

Validation and Verification: A Practical, Industry-driven Framework Developed to Support the Requirements of the Food Safety Modernization Act (FSMA) of 2011

Robert E. Brackett,^{1*} Wilfredo Ocasio,² Kevin Waters,² Jeffrey Barach³ and Jason Wan¹

¹Institute for Food Safety and Health, Illinois Institute of Technology, 6502 South Archer Road, Bedford Park, IL 60501, USA

²The National Food Laboratory LLC, 2441 Constitution Drive, Livermore, CA 94551, USA

³Barach Enterprises LLC, 2904 Melanie Lane, Oakton, VA 22124, USA

ABSTRACT

A joint workshop of industry and academia, The Preventive Controls Summit 2013 — Validation and Verification Principles, was held in October 2013 to gather input and current thinking on the validation and verification practices industry needs in order to comply with new Food Safety Modernization Act (FSMA) regulations. The workshop discussions resulted in development of a framework approach that proposes several activities that are important to achieve FSMA food safety goals and regulatory requirements. These include: (1) using science-based tools to construct and validate effective preventive controls for hazards, (2) considering validation and verification as separate programs, and (3) managing the food safety system with appropriate verification activities and conscientious staff that can recognize and adapt when change is needed. The framework strategy was built around the background teachings of the Hazard Analysis and Critical Control Points (HACCP) validation and verification principles, industry experiences and the information provided in the proposed FSMA rules. This white paper describes such a framework and suggests how food industry companies can meet Food and Drug Administration (FDA) expectations regarding FSMA validation and verification activities. With over 150 industry and academia participants sharing their ideas and input at breakout sessions, this framework represents a broad spectrum of current thinking regarding this important subject.

PREFACE

Why the Summit and Framework?

Purpose

The purpose of this white paper and framework is to assist food companies in meeting the validation and verification requirements that are expected to be promulgated in response to the Food Safety Modernization Act. Experience with Hazard Analysis Critical Control Point (HACCP) systems has shown that to build an effective Food Safety Management System that is scientifically and technically sound, it is essential to have scientific evidence of preventive control effectiveness (validation) and to assess compliance with the Food Safety Plan and the supporting programs (verification). Regardless of size, all establishments need to validate and verify the activities described in their Food Safety Plan and the risk-based preventive controls that have been or will be implemented to control food safety hazards. A framework approach is offered to provide the user with a set of tools and guidance will make it easier to accomplish

the tasks of validation and verification. The framework builds on existing industrial practices and guidance on how to conduct and document validation and verification tasks.

Applicability

The production of safe food is the responsibility of food establishments. This means that not only must companies meet minimum regulatory requirements but they should endorse and establish programs and practices that exceed the basic requirements. Companies recognize that this enhanced level of responsibility is not only good business, but is “the right and responsible thing to do.” This white paper is intended to offer practical guidance to assist all size food facilities to meet their validation and verification requirements under the Food Safety Modernization Act (FSMA) regulations and to give insight into how companies can build world class food safety systems that meet regulatory requirements, minimize or eliminate food safety risks, and demonstrate enhanced stewardship.

Facilities initiating a new Food Safety Management System to meet FSMA requirements, as well as those currently implementing voluntary HACCP, should benefit from the approaches and practices described here to help them develop a new Food Safety Management System or to upgrade their current system so as to be better positioned to address FSMA regulations and enhance the safety of their products. It is important to note that this document is not a one-size-fits-all guide. Each company must decide on its own what is the best way to develop and implement the operational and regulatory programs needed to address validation and verification requirements. For small- to medium-size companies, this may be especially challenging and could mean they will need to seek outside expertise when establishing the programs for their Food Safety Management System.

INTRODUCTION

The Food Safety Modernization Act (FSMA) of 2011 and the proposed regulations (9) gives the Food and Drug Administration (FDA) a mandate for regulatory oversight of food safety systems that scientifically addresses hazards and that puts greater emphasis on preventing foodborne illness rather than just managing food safety failures. The intended outcome of these new regulations is to further ensure the United States' food supply is safe by shifting the focus away from responding to contamination and toward preventing it. FSMA advances the principles and practices of the globally accepted HACCP systems approach to a new level of managing food safety issues. Like HACCP, FSMA is a risk-based safety management approach focused on hazard analysis and prevention of problems in order to ensure the production of food products that are safe to consume. They are both based on a common-sense application of technical and scientific principles to the food production process from harvest to production and to consumption. The seven principles of HACCP are incorporated into the FSMA framework and are applicable to all aspects of food production that FDA regulates. FSMA carries forward the most basic concept underlying HACCP, that prevention is far more effective than inspection.

By themselves or with the assistance of others, food establishments should have sufficient information concerning the food and the related production procedures they are using to be able to identify where and how food safety problems may occur. If the “where” and “how” are known, risk-based prevention becomes manageable. As noted early on with those adopting HACCP, finished product inspection and testing is not

the most effective way to ensure food safety. A modern Food Safety Management System deals with hazard analysis and control measures (resulting in specific process controls, operational controls, and prerequisite programs) affecting the safety of ingredients, the processes, and the product. The objective is to use risk-based decisions, based on sound science, with a systems approach to make the product safe and to enable management to prove its safety.

Many in the food industry are already familiar with HACCP and its principles; however, some are seeking additional resources to help them upgrade their Food Safety Management System to conform with FSMA regulations. Experience with HACCP has shown that two of the system's operational activities are typically difficult to understand and can be complicated to put into practice. The hazard analysis and the assignment of preventive controls require a level of food safety experience and significant knowledge of hazards and controls. The activities of validation and verification are likewise difficult concepts to grasp and present a challenge to the food safety team. The hazard analysis activity and how it is achieved is sufficiently described in available literature and technical publications; however, industry has recognized the need for additional assistance and guidance with FSMA validation and verification. Industry leaders at the Institute for Food Safety and Health (IFSH) and The National Food Laboratory, LLC (The NFL) assembled a workshop, The Preventive Controls Summit 2013 — Validation and Verification Principles, on October 9, 2013, to provide helpful guidance to assist industry with the understanding, establishment, and implementation of the principles of validation and verification in development of FSMA food safety plans.

VALUE OF A FRAMEWORK APPROACH WITH MANAGEMENT INVOLVEMENT

HACCP principles were first adopted by the industry and subsequently incorporated into U.S. and international regulatory schemes. This shifted the primary food safety focus away from the activities of regulatory inspection to a more comprehensive “systems approach” that utilizes the power of prevention to mitigate food safety hazards. Although the systems approach is more complex, it is more effective than a mode of action that reactively finds and fixes problems. Experience with many years of HACCP implementation has shown that validation and verification activities remain somewhat difficult to understand and manage because their functions are often interpreted

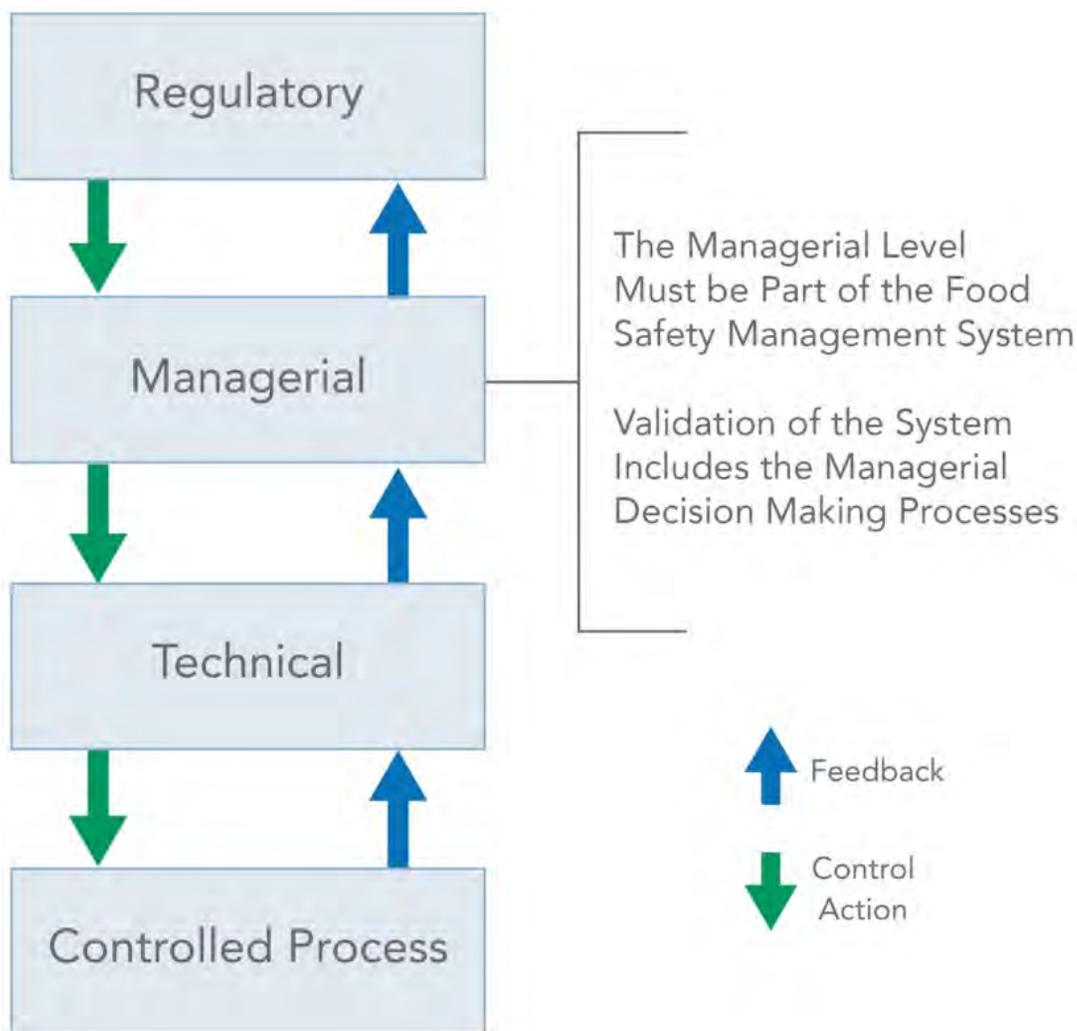
HACCP Principles

- 1 Hazard Analysis
- 2 Critical Control Points
- 3 Critical Limits
- 4 Monitoring
- 5 Corrective Actions
- 6 Verification, including Validation
- 7 Record-keeping

differently than intended. The food safety team may find these concepts hard to grasp and conclude that it is difficult to derive a comprehensive Food Safety Management System that operates effectively. In simple terms, difficulty is generally related to: (1) the distinction between monitoring procedures and verification activities and; (2) the differences between validation and verification activities and actions. Since validation is generally described as one of the activities of verification, the two become intertwined and the distinction between the two can become vague. This ambiguity can result in confusion and an inappropriate food safety plan.

The framework approach presented here is a way to deconstruct the two activities (validation and verification) into simple language that allows even inexperienced persons to understand what needs to be done and

to assemble resources, both internal and external, to address the tasks. A framework can convey a systems pathway describing what tasks to do, how to go about doing them and how these actions make the Food Safety Management System more effective. A framework can also remove barriers to understanding and implementation, as well as assist management with proper training and task inspection. There is value in considering these two activities within the context of a systems structure. Other industries have considered applying system engineering approaches to enhance safety. Nancy Leveson (19) has proposed the application of system engineering to pharmaceutical safety, with potential outcomes of enhancing the safety of current drugs while at the same time encouraging the development of new drugs.



Adapted from graphic by John Helferich, Engineering Systems Division, Massachusetts Institute of Technology (MIT)

FIGURE 1. The food safety management system: Systems–Theoretic based design showing a hierarchical safety control structure

The FSMA shifts the food safety focus away from reaction and response and toward prevention, so that prudent preventive measures can be built into all parts of the Food Safety Management System. Following a framework can guide development of system components and provide ongoing improvements in safety by adopting proven safety strategies and addressing structural constraints. In order for the system to be effective and to function properly, all managers must be deeply committed and engaged with all aspects of the program. One may ask, “Who is responsible for the safety of products produced?” As was confirmed by the Summit participants, several levels of employees (corporate management, supervisors and lineworkers) set the tone and carry out the food safety functions that lead to a first class food production operation. For validation and verification activities, the same is true. It takes: (1) corporate managers to set the policies and standards, define accountability, and identify the roles of all, and (2) supervisors and line workers to implement the programs and ensure that the functions are effective and are carried out properly. Generally one person has ownership of the food safety program and policy for the company. This individual’s role is oversight of establishment and effectiveness of the system, implementation, management of operations, change management, and setting a goal of continuous improvement. Many companies have assigned this role to a manager with a title such as Vice President (VP) of Food Safety or Food Safety Coordinator.

One often overlooked means of achieving a truly dynamic and resilient system is that of providing managers and workers with information about changes occurring with food safety hazards and emerging risks, thus allowing them the ability to develop new means of addressing these new vulnerabilities. Information shared across all levels of the Food Safety Management System about new risks, changes in the production process, management changes, consumer complaints, production failures, and near-misses enhances the continuous improvement of the process by triggering revalidations and verification tasks. The application of system engineering practices through the required verification activities will also improve food safety system outcomes.

Figure 1 shows the integration of management into a Food Safety Management System, a Systems-Theoretic based design. Safety is enhanced through managerial involvement and decisions regarding process changes. Managers are an integral part of the Food Safety Management System. Thus, validation and verification of the system must include the manager’s role and responsibilities in the Food Safety Management System. An important aspect is the need for management to be included in the Food Safety Management System and for processes to be routinely validated and verified with the collection of data and documentation regarding the performance of the system. Part of food safety verification is the opportunity for continuous improvement to avoid future failures. With the tools of corrective actions for non-conformance occurrences and record keeping with review, management can continually revise and improve the food safety system making it more effective. Progress on improving safety therefore ultimately depends on providing workers and managers with the information and data about changing vulnerabilities and then giving them the ability and means for meeting these challenges (14).

VALIDATION AND VERIFICATION

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) defines verification as those activities, other than monitoring, that determine the validity of the HACCP plan and verify that the system is operating according to the plan (21). There are two objectives to the 6th HACCP principle: (1) to determine if the plan is valid, i.e., that it is adequate to control hazards associated with the product when the plan is properly implemented, and (2) to verify that the HACCP system is operating according to the plan, i.e., that the plan is being followed.

It is important to realize that application of this principle includes a wide array of activities in two major areas, validation of efficacy and verification of compliance. The fact that the NACMCF definition of verification includes the activities of validation has resulted in much confusion about which activities are verification and which are validation. Perhaps changing the names would lessen the confusion.

Do!

- ✓ Divide validation and verification into separate tasks.
- ✓ Think of validation as your scientific evidence and proof the system controls the hazards.
- ✓ Think of verification as an audit process.
- ✓ Use science-based information to support the initial validation.
- ✓ Use management to participate in validation development and operations of verification.
- ✓ Use lessons from “near-misses” and corrections to adjust and improve the food safety system.

Nevertheless, it will be helpful to many to consider validation and verification as distinct functions. The role and position of these operations in a FSMA food safety system is shown in *Fig. 2*. They help complete the systems approach and, as shown, have a major role in the initiation, implementation, reanalysis, and audit aspect of system improvement.

Initial validation of the food safety system (FSS) determines if the system is doing the right thing and effectively controlling the hazard. Once the food safety system is initiated and operational, verification of the system ensures that the system has been implemented correctly and followed. Validation activities that result from reanalysis and verification audits supply the continuous improvement of the food safety system. The foundation of the Food Safety Management System is the Corporate Food Safety Policy and in turn a functioning Food Safety Culture. Management's job is both to establish the environment for a strong functioning food

safety system and to ensure personnel help to complete the cycle depicted within the food safety system so that the Food Safety Management System always controls the food safety hazards.

Validation

Validation consists of establishing and documenting the scientific evidence that food safety hazards are being effectively controlled through preventive means. That proof can come from a variety of sources (e.g., scientific literature, in-house studies, mathematical modeling, and regulatory resources). An "initial validation" takes place as the food safety system is being developed and during its initial implementation. The goal is to ensure that the food safety system is valid (i.e., actually works) for controlling food safety hazards associated with the operations, ingredients, process, and product. The importance of selecting and establishing the correct science-based procedures during the validation process



FIGURE 2. Validation and verification of the food safety management system

cannot be overstated. It does no good to monitor and verify ineffective control measures. Often, small- to mid-sized companies will not have sufficient internal expertise to determine the scientific basis for their validation processes. To complement internal staff, external expert guidance and outside resources may be needed for complex validation activities. In documenting the scientific basis for control, the validation team establishes a validation plan to be used for validating the food safety system ([Appendix A-1](#)). This information forms part of the structure and support documentation that regulatory agencies will seek as they inspect the company's food safety plan.

Validation, then, is considered an ongoing component of the system that is set in place initially, and one that may need revision if certain aspects of the operations, management, food safety objective, ingredients, or the process changes. A significant change or a scheduled review (the proposed FSMA rule says at least once every 3 years) could trigger a "reanalysis" of the safety needs to adjust the parameters of control (such as modifying critical limits because of discovery of a more resistant pathogen). The reanalysis could lead to a new revalidation that replaces the initial validation in response to new information suggesting the system needs to be revised (see [Appendix A-2](#), and its list of reasons for reanalysis). Thus, the primary objective of validation is to: (1) set the initial scientific basis for the preventive controls' ability to effectively control the hazards, and (2) make adjustments in the controls, if needed, to ensure the food produced is safe. This type of systems approach, being conducted before, during, and after a scheduled time frame, is very effective in establishing and maintaining food safety as well as in providing continuous improvement.

Some well-known and established rules for achieving food safety, often used as the basis for process controls, are referred to as "safe harbors." The proper use of safe harbors can give legitimacy to a control measure, but caution is advised to ensure that if a safe harbor (see examples in FDA's Juice or Fish and Fishery Products Hazards and Control Guides) ([10](#), [11](#), [12](#), [24](#), [25](#)) is used, it is seen as a starting point that needs to be carefully reviewed for applicability to the

specific product and process. The validation team must be sure to connect the safe harbor and the process details together for it to be valid and for it to achieve "doing the right thing" from the standpoint of an effective and science-based validation.

Not all control measures are amenable to validation in the way most process controls can be validated. For example, potential physical hazards from a vegetable slicer could be mitigated by a suitable preventive maintenance program. Validation of the preventive maintenance program for the slicer would use a different type of proof than validation of a thermal kill step. The preventive maintenance program, as designed by the equipment manufacturer and the plant operations and maintenance staff, would have procedures with proven efficacy as part of the program.

Verification

Verification activities are performed to ensure that preventive controls are consistently implemented and are effectively carried out ([Appendix A-3](#)). Verification should be carried out by someone other than the person responsible for performing the monitoring and corrective actions. If certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

Examples of verification activities include (see also [Appendix B](#)):

- Review of the food safety plan and its records,
- Review of deviation analyses and product dispositions,
- Confirmation that CCPs and other Preventive Controls are kept under control, and
- Ensuring that proper change control procedures are in place and are followed.

Where possible, verification activities should include actions to confirm the efficacy of all elements of the food safety system (see [Appendix A-3](#)).

The FSMA proposed regulations (9) are in line with the NACMCF (1997) ([21](#)) regarding the definition and intent of verification. FSMA defines verification as "those activities, other than monitoring, that establish the validity of the Food Safety Plan and that the system is operating according to the

Don't!

- ✓ Confuse the activities of verification with those of routine monitoring.
- ✓ Rely on literature or studies that are unlike your process/product to prove controls are valid.
- ✓ Conduct audit processes and then not review the results.
- ✓ Perform corrective actions without determining if a system change may be needed to fix the problem.
- ✓ Forget, reanalysis is done every 3 years or sooner if new information or problems suggest.

plan.” Thus, two objectives of verification under FSMA are very similar to those of HACCP regulations:

1. Determine if the plan is effective, i.e., that it is adequate to control hazards associated with the product when the plan is properly implemented; and
2. Verify that the system is operating according to the plan, i.e., that the plan is being followed.

Verification activities, which ensure that preventive controls are consistently implemented and followed, should include confirmation that the preventive controls are adequate for their purpose and are controlling the hazard. Confirmation activities include measures that verify that controls are operating as intended and that reviews of monitoring records have occurred. In some cases, environmental testing programs that are science-based may be used as verification activities in some sectors of the

food industry. Another source of verification that the food safety system is working can come from positive remarks when customer responses are reviewed or when only a small number of unremarkable consumer complaints are observed.

DEFINING THE FRAMEWORK

The breakout sessions during the Summit helped define the framework being presented. The insights and takeaways from the discussions were based on points on which industry leaders agreed with regard to the context and responses of the questions posed at their sessions. The key questions and their respective answers from each of the three breakout sessions (Defining Validation and Verification, Validation Practices and Tools, and Managing and Implementation) can be viewed in the following lists, along with the highlights captured from the participants’ discussions.

Breakout 1: Defining Validation and Verification

KEY QUESTIONS	KEY INSIGHTS
What are the tasks and their definitions?	Multiple definitions exist from HACCP and now from FSMA. It is important to keep all these tasks separate (monitoring, validation and verification) and to understand their role in food safety.
What are the differences between validation and verification?	Validation is “doing the right thing (using sound science) to control the hazard” and verification is “confirmation (using auditing) that you are doing what you said you should do and that it is effective.”
What will FSMA preventive controls require in addition to HACCP for validation and verification?	The requirements are nearly identical. FSMA may go beyond traditional validation of critical control points and may require verification/ validation of some prerequisite programs.
What is the scope of validation and verification and when does validation end and verification begin?	Validation is applied to the food safety plan; including some prerequisites, the hazard analysis, preventive controls, and corrective actions. Management participation, documentation and change control programs enhance the effectiveness of validation. Verification is applied to some prerequisite programs, preventive controls, the food safety plan, corrective actions and regulatory compliance once the plan has been validated and implemented. With the start of production Validation and Verification work side by side for continual improvement.

Breakout 2: Validation Practices and Tools

KEY QUESTIONS	KEY INSIGHTS
<p>We know what has been written, but does it work?</p>	<p>While validation can be done using different approaches and many useful documents have been written (1, 22), strong endorsement is given to the use of Codex (CAC/GL 69-2008, Guidelines for the Validation of Food Safety Control measures) (4). This guidance is recommended for the following reasons: Codex is recognized as a scientifically sound source It is an international standard that is widely accepted throughout the world, and The guidance document is clear, well written and matches well with the requirements of the Preventive Controls Rule</p>
<p>How does industry currently conduct validation (i.e., validation plan)?</p>	<p>Industry uses tools like guidelines, worksheets, checklists, examples, and outlines (see Appendices) to assist with these tasks. However, industry lacks consensus and consistency in what control measures require validation and how the validations are conducted. Some control measures, such as those used in aseptic filling operations to control microbiological hazards, are highly refined, while others, such as those used for extrusion, baking and drying, must be further developed. It is evident that the validation template developed over many years for activities such as canning and aseptic applications could serve as a “blueprint” for other applications. External resources are often used (13, 15, 16, 17, 18, 20). In these applications, the use of a qualified individual presiding over a validation team consisting of subject matter experts serves as the basis for a successful validation.</p>
<p>What does work and are there tools that still need to be developed?</p>	<p>Many useful tools exist, as evidenced through publications by NACMCF, Codex, scientific literature and industry guidelines, to assist with these tasks (see references and resources). The scientific literature, through peer reviewed documents, provides sufficient validation data for many applications. In other cases, it is best to use scientific information from the public domain combined with validation (experimental) activities focusing specifically on the given process/product. Also, most of these tools focus on microbiological hazards. Additional tools and guidance are needed for chemical and physical hazards. Furthermore, more “safe harbor” processes for addressing microbial hazards are urgently needed. “Safe harbor” processes and/or microbial challenge studies conducted using “worst-case” product/formulas/processes allow processors to cover various products/formulations with a single effort rather than multiple validation efforts as new product/processes are introduced.</p>
<p>Are universal approaches (like safe harbors) and models helpful?</p>	<p>Mathematical models such as the application of D and z values in the development of thermal processing have proven extremely useful (2, 3, 5, 6, 7, 8, 23). However, careful consideration should be given as to the applicability of information available in the scientific literature to a specific food/process. Mathematical models and safe harbors can be used successfully as a screening procedure or preliminary steps in the development of effective control measures. Such models need to be carefully reviewed for applicability to the specific product and process by a qualified individual.</p>

Breakout 3: Managing and Implementation

KEY QUESTIONS	KEY INSIGHTS
Who are the different people that have responsibility of the validation/verification program and what are their roles?	Management sets the “food safety culture” and defines the plan and implementation steps. Management also ensures the system is working through verification. Line workers implement the plan and conduct operations to make the plan work. A Food Safety Coordinator is responsible for the overall design, development and effectiveness of the food safety system.
What are the qualification needs for each of the responsible individuals?	Corporate Management: Understanding of the importance of food safety; Food Safety Coordinator: trained in FSMA implementation; Line Workers: basic food safety training with emphasis on sanitation, allergens and process controls.
Is validation an “individual” or a “team” function?	Validation is a multifunctional task and is best accomplished by a team with varied knowledge and skills.
If some of the validation is outsourced, how does the processor manage responsibility?	The effectiveness of validation is proven through verification tasks that reflect conditions of safety such as absence of recalls, limited incidences of non-conformance, and minimal relevant consumer complaints.
What are the responsibilities and roles of those in the change control program?	Routine review and following change management guidelines is essential for continued safety of the system. This includes procurement, production, quality assurance and legal staff.
What is the technical expertise required to support validation?	The validation team needs to be able to scientifically understand the process and develop the documentation needed to demonstrate the process is safe. In some cases management may need to identify the need for external expertise.

The participants expressed that, although HACCP regulations were implemented over 15 years ago, the aspect of verification, including validation, and its role in a food safety system has been especially challenging for many food establishments, and even today it remains a complex task. We anticipate that companies developing food safety systems for FSMA will face similar complexities in designing systems and implementing them because of an incomplete understanding of these two concepts, their operational functions, and the value they bring to the Food Safety Management System.

Therefore, the framework built upon the findings of the Summit is designed to:

- Clarify the requirements of validation and verification for a Food Safety Management System,
- Designate the importance of these practices and provide available tools and resources,

- Show the integration and importance of these activities within the Food Safety Management System, and
- Provide examples and outlines to facilitate system design and understanding.

The following table and graphic (*Fig. 3*) are presented to explain the steps and component parts of the framework and describe the outcome regarding food safety.

CONCLUSIONS

This white paper presents a framework suggesting how food industry companies can meet FDA expectations regarding FSMA validation and verification activities. The framework was built around the background teachings of the HACCP validation and verification principles, industry experiences, and the information provided in the proposed FSMA rules. The guidelines expressed here represent the shared ideas and best practices from more

THE FRAMEWORK STEPS

1. Use available tools, such as guidelines, outlines, worksheets, examples and checklists, to assist with organizing what needs to be done and how it should be done. Use external resources for science-based validation when internal expertise is not present.
2. Treat the programs of validation and verification separately.
3. Ensure all levels of employees (corporate management to line workers) are engaged in a food safety culture, trained to their task and empowered to manage change in the system to achieve continuous improvement.



FIGURE 3. Framework for understanding and implementing FSMA validation and verification requirements

than 150 industry and academia participants that were captured in the Preventive Controls Summit 2013 during three breakout sessions. The framework focuses on the specific activities that are important to achieve FSMA food safety goals and to meet regulatory requirements. The approach presented here recommends: (1) use of science-based tools to construct effective controls for hazards, (2) consideration of validation and verification as separate programs, and (3) management of the food safety system with responsible and qualified staff who can recognize and adapt when change is needed.

DEFINITIONS

FSMA Definitions:

Validation: That element of verification focused on collecting and evaluating scientific and technical information to determine whether the Food Safety Plan, when properly implemented, will effectively control the identified hazards.

Verification: Those activities, other than monitoring, that establish the validity of the food safety plan and ensure that the system is operating according to the plan.

Reanalysis: Activity required whenever a significant change is made in the activities conducted at a facility if

the change creates a reasonable potential for a new hazard or if a significant increase in a previously identified hazard makes it likely that reanalysis would occur more frequently than every 3 years because such changes are likely to occur more frequently than every 3 years (described as a set of requirements in the proposed rules, not as a definition).

Codex HACCP Definitions:

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.

NACMCF HACCP Definitions:

Validation: That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and ensure that the system is operating according to the plan.

ACKNOWLEDGMENTS

The following task force members (*) and speakers/panelists are acknowledged for their contributions in organizing and participating in The Preventive Controls Summit 2013 — Validation and Verification Principles:

David Anderson (Del Monte Foods), Dimitrios Apostolopoulos (Ruprecht Company), Jeanne Arens* (Illinois Institute of Technology, IIT), Tim Birmingham (Almond Board of California), Glenn Black (Grocery Manufacturers Association, GMA), Matt Botos* (ConnectFood), Deanne Davis* (Kraft Foods Group), Kurt Deibel* (HJ Heinz), John Helferich (Massachusetts Institute of Technology, MIT), Scott Hood* (General Mills), Tim Jackson* (Nestlé North America), Dawn Johnson* (Institute for Food Safety and Health, IFSH, IIT), Jeff Korengel* (ConAgra Foods), Jeff Kornacki (Kornacki Microbiology Solutions, Inc.), Cindy Koschetz* (IFSH, IIT), John Larkin* (FDA), Eric Larson* (Safe Foods International Holdings, LLC), Loralyn Ledenbach* (Kraft Foods Group), Nancy Leveson (MIT), Daryl Lund (University of Wisconsin-Madison), Alejandro Mazzotta* (Campbell Soup Company, currently Chobani), Joan Menke-Schaenzer* (ConAgra Foods), Phil Minerich* (Hormel Foods Corporation), William Moeller* (Safe Foods International Holdings, LLC), Theodora Morille-Hinds* (Kellogg Company), Dale Morton* (PepsiCo), Ruth Petran (Ecolab), Skip Seward (Seward Global Consulting), Faye Sigers* (Keen Scout, LLC), Priya Sundaram* (Kraft Foods Group), Katherine Swanson (KMJ Swanson Food Safety, Inc), Greg West (National Pasteurized Eggs, Inc.), B Wu* (Safe Foods International Holdings, LLC).

REFERENCES

- Almond Board of California (ABC). 2007. Validation guideline documents. Almond Board of California. Modesto, CA. Access June 26, 2014, at: <http://www.almondboard.com/Handlers/Documents/pem%20book.pdf>.
- American Meat Industry Foundation (AMIF). 2010. Instructions for using the AMI Process *Lethality Determination Spreadsheet, named Process Lethality Spreadsheet - August 2010.xls*. Access June 26, 2014, at: <http://www.amif.org/process-lethality/>.
- Anderson, D. G., and L. A. Lucore. 2012. Validating the reduction of *Salmonella* and other pathogens in heat processed low-moisture foods. Alliance for Innovation & Operational Excellence, Alexandria, VA. Access June 26, 2014, at: <http://community.pmmi.org/Alliance/Home>.
- Codex Alimentarius Commission. 2008. Guideline for the validation of food safety control measures (CAC/GL 69-2008).
- ComBase Consortium. 2011. ComBase predictive software. (2009). Collaborative effort of the Institute of Food Research (IFR) in the United Kingdom, the USDA Agricultural Research Service (USDA-ARS) in the United States, and the University of Tasmania Food Safety Centre (FSC) in Australia. The website is hosted by Institute of Food Research, Norwich Research Park, Colney, Norwich NR4 7UA, UK. Access June 26, 2014, at: <http://www.combase.cc/index.php/en/all-articles/83-combase-software/combase-predictivemodels/113-predictive-models>.
- Doyle, M. E., and Alejandro S. Mazzotta. 2000. Review of studies on the thermal resistance of salmonellae. *J. Food Prot.* 63:779-795.
- Duffy, G., A. Ellison, W. Anderson, M. B. Cole, and G. S. A. B. Stewart. 1995. Use of bioluminescence to model the thermal inactivation of *Salmonella* Typhimurium in the presence of a competitive microflora. *J. Appl. Environ. Microbiol.* 61:3463-3465.
- Ellison, A., W. Anderson, M. B. Cole, and G. S. A. B. Stewart. 1994. Modelling the thermal inactivation of *Salmonella* Typhimurium using bioluminescence data. *Int. J. Food Microbiol.* 23:467-477.
- Federal Register. 2013. Current good manufacturing practice and hazard analysis and risk-based preventive controls for human food, January 16, 2013: 78(11), p. 3646.
- Food and Drug Administration (FDA). 2004. Guidance for industry: Juice HACCP hazards and controls guidance. 1st ed. Part V — Control Measures. Food and Drug Administration, Washington, D.C. Access June 26, 2014, at: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm072557.htm>.
- FDA. 2011a. Fish & fishery products hazards & controls guide, 4th ed. Appendix 4. Food and Drug Administration, Washington, D.C. Access June 26, 2014, at: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm2018426.htm>.
- FDA. 2011b. Grade "A" pasteurized milk ordinance. (FDA Public Health Service – PMO, 2011 Revision).
- Grocery Manufacturers Association (GMA). 2009. Control of *Salmonella* in low-moisture foods; and, Annex to Control of *Salmonella* in low-moisture foods. Access at: www.gmaonline.org.
- Hollnagel, E., D. Woods and N. Leveson. 2006. Resilience engineering: Concepts and precepts. Ashgate Publishing Co., Vermont, USA.
- International Commission on Microbiological Specifications for Foods (ICMSF). 1996. Microorganisms in Food 5. Microbiological Specifications for Foodborne Pathogens. Blackie Academic & Professional, London.

16. ICMSF. 2002. Microorganisms in Food 7. Microbiological Testing in Food Safety Management. Kluwer Academic & Plenum Publishers, New York.
17. ICMSF. 2005. Microorganisms in Food 6. Microbial Ecology of Food Commodities. 2nd edition. Kluwer Academic & Plenum Publishers, New York.
18. ICMSF. 2011. Microorganisms in Food 8. Use of Data for Assessing Process Control and Product Acceptance. Springer, New York.
19. Leveson, N., M. Couturier, J. Thomas, M. Dierks, D. Wierz, B. Psaty and S. Finkelstein. 2012. Applying system engineering to pharmaceutical safety. *J. Healthcare Eng.* 3(3):391–414.
20. Mazzotta, A. S. 2001. Thermal inactivation of stationary-phase and acid-adapted *Escherichia coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* in fruit juices. *J. Food Prot.* 64:315–320.
21. National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1997. Hazard analysis and critical control point principles and application guidelines. USDA/FSIS. Washington, D.C. (Subsequently published in 1998, *J. Food Prot.* 61:762–775).
22. Scott, V. N. 2005. How does industry validate elements of HACCP plans? *Food Control* 16:497–503.
23. United States Department of Agriculture - Agricultural Research Service (USDA ARS). 2011. Pathogen Modeling Program (PMP) Online. Access June 26, 2014, at: <http://pmp.errc.ars.usda.gov/PMPOnline.aspx>.
24. USDA Food Safety Inspection Service (USDA/FSIS). 1999. Process control verification criteria and performance standard regulations for meat and poultry products. Appendix A – Compliance guidelines for meeting lethality performance standards for certain meat and poultry products. Appendix B – Compliance guidelines for cooling heat-treated meat and poultry products. Federal Register 64: 746, January 6, 1999.
25. USDA/FSIS. 2005. Meat and poultry hazards and controls guide. Food Safety and Inspection Service, Washington, D.C. Access June 26, 2014, at: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5100.2/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf.

APPENDIX A. Validation and Verification Outlines

A-1 Initial Validation Outline

Elements to be in place prior to validation:

1. Corporate Food Safety Policy
2. Food Safety Culture
3. Management System
4. Development of Food Safety Team (internal/external resources)
 - Development of validation team, by name and function
 - Development of list of additional resources (external experts, etc.), by name and role
5. Development of Food Safety Plan
 - Known regulatory requirements
 - Prerequisite programs in place (for example: sanitation control, maintenance and repair, pest control, change control, etc.)
 - Identification of hazards (via the hazard analysis) that need to be controlled and the designated preventive control measures to mitigate the hazards
 - Identification of the food safety outcome required

Steps involved in initial validation: Developing a written validation approach

1. Assemble relevant validation information and data, conduct studies where needed for missing information
 - a. Evaluation of product and process
 - i. Are all product descriptions available and correct food safety characteristics identified?
 - ii. Do all products have a valid process flow?
 - iii. Have all of the production steps been assessed regarding adequate control measures for all biological, physical and chemical hazards?
 - iv. Are all of the hazards for all raw materials correctly assessed?
 - b. Product category safety, history, and trends
 - i. Are there any emerging hazards that need to be included?
 - ii. Are there any recent trends in hazard identification?
 - iii. Are there changes/trends that indicate process capability needs to be reassessed?
 - iv. Are there any trends in consumer complaints?
 - c. Preventive control management
 - i. Based on a Codex type decision tree, or another analysis tool, are the appropriate preventive controls applied?
 - ii. Are the preventive controls documented appropriately at the plant?
2. Analyze the results from the information and data collected for food safety implications
 - a. Determine and implement corrective actions
 - b. Decide if the step, procedure, SOP, program and control measure is sufficient and can be implemented
 - c. If not, modify parameters, equipment, procedures, etc. to address the control measure
3. Document the results and approve the validation plan
 - a. Management agrees with results of the validation plan – with signatures
 - b. Management is engaged with implementation of the validated plan
 - c. Documentation identifies conditions when the plan needs to be revalidated
 - d. Documentation is archived for use during reanalysis/revalidation

Note: These outlines were developed for informational purposes only and are not intended to replace the processor's validation and verification programs or procedures. Each company must decide on its own what is appropriate regarding validating and verifying the elements of its food safety system.

A-2 Validation Reanalysis Outline

Identify members of the validation team by name and function

Identify any additional resources (external experts, etc.) by name and role

Date of Reanalysis/Revalidation _____

Date of Previous Validation _____

Process under Reanalysis _____

Potential Reasons for Validation Reanalysis:

- It has been 3 years since last validation
- A new product, process or processing equipment has been added or changed
- A significant change in formulation has occurred that suggests a need for reanalysis
- New/different hazard(s) have been identified
- Preventive controls are not appropriate or no longer controlling hazards
- Critical limits or parameters are no longer valid (e.g., due to new experimental/regulatory data)
- Monitoring actions (procedures and/or frequency) are no longer assessing the effectiveness of the preventive control
- Corrective actions are too frequent and/or not effective
- Ongoing verification activities (including validation) do not ensure that food safety system is adequate to control hazards and that the procedures are consistently being followed
- Records do not provide adequate documentation that the procedures/employees are doing what they are assigned to accomplish
- A new or updated regulatory requirement is identified
- Other reason(s) for reanalysis

Reanalysis Outline

1. Review prior written validation approach and procedures
2. Assemble relevant validation information and data, conduct studies where needed to address any changes to the product/process
 - a. Evaluation of product and process
 - i. Are all product descriptions available and correct food safety characteristics identified?
 - ii. Do all products have a valid process flow?
 - iii. Have all of the production steps been assessed regarding adequate control measures for all biological, physical and chemical hazards?
 - iv. Are all of the hazards for all raw materials correctly assessed?
 - b. Product category safety, history, and trends
 - i. Are there any emerging hazards that need to be included?
 - ii. Are there any recent trends in hazard identification?
 - iii. Are there any trends in deviations in process capability?
 - iv. Are there any trends in consumer complaints?
 - c. Preventive control management
 - i. Based on a Codex type decision tree, or another analysis tool, are the appropriate preventive controls applied?
 - ii. Are the preventive controls documented appropriately at the plant?
3. Analyze the results from the information and data collected for food safety implications
 - a. Determine and implement corrective actions
 - b. Decide if the revised step, procedure, SOP, program and control measure is sufficient and can be implemented
 - c. If not, modify parameters, equipment, procedures, etc. to address the control measure
4. Document the results and approve the written validation procedures
 - a. Management agrees with results of the validation procedures – with signatures
 - b. Management is engaged with implementation of the validated procedures
 - c. Documentation identifies conditions when the procedures need to be revalidated
 - d. Documentation is archived for use during reanalysis/revalidation

Next Revalidation Due Date _____

Note: These outlines were developed for informational purposes only and are not intended to replace the processor's validation and verification programs or procedures. Each company must decide on its own what is appropriate regarding validating and verifying the elements of its food safety system.

A-3 Verification Outline

Identify members of the verification team by name and function

Identify any additional resources (external experts, etc.) by name and role

1. Procedures/Systems to be Verified

- a. Routine verification activity as per the Food Safety Plan
- b. Step, activity, program or item to be verified
 - i. Prerequisite Programs (e.g., periodic evaluation of raw materials to verify compliance with a certificate of analysis, preventive maintenance, equipment operations, etc.)
 - ii. Process Controls (e.g., pasteurization)
 - iii. Sanitation Controls (e.g., environmental monitoring to confirm absence of pathogens on equipment used to package Ready-to-Eat foods)
 - iv. Allergen Controls (e.g., proper labeling of product where allergens are present)
- c. Verification process
 - i. Records review
 - ii. Calibration
 - iii. Independent check (e.g., on-site observation, pH check, temperature measurement, or sampling and testing)
 - iv. Other procedure

2. Activities/Actions to be Verified

- a. Prerequisite Programs
 - i. The standard operating procedure (SOP) is followed correctly
 - ii. The SOP is up to date
 - iii. Those responsible for SOP operations are properly trained
- b. Preventive Controls
 - i. Monitoring is done correctly
 - ii. Equipment is calibrated accurately and as per schedule
 - iii. An independent check is used to confirm the critical limits or parameters are within those needed to control the hazard
- c. Components of the Food Safety System
 - i. Personnel are performing activities and following procedures as assigned by the written Food Safety Plan
 - ii. The record keeping system is establishing and maintaining accurate and appropriate records for both operations and regulatory review
 - iii. Corrective actions are carried out as described in the Food Safety Plan
 - iv. The Recall Plan is verified to be effective, as demonstrated by a mock recall
 - v. Regulatory compliance (for example: do the records meet the requirements of the regulation)

3. Procedures/Systems to be modified if verification uncovers inadequacy or non-conformance

- a. Required corrective action
- b. Recommended actions to improve the food safety plan
- c. Documentation of change control
- d. Management agreements – with signatures
- e. Changes that require a step, procedure, or process to be revalidated

Note: These outlines were developed for informational purposes only and are not intended to replace the processor's validation and verification programs or procedures. Each company must decide on its own what is appropriate regarding validating and verifying the elements of its food safety system.

APPENDIX B. Verification Activities – Examples*

1. Verification Procedures May Include:
 - a. Establishment of appropriate verification schedules
 - b. Review of the Food Safety Plan for completeness
 - c. Confirmation of the accuracy of the flow diagram
 - d. Review of the Food Safety Plan to determine whether the facility is operating according to the plan
 - e. Review of Preventive Control monitoring records
 - f. Review of records for deviations and corrective actions
 - g. Review of modifications of the Food Safety Plan
 - h. Sampling and testing to verify Preventive Controls

2. Verification Should be Conducted:
 - a. Routinely to ensure that Preventive Controls are under control
 - b. When there are emerging concerns about the safety of the product
 - c. When foods have been implicated as a vehicle of foodborne disease
 - d. To confirm that changes have been implemented correctly after a Food Safety Plan has been modified

3. Verification Reports May Include Information on the Presence and Adequacy of:
 - a. The Food Safety Plan and the person(s) responsible for administering and updating the Food Safety Plan
 - b. The records associated with Preventive Control monitoring
 - c. Direct recording of monitoring data of the Preventive Control while in operation
 - d. Certification that monitoring equipment is properly calibrated and in working order
 - e. Corrective actions for deviations
 - f. Sampling and testing methods used to verify that Preventive Controls are under control
 - g. Modifications to the Food Safety Plan
 - h. Training and knowledge of individuals responsible for monitoring Preventive Controls

* Adapted from NACMCF. 1997. *Hazard analysis and critical control point principles and applications guidelines* (21).