

Alternative Supplier Verification Activities in Emergency Situations¹

I. Background²:

The Preventive Controls for Human Food Final rule mandates that a food manufacturing/processing facility have a risk-based supply chain program for those raw materials and other food ingredients for which it has identified a hazard requiring a supply-chain-applied control. Covered food facilities are responsible for ensuring that these raw materials and ingredients are received only from approved suppliers, or on a temporary basis from an unapproved supplier whose materials are subject to verification activities before being accepted for use.

21 CFR 117.430(b)(1) requires that when a hazard in a raw material or other food ingredient will be controlled by the supplier and is one that presents a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans: 1) the appropriate supplier verification activity is an onsite audit of the supplier (21 CFR 117.430(b)(1)(i)); and 2) the audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter (21 CFR 117.430(b)(1)(ii)).

[FDA's draft Supply Chain Program Guidance](#) states, “We realize there could be practical reasons which preclude meeting this [annually] timeframe, e.g., if a third-party auditor needs to delay a previously scheduled audit. We do not expect to take action if the timeframe between annual audits is reasonably close to one year (e.g., within 13-14 months)”; however, we recognize there could still be extenuating situations where the timeframe between audits is greater than 14 months. 21 CFR 117.430(b)(2) states, “the requirements of paragraph (b)(1) do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled”.

In widespread emergency situations ¹, it may not be possible for facilities to complete annual supplier audits and alternate supplier verification activities may need to be implemented until such time that the onsite supplier audit can be completed. The recommendations provided below represent industry best practices when an annual onsite audit cannot be conducted due to a widespread emergency situation.

II. Examples of Alternative Supplier Verification Activities in Lieu of Annual Audit in Emergency Situations³

¹ Emergency situations are where there are travel restrictions due to a multinational disaster (e.g., [travel advisory level](#), pandemics, terrorism or disaster areas) preventing or minimizing the ability to conduct the supplier verification activity of onsite audits.

² This document was developed under the lens of Preventive Controls for Human Food but there are parallel supply chain requirements in Foreign Supplier Verification Programs and Preventive Controls for Animal Food. Hence, the same logic presented in this document would apply to these rules.

³ The examples of supplier verification in this document are not all inclusive. These are just examples of how a company might approach supplier verification in emergency situations.

- The receiving facility could perform the annual audit virtually using available technology., e.g., virtual platform, 360 video capability etc.
- The receiving facility or supplier at the request of the receiving facility, could implement or increase sampling and testing of those raw materials or food ingredients with an identified hazard controlled, - during the timeframe that an annual onsite audit cannot be conducted due to the emergency.
 - Example: A receiving facility could conduct sampling and testing for *Salmonella* for each lot of roasted pecans it obtains from its supplier from the point in time the annual audit was to be completed until the audit is conducted following resolution of the emergency.
- The receiving facility could review each of its supplier's relevant food safety records for all raw materials and ingredients requiring a supply-chain-applied preventive control, to assure that identified hazards are controlled during the timeframe that an annual onsite audit cannot be conducted due to the emergency.
 - Examples of Review of Relevant Food Safety Records:
 - Records demonstrating processing times and temperature when a supply-chain-applied control is needed for the hazard of vegetative pathogens such as *Salmonella*;
 - Environmental monitoring records when an environmental pathogen is a hazard requiring a preventive control; and/or
 - Allergen control program and associated records such as allergen label verification logs when a supply-chain-applied control is determined necessary for the hazard of undeclared allergens.
 - Example: A receiving facility that obtains roasted pecans from a supplier could review the food safety records demonstrating the roasting of pecans at a specified temperature for a specified time period, e.g., indicating an appropriate log reduction for *Salmonella*. In addition, the receiving facility might review the supplier's environmental monitoring records to assure there is not the potential for post lethality contamination of roasted pecans when there is a delay annual onsite audit.
- Receiving facilities that receive a raw materials or food ingredients could select a combination of verification measures during the timeframe when an annual onsite audit is not possible due to an emergency situation. A combination of verification activities is optional but in emergency situations may provide receiving facilities with added assurance that identified hazards are controlled.

Scenario 1: A receiving facility obtains roasted pecans from a supplier could select the following combination of verification measures when there is a delay in the annual onsite audit due to an emergency situation: 1) Conduct enhanced sampling and testing for *Salmonella* for all lots during the period of time that the annual onsite audit is delayed and 2) Using a virtual platform, review the suppliers' food safety records and document this review (e.g., records demonstrating the roasting of pecans occurred at a specified temperature and time period, supplier's environmental monitoring records, sanitation records for the post-lethality area).

Scenario 2: A receiving facility that obtains trail mix from a supplier has a supply-chain-applied control for the hazard of undeclared allergens (almonds⁴). The receiving facility could select the following combination of verification⁵ measures during the timeframe when an annual onsite audit is not possible due to an emergency situation: 1) Using a virtual platform, review the supplier's food safety records and document this review (e.g., review of the supplier's overall allergen management program to include cleaning procedures for allergen cleans) 2) Using a virtual platform, review the supplier's records such as allergen label verification logs and allergen changeover logs along with sanitation records that document allergen cleans.

- Other supplier verification activities based on the risk associated with the ingredient and the supplier.

III. Documentation

It is important that the receiving facility document the alternative procedures it puts in place when there is a delay in performing an annual supplier verification audit. The receiving facility should document the specific suppliers and raw material/ingredients that are subject to the alternate supplier verification activities during the emergency situation. In addition, the receiving facility should have a written determination that other verification activities provide adequate assurance that the hazards are controlled (§117.4230 (b)(2)). The written determination should explain why the alternate supplier verification activity was selected. This should all be documented in records which are subject to inspection.

⁴ Receiving facility has a supply chain applied control for the undeclared allergen of almonds as the trail mix the receiving facility receives does not contain almonds but another trail mix that is manufactured on the same line at the supplier's facility contains almonds.

⁵ Supplier verification measures would include measures to verify adequate label controls are in place and there are adequate controls to manage the risk of allergen cross-contact.