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An Overview of Food Safety System Certification (FSSC) 22000	2
TÜV SÜD America to present at Food Safety Summit	4
Validation and Verification in Food Safety: What's the Difference?	6
Recent Food Safety Recalls	7
TÜV SÜD America Announces New Food Safety Webinars	8

## Editorial

Dear Readers,

Welcome to the May 2012 issue of Food Safety E-ssentials, the quarterly e-newsletter from the food safety professionals at TÜV SÜD America!

Food Safety System Certification (FSSC) 22000 is a recently recognized food safety certification scheme under the Global Food Safety Initiative (GFSI), and has been created to provide a food safety program that is more closely aligned with the structure of existing management systems. Our lead article, "An Overview of Food Safety System Certification (FSSC) 22000," discusses the differences between FSSC 22000 and other food safety schemes, as well as the potential benefits of FSSC 22000 certification for food producers and suppliers.

TÜV SÜD America's food safety professionals have worked with food producers and processors, large and small, providing certification services to GFSI standards. The case study, "Keystone Foods and TÜV SÜD America Partnership Meets Growing Food Safety Challenges," offers a summary of a recent project with Keystone Foods, a global food supplier and distributor, and a leader in food safety, quality and innovation. The case study also showcases TÜV SÜD America's flexibility in meeting certification challenges within demanding deadlines.

Within the context of food safety programs, the purpose and role of validation and verification activities are often misunderstood. Our article "Validation and Verification in Food Safety: What's the Difference?" provides a brief summary of validation and verification activities within the context of certified food safety programs, and identifies areas where food safety producers go wrong.

Rounding out the editorial lineup for this issue is a brief summary of recent food safety recalls reported by the FDA, as well as a list of new and on-demand Food Safety FREE webinars offered by TÜV SÜD America.

We hope that you enjoy this issue of Food Safety E-ssentials. If you have comments or suggestions on how we can improve this e-newsletter, or ideas for future topics, please let us know. Thanks!



Craig Casillas  
Vice President of Management Services  
TÜV SÜD America Inc.

## An Overview of Food Safety System Certification (FSSC) 22000



The growing interest in certification programs that verify compliance with food safety standards reflects the continued importance of mitigating potential food safety risks throughout the entire distribution chain. But the effort and time required to achieve food safety certification is often compounded by seemingly duplicative efforts to achieve and maintain other management systems certifications, such as ISO 9001 (for quality management systems) and ISO 14001 (for environmental management systems).

In response to industry interest in an independent food safety certification scheme more closely aligned with the approach and structure of existing management systems, the Foundation for Food Safety created the Food Safety System Certification (FSSC) 22000 food safety certification scheme. Based on independent standards produced under the auspices of the ISO (International Organization for Standardization), FSSC 22000 is a recognized food safety scheme under the Global Food Safety Initiative (GFSI). Since its inception in 2010, more than one thousand FSSC 22000 certificates have been issued by the more than 60 FSSC associated certification bodies operating worldwide.

This article provides an overview of the FSSC 22000 certification scheme. It discusses the differences between FSSC 22000 and other food safety schemes, as well as the potential benefits of FSSC 22000 certification for food producers and suppliers.

### WHAT IS FSSC 22000?

The FSSC 22000 certification scheme for food safety management systems is based on the international standard ISO 22000, *Food safety management systems—Requirements for any organization in the food chain, and ISO/TS 22002-1, Prerequisite programs on food safety—Part 1: Food manufacturing*. By design, the certification and auditing scheme in FSSC 22000 is similar to those found in other management systems schemes, such as ISO 9001 (quality management) and ISO 14001 (environmental management).

FSSC 22000 covers the processing and manufacturer of a wide range of foods, including the following products:

- Perishable animal products, such as meat, poultry, eggs, dairy and fish products
- Perishable vegetal products, like packaged fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables and preserved vegetables
- Products with long shelf life at ambient temperature, including canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar and salt
- Biochemical food ingredients like vitamins, additives and biocultures, but excluding technical and technological aids

FSSC 22000 can also accommodate the requirements of packaging manufacturers through the addition of Publicly Available Specification (PAS) 223:2011, *Prerequisite programs and design requirements for food safety in the manufacture and provision of food packaging*.

FSSC 22000 was developed with the support of the European Food and Drink Association (CIAA) and the American Groceries Manufacturing Association (GMA), in an effort to address industry requests for an independent, ISO-based food safety scheme. The scheme can be applied to all

types of organizations within the food chain, regardless of ownership, size or profit status. FSSC 22000 was fully recognized as a food safety certification scheme by the GFSI in 2009

## STRUCTURE OF THE SCHEME

The structure of the FSSC 22000 certification scheme is presented in the document *Food Safety System Certification 22000*, issued by the Foundation for Food Safety Certification, and last updated in October 2011. The document consists of an introduction, and four main parts, as follows:

*Part 1—Requirements for organizations that require certification*—This part references ISO 22000 as the source for the requirements for the development, implementation and maintenance of an organization's food safety program, and the basis for decisions by certification bodies regarding FSSC 22000 certification. In addition, technical specifications (TS) that detail specific programs for different types of organizations in the food chain can be used along with ISO 22000.

*Part 2—Requirements and regulations for certification bodies*—This part of the FSSC 22000 certification scheme stipulates the requirements for certification bodies, and the processes used to assess an organization's qualifications for certification. This part references ISO/TS 22003, *Food safety management systems—Requirements for bodies providing audit certification of food safety management systems*, for additional guidance related to food safety certification.

*Part 3—Requirements and regulations for providing accreditation*—This part details the requirements for the accreditation of certification bodies, and includes requirements for accreditation and regulations for the assignment of accreditation bodies. In brief, the certification process must be in compliance with the requirements of ISO/IEC 17021, *Conformity assessment—Requirements for bodies providing audit and certification*

*of management systems*, and the complementary requirements of ISO/TS 22003.

*Part 4—Regulations for the Board of Stakeholders*—This part of the FSSC 22000 certification scheme outlines the regulations governing the activities of the Board of Stakeholders regarding its operation of the scheme.

## DIFFERENCES BETWEEN FSSC 22000 AND OTHER FOOD SAFETY SCHEMES

The FSSC 22000 food safety certification scheme differs in important ways from other current food safety schemes and standards, such as the Safe Quality Food (SQF) scheme operated by the Safe Quality Food Institute (SQFI), the IFS Food standard and the BRC Global Standard for Food Safety. The sections below address some of the key differences.



## BASED ON INDEPENDENT, INTERNATIONAL STANDARDS

Unlike other GFSI-recognized food safety certification schemes based on standards developed by specific stakeholder organizations, the FSSC 22000 scheme uses international, independent ISO standards along with additional requirements. These standards are developed and regularly reviewed and updated by food safety experts from all sectors of the food supply chain, including producers and processors, retailers and even food regulatory authorities. All standards development work is coordinated under the auspices of the ISO, thereby providing assurances of objectivity, independence and transparency.

## A MANAGEMENT SYSTEM APPROACH TO CERTIFICATION

The FSSC 22000 food safety certification scheme follows the structure of other

widely used management systems certification programs such as those for quality management (ISO 9001) and environmental management (ISO 14001) systems. This characteristic results in an audit approach that is different from process and/or product-focused food safety certification schemes.

Instead of an annual audit, the FSSC certification audit process consists of a three year audit cycle, which includes the following stages:

- Stage 1:* Stage 1 of the FCCS audit represents an initial review of the existing food safety management system and HACCP plan to assess depth of coverage and completeness.
- Stage 2:* Conducted after the initial review, Stage 2 of the audit involves a thorough assessment of the implementation and effectiveness of the existing food safety system. A successful Stage 2 audit results in certification, which is valid for three years.
- Stage 3:* Annual surveillance audits are conducted to determine whether the food safety system is being consistently and effectively implemented and maintained. A full re-certification audit is then conducted on the third anniversary of the original certification to review the entire system. A successful re-certification audit will extend the certification for an additional three years.

In addition to the differences in the audit cycle, the FSSC 22000 audit and certification process is closely aligned with that of other management systems, with an emphasis on management commitment and continuous improvement over time.

## INTEGRATION WITH OTHER MANAGEMENT SYSTEMS

The FSSC 22000 scheme is based on ISO 22000, a management system standard specific to the management and maintenance of food safety. As

such, it follows the same format as other management system standards, including ISO 9001 (for quality management), ISO 14001 (for environmental management) and SA 8000 (for corporate responsibility management). The management system basis that is common to these standards allows for closer integration of efforts to achieve and maintain certifications for multiple management systems, saving time and expense. It also facilitates the development of an organization-wide integrated approach to management system, further supporting the achievement of corporate objectives.

### **BENEFITS OF FSSC 22000**

Presently, the FSSC 22000 scheme for food safety management systems covers the manufacturing of food products and food ingredients, based on technical requirements found in ISO 22000 and ISO/TS 22002-1. As noted above, FSSC 22000 can also accommodate food packaging manufacturers by applying the requirements of PAS 223: 2011. Additional TS documents are currently being developed for packaging manufacturers and for other sectors of the food supply chain, including food growers, restaurants and animal food producers. As these and other TS documents are developed and

released, the scope of FSSC 22000 will be extended, eventually covering the whole food supply chain.

Further, all FSSC approved certification bodies must be reviewed and accredited against the management system requirements detailed in ISO/IEC 17021. The use of this standard assures across-the-board uniformity and consistency in the auditing and certification of food safety programs for compliance with the requirements of the FSSC 22000 scheme. In addition, the FSSC scheme includes an ongoing integrity program to review the performance of certification bodies, including an assessment of individual certification body performance against standard indicators, a review of audit reports by independent experts, and a formal complaint and appeal procedure.

Finally, the FSSC 22000 food safety scheme is fully transparent. All relevant information regarding the scheme is available at no cost at the FSSC website ([www.fssc22000.org](http://www.fssc22000.org)), including scheme requirements, contact information for all approved certification bodies, and the names of the members of the program's Board of Stakeholders. Unrestricted access to this information allows food producers

and manufacturers to fully research the scheme and independently determine its applicability to their specific situation.

### **CONCLUSION**

A recognized GFSI food safety scheme, the FSSC 22000 program is based on independent, international standards and offers food producers and manufacturers the flexibility to integrate their food safety management efforts with other management system efforts. TÜV SÜD is a licensed certification body under the FSSC 22000 scheme, and TÜV SÜD America food safety professionals can provide auditing and training on FSSC 22000 as well as other food safety programs and standards.

TÜV SÜD America staff can also evaluate and verify HACCP plans for compliance with regulations of the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). For more information, contact John Petie, Food Safety Program Manager at [jpetie@tuvam.com](mailto:jpetie@tuvam.com), or at 978-573-2609. ■

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## **TÜV SÜD America to present at Food Safety Summit**

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John Petie, TÜV SÜD America's Food Safety Program Manager, will present as part of the Food Safety Summit's Exhibitor Showcase Theatres. The Showcases are special learning areas set up on the exhibition hall floor and are free to attend and are open to all registered attendees.

Please join John for his presentation on *Verification and Validation (V&V) - What is the Difference?*

Date: Wednesday, April 18th

Time: 3:30-4:00 PM

Location: Theatre B

Please also stop by and meet our Food Safety experts at Booth #402.

For more information, please visit <http://www.foodsafetysummit.com>. ■



## Validation and Verification in Food Safety: What's the Difference?



This article offers a brief overview of food safety program validation and verification activities, within the context of Global Food Safety Initiative (GFSI), including Safe Quality Food (SQF) and British Retail Consortium (BRC) food safety schemes.

### WHAT IS VALIDATION?

Validation involves conducting scientific tests and experiments to demonstrate that the specific parameters chosen are sufficient to determine whether or not a product is safe for human consumption. In the area of food safety, it is documentary evidence that the testing and evaluation parameters chosen for prerequisite programs (PRPs) and critical control points (CCPs) are supported by empirical data, regulation, or a combination of both, and will achieve the desired level of safety.

Because regulatory requirements are usually supported by a wealth of scientific data, validation activities often involve the review and application of regulatory requirements. However, reliance on regulatory requirements alone is usually not sufficient to provide assurances of food safety. Validation testing should be performed using the equipment and processes performing the activity.

(For example, cooking temperatures and times are found in USDA Schedule A. The use of this document is only one piece of the required validation. The second part is to actually run heat penetration studies in the most severe conditions and in various

locations to ensure the temperature throughout the heating chamber.)

### WHAT IS VERIFICATION?

Verification, on the other hand, is the process of ensuring that validated parameters are being monitored and tested in the prescribed manner and at the prescribed frequency necessary to ensure safety.

Verification can be achieved in a number of ways, for example:

- Making independent, direct observation of the system (either people or equipment) designed to monitor the parameter
- Conducting independent testing and measurement to determine if the results are consistent
- Conducting an independent review of applicable paperwork
- Conducting an independent review of equipment calibration methods, results and records;

### HOW DO VALIDATION AND VERIFICATION INTERRELATE?

Validation ensures that the correct parameters have been identified and stipulated to control for a specific risk. Verification provides assurances that the stipulated parameters are being applied and followed on a consistent basis in day-to-day operations. In other words, validation is identifying the steps necessary to reduce risk to an acceptable level, and verification is making sure that the requisite steps and actions are being performed as prescribed.

### HOW ARE VALIDATION AND VERIFICATION USED WITHIN THE GFSI CONTEXT?

Validation and verification activities are directly referenced in Version 6 of the SQF Food Safety Code, as well as in Issue 6 of the BRC Global Standard for Food Safety, as follows:

#### *Validation—SQF Version 6 (4.5.2.1)*

“The methods, responsibility and criteria for validating Pre-requisite Programs and critical food safety and quality limits to ensure they achieve their intended purpose shall be documented and implemented. The methods applied shall ensure that:

- Critical limits are selected to achieve the designated level of control of the identified food safety hazard(s) or threat to the achievement of food quality; and
- All critical limits and control measures individually or in combination effectively.”

#### *Validation—BRC Global Standard for Food Safety, Issue 6*

“Confirmation through the provision of objective evidence that the requirements for the specific intended use or application have been fulfilled.

- 2.7.3 - The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing pre-requisite programs, this shall be stated and the adequacy of the program to control the hazard validated. Consideration shall be given to using more than one control measure.
- 2.9.2-The HACCP team shall validate each CCP. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.”

#### *Verification—SQF Version 6 (4.5.3.1 and 4.5.3.2)*

“The methods, responsibility and criteria for verifying the effectiveness of monitoring Pre-requisite Programs, critical control points, critical quality points and other food safety and quality controls identified shall

be documented and implemented. The methods applied shall ensure:

- i. Personnel with responsibility for verifying monitoring records sign and date each record verified....

Records of the verification of monitoring activities shall be maintained.”

*Verification—BRC Global Standard for Food Safety, Issue 6*

“Confirmation through the provision of objective evidence that the requirements have been fulfilled.”

### SO WHY DO PEOPLE FAIL TO GET IT RIGHT?

There are several key reasons why validations and verification activities

related to food safety fail. First, many food safety professionals don't really understand the meaning of the terms validation and verification, and how validation and verification activities should be applied to their food safety processes. Second, companies fail to implement a detailed and documented food safety process that supports validation and verification activities, including procedures, defined activities for each PRP or CCP, and forms for documenting those activities. Third, there is little or no review of food safety process, thereby allowing non-compliance issues to fester. Finally, data and/or information generated by the process is not reviewed or is misinterpreted.

John Petie, TÜV SÜD America's Food Safety Program Manager, and Debra Tesch Kriss, Director of Food Safety and Quality at Schwann's Shared Services LLC will present an one-hour webinar on the subject of "Verification and Validation" on Thursday, May 17th, at 1pm (EST). For more information on this complementary webinar, or to register, go to <http://www.tuvam.com/industry/foodsafetyservices.cfm>.

For more information, contact John Petie, Food Safety Program Manager, at [jpctie@tuvam.com](mailto:jpctie@tuvam.com), or at 978-573-2609. ■

## Recent Food Safety Recalls

The U.S. Food and Drug Administration has announced the following voluntary recalls of food products due to potential health issues:

### CREAM PUFFS WITH MISLABELED MILK ALLERGEN:

Crème Curtis Bakery of Hudsonville, MI has initiated a nationwide recall of its Simply Enjoy brand frozen vanilla cream puffs. According to the company, the recalled cream puffs contain sodium caseinate, but the label does not identify milk as the source of sodium caseinate. Consumers with allergic reactions to milk may be at risk, and the company has received one consumer report of an allergic reaction. The cream puffs were distributed nationwide through retail grocery chains.

### MINI CHOCOLATE CHIP COOKIES WITH UNDECLARED WALNUTS:

Whole Foods Market has recalled certain mini chocolate chip cookies sold in stores in Arkansas, Louisiana, Oklahoma and Texas. According to the company, the cookies contained undeclared walnuts. The recall was initiated when a labeling error

was discovered by an employee, and no illnesses have been reported in connection with the recalled cookies.



### JALEPENO PEPPERS WITH SALMONELLA:

Castellini Company LLC is recalling certain jalapeno peppers due their potential contamination with salmonella. The recalled peppers were sold to commissaries, food service distributors and retailers in ten mid-western states between March 8th and March 20th, 2012. The recall was initiated following a random test by the Ohio Department of Agriculture. No illnesses have been reported in connection with the recalled product.

### CHEESE WITH LISTERIA MONOCYTOGENES:

El Ranchero Del Sur, LLC of South River, NJ

has announced the recall of a variety of cheeses and cheese products that may be contaminated with listeria monocytogenes. The company says that the recalled cheeses and cheese products were distributed to retail stores, supermarkets and restaurants located in New Jersey and Pennsylvania through mid-March 2012. The product recall was initiated following testing by the New Jersey Department of Health and Human Services.

### BEEF STEW MIX CONTAINING UNDECLARED MILK:

McCormick & Company has issued a voluntary recall for a selected lot of its beef stew mix sold by Publix Super Markets in Alabama, Florida, Georgia, Tennessee and South Carolina. According to the company, the recalled stew mix may have been mispacked with brown gravy and may contain undeclared milk. No illnesses have been reported in connection with the recalled product.

### FRUIT PIES WITH UNDECLARED EGGS:

Price Chopper Supermarkets is recalling its Price Chopper Bakery five and eight inch apple, blueberry, cherry and peach streusel

pies. The company says that the ingredients label does not note that the streusel topping contains eggs, a potential allergen for some consumers. The recalled product was sold in Price Chopper stores in New York, Vermont, Connecticut, Pennsylvania,

Massachusetts and New Hampshire. The above recalls were voluntarily initiated by the food producers involved. However, under the Food Safety Modernization Act of 2011, the FDA has the authority to order mandatory recalls of unsafe food in those

instances where a company fails to issue a voluntarily recall of its own accord. Additional details regarding these and other food product safety recalls are available at the FDA's website at [www.fda.gov/safety/recalls](http://www.fda.gov/safety/recalls). ■

## TÜV SÜD America Announces New Food Safety Webinars

As part of our ongoing effort to provide industry professionals with the latest in food safety information, TÜV SÜD America is pleased to announce a new line-up of live webinars. Please visit <http://www.tuvam.com/tuvnews/webinars.cfm> for additional information and to register.

TOPIC	DATE
Verification and Validation— What's the Difference?	Tuesday, May 17, 2012
Pitfalls of GFSI	Thursday, June 14, 2012
GFSI Food Standards Comparison	Thursday, August 16, 2012
Packaging Food Standards Comparison	Thursday, September 13, 2012

TÜV SÜD America also offers on-demand access to a number of other webinars that may be of interest to food safety professionals. To access any of these on-demand food safety webinar programs, go to <http://www.tuvam.com/tuvnews/webinars.cfm>. ■

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