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(**1**) Codex GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES CAC/GL 69 - 2008

Validation: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.
IV. CONCEPT AND NATURE OF VALIDATION
Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control. Validation involves measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control.
Validation is performed at the time a control measure or a food safety control system is designed, or when changes indicate the need for re-validation (see section VII). Validation of control measures is, whenever possible, performed before their full implementation.

Interrelationships among Validation, Monitoring and Verification

There is often confusion among the concepts of validation, monitoring and verification. Validation of control measures as described in this document is different from monitoring and verification, which both take place after the validated control measures have been implemented. Monitoring and verification are the tools used to check whether the control measures are being adhered to and to demonstrate that they are operating as intended.
- Monitoring of control measures is the on-going collection of information at the step the control measure is applied. The information establishes that the measure is functioning as intended, i.e., within established limits. Monitoring activities are typically focused on “real-time” measurements and on the performance of a specific control measure.
- (**1**) *Verification is an ongoing activity used to determine that the control measures have been implemented as intended. Verification occurs during or after operation of a control measure through a variety of activities, including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design.*

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Verification definition: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

(3) NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS HACCP Principles & Application Guidelines

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 that the system is operating according to the plan.

Establish verification procedures (Principle 6)
Another important aspect of verification is the initial Validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Information needed to Validate the HACCP plan often include (1) expert advice and scientific studies and (2) in-plant observations, measurements, and evaluations. For example, Validation of the cooking process for beef patties should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty.

In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority.

APPENDIX G Examples of Verification Activities

A. Verification procedures may include:
Establishment of appropriate verification schedules.
Review of the HACCP plan for completeness.
Confirmation of the accuracy of the flow diagram.

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Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
Review of CCP monitoring records.
Review of records for deviations and corrective actions.
Validation of critical limits to confirm that they are adequate to control significant hazards.
Validation of HACCP plan, including on-site review.
Review of modifications of the HACCP plan.
Sampling and testing to verify CCPs.
B. Verification should be conducted:
Routinely, or on an unannounced basis, to assure CCPs are under control.
When there are emerging concerns about the safety of the product.
When foods have been implicated as a vehicle of foodborne disease.
To confirm that changes have been implemented correctly after a HACCP plan has been modified.
To assess whether a HACCP plan should be modified due to a change in the process, equipment, ingredients, etc.
C. Verification reports may include information on the presence and adequacy of:
The HACCP plan and the person(s) responsible for administering and updating the HACCP plan.
The records associated with CCP monitoring.
Direct recording of monitoring data of the CCP while in operation.
Certification that monitoring equipment is properly calibrated and in working order.
Corrective actions for deviations.
Sampling and testing methods used to verify that CCPs are under control.
Modifications to the HACCP plan.
Training and knowledge of individuals responsible for monitoring CCPs.
Validation activities.

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BRC Global Standard for Food Safety Issue 7 Interpretation Guideline

VALIDATION

Validation is defined as obtaining evidence that a control measure (or combination of measures), if properly implemented, is capable of controlling a hazard to a specified outcome. Validation activity is completed before the controls are introduced or when changes are expected (e.g. new products, new processes or new equipment). Validation might include:

• document and data review – previous test results, industry data, codes of practice and legislation may all contain useful information

• experiments/testing – consider tests on the product or factory environment that will demonstrate control (worst-case-scenario tests, final product tests etc.)

• challenge studies – for example microbiological tests to establish whether a micro-organism of concern can grow in the product using the relevant time/conditions

• modelling – a number of predictive tools are available.

Several worked examples of validation can be found in Codex guideline CAC/GL 69-2008, available at www.codexalimentarius.org/standards/list-of-standards

VERIFICATION

Verification is defined as obtaining evidence, on a predetermined and ongoing basis, that a control is operating within the correct parameters. Verification requires the application of methods, procedures, tests or evaluations, in addition to monitoring, to determine whether the control measure is operating as intended. Verification activities may include:

• audits – both internal and third party

• review of records (e.g. records of the monitoring of temperatures and times, or other records completed during production)

• corrective action review

• test results – depending on the control being verified, these might include final products, raw materials, swabs, rapid tests etc.

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BRC Global Standard for Food Safety Issue 7 - 17 References to Validation/Validated

2.7 LIST ALL POTENTIAL HAZARDS ASSOCIATED WITH EACH PROCESS STEP, CONDUCT A HAZARD ANALYSIS AND CONSIDER ANY MEASURES TO CONTROL IDENTIFIED HAZARDS – CODEX ALIMENTARIUS STEP 6, PRINCIPLE 1
2.7.3 The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing prerequisite programmes, this shall be stated and the adequacy of the programme to control the specific hazard Validated. Consideration may be given to using more than one control measure.

2.9 ESTABLISH CRITICAL LIMITS FOR EACH CCP – CODEX ALIMENTARIUS STEP 8, PRINCIPLE 3
2.9.2 The HACCP food safety team shall Validate each CCP.

2.14 REVIEW THE HACCP PLAN
Appropriate changes resulting from the review shall be incorporated into the HACCP plan and/or prerequisite programmes, fully documented and Validation recorded.

4.3 LAYOUT, PRODUCT FLOW AND SEGREGATION
4.3.6 Where physical barriers are not in place, the site shall have undertaken a documented risk assessment of the potential for cross-contamination, and effective, Validated processes shall be in place to protect products from contamination.

4.10.1FOREIGN-BODY DETECTION AND REMOVAL EQUIPMENT
4.10.1.2 The location of the equipment or any other factors influencing the sensitivity of the equipment shall be Validated and justified.

4.10.3METAL DETECTORS AND X-RAY EQUIPMENT
4.10.3.4 Where in-line metal detectors are used the test piece shall be placed in the product flow wherever this is possible and the correct timing of the rejection system to remove identified contamination shall be Validated.

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4.11 HOUSEKEEPING AND HYGIENE

4.11.3 Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard the cleaning and disinfection procedures and frequency shall be Validated and records maintained.

4.11.7.2 A schematic diagram of the layout of the CIP system including process piping circuits shall be available. There shall be an inspection report or other Validation that:

- systems are hygienically designed with no dead areas, limited interruptions to low streams and good system drain ability
- scavenge/return pumps are operated to ensure that there is no build-up of CIP solutions in the vessels
- spray balls and rotating spray devices effectively clean vessels by providing full surface coverage and are periodically inspected for blockages
- CIP equipment has adequate separation from active product lines (e.g. through the use of double seat valves, manually controlled links, blanks in pipework or make-or-break connections with proxy switches as interlocks) to prevent or safeguard against cross-contamination.

The system shall be reValidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.

4.11.7.3 The CIP equipment shall be operated to ensure effective cleaning is carried out:

- The process parameters, time, detergent concentrations, low rate and temperatures shall be defined to ensure removal of the appropriate target hazard (e.g. soil, allergens, vegetative micro- organisms, spores). This shall be Validated and records of the Validation maintained.

5.1 PRODUCT DESIGN/DEVELOPMENT

5.1.3 Trials using production equipment shall be carried out where it is necessary to Validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.

5.2 PRODUCT LABELLING

5.2.3 Where a product is designed to enable a claim to be made to satisfy a consumer group (e.g. a nutritional claim, reduced sugar), the company shall ensure that the product formulation and production process is fully Validated to meet the stated claim.

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5.3 MANAGEMENT OF ALLERGENS

5.3.7 Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the site shall ensure that the production process is fully Validated to meet the stated claim and the effectiveness of the process is routinely verified. This shall be documented.

5.3.8 Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens. The cleaning methods shall be Validated to ensure they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use.

6.1 CONTROL OF OPERATIONS

6.1.4 Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be Validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).

7.4 PROTECTIVE CLOTHING: EMPLOYEES OR VISITORS TO PRODUCTION AREAS

7.4.3 Laundering of protective clothing shall take place by an approved contracted or in-house laundry using defined criteria to Validate the effectiveness of the laundering process

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SQF Code - A HACCP-Based Supplier Assurance Code for the Food Industry Edition 7.2 MARCH 2014

2.1.4 Management Review (M)
2.1.4.4 Changes to food safety fundamentals and food safety plans that have an impact on the supplier's ability to deliver safe food are to be Validated.
2.1.4.5 Records of all reviews and reasons for amending documents, Validations and changes to the SQF System shall be maintained.

2.3.1 Product Development and Realization
2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be Validated by facility trials, shelf life trials and product testing.

2.3.1.3 Shelf life trials where necessary shall be conducted to establish and Validate a product's:
i. Handling, storage requirements including the establishment of "use by" or "best before dates";
ii. Microbiological criteria; and
iii. Consumer preparation, storage and handling requirements.

2.3.1.4 A food safety plan shall be Validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety.

2.3.2 Raw and Packaging Materials
2.3.2.4 Raw and packaging materials and ingredients shall be Validated to ensure product safety is not compromised and the material is fit for its intended purpose. Validation of raw materials and ingredients shall include Certificate of conformance; or certificate of analysis; or sampling and testing.

2.3.2.5 Validation of packaging materials shall include:
i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency.

ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

2.5 SQF System Verification
2.5.1.1 Validation and verification activities shall be conducted.
2.5.1.2 The frequency and methods used to Validate and verify food safety fundamentals, critical limits, and other food safety controls identified in food safety plans shall be documented and implemented and meet their intended purpose.

2.5.2 Validation & Effectiveness (M)
2.5.2.1 The methods, responsibility and criteria for ensuring the effectiveness of pre-requisite programs, and Validating critical food safety limits to ensure they achieve their intended purpose shall be documented and implemented. The methods applied shall ensure that:
i. Pre-requisite programs are confirmed to ensure they achieve the required result.
ii. Critical limits are selected to achieve the designated level of control of the identified food safety hazard(s); and
iii. All critical limits and control measures individually or in combination effectively provide the level of control required.
iv. Changes to the processes or procedures are assessed to ensure controls are still effective.
v. Critical food safety limits are re-Validated at least annually.
2.5.2.2 Records of all Validation activities shall be maintained.

2.5.6 Product Sampling, Inspection and Analysis
2.5.6.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure:
iii. All analyses are conducted to nationally recognized methods or alternative methods which are Validated as equivalent to the nationally recognized methods.

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2.8.2 Allergen Management
2.8.2.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include:
viii. Based on risk assessment, procedures for Validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.

3.7.5 Detection of Foreign Objects
3.7.5.1 The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented.
3.7.5.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, Validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

4.7.6 Detection of Foreign Objects
4.7.6.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, Validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product
and indicate when it is rejected.

5.5 Water Management
5.5.1.2 The producer shall conduct an analysis of the hazards to the water supply from source through to application, establish acceptance criteria for the monitoring of water and Validate and verify the integrity of the water used to ensure it is fit for the purpose.

5.7.4 Soil Amendment
5.7.4.2 Soil amendment protocol shall outline the methods used to treat manure and other untreated organic fertilizers ensuring:
iii. Treatment methods are Validated and treatments of organic soil amendments are verified as being in compliance with the method applied;
iv. Records of the Validation and verification of organic soil amendment treatments are maintained.

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6.5 Water Management
6.5.1.3 The producer shall conduct an analysis of the hazards to the water supply from source through to application, establish acceptance criteria for the monitoring of water and Validate and verify the integrity of the water used to ensure it is fit for the purpose.

7.5.2 Irrigation Water
7.5.2.1 Agricultural water shall be drawn from a known clean source or treated to make it suitable for use. The producer shall conduct an analysis of the hazards to the irrigation water supply from source through to application, establish acceptance criteria for the monitoring of water and Validate and verify the integrity of the water used to ensure it is fit for the purpose.

7.7.2 Soil Amendment
7.7.2.2 Soil amendment protocol shall outline the methods used to treat manure and other untreated organic fertilizers ensuring:
iii. Treatment methods are Validated and treatments of organic soil amendments are verified as being in compliance with the method applied;
iv. Records of the Validation and verification of organic soil amendment treatments are maintained.

8.5.2 Irrigation Water
8.5.2.1 Agricultural water shall be drawn from a known clean source or treated to make it suitable for use. The producer shall conduct an analysis of the hazards to the irrigation water supply from source through to application, establish acceptance criteria for the monitoring of water and Validate and verify the integrity of the water used to ensure it is fit for the purpose.

8.7.2 Soil Amendment
8.7.2.2 Soil amendment protocol shall outline the methods used to treat manure and other untreated organic fertilizers ensuring:
iii. Treatment methods are Validated and treatments of organic soil amendments are verified as being in compliance with the method applied;
iv. Records of the Validation and verification of organic soil amendment treatments are maintained.

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9.7.5 Detection of Foreign Objects
9.7.5.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, Validated and verified for operational effectiveness. The equipment shall be designed to isolate defective products and indicate when it is rejected.

10.7.5 Detection of Foreign Objects
10.7.5.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, Validated and verified for operational effectiveness. The equipment shall be designed to isolate defective products and indicate when it is rejected.

11.7.6 Detection of Foreign Objects
11.7.6.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, Validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

14.7.6 Detection of Foreign Objects
14.7.6.2 The broker shall ensure that metal detectors or other physical contaminant detection technologies at contracted sites are routinely monitored, Validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

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Guidance for Developing, Documenting, Implementing, Maintaining and Auditing an SQF System SQF Code, Edition 7.2 – Module 2: SQF System Elements

Preface
The purpose of SQF Code implementation is not only to achieve certification, but to assure constant and continual Validate and review of a supplier's SQF System for currency and completeness.

2.1.2 Management Responsibility (M)
2.1.2 Implementation Guidance
This is a key role within the supplier's facility, being the person designated by senior management to manage the development, implementation, daily operation, Validation and verification of the SQF System.
The SQF practitioner is the individual designated by senior management to develop, Validate, verify and maintain the company's Food Safety and Quality Plans, and assume control of the daily operation of the SQF System. The SQF practitioner may engage the services of an SQF consultant to assist with the development of the SQF System, or support its Validation and verification, but overall responsibility remains with the supplier through the SQF practitioner.

2.1.4 Management Review (M) Implementation Guidance
The review shall measure the effectiveness of the SQF System against the food safety and quality objectives established by senior management and the effectiveness of corrective actions taken in response to deficiencies in the System. The focus shall also be on the effectiveness of pre-requisite programs and the ongoing accuracy and Validation of the Food Safety Plan (s) and Food Quality Plan (s).
Any major changes to Food Safety or Quality Plans shall be Validated and verified before implementation.
Evidence may include: The extent to which changes in materials, process or products have been Validated. Records of product and process changes and their Validation.

2.3.1 Product Development and Realization
The supplier must have a procedure in place to ensure the safety and quality of products escalated from bench/pilot scale production to full commercial production. This will include a food safety and quality plan for new or revised

products, shelf-life trials and Validation, label declarations, allergen cross-contact trials, raw material, ingredient and packaging trials.

Any adjustments to food safety or food quality plans must be Validated and verified by the SQF practitioner prior to commercial production of the subject product.

2.3.2 Raw and Packaging Materials
All raw and packaging materials must be Validated to ensure hazards and risks to finished product safety and quality are identified and controlled. Raw and packaging materials should be included in the HACCP Food Safety Plan (refer 2.4.3) and Food Quality Plan (refer 2.4.4) to ensure that controls are in place to eliminate hazards or reduce them to an acceptable level.
Validation is testing over and above daily monitoring to ensure that established food safety and quality limits are effective, i.e., they achieve the desired results, so that the supplier can have confidence that the product and process are safe.
Validation methods will vary depending on the risk to finished product safety.
Validation for low risk materials may include certificates of analysis or certificates of conformance, provided by a trusted vendor. For high risk materials, testing and analysis is required for Validation, and must be carried out annually (refer 2.5.2).
For food-contact packaging material, this may include testing or assurances for potential chemical migration to the food product.
During the first and subsequent facility audits, the auditor will confirm compliance to this procedure; the material specification register and the process for checking compliance to specifications, Validating specifications and ensuring relevant employees have access to current copies of specifications (refer also 2.2.1).
Interview of staff conducting Validation activities
Review of records of Validation checks

2.4.2 Food Safety Fundamentals (M)
Documentation for the pre-requisite programs (PRPs) will be checked at the desk audit. This includes procedures and work instructions applicable to the relevant PRP module(s), or alternative methods of control. The auditor will confirm compliance to this element at the facility audit by interview, observation and sampling and checking records. Evidence may include:
Records of PRP Validations are available;

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2.4.3 Food Safety Plan (M)
Critical limits must be established for each CCP and must be scientifically Validated (refer 2.5.2), or justified by regulation, customer requirements or industry code of practice.
Critical limits must be re-Validated at least annually
Staff with responsibility for monitoring, Validation, verification of critical limits, or any other food safety control measures are aware of their responsibility, trained, and are carrying out their functions correctly;

2.4.4 Food quality plan
Critical quality limits are in place for every CQP, and are Validated to ensure consistent product safety;
Staff with responsibility for monitoring, Validation, verification of critical quality limits are aware of their responsibility, trained, and are carrying out their functions correctly;
2.5 SQF System Verification
Definitions of Validation and verification differ slightly from standard to standard. The GFSI Guidance Document version 6.2 defines Validation as "an activity to obtain evidence that a requirement is controlled effectively" and verification as "a confirmation through the review of effective evidence that requirements have been fulfilled." SQF uses the Codex definition. In other words, Validation applies to scientific authentication that the critical limits set for each CCP and CQP will achieve the intended results (refer 2.5.2). Verification applies to the entire SQF System and includes methods such as sampling, internal audit and re-Validation to demonstrate that the SQF System is working and is effective.
The SQF practitioner is responsible for ensuring that all Validation and verification activities are carried out.
Examples of Validation shall include studies to prove the effectiveness of critical limits. Examples could be reviewing product temperature on a scheduled thermal process, microbiological testing of product to ensure desired reduction of product rinse system and product quality panel reviews for finished product.

The SQF practitioner is responsible for establishing a frequency schedule and methods for Validating and verifying all parts of the supplier's SQF System. An SQF consultant may be utilized by the facility to aid in verification activities, however ultimate responsibility for verification and Validation must belong to the supplier management and the SQF practitioner.

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Results of Validation and verification activities shall provide input into the management review (2.1.4) and shall be used to upgrade the food safety and quality management system (2.1.3).

2.5 SQF System Verification
2.5.1 Responsibility, Frequency, and Methods Auditing Guidance
Validation and verification procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF Practitioner, interviews with other relevant staff responsible for Validation and verification activities and review of records at each facility audit. Evidence may include:
The SQF practitioner understands the need for Validation and verification activities and is competent to organize, or supervise Validation and verification activities;
There are adequate competent resources available to carry out Validation and verification activities;
A Validation and verification procedure has been prepared (refer 2.5.3);
The procedure indicates the frequency and methods used to Validate and verify all applicable aspects of the SQF System including pre-requisite programs, control measures, critical limits, all quality control measures, and other aspects contained in the food safety plan and food quality plan (refer 2.5.2);
Personnel conducting Validation activities understand their roles and responsibilities (refer 2.5.2);
The Validation and verification procedures are effectively implemented;

2.5.2 Validation & Effectiveness (M)
Confirmation of the effectiveness of pre-requisite programs and Validation of critical food safety and quality limits is vital to ensuring that the programs and limits achieve their intended purpose, resulting in the production of safe, quality food.
Validation involves testing over and above daily monitoring to ensure that established food safety and quality limits are effective, i.e. achieve the desired results, so that the supplier can have confidence that the product and process are safe. Validation methods will vary depending on the risk to finished product safety. For hazards assessed as high risk, the critical limits must be re-Validated annually.

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Critical food safety and quality limits are said to be Validated because they have been confirmed by scientific analysis. Pre-requisite programs and other food safety and quality controls, however are confirmed by observation, inspection or audit to ensure that they are achieving the desired result.
The SQF practitioner is responsible for documenting and implementing the methods, responsibility and criteria for confirming the effectiveness of pre-requisite programs and Validating critical food safety and quality limits to ensure they achieve their intended purpose. The supplier must demonstrate how the Validation methods ensure that the selected critical limits achieve the level of control required for the targeted food safety hazard or threat to product quality.
Validation methods for CCP's or CQP's must demonstrate that the hazard is adequately controlled. Possible Validation for intervention steps used in the processing of product such as a "kill" step, may be one of the following:
Scientific literature;
Peer-reviewed published research;
In-house or laboratory challenge studies;
Reference to legally defined CCP's, such as for the pasteurization of milk.

If technology is being used in a manner that is different from that described within literature or research then the supplier must demonstrate how the revised manner of use conforms to the original claim of intervention.
Validation is required for the critical limits identified for ALL CCPs and CQPs.
Validation of a CQP must prove that the chosen intervention controls the identified threat to the quality of the product.
All Validation activities must be recorded to confirm and demonstrate they have been completed.

2.5.2 Auditing Guidance
Validation procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF practitioner, interviews with other relevant staff responsible for Validation activities and review of records at each facility audit. Evidence may include:
Documentation of the methods and responsibility and criteria for ensuring the effectiveness of the pre-requisite programs;
Implementation of the methods and responsibility and criteria for ensuring the effectiveness of the pre-requisite programs;
Pre-requisite programs achieve their intended purpose;

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Critical food safety and quality limits are Validated annually or when changes to process occur;
Methods used to Validate critical limits ensure that the process step is safe (and quality criteria achieved) if critical limits are met;
Critical limits effectively provide the designated level of control;
Personnel conducting Validation activities understand their roles and responsibilities (refer 2.5.1);

2.5.3 Verification Schedule
Elements 2.5.1 and 2.5.3 require the supplier to define their Validation and verification activities.
The verification schedule shall be reviewed initially at the desk audit and compliance to the schedule by observation, interview with the SQF practitioner, interviews with other relevant staff responsible for Validation and verification activities and review of records at each facility audit.

2.5.4 Verification of Monitoring Activities
2.5.4 Auditing Guidance
The verification procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF practitioner, interviews with other relevant staff responsible for Validation and verification activities and review of records at each facility audit (refer 2.5.1).

2.5.6 Auditing Guidance Product sampling and testing procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF practitioner and other relevant staff responsible for sampling and testing, and review of records at each facility audit.
Evidence may include:
Alternative methods used are Validated as equivalent to the national approved standard methods;

2.8.2 Allergen Management
What the SQF Code says
viii. Based on risk assessment, procedures for Validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.
What do I have to do?

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Appendix 2 Allergen Cleaning and Sanitation Guide of this document includes a detailed outline of allergen management requirements where intentional or cross-contact allergens are considered an identified hazard.

2.8.2 Auditing Guidance
Verification of sanitation effectiveness is carried out. Cleaning of equipment containing allergens is verified prior to product changeover;

(2) Appendix 1: Allergen Cleaning and Sanitation Guide
2.8.2.1.viii. Based on risk assessment, procedures for Validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.
Cleaning and sanitation procedures on lines producing allergenic and non-allergenic products must be effective and Validated.
Effectively documented, implemented and Validated cleaning procedures are essential to avoid cross-contact allergens transferring across products. This is discussed in greater detail in section 2.

Cleaning Validation and Verification
One of the areas of possible confusion is the requirements for allergen cleaning Validation and verification.
Section 2.8.2.1.vii states; “Cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact.”
Section 2.8.2.1.viii states “Based on risk assessment, procedures for Validation and verification of the effectiveness of the cleaning and sanitizing of areas and equipment in which allergens are used shall be effectively implemented.
Interpretation
The SQF Code requires Validation and verification of cleaning and sanitizing procedures for the product contact equipment, and therefore the use of finished product testing for Validation of cleaning is not considered adequate. A program of verification needs to be built on an initial Validation study that identifies the target allergen(s), threshold levels, and the severity of contamination, and shows the cleaning process and testing used are effective to give the desired results consistently. Once the cleaning process has been Validated as effective, a

verification/monitoring/inspection program shall be established to assure that the Validated cleaning process is being used, is maintained and effective.

Validation

The purpose of Validation is to prove that the cleaning process employed is effective in removing the allergen of concern. This proof requires evidence that the specific allergen was in fact removed, or reduced to an acceptable level by the cleaning procedure. Therefore, only an allergen specific test will provide that evidence.

The acceptable Validation testing methods involve the use of a test specific to the allergen being removed. These generally require the use of a test method which uses an antigen (the allergen) and an antibody specific to the antigen. One example of the antigen and antibody test is the enzyme linked immuno-assay or ELISA method.

Verification

Once a Validated cleaning method has been shown to remove the allergenic material of concern, the facility must verify that the Validated procedures were used each time. This verification must be documented by a responsible person from the facility who has been trained in the Validated cleaning method. The most common method used is direct observation of the Validated cleaning procedure during the sanitation process. Another acceptable verification method is the use of highly sensitive swabs that test for proteins. These recently developed swabs will detect total protein at approximately 20 ppm. Since these devices only test for total protein and not specific allergens, they are not acceptable for Validation but will serve to verify that equipment has been thoroughly cleaned. There are also sensitive ATP test swabs available however the presence of ATP does not indicate the presence of protein which is the allergenic material. The use of these total protein swabs or the ATP sensitive swabs must be calibrated with the Validated cleaning procedure by using them immediately after the Validated method is used and recording the results of both the allergen specific test and the protein or ATP swab test. It is also to ensure surface swabbing is occurring at corners, joins, and crevices in the equipment as well as open surfaces, to check for protein held up in equipment.

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The purpose of a Validated cleaning program is to confirm that the specifics of the cleaning process used are complete, effective, sufficient, and when implemented, will produce that same results every time.

• When there is a mixture of different allergens in use, the acceptable method for confirming the thoroughness of cleaning is to test for the highest risk allergens, the highest concentration allergens, or the ones that are most difficult to remove. Examples of difficult to remove allergens include milk proteins, such as in chocolates or caramels, and cooked eggs

• Suppliers using whole or partial nuts on their products, such as in a muffin topping, may have to verify removal of all the nuts fragments from the equipment based on visual inspection. Ground nuts and nut butters do require the use of a Validated cleaning procedures and a recognized allergen specific cleaning test on equipment such as conveyors, augers, and other product transfer devices. This due to the presence small nuts particles and oil/protein residues.

• The SQF Code requires that facilities Validate their cleaning methods against the allergens of concern in the country of manufacture and the country of destination. New allergens are emerging all the time so both the supplier and the auditor need to ensure they address the most current list.

• Finished product testing is not sufficient by itself to Validate cleaning methods since any allergen present is diluted by the product and can become nearly undetectable thus rendering a questionable result.

Conclusion

It is the responsibility of the SQF supplier to Validate their cleaning procedure to ensure it removes allergenic material of concern to prevent cross-contact with non-allergen or dis-similar allergenic foods. This must be accomplished to meet the regulatory requirements in the country of origin and the country of destination, as well as all customer requirements. The methods for Validation and verification of the cleaning procedures as well as the other allergen safety procedures used in the facility must be documented as part of the food safety manual. The procedures must be scientifically Valid and any exclusions or exemptions must be thoroughly documented with a detailed risk assessment. There must be a documented re-assessment of the allergen control program performed at least annually.

IFSQN Validation Blog References January 2015

Guidance for Developing, Documenting, Implementing, Maintaining and Auditing an SQF System SQF Code, Edition 7.2 – Module 11: Food Safety Fundamentals – Good Manufacturing Practices for Processing of Food Products

11.3.2 Hand Washing
Where alternative methods of hand-drying are preferred (e.g. high-speed air dryers). Their use must be justified and their effectiveness Validated (refer 2.4.2.2).

11.5.7 Air Quality
Food operations must verify and Validate that the compressed air used is appropriate and does not serve as a source of contamination.
11.5.7.2
Testing can be conducted to Validate the compressed air-filtration control system's effectiveness based on the risk to the product; however, testing must be conducted at a minimum of once a year. Testing can be done in-house or by a contracted party. Test requirements and number of samples will be based on the risk to the product and process.
The site may consider the following controls for particulates
i. Intake filters to remove atmospheric dirt and solid particulates.
ii. Microorganisms – A point-of-use filter, minimum 0.01 micron, prevent pathogenic microorganisms from contaminating food. An effective PM program should be in place to maintain the integrity of the filter. Validation from the filter manufacturer is often considered adequate Validation.

11.6 Storage and Transport
Monitoring and Validation of the cooler temperature shall be done in accordance with the site's Food Safety Plan or similar document.
The site shall be able to verify and Validate cooling or storage temperatures prescribed by legislation.
Cold storage, freezing, and chilling procedures (SOPs) and temperature Validation procedures will be reviewed as part of the initial desk audit. Subsequently
SOPs exist for Validation of chilled and frozen temperatures and times;

11.7.3 Thawing of Food
Time and temperature of product thawing must be established and Validated, as must the shelf life of the food prior to use after thawing.

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11.7.3 Auditing Guidance
This element will be audited as part of each facility audit through observation. Evidence may include:
Time and temperature of the thawing process have been established and Validated;

11.7.6 Detection of Foreign Objects
Metal detectors, x-ray, color sorters (if used for defects or foreign material) and all other detection devices must be Validated to ensure that they can effectively detect a foreign object within the packaged product that is passed through the device. The passing of wands through the device to ensure that it is working is verification. An example of a means for Validation of a metal detector could be the placing of a piece of metal within the package of product (product would be marked to ensure it does not enter market). All types of packaging and sizes of product that are passed through the device must be Validated as well as all new packaging or size of product.
11.7.6 Auditing Guidance
Procedures for foreign object detection devices shall be reviewed as part of the initial desk audit. Subsequently, procedures will be audited as part of each facility audit through observation, review of records and interviews with operating personnel. Evidence may include:
Physical contaminant detection technology is Validated;
Records are ***Not*** maintained of the Validation of foreign body detection equipment.

11.8 On-Site Laboratories
11.8.1 Implementation Guidance
What does it mean?
In most instances, testing for monitoring purposes may be carried out in an on-site laboratory, while Validation activities are outsourced to an accredited laboratory.

Error?

IFSQN Validation Blog References January 2015

IFS Standard for auditing quality and food safety of food products Version 6 January 2012 8 - References to Validate/Validation

2.2.3.7 Establish critical limits for each CCP (CA Step 8 – Principle 3)
For each CCP, the appropriate critical limits shall be defined and Validated in order to clearly identify when a process is out of control.

4.3. Product development/Product modification/Modification of production processes
4.3.4 When establishing and Validating the shelf life of the product (including long shelf life product i.e. labelled with a "best before date"), the results of organoleptic tests shall also be taken into account.
4.3.8 The company shall demonstrate through studies and/or perform relevant tests in order to Validate nutritional information or claims which are mentioned on labelling. This applies both for a new product and during all its period of sale.

4.12 Risk of foreign material, metal, broken glass and wood
4.12.6 In cases where special equipment or methods are used to detect foreign material, these shall be properly Validated and maintained.

5.3 Process Validation and control
5.3.1 The criteria for process Validation and control shall be clearly defined.
5.3.3 All rework operations shall be Validated, monitored and documented. These operations shall not affect the product requirements.
5.3.5 Process Validation shall be performed using the collected data that is relevant for product safety and the processes. If substantial modifications occur, a reValidation shall be carried out.

IFSQN Validation Blog References January 2015

ISO 22000:2005 5 - References to Validation

Definitions
3.15 Validation obtaining evidence that the control measures (3.7) managed by the HACCP plan and by the operational PRPs (3.9) are capable of being effective
3.16 verification confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

8 Validation, verification and improvement of the food safety management system
8.1 General
The food safety team shall plan and implement the processes needed to Validate control measures and/or control measure combinations, and to verify and improve the food safety management system.
8.2 Validation of control measure combinations
Prior to implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change therein (see 8.5.2), the organization shall Validate (see 3.15) that
a) the selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated, and
b) the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels.
If the result of the Validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed (see 7.4.4).

8.5.1 Continual improvement
Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication (see 5.6), management review (see 5.8), internal audit (see 8.4.1), evaluation of individual verification results (see 8.4.2), analysis of results of verification activities (see 8.4.3), Validation of control measure combinations (see 8.2), corrective actions (see 7.10.2) and food safety management system updating (see 8.5.2).

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TECHNICAL SPECIFICATION ISO/TS 22004:2005(E) Food safety management systems - Guidance on the application of ISO 22000:2005

7 Guidance on the use of ISO 22000:2005, Clause 7: Planning and realization of safe products
7.1 General
Clause 7 of ISO 22000:2005 addresses planning (see Figure 2) and operating phases, whereas Clause 8 addresses checking and acting phases. Maintenance and improvement of the system is addressed through a number of cycles of planning, Validation, monitoring, verification and updating required in these two clauses. Within an operating system, system changes can be initiated at any of these phases.

7.4.4 Selection and assessment of control measures
Categorization of control measures facilitates the application of different management strategies to each group with respect to Validation, monitoring, and verification of measures to control nonconformities, including handling of resulting products.

Sub clause 8.2 of ISO 22000:2005 requires that Validation demonstrates that the combination of control measures is capable of achieving the intended level of control. Failure to demonstrate such capability must result in modification of the combination. Where a control measure cannot be Validated, it cannot be included within a HACCP plan or in operational PRPs, but it can be applied within PRPs.

The assessment and Validation processes may yield the result that previously applied or drafted control measures are demonstrated to be in excess of what is actually required to deliver the necessary controls. Such control measures may be (re)considered with regard to their general relevance for the food safety management system of the organization or may be integrated in the PRPs if their (continuous) use is desired.

As the effects of the combination of control measures are Validated prior to categorization, food safety will be achieved in cases even when all control measures are to be managed through operational PRPs.

7.6.4 System for the monitoring of critical control points

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Most monitoring procedures for CCPs should provide real-time information related to on-line processes.
Furthermore, monitoring should provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Therefore there may not be time for lengthy analytical testing.
Physical and chemical measurements that give information about the degree of microbiological control are often preferred to microbiological testing because they can be done rapidly. For the Validation and verification of such measurements, microbiological testing may be used.

7.8 Verification planning
The concepts of Validation, verification and monitoring are often confused.
— Validation is an assessment prior to operation, the role of which is to demonstrate that individual (or a combination of) control measures are capable of achieving the intended level of control.
— Verification is an assessment carried out during and after the operation, the role of which is to demonstrate that the intended level of control has actually been achieved.
— Monitoring is a procedure to detect any failures in the control measure.

The frequency of verification depends on the degree of uncertainty in the effect(s) of the control measure(s) applied relative to the determined acceptable level(s) of food safety hazard(s) or predetermined performance(s), as well as on the ability of the monitoring procedures to detect loss of control. Hence, the frequency required will depend on the uncertainties associated with the result of Validation and the functioning of the control measure (e.g. process variability). For instance, where Validation demonstrates that the control measure delivers a hazard control significantly higher than the minimum required to meet acceptable levels, verification of the effectiveness of that control measure may be reduced or might not be required at all.

8 Guidance on the use of ISO 22000:2005, Clause 8: Validation, verification and improvement of the food safety management system
The food safety management system should be developed using sound scientific principles. The means to collect the necessary information for the system design can usually be obtained from academic institutions, regulatory agencies, trade associations, consultants, or any party that has educated expertise in the food

process and product. Once the control measure combination is designed on paper, it must be Validated.

8.2 Validation of control measure combinations

The Validation process provides assurance that the combination will deliver products that meet identified acceptable levels. The Validation usually includes such activities as

a) reference to Validations carried out by others, to scientific literature, or to historical knowledge,

b) experimental trials to simulate process conditions,

c) biological, chemical and physical hazard data collected during normal operating conditions,

d) statistically designed surveys,

e) mathematical modelling, and

f) use of a guide approved by competent authorities.

If relying upon Validations carried out by others, care should be taken to ensure that the conditions of the intended application are consistent with those identified in the referenced Validations. Generally accepted industrial practices may be used. Scaling up of laboratory-based experimental trials in a pilot plant may be required to ensure that the trials properly reflect actual processing parameters and conditions. Intermediate and/or finished product sampling and testing based on the use of statistical sampling plans and Validated testing methodology may be used. Validations may be conducted by external parties, and microbiological or analytical testing can effectively be used to verify that a process is in control and that acceptable product is being produced.

If additional control measures, new technology or equipment, changes in the control measures, product (recipe) changes, identification of new or emerging hazards or changes in their frequency of occurrence, or unexplained failures of the system occur, reValidation of the system might be necessary.

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GFSI Guidance Document Sixth Edition Version 6.3 Requirements

Definitions
Validation - An activity to obtain evidence that a requirement is controlled effectively.
Verification - A confirmation, through the review of objective evidence that requirements have been fulfilled.

References to Validation:
Table IX – Food Safety Management Requirements
Scope of Recognition M
FSM M1 Food safety management for packaging materials general requirements
The management system shall: g) Validate packaging design and development to ensure food safe and legal manufacture.
FSM M 20 Control of measuring and monitoring devices
The standard shall require that the organisation identify the measurement of parameters critical to ensure food safety from packaging materials.
The measuring and monitoring equipment required shall have an adequate degree of accuracy and methods recognised and Validated.

Table X – Good Manufacturing Practice
Requirements M
GMP M 5 Equipment The standard shall require that equipment is suitably designed and Validated for the intended purpose and be used and stored so as to minimise food safety risks from packaging materials.
GMP M 10 Housekeeping, cleaning and hygiene
The standard shall require that appropriate standards of housekeeping, cleaning and hygiene be maintained at all times and throughout all the stages with Validation and recording of the effectiveness of the cleaning.

Food Sector Categories EI, EII, EIII, EIV & L are required to have HACCP Systems where in all cases, the 7 Codex Alimentarius HACCP principles and the 12 step logic sequence for application of HACCP specified in the document, Recommended International Code of Practice – General Principles of Food Hygiene CAC/ RCP 1-1969, Rev. 4 -2003, shall apply.

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Food Sector Category

EI Processing of perishable animal products
Production of animal products including fish and seafood Meat, eggs, dairy and fish products
Deboning, cutting, washing, trimming, grading, pasteurisation, cooking, curing, fermentation, smoking, chilling, freezing, packed in modified atmosphere, packed in vacuum packing
EII Processing of perishable plant products
Production of plant products (including grains, nuts, and pulses)
Washing, slicing, dicing, cutting, shredding, peeling, grading, pasteurisation, cooking, chilling, juicing, pressing, freezing, packed in modified atmosphere, packed in vacuum packing or any other activity that significantly transforms the product from its original whole state
EIII Processing of perishable animal and plant products (mixed products)
Production of animal and plant products
Mixing, cooking, chilling, freezing, packed in modified atmosphere, packed in vacuum packing
EIV Processing of ambient stable products
Production of food products from any source that are stored and sold at ambient temperature
Aseptic filling, baking, bottling, brewing, canning, cooking, distilling, drying, extrusion, fermentation, freeze drying, pressing, frying, hot filling, irradiating, milling, mixing and blending, packed in modified atmosphere, packed in vacuum packing, pasteurising, pickling, roasting, salting and refining
L Production of (Bio) Chemicals (Additives,
Vitamins, Minerals, Bio-cultures, Flavourings , Enzymes and Processing aids)
Production of food and feed additives, vitamins, minerals, bio-cultures, flavourings, enzymes and processing aids

References to CODEX and NACMCF

GAP AI 1 Agricultural input requirements
Codex Alimentarius Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP1-1969, Rev 4 -2003 and specifically Code of Hygienic Practice for Meat CAC/RCP 58-2005]
GAP AI 20 Pest control systems

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Codex Alimentarius Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP1-1969, Rev 4 -2003, and specifically Code of Hygienic Practice for Meat CAC/RCP 58-2005
GAP AII 1 Aquaculture input requirements
Codex Alimentarius Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP1-1969, Rev 4 -2003 and specifically Code of practice for fish and fishery products CAC/RCP 52-2003]
GAP AII 19 Pest control systems
Codex Alimentarius Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP1-1969, Rev 4 -2003, and specifically Code of practice for fish and fishery products CAC/RCP 52-2003]
GAP BI 1 Agricultural input requirements
Codex Alimentarius Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP1-1969, Rev 4 -2003
GAP BI 8 Agricultural chemicals
Residues shall not exceed levels as established by the Codex Alimentarius Commission or local regulatory requirements.
GAP BII 1 Agricultural input requirements
Codex Alimentarius Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP1-1969, Rev 4 -2003
GAP BII 7 Agricultural chemicals
Residues shall not exceed levels as established by the Codex Alimentarius Commission or local regulations.
HACCP AB 1 Hazard Analysis and Critical Control Point (HACCP)
Be prepared in accordance with Codex or NACMCF HACCP development methodology
HACCP CD 1 Hazard Analysis and Critical Control Point (HACCP)
HACCP EL 1 Hazard Analysis and Critical Control Point (HACCP)
The HACCP based system shall be systematic, comprehensive and thorough and shall be based on the Codex Alimentarius HACCP principles or those principles specified by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The HACCP based system shall be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments. The hazard analysis, where appropriate, shall include allergens.
The 7 Codex Alimentarius HACCP principles and all 12 HACCP implementation steps must be implemented and documented and shall apply for all processes

except for some cases of handling where the hazard analysis outcome may show that not all of the HACCP principles are necessary.
HACCP FD 1 HACCP Based System The HACCP based system shall be based on the Codex Alimentarius HACCP principles.
HACCP J1 Hazard and Risk Management System
HACCP M 1 Hazard and Risk Management System
The standard shall require that the organisation have in place a Hazard and Risk Management system including pre-requisite programmes.
This maybe a HACCP based system or another Hazard and Risk Management system that covers the Codex Alimentarius HACCP principles.