WHITE PAPER

EFFECTIVE VERIFICATION

Making the most of your verification activities to improve food safety and quality

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WHY VERIFY?

You know you need to verify your food safety controls and suppliers if your company's activities are subject to regulation under the U.S. Food Safety Modernization Act (FSMA) or if you are certified to a Global Food Safety Initiative (GFSI) benchmarked scheme. But, why are verification activities so critical to the effectiveness of food safety management and how can you make the most of material, process and product data to protect your brand and the safety of consumers?

Verification activities are a part of everyday business operations. We verify everything from employment eligibility to vendor certifications to financial reports and so many other operation-dependent resources.

In a broad sense, verification provides assurance as to the authenticity and accuracy of information used to make key decisions and drive the business forward. From an engineering perspective, verification has the very specific role of ensuring a system is built right by comparing it against a set of specified requirements.

In food production, verification takes on the role of ensuring that all food controls are consistently and fully implemented to produce food that is safe for consumers to eat when purchased.

Thus—for food safety management system verification to be effective—it should be flexible and performed to the fullest extent possible to include methodologies and activities applicable to a range of food safety controls spanning the continuum from business activity (e.g., supplier approval and onboarding) to process control (e.g., pasteurization).

This white paper discusses the role of verification in FSMA and across GFSI schemes, effective ways to implement verification activities and how to make the most of verification data to drive the food safety and quality management system forward.

VERIFICATION REQUIREMENTS OF GFSI SCHEMES AND FSMA

Before we can start a meaningful discussion on how to implement an effective verification program, it is necessary to review some of the primary verification activities and methods currently required by food safety certification schemes and U.S. food regulation.

And, as a primer to a discussion on verification requirements, we must consider the meaning and role of validation to understand its place within the realm of verification.

In the food industry, validation and verification have been treated as separate and independent activities. However, in recent years, guidance and regulation more frequently refer to validation as an element of verification to determine if controls are capable of preventing, eliminating or reducing food hazards.[1]

Validation of controls is typically performed initially and periodically thereafter. It is additionally important for establishing criteria to conduct verification activities.

In engineering, a useful distinction between validation and verification is made when considering that

VALIDATING IS BUILDING THE RIGHT SYSTEM

VERIFYING IS BUILDING THE SYSTEM RIGHT

Across GFSI schemes and food regulation there are numerous requirements for the validation of food safety controls, which require scientific or technical evidence to demonstrate that the control—when implemented—is capable of controlling the target hazard at an acceptable and specified level.

Within the food safety system, validation proves that an applied control is capable of mitigating the associated hazard whereas verification proves that the control is applied as intended and consistently mitigates the hazard.

GFSI

All GFSI benchmarked schemes require varying levels of verification depending upon the scheme and operation.

The most consistent requirement for verification across schemes stems from the GFSI Guidance Document requiring benchmarked schemes to implement requirements for verifying the effectiveness of the food safety system or HACCP plan where verification is based on Codex Alimentarius HACCP principles. [2] However, most schemes go beyond this extending verification to other critical activities of the food safety and quality management system such as prerequisite programs, allergen controls, labeling, and product claims.

Common examples of verification requirements applied in GFSI food safety management schemes across food production, storage and distribution, agent and broker operations, and food packaging include one or more of the following:

- Verifying the effectiveness of food safety controls and associated monitoring
- Verifying the implementation and effectiveness of corrective actions
- Verifying cleaning and sanitation effectiveness—in particular, in high-risk environments or where used for allergen control
- Verifying traceability and recall systems
- Verifying materials against established specifications
- Verifying product formulations and shelf-life
- Verifying the legal status of products (e.g., certifications, claims, weight)
- Verifying product labels—especially where product claims and allergen statements are used
- Additional verification requirements typically in the form of internal audits, which provide assurance that all standard requirements are fully implemented and verify the effectiveness of the system

It is important to note that the activity of monitoring is not listed as a verification activity because monitoring—according to Codex—is the act of conducting a planned sequence of measurements or observations for a given parameter to determine whether a process or activity is in control or out of control (i.e., within or outside of established limits).

Verification, on the other hand, is the application of methods, procedures, tests and other evaluations outside of monitoring to assess whether food safety controls are functioning as intended. Failure to understand this distinction and apply monitoring as a verification activity can have certification and regulatory consequences.

FSMA

Most of the FSMA rules require verification of applicable controls but this is most notable in Preventive Controls and Foreign Supplier Verification Program (FSVP) regulation.

PREVENTIVE CONTROLS

Both the Preventive Controls for Human [3] and Animal Food [4] rules require prescribed and determinable verification activities to ensure that food safety controls are effective and consistently implemented. Verification of preventive controls, the food safety plan and management components cover a wide scope of activities including: the validation of process controls and other controls as appropriate, record review, and reanalysis of the food safety plan.

Prescribed verification activities for the purpose of demonstrating system effectiveness include: calibrating monitoring and verification instruments, product testing for pathogens, review of monitoring and corrective action records, and verifying approved suppliers through onsite audits or other activities.

For ready-to-eat (RTE) products, sites may be required to verify sanitation and other controls through pathogen environmental monitoring where the pathogen is an identified hazard, the product is exposed to the environment prior to packaging, and the packaged food does not receive a kill step.

FOREIGN SUPPLIER VERIFICATION PROGRAM

FSVP [5] requires U.S. importers to establish a program, which provides assurance that foreign suppliers produce food sold in the U.S. in a manner consistent with the requirements of Preventive Controls and Produce Safety regulation as well as other provisions of the U.S. Food, Drug and Cosmetic Act to prevent adulteration and misbranding.

Under the regulation, importers must apply initial and ongoing verification activities, which are commensurate with the supplier's risk level, to ensure suppliers control identified food hazards. These verification activities are similar in expectation to those defined in Supply Chain Program requirements of the Preventive Controls rules and may include a combination of activities spanning inspection, analysis of records and testing.

OTHER FSMA RULES

The Food Defense [6] rule broadly requires verification of food defense activities, which includes: monitoring and corrective action record review akin to Preventive Controls, assurance that mitigation strategies prevent significant vulnerabilities, and planned reanalysis of the food defense plan. These activities may take the form of observational inspections (e.g., internal audits), review of security logs or other site activity monitoring logs, and challenge of the food defense plan.

Verification activities of FSMA's Sanitary Transportation [7] rule largely lies in the requirement for loaders to verify the adequacy of cold storage unit preparation (e.g., pre-cooling and temperature control) according to the shipper's sanitary specifications. Verification activities for this requirement would largely be performed through inspection.

EFFECTIVE VERIFICATION

Verification is only as effective as the system which manages the implementation and documentation of verification activities. One of the best methods for accomplishing this is through the use of a Verification Matrix adapted from engineering disciplines.[8]

In food safety management, some certification schemes are more formal in their requirement for a verification schedule to include the activity, frequency and responsibility (e.g., SQF Code) while others state expectations for written verification procedures and documented activities (e.g., BRC Standard for Food Safety).

Regardless of a specific scheme or regulatory requirement, a Verification Matrix will increase verification efficiency and effectiveness by ensuring a succinct format and systematic process for verifying the food safety management system.

Verification Matrix

A well-defined Verification Matrix can help make establishing and implementing effective verification activities relatively easy. A verification program can be accomplished by first identifying all food safety controls, processes or procedures requiring verification followed by the development of a verification plan.[9] The plan (or matrix) should be constructed in such a manner as to enable determination of whether food safety controls are functioning as intended.

Establish the Verification Matrix by first defining core criteria.[10] For a food safety system, this should include:

- Verification requirement
- Success criteria
- Verification method
- Frequency
- Responsibility
- Result

Continue the process by answering key questions for established criteria to enable accurate verification. Refer to the table below as an example when building your Verification Matrix.

Verification Requirement	Success Criteria	Verification Method	Frequency	Responsibility	Result
What are you trying to verify and why?	How is successful verification determined? What triggers corrective action?	What method will be used to verify?	How often does the verification activity need to be conducted to provide assurance?	Who is responsible for conducting the verification activity?	How are verification results documented?

Verification Methods and Activities

The type of verification method applied and activity conducted must be appropriate for the control or activity requiring verification. Not only is this a requirement of select FSMA rules previously discussed, but it is necessary to achieve meaningful verification.

Referring back to the Codex definition, we understand verification as the application of a method, procedure, test, and other evaluations to determine compliance with the HACCP plan (or other verification requirement). In engineering, we see a parallel where verification activities are commonly grouped according to the following primary methods: inspection, analysis, demonstration, and test.[11]

Putting this together, we can categorize many common food safety verification activities according to the manner in which they are conducted. This is useful when establishing the Verification Matrix as it helps in determining appropriateness to the control. For example, when verifying the effectiveness of a food safety control such as an allergen cleaning procedure, it would be important to select "testing" as the verification method since allergens may not be visible (e.g., residues) and thus, visual line inspection would not provide sufficient assurance that cleaning methods eliminate the hazard. In this example, surface swabs or rinsate should be analyzed for the presence of the target allergen to the specified acceptable limit.

To better understand how many verification activities of GFSI schemes and FSMA regulation fit into the above-described methods, refer to the examples below (this is not an exhaustive list).

INSPECTION

Visual observation and examination or assessment

- Internal audit
- Second or third-party audit
- Pre-operational line inspection
- Observe control (e.g., CCP) operators
- Packaging and label checks

ANALYSIS

Data review and data trending

- Record review against established limits or criteria—i.e., review of monitoring, corrective action, calibration records, etc.
- Review of a supplier's food safety plan, policies and procedures
- Review of Certificates of Analysis (COA's) against specifications
- Trending of process deviations (statistical process control)
- Customer complaint trending

DEMONSTRATION

Performing an activity to a set of specifications

- Equipment or instrument calibration
- Mock recall within specified time and recovery target

TEST

Analytical measurement using specialized equipment or instruments

- Pathogen environmental monitoring
- Finished product testing for pathogens
- Raw material sampling and testing for hazards controlled by supplier—e.g., pathogens, mycotoxins, pesticides, etc.

Making the Most of Material, Process and Product Data

You've established and implement the Verification Matrix, collected a mountain of data; now what? Report findings for each verification activity conducted and analyze to determine areas for improved food safety control and process efficiency.

For example, a lack of training effectiveness may be realized through internal audits. This may have a significant impact on food safety controls where a lack of understanding is related to CCP or preventive control operation. Alternatively, product variation—and indirectly, process inefficiency—may be identified through trending of finished product test results or customer complaints. Analyzing these verification results can not only ensure that the system remains in control but can also provide the necessary data to identify areas for impactful process improvement.

Qualified individuals with training and experience in validation and verification principles should be responsible for reviewing verification results and providing technical support on downstream decision-making. Additionally, adhere to objectivity and statistically significant methods where possible when analyzing verification results.

All verification results—when performed in accordance with the Verification Matrix and by accredited or reference methodologies—should be considered as valid and representative of the effectiveness of the system. Where results demonstrate a lack of control or implementation, these should be thoroughly investigated to reestablish control and correct any affected product.

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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. We also provide third-party HACCP, organic and gluten-free certification. 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.

Need training support? TUV USA Academy can help. We provide FSPCA Preventive Controls Qualified Individual (PCQI) training, ISO Lead Auditor training and many more offerings for the general public!

Contact us for more information about our food safety services.

Meet the Food Safety Division Team

At TUV USA, our team is committed to customer service and assessing your company in a fair and impartial manner. Most importantly, we focus on understanding your company's system and contractual obligations to its customers when determining compliance to provide the most comprehensive and accurate evaluation.

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