

## TUV Staff Highlight



Last fall, TUV USA welcomed Paul Fallaw as Program Manager of the Food Safety Division. Paul spent the last 10 years auditing and consulting and is a recognized food specialist with in-depth expertise in quality assurance, product development, regulatory affairs, manufacturing, and packaging.

Prior to a career in third-party certification, Paul held various roles in Quality Assurance and Regulatory Compliance with Hain Celestial Food Group, Cargill and Kraft Foods. His strong analytical abilities, proven technical leadership and management skills make him a great addition to the TUV USA team. Paul has a B.S. in Chemical Biology from Rhodes College in Memphis, TN.

# FSVP: 6 Key Points for Compliance

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*By Paul Fallaw and Lori Carlson*

The Foreign Supplier Verification Program (FSVP) compliance date is fast approaching for companies importing food into the U.S. By May 27, 2017, the FDA expects all importers to have an established risk-based verification program, which ensures foreign suppliers meet regulation established under the Food, Drug, and Cosmetic Act (FD&C Act)—most notably, Produce Safety and Preventive Controls regulation.

To help importers achieve compliance, TUV compiled the following short list of key points to consider when assessing foreign supplier risk and establishing verification activities.

1. By now you know you need one or more Qualified Individuals (QI) to establish the FSVP and carry out its activities, but importers must also ensure designated QI's understand the language of all records requiring review.

Additionally, QI's should have completed the [Food Safety Preventive Controls Alliance \(FSPCA\) FSVP Training course](#) to ensure a thorough understanding of how to conduct a risk-based hazard analysis, identify hazards requiring a control, and determine appropriate verification activities that provide assurance as to the implementation of supplier or downstream controls.

2. A written hazard analysis must be performed by a Qualified Individual for each type of food imported. This includes evaluation of biological, chemical (including radiological) and physical hazards. The hazard analysis must also consider hazards where the source is
  - Naturally occurring (e.g., mycotoxins)
  - Unintentionally introduced (e.g., allergen cross-contact)
  - Intentionally introduced (e.g., melamine)

QI's may use their supplier's hazard analysis where developed by a Preventive Controls Qualified Individual, but must document a subsequent review and assessment of the prepared analysis.

3. In addition to the hazard analysis, the QI must also evaluate each foreign supplier's ability to provide safe food in compliance with U.S. regulation based on hazards associated with the food type being supplied, the supplier's food safety plan and/or procedures, and the supplier's past performance. A documented supplier risk assessment shall serve as the basis for determining supplier approval, verification activities and frequency.
4. Where a serious hazard is identified in the hazard analysis (e.g., foodborne pathogens or unapproved chemicals), the QI must establish an annual on-site audit by a Qualified Auditor as the corresponding verification activity. Individuals performing this verification activity must ensure compliance with the regulatory definition of a Qualified Auditor and typically, be employed as a government inspector or work as a third-party auditor for an accredited certification body.
5. For *hazards requiring a control*, which are mitigated by the importer's customer or a subsequent manufacturer, the importer must maintain annual written assurance by the downstream company that they take responsibility for controlling the hazard and will do so in compliance with all applicable U.S. food regulation (e.g., Preventive Controls). Where this occurs, the importer must ensure that all purchasing and trade documents for the food product are labelled as "not processed to control [identified hazard]".
6. Finally, the QI is responsible for implementing corrective actions where verification activities (or other methods) determine that an imported food is not in compliance with Preventive Controls or Produce Safety regulation and/or is adulterated or misbranded according the U.S. FD&C Act. Importantly, where a non-compliant determination is made outside of verification activities (e.g., customer complaint), the QI must investigate the cause and reevaluate the FSVP to ensure its adequacy in verifying foreign supplier compliance with applicable U.S. food regulation.

### **About TUV USA, Inc.**

TUV USA, Inc. is an ISO accredited certification body offering food safety certification against the BRC, SQF, FSSC 22000, IFS, and GLOBALG.A.P. standards. TUV USA, Inc. has experienced and highly competent auditors in all categories of the BRC Food Safety Standard and SQF Code and additionally certifies against the BRC Global Standards for Packaging and Packaging Materials, Storage and Distribution, Agents and Brokers, and Consumer Products. [Contact us](#) for more information about our food safety services. Click [here to subscribe](#) to our monthly newsletter.

### **About the Author**

Lori Carlson is an independent technical writer, trainer and consultant for the food and beverage industry with a background in food safety management systems, GFSI benchmarked schemes and regulatory compliance.