

## Lessons Learned

# FSMA Third Party Audits Voluntary Qualified Importer Program

## Food Safety Summit

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## Differences – FSMA & GFSI

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- Some level of confusion between FSMA Third-Party Certification and the Global Food Safety Initiative (GFSI) Benchmarked Standards.
  - FSMA has created a multi-layered safety net with respect to foods specifying distinct roles for manufacturers, importers, third-party auditors and foreign regulatory bodies. The certification is a regulatory audit.
  - Global Food Safety Initiative (GFSI) has created an industry-driven global collaboration to advance food safety. The certification is not a regulatory audit.

## Differences – FSMA & GFSI

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- GFSI provides guidance on food safety requirements and management. GFSI is science-based and aligned with the CODEX internationally-recognized food safety standards. The benchmark document promotes harmonization by establishing equivalency between food safety management certification programs.
- GFSI is more demanding for validation, while FSMA's validation is limited to process control (e.g. no validation for allergen control, no validation for sanitation control).

## Differences – FSMA & GFSI

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- FSMA's Preventive Controls concept is somewhat similar to ISO 22000.
- Preventative Control Qualified Individuals are NOT included in GFSI.
- Defect Action Levels and quality control to reduce defects is NOT in GFSI.
- Neither VQIP certification nor GFSI is mandatory for suppliers, however foreign suppliers that import to the U.S. must comply with U.S. regulations.

## Differences – The Audit

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- The VQIP audit **must** include records review prior to the onsite audit. When agreed with the customer, the records review may be scheduled and may be carried out off-site.
  - The scheduled / off-site records review may include the following:
    - Hazard analysis, Food safety plan, written procedures (e.g. measuring equipment calibration; product testing; environmental monitoring; receiving raw material, internal auditing, etc.), supply chain program, training records (supervisors, internal auditors, PCQI, etc.) and Management Review.

## Differences – The VQIP Audit

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- The Third-Party Certification Body will develop own audit checklist to the FDA regulations.
- The on-site operational audit must be **unannounced** during the 30-day timeframe identified.
- The report must be submitted to FDA and ANSI within 45 days of the audit, regardless of whether a certification has been issued to the eligible entity.
- FDA has authority under section 801(q) to refuse to accept a certification under section 801(q), if FDA reasonably believes that the certification is not valid or reliable.

## Differences – Web Site Listing

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- DNV GL must maintain on its Web site an up-to-date list of the eligible entities to which it has issued food or facility certifications within the VQIP certification scheme.
- For each such eligible entity, the Web site also must identify the duration and scope of the food or facility certification and date(s).

## Differences – Auditor Qualification

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- FDA does not specify the auditor qualification requirements. GFSI Food Safety Certification Program Owners (CPOs) specify the training and testing requirements for auditors.
- For VQIP, ANSI will interview auditors as part of the Certification Body Accreditation process.



## Main Differences – FDA's role in Certification

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- FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP, if FDA determines, that such food or facility certification is not valid or reliable.
  - The certification is offered in support of the admissibility of a food that was not within the scope of the certification.
  - The certification was issued by an accredited third-party certification body acting outside the scope of its accreditation.
  - The accreditation renewal was denied.

## Differences – FDA's Role

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- FDA may, at any time, conduct an onsite audit of an eligible entity that has received food or facility certification from an accredited Third-Party Certification Body.
- Where FDA determines necessary or appropriate, the unannounced audit may be conducted with or without the accredited third-party certification body or the recognized accreditation body (where applicable) present.
- An FDA audit conducted under this clause will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule.

## Main Differences - VQIP

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- Importers apply for VQIP, however are not certified. The Foreign supplier(s) obtain the FSMA VQIP certification.
- Certification is suspended when Suppliers are involved in a recall until further investigation.
- Third-party certification bodies must report to the FDA when they discover conditions that could cause or contribute to a serious risk to public health.
- Audit information from a Third-party Certification Body is shared with the FDA and is listed publicly for its certification status.

# Thank you

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