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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

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PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES

Prepared by the United States of America with the assistance of Australia, Canada, France, Italy, New Zealand, Thailand, Sweden, the International Dairy Federation and the International Commission for Microbiological Specifications for Foods

Governments and interested international organizations are invited to submit comments on the attached Draft Code 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, Twelfth Edition*, pages 19-20) **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 February 15, 2004.**

I. INTRODUCTION

In the current environment of outcome-based codes of hygienic practice and codes of practice that provide flexibility with the selection of control measures, validation of food hygiene control measures acquires increased importance. It is through the validation process that one demonstrates that the selected control measures actually are capable, on a consistent basis, of achieving the intended level of food hazard(s) control. It is important to note that, while the initial demonstration of achievement of the desired food safety outcome is validation, the on-going demonstration that the control measure(s) is (are) being delivered properly is achieved by monitoring and verification.

These guidelines present information on the nature of food hygiene control measures, the concept and nature of validation, the difference between validation and verification, steps prior to validation, approaches to validation, factors which limit the ability to validate food hygiene control measures, the need for re-validation and priorities for validation/re-validation. These guidelines also address the relationship of HACCP to the validation of food hygiene control measures.

While the focus of this Paper is on the control of microbial hazards, reference is also made to control measures for chemical and physical hazards, since the scientific principles for validating control measures for these classes of hazards are similar to those for microbiological hazards.

In addition to validation of control measures, validation of the overall performance of a food safety system (the management control) normally constitutes an element in properly designed HACCP systems and food safety management systems. Such validation is not specifically addressed within these Guidelines, but references are made to it, where appropriate, to enable food industry to put the recommendations of this document into the context of their overall management system.

II. SCOPE

These guidelines apply to validation of the full range of food hygiene control measures used at any step within the food chain, including production, processing, distribution, storage and consumer handling of any type of food and which are intended to control microbial, chemical or physical hazards. The guidelines present information for use by the food industry to validate food hygiene control measures used to control hazards in food that can be used within the context of implementing HACCP principles as well as in other situations outside the HACCP context where there is the need to establish the efficacy of food safety control measures. The guidelines also provide information for use by national governments to verify that control measures have been appropriately validated. The guidelines are intended to apply to the validation of individual control measures or a limited combination of control measures against a performance criterion or performance objective as well as to the validation of entire sets of control measure combinations against an established performance objective or food safety objective.

III. DEFINITIONS[1]

Appropriate Level of Protection: 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.[2]

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.[3]

Food Safety Control System: The combination of control measures that, when taken as whole, ensure that food is safe for human consumption.

Food Safety Objective: The maximum frequency and/or concentration of a [microbial] hazard in a food at the time of consumption that still provides the appropriate level of health protection.[4]

Performance Criterion: The desired change in the level of microbial or other hazard(s) in a product that must be achieved by the application of one or more control measures in order to meet or contribute to meeting a performance objective.[5]

Performance Objective: The maximum frequency and/or concentration of a [microbial] hazard in a food at a specified step in the food chain before time of consumption that still provides or contributes to the achievement of an FSO or ALOP, as applicable.[6]

Monitoring: The process of conducting a planned sequence of observations or measurements to assess whether a control measure or combination of control measures are operating as intended and meeting specified limits.

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[1] 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.

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

[3] *International Recommended Code of Practice: General Principles of Food Hygiene*, CAC/RCP1-1969, Rev. 3 (1997), HACCP Annex.

[4] Based on the definition in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development).

[5] Ibid.

[6] Ibid.

Validation: The obtaining of evidence that the food hygiene control measure or measures selected to control a hazard in a food are capable of consistently controlling the hazard to the level specified by the performance objective.

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

IV. NATURE OF CONTROL MEASURES

The range of food hygiene control measures is extensive and encompasses measures applied throughout the food continuum, from primary production, through processing, to consumption. Food hygiene control measures may include: good agricultural and animal production practices; good hygienic practices; measures applied during processing (including the control of hazards through product formulation) and distribution (including transport), storage and retail sale; and good consumer practices during handling and consumption of the food. Food hygiene control measures can also encompass observation or sorting based on inspectional procedures, including product sampling and testing, as well as certain types of product labelling. Because of this broad range of control measures that can be applied in a food safety management system, and recognizing that there may be different ways of classifying control measures, one approach is to categorize control measures as illustrated below, with included examples.

Controlling initial levels of hazard(s)

- Employing good agricultural and animal production practices to minimize contamination during primary production.
- Using vaccines or competitive inhibition/exclusion to minimise microbial pathogens in food animals.
- Requiring verifiable documentation (e.g., letters of guarantee or certificates of analysis) attesting to the status of microbiological, chemical and physical hazards in the incoming raw material.
- The use of sampling and analyses (for monitoring purposes), as necessary, using appropriate methods based on established criteria to reject unacceptable ingredients or products.

Preventing an unacceptable increase of hazard(s)

- Limiting growth of pathogens during processing, storage and transportation through proper chilling and holding temperatures, acidification, reduction of water activity levels, use of preservatives, use of competitive microflora, etc.
- Employing good cleaning and disinfection practices to minimize microbial or chemical loads in establishments and/or on processing equipment that would otherwise contaminate the product.
- Preventing cross-contamination between raw and cooked product.
- Using packaging techniques and materials to protect food from contamination.
- Implementing practices that minimise product contamination.
- Effective implementation of environmental controls (e.g., pest control, housekeeping, etc.)

Reducing the level of hazard(s)

- Destroy pathogens (e.g., disinfectants, pasteurization, commercial sterilization, irradiation, freezing to kill certain parasites) or inactivate chemical hazards in the food.
- Remove pathogens (e.g., physical inspection, sorting, trimming, washing, micro-filtration, and centrifugation), toxic chemicals or physical hazards in the food.

V. CONCEPT AND NATURE OF VALIDATION.

The safety of a food product depends upon the prevention and control of hazards. The use of a properly designed and implemented single food control measure or combination of control measures, if available to a

particular sector of the food chain, may accomplish hazard prevention and control at that particular step in the continuum. When designing or revising a food safety control system for a product or product group, it is essential to determine that the control measures used are capable of controlling the hazard to the level specified and that this level of control can be achieved consistently.

The spectrum of food hygiene control measures includes both those for which effectiveness can be shown through direct experimental scientific studies and data collection as may be the case with certain hazard reduction control measures and those whose effectiveness can be inferred as may be the case with preventative control measures such as certain recommended agricultural practices, animal production practices and manufacturing practices. The overall safety of ready-to-eat foods is the combined effect of the food hygiene control measures that are applied under the direct control of food producers and manufacturers and those which are applied in other steps of the food chain over which the producer/manufacturer has no direct control (e.g., measures that are applied during primary production as well as during distribution, retail sale and consumer handling practices).

Statistical modelling can be a useful validation tool where combinations of control measures include measures that are beyond the control of the producer/manufacturer.

When a specific control measure in a food safety control system is historically known to be effective in controlling a specified hazard in a defined food, additional validation of that measure against performance criteria may not be necessary.

When the combination of control measures includes an essential control measure that is historically known to be effective in controlling a specific hazard in a defined food (e.g., a microbiocidal process that includes a substantial margin of safety), additional validation of that system against performance objectives may not be necessary. The same is true when a control measure has a large margin of safety based on information in the scientific literature (e.g., a pH or water activity well below that known to control a specific pathogen).

Validation vs. Verification and Monitoring

Validation of food hygiene control measures is different from verification and from routine monitoring. Validation focuses on collecting and evaluating scientific and technical information to determine whether the specified control measures will effectively control the hazard. Validation is not the on-going assurance that a critical control point is operating properly within specifications for the control of a hazard in a food product (monitoring). Additionally, it should not be confused with the verification activities of HACCP.

Monitoring is the on-going collection of information on a food hygiene control measure or attribute of a food that is critical for the control of a specific hazard at the time the control measure is applied. The information establishes that the measure or attribute is meeting or functioning within established limits, i.e., is under control.

Verification is used to determine that the food hygiene control measures have been properly implemented, i.e., that monitoring is being conducted and documented as specified, and thus are achieving the level of hazard control required. Verification occurs during operations or after operations through a variety of activities including review of records to confirm that the control measures, as designed, have been adequately implemented, i.e., to confirm compliance.

Validation of an individual or a defined set of control measures requires that effectiveness be measured against an expected outcome, frequently expressed in terms of a performance criterion (e.g., reduction of the level of *Salmonella* by 99.999% [5-log reduction] in a product). Thus, control measures are validated to prove that they can achieve a performance criterion established to deliver/reach the level of control needed for a specific hazard(s) in a food (s). Validation of the entire combination of control measures (the full food safety control system) requires that effectiveness be measured against an expected outcome, frequently expressed in terms of a performance objective established for the end product (e.g. maximum level of *Salmonella* to be <0.04 cfu/g). Such validation can under certain circumstances be focused on an essential individual or limited combination of control measure(s).

Validation is performed at the time a new food safety control system is designed/implemented, or when changes are made to the food safety control system that are significant enough to require re-validation to confirm that the control measures are capable of achieving the intended level of control.

Relationship of Validation to the Appropriate Level of Protection

It is helpful to note the relationship between validation, within the context of these guidelines, and the appropriate level of protection (ALOP), since the ALOP and validation have meaning under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Countries normally express an ALOP in terms of broad public health goals (e.g., reasonable certainty of no harm). Countries may require an objective demonstration that a particular set of control measures indeed meets their ALOP. From an operational standpoint, countries may utilize a performance criterion or a food safety objective or performance objective to provide a means to implement the ALOP for a particular hazard in a particular commodity (ies) or a performance criterion to provide a means to meet performance objectives (useful in particular where the food safety system relies on the validation of a single control measure). A performance criterion is always associated with the application of one or more control measures whereas a performance objective is associated with the acceptable level in the end product of the food business, when delivered to the next stage in the food chain. The process of validation will ensure that the selected set of control measures are effective in reaching a performance objective and the underlying FSO, and thus in ensuring that the ALOP is achieved.

Relationship of HACCP to Validation of Food Hygiene Control Measures

Application of validation within the context of the HACCP principles includes also the validation of the management of a food control system, including the validity of data used for the hazard analysis, the critical limits applied and specified corrective actions. The application of HACCP permits the clear identification of both hazards and essential, effective control measures. Successful implementation of HACCP is dependent on validation of a HACCP plan as consistently achieving food safety outcomes (performance objectives) for specific hazards. It also permits the clear identification of hazards, control measures available, Critical Control Points, if any, and Critical Limits, and corrective actions. The outcomes of monitoring and verification activities associated with a HACCP system will assist in determining when revalidation of a food safety control system may be necessary.

VI. STEPS PRIOR TO VALIDATION

Prior to validation by the food establishment, the scope of the validation (i.e., which control measures to validate), as well as the application of the control measure(s) within the food safety control system used to control a particular hazard(s) in a particular product(s) should be clearly known. This is achieved through completion of the following initial steps.

1) Identify the applicable points in the food safety control system where the control measure or measures are to be applied. These points may include:

    - Primary production
    - Transport to the processing facility
    - All processing inputs
    - Processing facility environmental controls
    - Product manufacture
    - Product storage
    - Product distribution

- Retail sale of the product
- Consumer handling practices
- Effectiveness of plant and/or government verification activities
- Product sampling and testing

2) Identify specific biological, chemical and physical hazard(s) that are reasonably likely to occur and need to be controlled i.e., to the specified level of the hazard that is acceptable. Evaluate their potential impact on the consumer.

3) Identify the food safety outcome required, including whether there is a FSO, and/or a performance objective established at a national or international level for the particular hazard/food combination under study. Where this is not the case, identify the performance objective needed for the hazard/end product combination, taking into account the stage of the food chain in which the control measure(s) is to be applied.

4) Identify the most appropriate step(s) for control of the hazard(s) in the food(s) for the particular process chosen by the business and the control measure(s) capable of controlling the hazard to the specified level. Techniques such as those used for the identification of Critical Control Points in a HACCP plan may be used, e.g., the CCP decision tree contained in the HACCP Annex to the General Principles for Food Hygiene.

5) Identify/establish the control measures that are subject to validation (e.g. the essential control measure, a limited combination of control measures, or the full combination of control measures intended to be applied – see section VIII). Emphasis should be given to ensure that effective control of the hazard(s) will be delivered given the scope of application of the food safety control system

6) Identify whether there is a regulatory performance criterion established for the particular control measure(s) under study. Where this is not the case, identify the performance criterion needed for the particular hazard/control measure combination, taking into account the performance objective(s) established (see (3) above) and the other control measures applied to control the particular hazard(s).

7) Identify whether any of the control measures have previously been appropriately validated or whether effectiveness of the control measures is so well established for the food safety control system under consideration that validation should be considered complete.

VII. DESIGN OF FOOD SAFETY CONTROL SYSTEMS

Where appropriate, all elements of the food safety control system should be considered in establishing food hygiene control measures. In some cases the control measure being validated may be such that points coming before and after the control measure are largely immaterial (e.g., a canning process). In some situations, some elements of the food safety control system (e.g., consumer handling practices) may lie outside the control of the entity undertaking the validation study (e.g., food manufacturer) but these elements and their variability will need to be taken into consideration in the establishment of the control measures.

The approach to validation should take into account the control that the organization undertaking the validation study (e.g., the food manufacturer) has over the relevant aspects of the food safety control system. In instances where the organization undertaking the study does not have direct control over one or more of the food safety control measures that are to be validated (e.g., the control measure occurs at the primary production level or in the product distribution chain), then appropriate data (e.g., survey data or statistically sound analytical testing results) will have to be obtained indicating the performance of such control measures under the range of conditions likely to be encountered both before and after the organization conducting the validation. In such instances procedures should be put into place to ensure that the data supplied to organizations undertaking the validation study are appropriate and accurate. This includes acquiring sufficient information such that the variability factors outside the manufacturer's control (e.g., raw ingredients and post-manufacturing conditions) can be reasonably estimated. If such information cannot be

obtained, the uncertainty resulting from the lack of knowledge of whether or not the hazard is controlled should be taken into consideration when designing and validating those aspects of the process over which control is maintained (e.g. through application of "safety factors" when establishing the performance criterion for the control measure and/or the performance objectives for the end product").

As indicated above, in certain cases, a single food safety measure, or a limited set of food safety measures will be the essential control measure(s), that when properly applied, will effectively determine the safety of the product. When such is the case, validation of the entire system can be focused on these measures.

When a single food hygiene control measure is the essential control measure, it is important not to ignore the other food hygiene control measures. While validation of these other measures may not always be required, it is important that these other control measures are in place and operate effectively to ensure that the controlling measure is adequate to ensure the safety of the food. If there are multiple control measures that are critical to the control of the hazard, all such measures have equal importance in the validation process.

VIII. APPROACHES TO VALIDATION

The precise approach to the validation of a set of control measures will depend on the nature of the hazard, the nature of the product, the type of control measures selected to control the hazard, and the intended extent of control. Usually a combination of approaches will be used since more than one control measure is normally employed to control a hazard (e.g., good hygienic practices, a microbiological kill step, refrigerated product storage). While the specific validation approach (es) employed may vary substantially, the goal remains the same across all products; i.e., documentation and demonstration that the control measures employed are properly designed to provide the level of hazard control required.

Although validation of the entire combination of control measures should be preferred, focused validation may suffice in certain cases. If focused validation is applied, it is important to carefully assess the nature of the food safety control system to determine what specific measures are essential to control the hazard. A decision will have to be made as to the specific control measures to be validated. It is normally not necessary to validate all control measures that comprise an entire food safety control system. Where microbiocidal processing with significant impact on hazard levels is the primary means of controlling the hazard, the actual control measures having significant impact may be few; in such a case it may be necessary only to validate these few control measures. Where hurdle technologies are employed as the means of control, there will be multiple control measures that will need to be validated simultaneously if they act synergistically. In some cases, on-farm practices will include essential food hygiene control measures and these will need to be validated. The control measures used at critical control points within a HACCP context are generally among the essential ones that require validation.

Approaches for validating food hygiene control measures:

1. **Reference to previous validation studies or historical knowledge of the effectiveness of the essential control measure(s).** For certain well-established processes (e.g., milk pasteurization at 72° C for 15 seconds), it may be sufficient to acquire only the data on a condition or attribute that controls a microbiological hazard (e.g., the temperature reached during cooking or the pH after acidification). In such instances, scientific literature, government regulations, international standards or guidelines (e.g., Codex Alimentarius) equipment manufacturer's validations, etc. may provide the scientific information needed to validate the control measures. However, if relying on such knowledge, care should be taken to ensure that the conditions of application in a new food safety control system are consistent with those identified in the scientific information examined.

2. **Scientifically valid experimental trials that document the adequacy of the control measure(s).** Laboratory challenge testing designed to mimic process conditions is such an approach as are pilot tests of particular aspects of a food processing system. It may be the case that a set of food hygiene control measures may be narrowed to a single essential control measure, for example where a pathogen reduction step is employed (e.g., an in-package finished product lethality treatment) whose adequacy may be confirmed and used to validate the entire set of measures. Documentation of log reduction of pathogens by the appropriate microbiocidal processes having a significant impact on hazard levels is an

example of this approach to validation. If the risk from the hazard is associated with growth of the pathogen to sufficient numbers, then the control of product, process or distribution conditions to prevent the growth of the pathogen should be validated and documented based on control of the growth limiting parameter. An example here might be the control of water activity to prevent growth of *Staphylococcus aureus*.

Scale up of laboratory-based experimental trials in a pilot plant may be necessary to ensure that the trials properly reflect actual processing parameters and conditions. Validation may have to be limited to a laboratory/pilot plant if there is no appropriate surrogate microorganism(s) available that can be used to acquire data on the hazard under actual production conditions; viable pathogenic microorganisms should not be purposefully introduced into a food production facility.

3. **Collection of biological, chemical and physical hazard data during normal operating conditions in the food operation.** For example, when good veterinary practices and good hygienic practices in the field and/or processing establishment constitute the food safety control system it may be necessary to validate these measures through the use of intermediate and/or finished product sampling and testing based on the use of statistical sampling plans and validated testing methodology. Sufficient data should be collected that appropriate statistical analysis can be carried out to assess the effectiveness of the measure being validated.

4. **Statistically designed surveys.** This approach can be used to document control measures that cannot otherwise be measured. For example, consumer practices related to the storage of perishable products is a control measure that can be measured through surveys. Competent authorities and/or industry can recommend control measures for consumers to apply and the information obtained from surveys can be incorporated into an overall approach for pathogen control. It is important to emphasize that this use of statistical surveys is separate from use of statistical surveys that may be employed in on-going monitoring. When statistical validation cannot be employed for a control measure that otherwise cannot be measured, the impact of the control measure should be taken into account elsewhere (e.g., the use of safety factors) in the design of the process over which control is maintained (see below).

5. **Mathematical modeling.** This approach can be used to estimate the combined performance of a combination of already validated control measures, including taking into account variation of individual control measures in order to validate the achievement of performance objectives and food safety objectives. An example of this can be found in existing approaches used to validate the adequacy of an established product shelf-life under variable storage, distribution and consumer handling conditions.

6. **Control measures required by competent authorities.** The scientific basis for establishing new control measures or changes in established control measures is often documented when regulatory requirements are established. If it can be determined that the scientific basis for such a risk management decision is sufficient, it can serve as the validation of a similar control measure being required elsewhere.

Steps Involved in the Validation Process

The process of validating food hygiene control measures includes the following steps:

- Carry out the necessary steps prior to validation presented in Section VI above.
- Select the approach (es) to use in validating the controlling measures.
- Assemble documentation of relevant previous validation efforts, evaluate its appropriateness and feasibility for the control measure(s) under consideration and assess the need for supplementary validation.
- If needed, conduct the validation studies.
- Document the findings of the validation studies.
- Assess the findings of the validation studies or other validation documentation against the performance objective or food safety objective or the performance criterion if appropriate.

- If the validation studies do not confirm that the expected level of hazard control can be achieved, adjust the process parameters applied and/or the control measures as appropriate and repeat the validation studies. If effectiveness still cannot be achieved, redesign of the food safety control system should be done, or the food product should not be produced/manufactured.

Subsequent to initial validation, organisations should:

- Periodically review the food safety control system to ensure that the set of control measures selected to control the hazard have not changed.
- Re-validate the food safety control system as needed if significant changes occur (see Section X).

Additional considerations

As noted above, it is important to differentiate validation from verification. If there is an indication that the hazard is not being controlled to the level specified, it is important to verify that all food hygiene control measures are being delivered properly prior to considering re-validation (including the selection of new control measures). Consideration should be given to setting pre-established criteria for the rate of failure for monitoring or verification information that would require a thorough re-examination of a food safety control system including re-validation.

The extent of work required for validation will be a function of the amount of scientific evidence available and previous validation studies on the process. As noted above, where a control measure is well known and established, such as the pasteurization of milk (at 72°C for 15 seconds), the process is so standardized that validation of parameter changes can be given by consulting a time/temperature chart. Novel processes with multiple control measures (e.g., many refrigerated ready-to-eat foods) may require greater resources for validation.

When validating control measures, it is important to determine whether the control measures are unique to a specific processing facility. If they are, validation studies that are specific to the unique situation may be necessary.

IX. LIMITATIONS TO VALIDATION

Validation depends on the application of the best science possible within practical economic and resource constraints. There are several factors, however, which place limits on the level of certainty of the validation and may dictate the incorporation of significant "safety factors" into the control measures established for the product. These factors, some of which are related to the design of food safety control systems, include the following:

- Lack of an ALOP, FSO, Performance Objective or Performance Criterion: The lack of a clearly defined ALOP, FSO, performance objective and/or performance criterion may limit the ability to clearly demonstrate that the desired outcome has been achieved.

- Constancy of Control Measures: The constancy of control measures will be greatest for physical processes (e.g., thermal kill steps), more variable with chemical or biological measures (e.g., competitive microflora) and the most variable for behavioural measures that include inspector-based activities. Information on the variability of control measures is often lacking.

- Number of Control Measures: Since variability occurs with each control measure, the greater the number of control measures for a particular hazard that require validation, the greater the overall statistical variability in the validation process. In some instances, it may be possible to validate a defined set of control measures as a single entity such that the overall variability of the set of control measures may be easier to determine.

- Process Variability (variability that occurs in each step of a food operation): The extent of variability in areas such as equipment performance and reliability, environmental conditions and potential for recontamination may impact significantly the effectiveness of control measures and thus have to be

considered in conducting a validation study. Process variability should be taken into consideration when evaluating the need to establish safety margins to assure product safety.

- Limitations of Sampling Plans and Analytical Test Methods: The use of appropriate validated analytical methodology and statistical-based sampling plans is essential when validating food hygiene control measures. The reliability of analytical testing is directly related to the precision parameters of the analytical methodology used and the statistical sampling plans employed. The performance characteristics of the sampling plan(s) to be used should be known. Performance characteristics specify the level of statistical error and uncertainty associated with a specific level of sampling. Sampling plans should be matched with the level of certainty desired in the validation study being undertaken.

- Resource Constraints: Validation activities are often resource intensive. Areas such as product sampling and analytical testing require significant resources, particularly when applied in an appropriate statistical fashion. The extent to which such activities can be undertaken will place limits on the ability to validate food hygiene control measures.

X. NEED FOR RE-VALIDATION

There are many changes that could lead to a need to re-validate a food safety control system. Examples include:

- The introduction of a new control measure, technology or a piece of equipment that has not previously been validated.
- The level of the hazard changes (e.g., the levels of a pathogen occurring in an ingredient are higher than originally encountered during the conduct of baseline studies).
- The response of the hazard to control measures has changed (e.g., microbial adaptation).
- There is the emergence of a previously unidentified hazard or concern related to a particular food (e.g., enterohaemorraghic *Escherichia coli* in apple juice).
- New information becomes available indicating that the current food safety control system is not adequate to control the hazard to the level specified and ensure the chosen level of protection (e.g., epidemiological findings confirm an increase in foodborne illness from the hazard in the food).
- A new pathogen is identified and the effectiveness of the control measure(s) against it is not known.

The need to re-validate may also arise when monitoring or verification identifies failures above a pre-established rate for which a process deviation cause cannot be identified. Non-compliance with monitoring or verification criteria may indicate a change in the parameters used to develop the current hazard analysis and control measures. In these situations, there is a need to investigate and, if necessary reaffirm, that the defined set of control measures is effective in controlling the hazard to the required level.

When there is any doubt regarding the efficacy of an essential control measure in the context of the specific processing application, it is essential to assess its effectiveness, which may require re-validation.

XI. PRIORITIES FOR VALIDATION/RE-VALIDATION

In principle, the validation of all control measure combinations used to control the various hazards in a food product or product group should be carried out. In practice, however, resource constraints normally prohibit a comprehensive approach to control measure validation. The following are some suggested parameters for determining how priorities should be determined and when validation may be required.

- Essential nature of a control measure(s): Validation priority should be given to the essential control measures in a food safety control system, i.e., prioritization should be done according to the relative importance of a given control measure in the overall scheme of a food safety control system.

- Level of risk: The higher the likelihood that a loss of control will lead to an adverse health effect from a hazard, and the more severe the adverse health effect which may result, the more attention should be paid to assuring that the set of control measures selected are effective.

- Historical experience: If little or no experience exists with respect to the control of a hazard, it becomes more important that the validation of control measures selected to control the hazard be undertaken. For many food production and processing scenarios, however, there is extensive history that the measures used to control food borne hazards are effective. When a sufficient basis can be established, there may be no need to validate what prior experience has shown to be effective when the desired food safety outcome is known. Care is needed, however, to avoid assuming that a food production or processing system is safe based solely on historical experience. Sampling and test procedures used to obtain the original data may have been insufficient in the context of current capabilities. New strains of microbial pathogens may now exist that do not behave in the same manner as those strains used for determining early food control processes. New epidemiological and/or clinical information may indicate that the previously used food hygiene control measures were less effective than previously thought. The current state of the science associated with both the microorganism and the control measure should be considered when determining whether or not historical information is sufficient to establish effectiveness.

- Degree of uncertainty: If it is known that a control measure, process, raw ingredients or consumer handling practices are highly variable, priority should be given to establishing safety factors that will assure that food safety outcomes are achieved.

- Process innovations: The addition of new technology to a process may require re-validation of control measures originally established for the food safety control system. While minor changes are less likely to require re-validation of the control measures, multiple minor changes will almost certainly result in the requirement for re-validation.

- New data: New clinical or epidemiological information, or new analytical methodology may demonstrate that the original control measures are inadequate and parameters may need to be changed or new control measures may need to be designed and implemented. This will also result in the need to re-validate the food safety control system.