

<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
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PURPOSE: To remove or ameliorate the hazard of contamination of foreign body and ensure the risk to consumer health as a result of contamination of foreign body is as low as is practicably possible given the nature of the structure.

RESPONSIBILITY: The Department Manager is responsible for ensuring this procedure is communicated and adhered to by all staff.

All members of staff must appreciate the potential risks associated with product contamination of foreign body and must follow the instructions outlined in this procedure.

DEFINITIONS

Control Measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.4

Food Safety Control System: The combination of control measures that, when taken as whole, ensures that food is safe for its intended use.

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.5

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.6

Verification: 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.7

Validation involves measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control.8

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. Validation of control measures is, whenever possible, performed before their full implementation.

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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.

1. 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.
2. 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.

The following example for uncooked fermented sausages illustrates the interrelationship of validation, verification and monitoring:

1. *Validation: The competent authority established the need for control measure(s) that achieve a specified log reduction in pathogenic Escherichia coli. The validation process indicated that industry could consistently achieve a specified log reduction through ensuring a specific decrease in pH during fermentation and a specific decrease in water activity during maturation, coupled with ensuring that the raw materials have less than a specified level of pathogenic E. coli based on statistically-based microbiological testing.*
2. *Monitoring: Measuring pH drop during fermentation and weight loss (or water activity) during maturation.*
3. *Verification: Periodic process control testing for pathogenic E. coli to verify that incoming levels in the raw materials are within specification and that fermentation and maturation achieve the intended outcome in the semi-finished or finished product. Examination of monitoring records to check for continuous control over time.*

INSTRUCTIONS:

The control of hazards potentially associated with foods typically involves the application of control measures in the food chain, from primary production, through processing, to consumption.

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TASKS PRIOR TO VALIDATION OF CONTROL MEASURES

Prior to the validation of control measures by the food establishment, it is important to complete certain tasks so that validation can be accomplished effectively and efficiently. The following tasks could be carried out either independently or in conjunction with the establishment of GHPs, HACCP, etc.

Tasks prior to validation include:

1. Identify the hazards that are intended to be controlled in the commodity and/or environment concerned, taking into account all relevant information, including information from a risk assessment if available.
2. Identify the food safety outcome required.

The food safety outcome can be determined in a number of ways. Industry should determine if there are existing food safety outcomes or targets, established by the competent authority, relevant to the intended use of the food. In the absence of food safety outcomes or targets established by the competent authority, targets should be identified by industry, as appropriate. Industry may also set stricter targets than those set by the competent authority.

3. Identify the measures that are to be validated, taking into account:
 - a) The importance of the control measure in achieving control of the hazard to a specified outcome. Examples might include:
 - Heat treatment step in a canning process
 - cooling to a specified temperature within a specific timeframe
 - b) Whether the control measure has already been validated.

Identify whether the control measure has previously been validated in a way that is applicable and appropriate to the food business (e.g. a control measure required by a competent authority or validated by a competent authority or other national or international organization) or whether its performance is so well established for the application under consideration that further validation is not necessary. In either case, a food business operator must ensure that the conditions (e.g. raw materials, relevant hazards, combinations of control measures, intended use, and distribution and consumption patterns) in their particular operation do not differ from the conditions under which the control measure was previously validated.

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c) Priority of validation

Considering that food safety outcomes are often dependent on multiple control measures, prioritization of validation activities may be necessary and may take into account:

- Adverse health effect: The higher the potential for an adverse health effect from a hazard, the more attention should be paid to assuring that the set of control measures selected is effective. Consideration should be given to the size of the population and the age/sex of groups most at risk.
- Historical experience: For many food production and processing scenarios, there is extensive history that specific measures used to control food borne hazards are effective. If little or no experience exists with respect to the performance of a control measure in controlling a particular hazard within a specified context, it becomes more important that validation be undertaken. In certain instances, these historical data may obviate the need to conduct validations. However, it is important to avoid assuming that a food production or processing system is safe based solely on historical experience. All relevant current information should be considered when evaluating the adequacy of historical information, as it may be outdated. For example, sampling and testing procedures used to obtain the original data may be insufficient in the context of current operating procedures. New strains of microbial pathogens may now exist that do not behave in the same manner as the strains of pathogens or surrogate microorganisms used for determining early food control processes. New epidemiological and/or clinical information may indicate that the control measures used in the past were less effective than previously thought.
- Other factors/constraints
 - Ability to monitor and verify the control measure.

In prioritizing control measures for validation, consideration should be given to the amenability of the control measure to monitoring and/or verification after implementation. Control measures that are of such a nature that it is not feasible to

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determine their quantitative effect on specific hazards may not always be considered priority for validation.

- Scientific and technical feasibility.

In prioritizing control measures for validation, consideration should be given to any scientific and/or technical challenges to validating the measure. This would include consideration of the variability associated with the control measure being validated, the food being considered, and the hazards being controlled.

- Resources.

Validation activities may be resource intensive. Particular validation activities, such as experimental trials, process capability studies, surveys, mathematical modelling, product or environmental sampling and analytical testing, particularly when applied in an appropriate statistical fashion, require significant resources. The extent to which sufficient resources are available and such activities can be undertaken will place limits on the ability to develop and validate food safety control measures. Necessary assistance (e.g. development of guidelines for industry, training and technical assistance), particularly to small and less-developed businesses, provided by national and international organizations could help to perform validation of food safety control measures.

THE VALIDATION PROCESS

A range of approaches to validation are available. The precise approach will depend, among other things, on the nature of the hazard, the nature of the raw ingredients and product, the type of control measures or food safety control system selected to control the hazard, and the intended stringency of control of the hazard.

Approaches for validating control measures

The following approaches to validation may be used individually or in combination, as appropriate. These are presented in no particular order.

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- **Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure.** Scientific or technical information needed to validate control measures may, in many instances, be available from many sources. These include scientific literature, government guidance, guidelines on GHP and HACCP control measures with a known history of good performance validated by competent authorities or independent scientific authorities, international standards or guidelines (e.g. Codex Alimentarius), and validation studies from industry and/or equipment manufacturers. However, if relying on such knowledge, care should be taken to ensure that the conditions of application in a food safety control system are consistent with those identified in the scientific information examined. For certain well-established processes (e.g. time and temperature combinations for milk pasteurization), it may be sufficient to acquire only the data on the conditions or attributes specific for the operation in question.
- **Scientifically valid experimental data that demonstrate the adequacy of the control measure.** Laboratory challenge testing designed to mimic process conditions and industrial or pilot plant trials of particular aspects of a food processing system are validation techniques that are used commonly, particularly in food processing unit operations. Quantitative demonstration and documentation of appropriate log reduction of a specified pathogen by a specific microbiocidal process is an example of validation of a control measure by experimental trials. If the risk from a hazard is associated with growth of the pathogen to unacceptable numbers, then the conditions (e.g. product formulation, processing parameters, packaging or conditions of storage and distribution) that prevent the growth of the pathogen may need to be validated and documented using appropriately designed experimental trials. For example, if water activity must be controlled in a product to prevent growth of *Staphylococcus aureus*, then validation can be achieved by demonstrating that the water activity of the product under expected conditions of storage and distribution will be equal to or less than the specified water activity. Scale up of laboratory-based experimental trials in a pilot plant is helpful in ensuring that the trials properly reflect actual processing parameters and conditions. However, this almost always requires the availability of appropriate non-pathogenic surrogate microorganisms, as viable pathogenic microorganisms should not be purposefully introduced into a food production facility. When surrogate microorganisms are used, validation should cover the appropriateness of the

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surrogates. Validation may have to be limited to a laboratory/pilot plant if there are no appropriate surrogate microorganisms available that can be used to acquire data under actual production conditions. Additional safety margins may be required to account for the uncertainty or variability of the control measure or combination of control measures in achieving the desired level of control when implemented in a full scale operation.

- **Collection of data during operating conditions in the whole food operation.** When this approach is used, biological, chemical or physical data relating to the hazards of concern are collected for a specified period (e.g. 3-6 weeks of full scale production) during operating conditions representative of the whole food operation, including periods where production is increased, e.g. holiday rush. For example, when the food safety control system is contingent upon the use of good veterinary or agricultural practices in the field or good hygienic practices in the processing establishment, it may be necessary to validate these measures through the use of intermediate/finished product and/or environmental sampling and testing. Sampling should be based on the use of appropriate sampling techniques, sampling plans and testing methodology. Data collected should be sufficient for the statistical analyses required.
- **Mathematical modelling.** Mathematical modelling is a means of mathematically 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. Mathematical models, such as pathogen growth models to assess the impact of changes in pH and water activity on the control of pathogen growth or the use of z-value models to determine alternative thermal processing conditions, are used extensively by industry. This can also include the use of risk-based models that examine the impact of a control measure or combination of control measures further along the food chain. Effective use of mathematical modelling typically requires that a model be appropriately validated for a specific food application. This may require additional testing. Validation based on the use of mathematical modelling should take into consideration the uncertainty/variability limits associated with the models' predictions.
- **Surveys.** Surveys can be used to validate control measures, as appropriate, in conjunction with other approaches to demonstrate the expected level of control of hazards can be achieved. For example, an evaluation of consumers'

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understanding of information on the label prior to or during the design of a label can be considered a validation approach for labelling as a control measure.⁹ Care should be taken to ensure that statistically valid surveys or other activity provide data that are accurate and appropriate for use by an individual food business operator or competent authority.

Steps Involved in the Validation Process

After completing the tasks needed prior to validation, the process of validating control measures includes the following steps:

- Decide on the approach or combination of approaches.
- Define the parameters and decision criteria¹⁰ 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.
- Assemble relevant validation information and conduct the studies where needed.
- Analyze the results.
- Document and review the validation.

Results of a validation will either demonstrate that a control measure or combination of control measures,

- is capable of controlling the hazard to the specified outcome if properly implemented, and thus, could be implemented, or
- is not capable of controlling the hazard to the specified outcome and should not be implemented.

The latter may lead to re-evaluation of product formulation, process parameters, or other appropriate decisions/actions.

NEED FOR RE-VALIDATION

There are many changes that could lead to a need to re-validate a control measure or combination of control measures. Examples include:

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1. System failure: If monitoring or verification identifies failures for which a process deviation cause cannot be identified, re-validation may be needed. Non-compliance with monitoring or verification criteria may indicate a need for a change in the parameters (i.e., the selection and specification of the control measures) on which the design of the food safety control system is based. A system failure may also result from an inadequate hazard analysis and may require re-validation.
2. Process changes: The introduction in the food safety control system of a new control measure, technology or a piece of equipment that is likely to have a decisive impact on the control of the hazard may necessitate that the system or parts of it be re-validated. Similarly, changes made in product formulation or the application of current control measures (e.g. time/temperature changes) may result in the need for re-validation of control measures.
3. New scientific or regulatory information: Re-validation may be needed if the hazard associated with a food or ingredient changes as a result of
 - a) higher concentrations of hazards than originally encountered and accounted for in the design,
 - b) a change in response of a hazard to control (e.g. adaptation),
 - c) emergence of a previously unidentified hazard,
 - d) new information indicating that the hazard is not being controlled to the level specified (e.g. new epidemiological findings or new validated and internationally accepted analytical technologies)
 - e) a new food safety outcome.

CLEANING AND DISINFECTING PROTOCOLS

1. Pre-validation Tasks
 - a) Hazard(s): Generic microbial contaminants
 - b) Food Safety Outcome: Effective sanitation of food-contact surfaces as demonstrated by compliance with microbiological criteria.
 - c) Control Measure(s): Cleaning and disinfection protocols (SSOPs) within a facility

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2. Approach: Collection of scientific data.
3. Parameters and Decision Criteria: SSOPs will be considered to be validated if, after implementation of cleaning and disinfection protocols, food contact surfaces meet microbiological criteria established for aerobic plate counts or other indicator microorganisms as appropriate.
4. Assemble the relevant validation information
 - a) SSOPs will be implemented as intended for 3-4 weeks of operation.
 - b) Microbiological testing of food contact surfaces will be conducted after cleaning and disinfection protocols have been used at the end of each day's production.
5. Analyze the results
 - a) Compare results obtained at the end of each day's production to the established microbiological criteria.
 - b) Conduct appropriate statistical analyses to determine the variability in efficacy of the cleaning and disinfection procedures.
6. Document and review the validation
 - a) Data from implementation of SSOPs should be documented.
 - b) All data from food contact surface testing should be documented.
7. Conclusion

If review and analysis of the validation results indicate that the SSOPs are capable of consistently delivering results that comply with the established microbiological criteria during 3-4 weeks of the validation period, then the cleaning and disinfection protocols can be considered validated.

This same protocol with a reduced rate of testing can be used as an ongoing verification activity that the SSOPs are being implemented properly.

CONTROL OF METAL FRAGMENTS

1. Pre-validation Tasks:

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- a. Hazard: Metal fragments
 - b. Food Safety Outcome: Less than 1 metal fragment over 2 mm in 100,000 kg of product.
 - c. Control Measure: Introduction of a sieve into a production line
2. Approach: Collection of data during normal operation.
 3. Parameters and Decision Criteria:
Control measure will be considered validated if a metal detector indicates that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product. Operational data will be collected for one month and reviewed to determine the size of any metal pieces in products rejected by the metal detector.
 4. Assemble relevant validation information.
 - a. Determine the size of metal fragments in products rejected by the metal detector.
 - b. Ensure that the metal detector is sensitive enough and calibrated to detect metal pieces of 2 mm or more in the specific product.
 - c. Ensure that the sieve remains intact during normal operations.
 5. Analyze the results
Determine the rate at which the sieve allowed fragments of 2 mm or more in the final product.
 6. Document and review the validation
 - a. Document all findings from the metal detector.
 - b. Document the integrity of the sieve and the sensitivity and calibration of the metal detector.
 7. Conclusion
 - a. Control measure can be implemented if data indicate that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product.
 - b. Validation will likely provide information on monitoring needed to ensure that sieve remains intact.

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- c. The metal detector can be used after the validation as an ongoing verification activity to ensure that the sieve is controlling the hazard as intended.

Foreign Material Control

A variety of devices appropriate to individual operations are available to suppliers to limit the presence of foreign materials. Suppliers may want to consider the use of these devices where appropriate and useful to minimize the potential for product to contain foreign material. Foreign material control devices should where necessary be placed in the process flow in the location(s) where they will have maximum product protection and effectiveness. Control devices should be routinely calibrated and checked. Foreign material control devices and guidelines for their effectiveness could include:

Metal detectors

- For end product testing or located as close as practical to end product packaging
- With an automatic reject or conveyor stopping mechanism and an alarm where appropriate
- Calibrated for effective rejection of product containing metal the time of installation and tested during production to ensure rejection of appropriate test pieces

Magnets

- Of rare earth construction
- Tested for effective placement, coverage, and pull strength at the time of installation and routinely thereafter

Filters

- Checked for breakage and proper placement

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Screen/Scalper/Sifters

- A mesh size that is the smallest possible that does not restrict product flow
- Inspections to assure their integrity Other foreign material control devices could include:
- Cyclones
- Tilt tables
- Flotation or water tanks
- De-stoners
- Optical sorting equipment
- Strategically placed protective line covers
- Bottle/jar washers, inverters, rinsers and other pre-filling clean-out devices
- X-ray or other vision control systems Operations packing in glass could have appropriate machinery identified above as well as adequate procedures in place to considerably limit the breakage of containers and the potential for contamination of products by glass fragments. Components of a thorough and comprehensive glass control program could include:
- Verification of incoming glass quality
- Proper design of conveyors and transfers to minimize pressure exerted on bottles and jars.
- SOPs for both accidental and intentional bottle/jar breaks (e.g., to clear a machinery jam)
- Employment of glass-free zones in manufacturing areas

SAFE-HANDLING LABEL FOR TABLE EGGS

1. Pre-validation Tasks:

- a) Hazard: *Salmonella* Enteritidis (SE) in table eggs (shell eggs).
- b) Food Safety Outcome: Reduced frequency of consumption of eggs contaminated with SE.

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- c) Control Measure: Labelling (one control measure among several beginning at primary production (on-farm practices) through consumer use (cooking, storage temperatures)). The label will state: "To avoid illness, refrigerate eggs at 5°C (41°F) and cook eggs until the yolk is firm."
2. Approach: A representative survey of consumers
 3. Parameters and Decision Criteria:
 - a) A risk assessment has shown that, in concert with control measures elsewhere in the food chain, the number of servings of eggs contaminated with SE will be significantly reduced if there is a 25% increase in the number of consumers that store table eggs at 5°C (41°F) and cook eggs until the yolks are firm.
 - b) The control measure (label) will be considered validated if a specified percentage of the population understands the label (i.e., having read it, they can state what they would do if following the label instructions) and indicates that they plan to follow the instructions.
 4. Assemble relevant validation information:
 - a) Identify target demographic for survey
 - b) Design a statistically-valid survey to determine
 - Current consumer practices
 - Whether the label is understandable
 - Whether consumers plan to change their current practices, if necessary, based on the label instructions.
 5. Analyze the results:
 - a) Determine the percentage of the population that is not currently following the practices described on the label.
 - b) Determine the percentage of the population that understands the label instructions.
 - c) Determine the percentage of the population that indicates that they plan to change their current practice and follow the label instructions.
 6. Document and review the validation:

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- a) Document the development of the survey
- b) Document the identification of the target demographics for the survey
- c) Document the survey results

7. Conclusion

The control measure can be implemented because data indicated that because of the label instructions more than 25% of the population plan to change their current practice and begin refrigerating eggs at 5°C and, when appropriate, cooking eggs until the yolk is firm.

MONITORING:

Regular audits / inspections of manufacturing areas and controls must be in place to ensure that procedures are effective and working.

VERIFICATION AND RECORD KEEPING:

Regular audits / inspections of manufacturing areas and controls must be in place to ensure that procedures are effective and working.

Internal audits records must be completed, which will include:

- non-conformances
- corrective action
- responsibility
- date of completion

RECORDS APPLIED TO THIS PROCEDURE:

- Internal Audit records
- Foreign Body Contamination risk assessment
- Hygiene and Housekeeping records

DOCUMENTATION RETENTION:

The records applied to this procedure are to be kept on file for a minimum of 3 years.