incomplete verification. Verification is a 100% activity in order to be assured of food safety. Partial verification is a gap that could intentionally or unintentionally be exploited.

Benefits of electronic verification

- Receiving facility meets legal requirements for verification compliance
- Assured of supplier ongoing operational compliance
- Foreign Supplier does not need to know the FSMA law; the technology intuitively guides the supplier through the law and be assured of FDA audit success.
- Receiving facility monitoring of supplier verification for each received lot reduces the potential for food fraud.
- Can verify product before the lot shipment and satisfies the 'periodic' requirement of the law
- Auto measures the individual supplier effectiveness of performed procedures
- Assesses suppliers' overall performance from trend charts
- Can compare the performance of same product suppliers
- Safeguards disruption of the supply chain
- Can issue corrective action online to a supplier. An alert is triggered when the corrective action is not completed within the legally required seven days.

Conclusion

The onsite audit for Foreign Supplier Verification upon examination demonstrates that it is unsuitable for verification. Both Receiving Facilities and Suppliers can end up with citations and re-inspection costs at rates of $277 and $330 per hour (for example periodic audits not being satisfied). Audits as the means for verification require an army of auditors to serve the 180000 plus FDA registered entities.

The supplier PCQI are the persons conducting the first verification, and the Receiving facility PCQI would be the second verifier. The technology verification supports the appropriate verification option more efficiently than auditing without an army of auditors.

By utilizing the technology solution, all the potential issues are resolved; for example, 1.504 (d) the receiving facility applies the 100% lot verification. There is no document sampling issue. If the FDA audits, they can audit the supply chain – rather than one entity at a time both remotely and onsite.
The fact that Nestles supports more verifications shuts down the audit argument. Food Safety audits as a tool for verification are not effective or efficient, principally because audits by their nature are sampling activities. Verification is incongruous with audits. The threat of punitive fines is intended as a deterrent, but audits have inherent gaps that subject companies to citations and further costs for re-inspections; especially for an army of auditors as individual auditors can have different interpretations of the same legalese.
The electronic verification is less costly than the current practices and for participating receiving facilities and their suppliers – offers an opportunity to be more competitive.

Jeffrey Lewis FCQI, PCQI, is director of fsma SaaS – technology for delivering end-to-end FSMA compliance paperlessly.