Validation of Microbial Reduction Processes For Spices*

American Spice Trade Association

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*Although some elements of this document may apply to seasonings, a separate evaluation should be made by seasoning manufacturers.

Executive Summary

The American Spice Trade Association (ASTA) developed the current white paper to assist the spice industry in validating microbial reduction techniques. Validation is a preemptive, or prospective, exercise by which quality and safety are built into the product via controls in the manufacturing process that maximize the probability that the finished product meets the expectations of regulators and consumers. Validation should focus on the critical control point(s) used to deliver the desired log reduction in *Salmonella* or other target organism. Here, ASTA recommends six sequential phases for validation of microbial reduction processes. Our approach emphasizes control of sources of variability that may influence the performance of the process, and hence, affect the quality and safety of the product.

Phase 1: Assemble a multi-disciplinary team to plan and oversee validation activities

- A team approach ensures that processes, protocols, and timelines are realistic and that relevant considerations are not overlooked.

Phase 2: Develop a master validation plan

- The master plan gives structure to the validation project, and specifies individual responsibilities, project phases, benchmarks, timelines, and budget.

Phase 3: Identify sources of product and process variability

- Preliminary trials may also be necessary to gain a complete understanding of sources of process and product variability and their impact on the process and product.
- Sources of variability that affect the results of microbial challenge studies must also be considered.

Phase 4: Develop and test validation protocols

- The three main protocols used to validate a microbial reduction process are 1) the "installation qualification" (IQ) protocol, which confirms that the equipment is installed correctly; 2) the "operational qualification" (OQ) protocol, which confirms that the lethality step delivers the critical limits required for the target log reduction, and 3) the "performance qualification" (PQ) protocol, or inoculation challenge, which determines the extent to which the process inactivates the target organism or a surrogate organism (ie, a non-pathogen used in place of the target organism if validation is performed in a food processing facility).

Phase 5: Prepare a validation report

- This report will aid future validation studies and may be requested by internal stakeholders, public health organizations, industry groups, or regulatory authorities.

Phase 6: Perform continuing process verification

- Once a process is validated, systems must be established to assure that the process remains in a state of control during full-scale commercial operation.

A successful validation requires diverse expertise, detailed planning, and a keen eye for sources of process variability. Protocols for measuring and testing the process are central to the validation project, and appropriate documentation is essential for demonstration of compliance with the Food Safety Modernization Act.

I. Introduction

The American Spice Trade Association (ASTA) is committed to assisting its members in assuring that spices sold to food processors and consumers are safe and wholesome. Because most spices are grown in developing countries where sanitation and food handling practices may not be adequate, the spice industry must develop processes that effectively and reliably eliminate pathogens from spices. Historically, *Salmonella* is the most common bacterial pathogen associated with product recalls and outbreaks in spices. The ASTA guidance document *Clean, Safe Spices* (ASTA, 2011) outlines control measures necessary to address *Salmonella* and other contaminants present in spices that may pose a public safety risk. The Guidance includes five principle recommendations:

1. Minimize risk for introduction of filth throughout the supply chain
2. Prevent environmental contamination, cross-contamination, and post-processing contamination during processing and storage
3. Use validated microbial reduction techniques
4. Perform post-treatment testing to verify a safe product
5. Test to verify a clean and wholesome manufacturing environment

ASTA developed the current white paper to assist the spice industry in validating microbial reduction techniques, a prerequisite for recommendation #3 above. The Codex Alimentarius ("Codex") defines validation as *obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome*. (Codex, 2008) Similarly, FDA has defined validation as *the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product*. (FDA, 2011) Thus, validation is a preemptive, or prospective, exercise by which quality and safety are built into the product via controls in the manufacturing process that maximize the probability that the finished product meets the expectations of regulators and consumers. (Keener and Roberts, 2011) Hazard Analysis and Critical Control Points (HACCP) is an example of another preemptive strategy that reduces the risk of food safety hazards in finished products by identifying and controlling the potential risks in the process. (ASTA, 2006) Process validation should not be confused with *verification*, which, according to the Codex, is *used to determine that the control measures have been implemented as intended*. (Codex, 2008) Verification is a retrospective process that involves testing, record inspection and/or inspecting finished products, and food scientists agree that food safety cannot be achieved through these measures alone. Furthermore, the cost to eliminate a defective product at the customer phase is estimated to be five times that required to correct a defect in the manufacturing phase. (Keener and Roberts, 2011)

Process validation has been used by the medical device and pharmaceutical industry for decades, (Keener and Roberts, 2011) and the canned food industry has applied the concept of validation to their processes since the implementation of the low-acid canned food (LACF) regulations in the 1970s. (Surak and Stier, 2009) Still, process validation has not been widely adopted by the food processing industry, nor has it been required by regulators until passage of the Food Safety Modernization Act. Only juice, meat, and seafood are currently subject to the preventive requirements of HACCP in the US. (Keener and Roberts, 2011) However, the Food Safety Modernization Act (FSMA), an amendment to the Federal Food, Drug, and Cosmetic Act, was signed into law on January 4, 2011. (FSMA, 2011) The FSMA aims to ensure the U.S. food supply is safe by shifting emphasis from incident response to prevention of contamination. FSMA requires food safety plans for the entire food industry. FSMA language relating to hazard analysis is consistent with the HACCP approach outlined in ASTA's HACCP Guide for Spices and Seasonings. (ASTA, 2006) FSMA Section 103 includes the following passage:

> In General.--The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

In FDA's proposed rule on preventive controls for human food, proposed §117.150(a)(1) would require that preventive controls be validated by a qualified individual. Specifically, FDA states:

> *"The validation of preventive controls includes collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies), as discussed in the next section of this document. The collected data or information, or the studies, would establish a scientific and technical basis for the preventive controls used, in particular those that involve critical control points. This scientific and technical basis largely must be established prior to producing a product to ensure that the food produced using those preventive controls will be safe. However, as a practical matter, the scientific and technical basis for some aspects of a preventive control may require production conditions and, thus, would be established by the collection of data or information during, rather than before, producing a product. For example, ensuring that limits for control parameters can be met during production would be done under production conditions. FDA tentatively concludes that preventive controls that require the collection of data or information, or studies, during production conditions are part of validation, and, thus proposed § 117.150(a)(1)(i) would require that the validation of preventive controls be performed, when necessary, during the first six weeks of production." (78 Federal Register 3753)*

Thus, spice manufacturers must develop a system of hazard identification, preventive controls, monitoring, and verification to control the safety of their finished products.

II. Approaches to Validation

As stated in *Clean, Safe Spices* (ASTA, 2011):

> Validation should focus on the critical control point(s) used to deliver the target log reduction. When a lethality step is needed to inactivate potential contaminants such as *Salmonella*, the processing parameters used should be adequate to inactivate the level of the organism likely to be present. Validation of lethality steps for spices involves determining the critical limits (eg, thermal and time parameters) required to achieve a significant reduction in the target organism and confirming the process equipment consistently delivers the critical limit parameters (NACMCF, 1998; Scott et al., 2006).

The Codex (Codex, 2008) describes several approaches to validation that are pertinent to microbial reduction processes. These approaches may be used individually or in combination with one another.

A. Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure

Scientific or technical information required for appropriate validation of a control measure may be found in the scientific literature, government guidance, international standards, or previous validation studies conducted by equipment manufacturers or industry. However, it is important to avoid assuming that a process is valid based solely on these data. The spice processor must verify that the process, process

conditions (eg, equipment, relevant hazards, control measures), and the product in the published report match those under study. (Codex, 2008)

B. Mathematical modeling

Mathematical modeling is a means of integrating scientific data on how factors affecting the performance of a control measure or combination of control measures affect their ability to achieve the intended food safety outcome. For example, D- and z-values derived from product-specific Thermal Death Time (TDT) studies or the published literature are often used to determine thermal process lethality in high-moisture canning and meat products and while it may be used for modeling in low-moisture foods, awareness of differences need to be included. (Anderson and Lucore, 2012) D-value is the time required to destroy 90% of cells or reduce the microbial load by 1-log under specified conditions. Z-value is the increase in temperature (°F) required to reduce the thermal death time by a factor of 10. These values are dependent on the product matrix, and other factors such as density both of the product and treatment configuration. Thus, effective use of mathematical modeling requires that a model be appropriately validated for a specific food application. Furthermore, validation based on mathematical modeling should take into consideration the uncertainty/variability limits associated with the models' predictions.

C. Scientifically valid experimental data that demonstrate the adequacy of the control measure

If relevant and adequate experience does not exist with respect to the performance of a process in controlling a particular hazard within a specified context, validation of a control measure by experimental trials is required. This approach to validation is the focus of the recommendations that follow.

III. Validation of Microbial Reduction Processes

Here, ASTA recommends six sequential phases for validation of microbial reduction processes. Our approach emphasizes control of sources of variability that may influence the performance of the process, and hence, affect the quality and safety of the product. The recommendations draw on existing guidance for the food, (GMA, 2010; ICMSF, 2011; Codex, 2008; Anderson and Lucore, 2012; Keener and Roberts, 2011) pharmaceutical, (FDA, 2011) and medical device (GHTF, 2004) industries and the expertise of ASTA members with experience in process validation. The goal is a process validation study that answers three core questions:

1. **Is the equipment installed correctly?**

   This question will be answered by the Installation Qualification (IQ) protocol.

2. **Does the process consistently deliver the physical requirements (eg, time/temperature profile), and critical control limits, that have been determined to achieve the target log reduction?**

   This question will be answered by the operational qualification (OQ) protocol, which confirms that the equipment performs as intended.

3. **Is the target lethality being consistently achieved?**

This question will be answered by the performance qualification (PQ) protocol, which determines the extent to which the process inactivates the target organism (eg, *Salmonella*) or a surrogate organism of equal or greater resistance. The presence of *Salmonella* or other target organism must be reduced to an extent sufficient to prevent illness. The extent of necessary reduction is usually determined by the estimated extent to which *Salmonella* may be present in the spice, combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1000 (ie, 3 logs) *Salmonella* organisms per gram of product and a safety factor of 100 (ie, 2 logs) is employed, a process adequate to reduce *Salmonella* would be a process capable of reducing the organism by 5 logs per gram. (FDA, 2012) When the extent to which a target organism is present in the spice is not known, one should assume a 5-log reduction is required. Processors may also need to take into consideration any regulatory lethality requirements for specific products and processes.

Members of the spice trade are encouraged to apply the principles outlined in this document to new or amended control measures, and to use them to determine whether or not existing processes have been properly validated. The tools, techniques, and statistical models used to validate specific food safety control measures are beyond the scope of the document.

Phase 1: Assemble a multi-disciplinary team to plan and oversee validation activities

Validation of a microbial reduction process is a complex undertaking. A team approach will help ensure that processes, protocols, and timelines are realistic and that relevant considerations are not overlooked. The validation team is responsible for all aspects of the project, and must gain the support of stakeholders who can provide the internal manpower and financial support necessary to complete it. A validation team should include members with expertise in the following (Anderson and Lucore, 2012; FDA, 2011; GHTF, 2004; Keener and Roberts, 2011):

- Quality assurance
- Process engineering
- Research and development
- Food safety
- Maintenance
- Microbiology
- Purchasing
- Data analysis and statistics
- Project management
- Regulatory affairs

It should be noted that the validation team may need to include external consultants if the appropriate qualifications and experience does not exist internally. Manufacturers of equipment may be able to offer advice on how to confirm that their products are functioning as intended. Scientific organizations, competent authorities, process control experts, or universities may also serve as resources for expertise in design and evaluation of validation studies. (Codex, 2008) Finally, if the validation must withstand regulatory scrutiny, involvement of regulatory authorities early in the validation project will allow protocols and documentation to be tailored to meet regulatory requirements.

Phase 2: Develop a master validation plan (Codex, 2008; GHTF, 2004; Keener and Roberts, 2011)

A master validation plan is a strategic document that guides the validation project from start to finish. Its development is paramount to building consensus and gaining required approvals. It is not overly

prescriptive or detailed, but gives the project structure amid numerous complexities. The master plan specifies the following:

- Business justification for the project
- Process to be validated
- Parameters and decision criteria that will demonstrate that a control measure or combination of control measures, if properly implemented, is capable of consistently controlling the hazard to the specified outcome
- Project phases, benchmarks, and timelines
- Responsibilities of each team member
- Project budget

Phase 3: Identify sources of product and process variability

In order to successfully control a process, one must know the process, understand the limitations of the process, and remove (or reduce) variability. Sources of variability may be evident in defect complaints, batch records, in-coming spice product records, and adverse event reports. In-plant processing staff and quality assurance staff may also provide insights into process variability and should be queried during this phase of the validation project. Preliminary trials may also be necessary to gain a complete understanding of sources of process and product variability and their impact on the process and product.

Ideally, preliminary trials should be performed:

- **Using the same equipment and product as used in the process**

  Some validation studies to qualify equipment will validate the equipment alone, without performing additional studies of the equipment with the product. Although validation of the equipment without product will provide information about the operation of the equipment itself, it will not provide the necessary details relative to how that equipment functions when loaded with product. Furthermore, it will not determine how the equipment will perform when it is not filled to capacity (eg, a partially loaded drier or sterilizer) or when loaded with different types of product in the same load. Partial loads and load configurations can significantly affect equipment operations and parameters such as air flow, humidity, and heat transfer. This is true for both batch type and continuous systems. (Hardin, 2012)

- **In the same facility where the process will take place**

  Another consideration at this stage is whether or not the validation study can be performed in the processing facility. If the equipment or process was initially developed or validated by the manufacturer or a research laboratory, additional on-site or pilot plant studies may be necessary to validate the process in the facility using in-house equipment and intended products. Microbial challenge studies can be conducted on-site or in a pilot plant if validated non-pathogenic surrogate organisms are used, but should be performed in a laboratory if viable pathogens are used.

- **Under a range of actual production conditions, including "worst-case" scenarios** (GMA, 2010)

  Finally, it is important to simulate a range of usual production conditions as well as "worst-case" situations. Worse-case conditions help define the minimum processing parameters

required to ensure product safety (i.e., operating tolerances). These may include the slowest air flow, coldest temperature, maximum load size, minimum residence time in the lethality zone (for continuous processes), and least-experienced operating personnel. Characterization of worst-case conditions should be complete prior to protocol development. For example, identification of "cold spots" may require temperature or dose mapping, heat transfer distribution, or heat penetration studies. Additional evaluations are required to determine the differential between process and product temperature in cases where heat is being employed and the temperature probe will not touch the product. Studies of product residence time in equipment or changes in product moisture throughout the process may also be helpful for determining worst-case conditions. (Anderson and Lucore, 2012) Worst-case conditions should be considered for each source of variability outlined below.

Potential sources of product variability

The physical properties of raw spices are highly variable. Pre-process product variability may affect the ability of a microbial reduction process to achieve the target lethality. Product-related factors are also potential sources of variability for microbial challenge studies. These factors include:

- Formulation and form (ie, stem, pod, seeds, leaves, ground [fine, coarse, powder])
- Size, shape, and density
- Total bio-burden of product, as well as any inherent microbial resistance
- Degree of air flow allowed through the product (air spaces within spice preparations affect heat and steam transfer)
- In-going product temperature
- Fat content
- Moisture content and water activity
- Packaging and package size
- Origin (ie, supplier and batch/lot differences)

Potential sources of process variability

When validating the ability of a process to consistently deliver the physical requirements necessary to achieve the desired lethality, the following variables should be considered:

- Equipment factors (GMA, 2010)
  - Type (batch vs continuous) and brand of processing equipment
  - Design features (eg, bed thickness and length, zone setup, air flow rate, exhaust/vent locations and sizes, internal equipment [eg, temperature sensors])
  - Installation and power requirements
  - Ease of operation
  - Maintenance needs/wear and tear
  - Cleanability
  - Complexity and frequency of calibration
- Human factors (e.g., operator qualifications)
- Atmospheric conditions (temperature, humidity, light); may be particularly important in subtropical regions
- Process water purity
- Size of load and load pattern
- Drive speed

- Depth of the product on a conveyor or in a drum (ie, how far does the physical process have to travel to reach the product?)
- Uniformity of conditions (eg, temperature, gas concentration) across the dimensions of the conveyor or tunnel
    - Potential for "cold spots" or "dead spots"
    - Possible nonlinear flow in a continuous system
        - Too much vibration can create a turbulent flow that causes product to pass through the system at different rates
        - A non-level bed may result in product placed on one side of the belt having a much thicker layer than the other side of the bed and thus the thermal penetration may differ.
- Type and placement of calibrated monitoring/recording devices (eg, for process time, temperature, and relative humidity)
- Method and location of measurement of product temperature (eg, external, product center, thickest pieces)
- Changes in operating conditions and personnel from day to day and shift to shift

Additional sources of variability that may affect microbial challenge studies include (Anderson and Lucore, 2012; GMA, 2010; ICMSF, 2011):

- Choice of strain or surrogate microorganism
- Conditions under which the culture is grown (eg, substrate, environmental conditions [temperature, humidity, light])
- Phase of growth in which microorganisms are harvested
- Inoculum preparation
- Intrinsic factors of the product being inoculated (eg, form, moisture content, preservative, background microbial population)
- Product preparation prior to inoculation (eg, packaging)
- Inoculation procedures (eg, method of mixing)
- Incubation duration and conditions
- Post-process sampling for enumeration (sample size, preparation, handling [ie, compositing, homogenizing, subsampling])
- Enumeration equipment and methodology
- Lethality computation
- Duration of studies

Once all conceivable sources of product and process variability are identified, additional preliminary testing may be required to determine which sources of variability are likely to have the greatest impact on the microbial reduction process, and thus, product safety.

Phase 4: Develop and test validation protocols

Protocol development is likely to be the lengthiest, most work-intensive phase of a successful validation. Whereas the master plan is a strategic document, validation protocols are tactical and very detailed. (Keener and Roberts, 2011) Validation protocols are designed to confirm process control. The three main protocols used to validate a microbial reduction process are 1) the "installation qualification" (IQ) protocol, which confirms that the equipment is installed correctly; 2) the "operational qualification" (OQ) protocol, which confirms that the lethality step delivers the critical limits required for the target log reduction, and 3) the "performance qualification" (PQ) protocol, or inoculation challenge, which

determines the extent to which the process inactivates the target organism (eg, *Salmonella*) or a surrogate organism. All three protocols may not be required to validate a process.

Numerous protocols exist for a variety of processes, and can be found in the scientific literature and/or obtained from industry associations, private laboratories, universities, or government agencies such as the US Department of Agriculture (USDA) Agricultural Research Service and Food Safety and Inspection Service or FDA. Although existing protocols will need to be reviewed to determine how closely they mimic the product and process to which they are being applied, a careful audit of these existing resources may reduce the time and expense involved in protocol development. The validity of the methods employed in the validation protocols is also of utmost importance. Validation of a method or device in the context of validation of a broader process is difficult, and should be avoided. Methods outlined in validation protocols should be accepted, standard methods whenever possible (Keener and Roberts, 2011). For example, methods used for enumeration of bacteria during a microbial challenge study may be those accepted by the USDA or FDA. (USDA, 1998; FDA, 2007) Prerequisite program principles (eg, HACCP [ASTA, 2006], International Organization for Standardization, maintenance programs, factory acceptance testing, and current Good Manufacturing Practices [FDA, 2010]) should be integrated into IQ, OQ, and PQ protocols where appropriate.

Installation Qualification (IQ) Protocol

The IQ Protocol verifies that the equipment and its ancillary systems (or subsystems) have been assembled and installed based upon the manufacturer's drawings and/or specifications. Key elements of the IQ protocol include (GHTF, 2004):

- Person or department to oversee conduct of the protocol
- Equipment vendor selection
- Environmental requirements (eg, room cleanliness, temperature, humidity)
- Key design features
- Installation and assembly guidelines based upon manufacturer's instructions (ie, construction materials, space, vacuum pump capacities, steam generation, temperature and pressure monitoring systems, software and controls)
- Calibration, preventive maintenance, and cleaning requirements and schedules
- Spare parts list
- Documentation requirements
- References (eg, equipment manuals)

Operation Qualification (OQ) Protocol

The OQ protocol determines whether or not critical limits are being met by the microbial reduction equipment. What to measure, how to measure, when to measure, and where to measure should all be considered. Key elements of this protocol include (FDA, 2011; GHTF, 2004):

- Person or department to oversee conduct of the protocol
- Description of the process
- Usual-case and worse-case conditions under which the process should be tested
- Descriptions of "cold spots" and "dead spots" previously identified
- Operator qualifications
- Equipment that delivers the lethality step (eg, brand, model) and accessory equipment
- Equipment used to monitor the process (eg, thermometers, pressure sensors, flow meters, timers, water activity meters, belt speed controller and recorder)
- Equipment operating parameters/settings
- Products to which the process will be applied

- Process load limits
- Process parameters/equipment components to be monitored, methods for monitoring, and data to be collected
- Product parameters to be monitored during the process, methods for monitoring, and data to be collected
- Critical limits (eg, minimum temperature, time, dose requirements)
- Number of times the protocol should be repeated
- Data analysis and statistical methods
- Pass/fail criteria (including degree of inter- and intra-batch variability permitted)
- Fate of product that does not reach kill step parameters
    - Particularly important in continuous systems; some continuous systems have a bypass mechanism via which a product that does not reach the kill step parameters is sent to a reject bin and does not pass through the rest of the system
    - Continuous systems that require all product to pass through the dryer and cooler are a concern, because product that has not reached kill step parameters contaminates these components of the system
- Forms for documentation of results
- Corrective actions to be taken if critical limits/operating tolerances are not met
- References (eg, published methods or critical values)

Performance Qualification (PQ) Protocol

The PQ protocol verifies that the process is effective and repeatable. In the context of validation of a microbial reduction process, the PQ protocol determines whether or not the target lethality (ie, 5-log reduction in the target organism or a validated surrogate) is being consistently achieved. Challenge studies using a validated surrogate organism can be conducted in the processing facility, whereas those employing the target pathogen should be performed in a laboratory. Core elements of the PQ protocol are (Anderson and Lucore, 2012; FDA, 2001; ICMSF, 2011):

- Person or department to oversee conduct of the protocol
- Specification of the process or OQ protocol on which the microbial challenge test should be based
- Challenge organism and rationale for selection of surrogate
- Culture methods
    - Conditions under which the culture is grown (eg, substrate, environmental conditions [temperature, humidity, pH, light])
    - Phase of growth in which microorganisms are harvested
    - Inoculum preparation
    - Intrinsic factors of the product being inoculated (eg, form, pH, moisture content, preservative, background microbial population)
- Inoculum level (typically cells/gram) and preparation
- Inoculation methods
- Duration of the study
- Considerations/adjustments for intrinsic factors of the spice (eg, water content, water activity, antimicrobial properties)
- Storage/incubation conditions
- Sampling plan and methods
- Enumeration procedure

- Lethality computation
- Number of times the protocol should be repeated
- Data interpretation
- Pass/fail criteria (including degree of inter- and intra-batch variability permitted)
- Corrective actions to be taken if the target reduction is not met
- Forms for documentation of results
- References (eg, standard laboratory methods, justification of surrogate used)

A number of published sources provide detailed guidance for conduct of microbial challenge testing. (Anderson and Lucore, 2012; FDA, 2001; ICMSF, 2011; NACMCF, 2010) Although it is not known which organisms are the best surrogates for *Salmonella* in spices, the Almond Board of California accepts *Enterococcus faecium* NRRL B-2354 (*Pediococcus*) as a surrogate under dry and wet heat processing conditions, and *Pantoea agglomerans* as a dry heat surrogate for *Salmonella* Enteritidis Phage Type 3 (ABC, 2007). Future research will determine the most appropriate surrogates for *Salmonella* in spices.

Once the data from protocol-based validation testing has been generated, it must be analyzed for patterns and trends. Statistical process control techniques and the application of control charts are useful for this type of analysis. Involvement of a skilled statistician is essential to verifying assumptions about the applicability of the analysis method and ensuring the appropriate statistical software is employed. (Anderson and Lucore, 2012) Based on the analysis of the experimental data collected, the process may need to be adjusted or new process controls established. The testing and adjusting should be repeated until repeatability and predictability for the process can be established. Only then should the validation protocols be finalized.

Phase 5: Prepare validation report

The validation report provides a summary of how validation was conducted, how data were recorded and analyzed, and how conclusions were drawn. (Anderson and Lucore, 2012) This report will aid future validation studies and may be requested by internal stakeholders, public health organizations, industry groups, or regulatory authorities. In the latter case, the validation team must ensure that the reporting mechanism is compatible with the applicable regulatory requirements. (Keener and Roberts, 2011) Key elements of the validation report may include (Anderson and Lucore, 2012; GHTF, 2004):

- Signatures of the validation team and key contact information
- Description of process validated, including major equipment required and critical control points
- Method of validation (with reference to specific IQ, OQ, and PQ protocols or mathematical modeling methods required to repeat the validation)
- Products for which the process was (or was not) successfully validated
- Summary of key data
- Conclusions regarding the success or failure of the validation and rationale for conclusions (ie, did the process achieve the desired IQ, OQ and/or PQ outcome specified in the master validation plan?)

Phase 6: Perform Continuing process verification

Once a process is validated, systems must be established to assure that the process remains in a state of control during full-scale commercial operation. These systems should include (FDA, 2011):

- Continuous monitoring of critical control points
- Periodic microbial testing of finished product

- Facility and equipment maintenance
- Cleaning and calibration schedules
- Adherence to prerequisite programs (eg, Current Good Manufacturing Practices [FDA, 2010], HACCP [ASTA, 2006])
- Comprehensive staff training

A statistician or individual with expertise in statistical process control techniques may need to be consulted to develop data collection plans and statistical methods based on variability estimates and other process attributes. (FDA, 2011) Annual re-validation should be conducted to ensure accuracy and verify the original validation data. Once sufficient data are obtained, the time period for re-validation may be extended. Re-validation is required in response to a regulatory mandate or when a process failure occurs and the root cause of the failure cannot be readily identified and corrected. Changes in the parameters listed below require a thorough review of the validation, and in many cases, a revalidation (ICMSF, 2011; FDA, 2011):

- Source of initial contamination
- Process environment
- Equipment design
- Product or product matrix
- Packaging
- Critical control points
- Target pathogen
- Product storage conditions
- Regulatory requirements
- Sources of process variability

IV. Summary and Conclusions

Confidence in any food process begins and ends with validation. Validation involves demonstrating that a process, when operated within specified limits, will consistently produce a product meeting pre-determined specifications. A successful validation requires diverse expertise, detailed planning, and a keen eye for sources of process variability. Protocols for measuring and testing the process are central to the validation project, and appropriate documentation is essential for demonstration of compliance with the FSMA. Finally, the time and expense required for process validation are wasted if subsequent steps are not taken to ensure the process remains in a state of control (ie, the validated state).

V. Appendices

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The American Spice Trade Association (ASTA) is committed to assisting companies in the spice trade, regulators and the public in assuring an adequate supply of clean, safe spices. This white paper is intended to serve as a resource for anyone with an interest in the important subject of the validation of microbial reduction processes for spices. ASTA is not responsible for either the use or nonuse of this document and the information in it, or for any actions or failure to act by anyone using this document. It is each individual's responsibility to verify the information in this report before acting on it and ASTA urges you to consult with competent experts. It is also each individual's responsibility to comply with all relevant federal, state, and local laws, regulations and ordinances.