codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES AT STEP 3

Prepared by the United States of America with the assistance of Australia, Brazil, Canada, the European Community, Finland, France, Germany, India, Italy, Japan, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, Thailand, FAO, WHO, the Industry Council for Development, the International Association of Consumer Food Organizations, the International Dairy Federation, the International Frozen Food Association, and the International Commission on Microbiological Specifications for Foods.

Governments and interested international organizations are invited to submit comments on the attached Draft Guidelines at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, sixteenth Edition*) to: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 1 October 2007.**

BACKGROUND

At the 36th Session of CCFH, the Committee agreed that the *Proposed Draft Guidelines for the Validation of Food Safety Control Measures* should be revised and a physical working group met on the document in 2004. Due to time constraints, the Draft Guidelines were not discussed at the 37th Session in Buenos Aires, Argentina, and the document was returned to Step 2 for further redrafting by an electronic working group. At the 38th Session in Houston, Texas, the Committee discussed the Draft Guidelines in general terms, focusing on responses to four questions to give the working group direction in further revising the document. Those four questions were:

1. Whether the current scope of the document should be retained or whether it needed to be limited and, if so, how?

2. Whether information on verification and monitoring should be included in the document—the current inclusion of this information seemed to be causing some confusion.

3. Whether specific examples of validation should be added to the document and, if so, which examples?

4. Whether Annex I (Nature of Food Safety Control Measures) should be retained or removed?

The Committee decided that the scope of the document should be control measures (or combinations/sets of control measures forming a food safety control system) at any point in the food chain. The Committee also decided that the Draft Guidelines should address both verification and monitoring in relation to validation with examples. Finally, Committee decided that Annex I on the nature of control measures should be replaced by an annex containing examples of validation. The Committee requested that the examples include validation scenarios for control measures for chemical and physical hazards, as well as microbial hazards, and that the examples explore the various roles of government and industry in validation.

As agreed by the Committee, a physical working group met to revise the document in Geneva, Switzerland, 25 – 27 June 2007. Significant progress was made on the document at this working group meeting and the current draft reflects the decisions taken by CCFH at its 38th Session. The most significant change to the document is new Annex I containing six examples of approaches to validating control measures. At the 38th Session, the Committee agreed to complete work on the Draft Guidelines in two sessions of the Committee, with final adoption at Step 8 by the Commission in 2009.

APPENDIX

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES AT STEP 3

I. INTRODUCTION

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. In the current environment of systems-based food safety controls that provide flexibility with the selection of control measures, validation of these control measures acquires increased importance. It is through the validation process that one demonstrates that the selected control measures are actually capable, on a consistent basis, of achieving the intended level of hazard control.

It is important to make a clear distinction between the role of industry[1] and the role of the competent authority in validating control measures. Industry is responsible for validation of control measures, while the competent authority ensures that industry has effective systems for validation and that control measures are appropriately validated. Governments may provide advice to industry on how to conduct validation studies and how validated control measures should be implemented. Governments or international organizations may also conduct validation studies in support of risk management decisions or provide information on control measures considered to be validated, especially where the resources are not available to conduct such studies (e.g., small and less-developed businesses).

These guidelines present information on the concept and nature of validation, tasks prior to validation, the validation process, and the need for re-validation. These guidelines also address the difference between validation, monitoring and verification. Annex I provides examples of validation scenarios.

II. SCOPE

These guidelines apply to validation of control measures at any stage of the food chain[2]. These guidelines are intended as guidance to industry and governments on the validation of individual control measures, a limited combination of control measures, or sets of control measure combinations forming a food safety control system (e.g. HACCP, GHP).

The tools, techniques, and statistical principles that would be used to validate specific food control measures are beyond the scope of the current document. Advice on specific applications should be acquired from scientific organizations, competent authorities, process control experts or related sources of scientific expertise that can provide the specific principles and best practices upon which the validation of a specific control measure should be based.

III. DEFINITIONS[3]

Appropriate Level of Protection (ALOP): The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.[4]

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[1] For the purposes of this document, it is understood that industry includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from *Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius* and taken from *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

[2] The focus of this document is the validation of elements of a food safety control system; however, the recommendations in this document also may be applied in the validation of other food hygiene measures.

[3] In many cases, existing definitions such as those contained in the SPS Agreement, the General Principles of Food Hygiene, HACCP Annex and the CCFH Risk Management document, were suitable for use in this document. In other cases, where a definition was too limiting outside of its original context (e.g., some HACCP Annex definitions), another definition was developed that was more suitable for use within the context of these guidelines.

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.[5]

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

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of health protection.[6]

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.[7]

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before time of consumption that provides or contributes to an FSO or ALOP, as applicable.[8]

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.[9]

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.[10]

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.[11]

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.[12]

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

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[4] WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The term Member refers to countries.

[5] *International Recommended Code of Practice: General Principles of Food Hygiene,* CAC/RCP1-1969, Rev. 4 (2003), HACCP Annex.

[6] *Procedural Manual*, 15th Edition, Codex Alimentarius Commission.

[7] Ibid.

[8] Ibid.

[9] Derived from *International Recommended Code of Practice: General Principles of Food Hygiene,* CAC/RCP1-1969, Rev. 4 (2003), HACCP Annex, but was modified to apply to all control measures, whether or not a HACCP system is employed.

[10] Ibid.

[11] Ibid.

[12] See *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* (ALINORM 05/28/13) and *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) ,

Validation, Verification and Monitoring

There is often confusion among the concepts of validation, verification and monitoring. Validation of control measures 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.

- Verification is used to determine that the control measures have been implemented as intended and thus should achieve the level of hazard control specified. Verification also provides an ongoing demonstration that the control measure continues to be effective and that the underlying parameters and assumptions upon which the control measure is based are still valid. 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:

- 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.

- Monitoring: Measuring pH drop during fermentation and weight loss (or water activity) during maturation.

- Verification: Pathogenic *E. coli* testing 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.

V. 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:

a) Identify the hazards that are intended to be controlled, taking into account all relevant information, including information from a risk assessment if available.

b) 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.

c) Identify the measures that are to be validated, taking into account:

- 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
- 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 validation should be considered sufficient. 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.

- Priority of validation

The control measures that have a decisive impact on the desired food safety outcome and are used to demonstrate that the system is capable of controlling the identified hazards should be validated. 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.
- 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.

- 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, should be provided by national and international organizations.

VI. 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.

1. **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.

2. **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 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.

3. **Collection of data during normal operating conditions in the 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 normal operating conditions in the food operation. 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.

4. **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.

5. **Representative surveys.** Representative surveys can be used to validate control measures. For example, an evaluation of consumers' 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.[13] Care should be taken to ensure that the 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.
- Define the parameters and decision criteria[14] 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.

[13] Note that surveys carried out after the product is in the market place to assess whether consumers are following the instructions is a verification activity.

[14] Decision criteria should take into account the uncertainty and variability associated with the validation methodology, including the performance of the control measure or combination of control measures.

- 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.

Information gained in the validation process may be useful in designing verification and monitoring procedures. For example, if a control measure or combination of control measures produces a reduction of a pathogen well in excess of the reduction needed for hazard control, it may be possible to decrease the frequency of verification e.g., frequency of microbiological testing of end product.

VII. 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:

- 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 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.
- 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.
- New scientific or regulatory information: Re-validation may be needed if the hazard associated with a food or ingredient changes as a result of (i) higher concentrations of hazards than originally encountered and accounted for in the design, (ii) a change in response of a hazard to control (e.g., adaptation), (iii) emergence of a previously unidentified hazard, (iv) 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) or (v) a new food safety outcome.

ANNEX I

EXAMPLES OF VALIDATION OF FOOD SAFETY CONTROL MEASURES

A broad range of control measures may be employed throughout the food chain to control microbial, chemical, and physical hazards. This Annex contains examples of several approaches to validating control measures or combinations of control measures. All of the examples described below are for purposes of illustration only and do not represent actual validations of control measures. Also, the examples below are presented in a specific format only for consistency and this format is not intended to be a general model for validation.

In the examples below, it is assumed that the control measures have not been previously validated, that they have a decisive impact on the control of the specific hazard, and that they have been prioritized for validation.

EXAMPLE ONE: VALIDATION OF POST-HARVEST DEHYDRATION TO PREVENT AFLATOXIN CONTAMINATION OF TREE NUTS

1. Pre-validation Tasks.

    a. Hazard: Aflatoxin contamination has been identified as a hazard that is reasonably likely to occur in tree nuts. Its control requires applications of measures both pre-harvest and post-harvest. Post-harvest measures are focused on rendering the tree nuts incapable of supporting continued aflatoxin production by *Aspergillus* spp.

    b. Food safety outcome required: The recognized international standard for aflatoxin B_1 is 20 µg/kg. However, to take into account process and analytical uncertainties, the food safety outcome is set at 10 µg/kg

    c. Control measure to be validated: Post-harvest dehydration of tree nuts

2. Approach: There are sufficient scientific data in the literature to allow the control measure to be validated without the need for additional studies.

3. Parameters and Decision Criteria:

    a. Parameters:

        i. Aflatoxin-producing *Aspergillus* spp. cannot grow and synthesize the toxins when the water activity of the product falls below 0.70.[15]

        ii. The amount of aflatoxin that is produced post-harvest is dependent on the speed that tree nuts can be dehydrated and the rate at which the mold can grow. The scientific literature suggests that germination of the spores and initiation of toxin synthesis can occur with 24 to 48 hours of exposure of post-harvest tree nuts to a moist environment.

        iii. The level of aflatoxin B_1 present in post-harvest tree nuts will also be dependent on the levels present prior to the initiation of dehydration.

    b. Decision Criteria:

        i. A post-harvest dehydration control measure will be validated if

[15] *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts* (CAC/RCP 59-2005).

1. The water activity in lots of tree nuts being treated can be consistently reduced to <0.70 within 24 hours,

2. After dehydration there is an absence of "wet spots" that have a water activity ≥ 0.70 in the lot.

3. The level of aflatoxin B_1 in the tree nuts after a water activity <0.70 has been attained does not exceed 10 µg/kg.

4. The treatment includes appropriate packaging/storage of the dried tree nuts

4. Assemble relevant validation information and conduct the studies where needed.

   a. Confirm incoming level of aflatoxin under a variety of harvest conditions

   b. Obtain scientific references documenting that aflatoxin-producing *Aspergillus* spp. cannot synthesize the toxins when the water activity of the product falls below 0. 70 and

   c. Obtain information to support that toxin production is not likely to occur if tree nuts are dried to this water activity in 24 to 48 hours; this may include use of mathematical models for the rate of growth and toxin production by *Aspergillus* species.

   d. Determine that the technology to be used will consistently produce tree nuts that have water activity levels < 0.70 within 24 h.

   The available scientific literature and related scientific data relating water activity levels to aflatoxin production in tree nuts should be reviewed to determine their pertinence to the specific procedures being employed by the business operator. If there is uncertainty about the applicability of the scientific literature, acquisition of additional analytical data may be required. At a minimum, data on the water activity of tree nuts after 24 hours drying should be obtained.

5. Analyze the results.

   a. Data acquired by the business operator on the ability of the dehydration technology employed by the operator to consistently achieve the dehydration outcomes should be analyzed to ensure key operating parameters of the equipment are being followed and are achieving the expected water activity within the expected timeframe in this specific operation.

   b. As appropriate, statistical analyses should be performed to assess the variability in the processes.

6. Document and review the validation.

   All analyses, data, and decisions should be documented.

7. Conclusion

   a. Data indicate that if the incoming level of aflatoxin B_1 in the untreated tree nuts is < 1 µg/kg, then the levels after dehydration can be appropriately controlled and thus the control measure can be implemented.

   b. Storage/packaging conditions must be adequate to maintain the desired water activity of the dried tree nuts.

   c. These data can be used to establish a program of monitoring for water activity levels, and periodic analysis of the dehydrated tree nuts for aflatoxin B_1.

EXAMPLE TWO: MEETING A PERFORMANCE OBJECTIVE FOR VERO-TOXIN PRODUCING *ESCHERICHIA COLI* IN A HARD RAW MILK CHEESE

1. Pre-validation Tasks:

   a. Hazard: Vero-toxin producing *Escherichia coli* (VTEC) in hard raw milk cheese.

   b. Food Safety Outcome: A performance objective (PO) of <0.001 cfu VTEC/g at the end of production.

   c. Control Measure: A combination of control measures (level of the pathogen in the raw milk, time/temperature during processing, pH, water activity) contribute to the level of VTEC at the end of production, which includes a defined ripening period under specified conditions.

2. Approach: Use of scientifically valid experimental data to demonstrate the adequacy of the control measures

3. Parameters and Decision Criteria: The combination of control measures will be considered validated as achieving the PO if the calculated geometric mean (μ) + 3 standard deviations (std) level of VTEC at the end of production (ripening) is < 0.001 cfu/g (-3 $\log_{10}$(cfu/g))

4. Assemble relevant validation information:

a. the level (e.g. μ + 3 std) of the pathogen in the raw milk is estimated, using microbiological testing of the milk

b. a model of the manufacturing process (time, temperature, pH, water activity) based on data collected from production (e.g. experimental production), including the possible variation in the process

c. growth/reduction rates during the manufacturing process are identified from literature, other sources, or from experimental trials if necessary

d. the changes in hazard levels that are reasonably likely to occur during processing steps (i.e. those steps that are technologically needed to manufacture the product)

e. Initial selection of the manufacturing process that is likely to simultaneously yield the desired level of VTEC control and the desired product quality—this will identify the control measures required (time, temperature, pH, water activity).

5. Design an experimental study that mimics the selected process:

a. Raw milk of the same status as intended for production is spiked with levels of VTEC (mixture of relevant strains, isolated from milk) that can be measured throughout the process

b. The cheese is manufactured (pilot scale) and samples are taken for analysis at relevant points needed to validate the initial model.

c. All parameters specifying the process are monitored during the trial to ensure comparability with full scale production

6. Analyze the results

a. Data on the end product

b. Data relating to the model and the process used

7. Document and review the validation

Documentation should include:

a. result of literature research

b. results of the experimental study

c. statistical analysis of raw data and analytical results

d. description of the various models

e. rationale for selecting the scenario for experimental trial (control measures and processing steps)

f. data on VTEC strains used for spiking

g. documentation of the variability in process

7. Conclusion

The PO can be met under the following conditions:

a. That the process parameters (time, temperature and pH profiles during cheese making) are within tolerance under monitoring and are not changed

b. That the raw milk does not exceed xx cfu/g

c. That the cheese is ripened for a minimum of yy days prior to release.

EXAMPLE THREE: VALIDATION OF CLEANING AND DISINFECTING PROTOCOLS (Sanitation Standard Operating Procedures, SSOPs)

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

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.

EXAMPLE FOUR: CONTROL OF METAL FRAGMENTS

1. Pre-validation Tasks:

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.

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.

EXAMPLE FIVE: VALIDATION BY A COMPETENT AUTHORITY (NEW ZEALAND) OF MEAT INSPECTION PROCEDURES FOR *TAENIA SAGINATA*

1. Pre-validation Tasks:

a. Hazard: Cysts of *Taenia saginata* in slaughtered cattle.

b. Food safety outcome: No increase in risks to consumers

c. Control Measure: A new post-mortem inspection procedure for the identification and removal of cysts. Post mortem inspection is the only available control measure. Traditional inspection involves slicing of a large number of tissues (and also results in a high degree of microbiological cross-contamination). The new inspection package would limit slicing to a minimum.

2. Approach: Experimental trial and mathematical modelling

3. Parameters and Decision Criteria

a. The food safety outcome is no decrease in the current level of consumer protection, i.e. mean rate of 1.1 cases of infection per year in the total population per year.

b. The decision criterion for validation is that any difference in non-detection rate at post mortem inspection does not result in a decrease in the current level of consumer protection.

c. The decision criteria included consideration of probability distributions generated by the model.

4. Assemble information and conduct studies

Detailed experimental trials to determine non-detection rates for the traditional and the alternative inspection measures, and mathematical modelling to determine impact on the chosen food safety outcome

5. Analyze the results

The food safety outcome of the new control measure was presented as a frequency distribution and a mean value was chosen for purposes of comparison. The level of consumer protection was estimated to be a mean rate of 1.3 cases of infection in the total New Zealand population per year. Given the uncertainty in the biological system, primarily related to the very low sensitivity of any type of post mortem inspection (less than 25%) and the extremely low prevalence of *Taenia saginata* in New Zealand, this result met the decision criteria for validation.

Note: This validation process would likely not give the same result in a country with a moderate to high level of infection in the slaughter population.

6. Document and review

a. Document the methodology for the experimental trials and the results

b. Document the development of the mathematical model and its validation.

c. Document the results of the modelling.

(This example is documented in Van der Logt, P., Hathaway, S. C. and Vose, D. (1997): Risk assessment model for human infection with the cestode *Taenia saginata*. Journal of Food Protection 60:1110-1119.)

7. Conclusion: The new inspection package results in the same level of consumer protection as the old inspection package that involved considerably more slicing.

EXAMPLE SIX: VALIDATION OF A SAFE-HANDLING LABEL FOR TABLE EGGS

1. Pre-validation Tasks:

a. Hazard: *Salmonella* Enteritidis (SE) in table eggs (shell eggs).

a. Food Safety Outcome: Reduced frequency of consumption of eggs contaminated with SE.

b. 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 5ºC (41ºF) 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 5ºC (41ºF) 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:

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 5ºC (41ºF) and, when appropriate, cooking eggs until the yolk is firm.