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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (at Step 3 of the Procedure)

(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 or information on the attached Proposed Draft Guidelines at Step 3 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, US Department of Agriculture, Room 4861, 1400 Independence Avenue, S.W., Washington DC, 20250 USA, preferably by email: syed.ali@fsis.usda.gov or fax: 1 (202) 720-3157, with a copy **to:** Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, viale delle Terme di Caracalla, 00100 Rome, Italy, by email: codex@fao.org or fax: +39 (06) 5705.4593 **before 15 November 2002**.

I. INTRODUCTION

1. In the current environment of outcome-based codes of hygienic practice and codes of practice that provide flexibility with the selection of control measures, the concept of validation of food hygiene control measures acquires increased importance since it is through this process that one demonstrates that the selected control measures actually are capable, on a consistent basis, of achieving the required 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 verification.

2. These guidelines present information for use by national governments and the food industry to validate food hygiene control measures used to control a specific hazard or hazards in a specific food or group of foods. The guidelines are applicable to the full range of food hygiene control measures used in food production, processing, distribution and storage of foods.

3. 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.

II. SCOPE

4. These guidelines apply to validation as it could be applied to food hygiene control measures throughout the food chain, including production, processing, distribution and storage of foods. The guidelines present information on the nature of food hygiene control measures, the concept and nature of validation, the difference between validation and verification, prerequisites to validation, approaches to validation, factors which limit the ability to validate food hygiene control measures, and the extent to which validation/re-validation is required. These Guidelines also address the relationship of HACCP to the validation of food hygiene control measures.

III. DEFINTIONS

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.[1]

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.[2]

Essential Control Measure: A control measure or combination of control measures that are required to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

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 [microbiological] hazard in a food at the time of consumption that provides the appropriate level of health protection.[3]]

Performance Criteria: The required outcome of one or more food control measures at a step or combination of steps in the production, processing, distribution, marketing, or preparation of food that contribute to assuring the safety of a food.[4]

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 properly.

Validation: The obtaining of evidence that the food hygiene control measures selected to control a specific hazard(s) in a specific food(s) are capable of consistently controlling the hazard to the level specified.

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

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

[3] Report of the 34th Session of CCFH, ALINORM 03/13, paragraph 123.

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

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a food safety system is operating properly.

IV. NATURE OF CONTROL MEASURES

5. The range of food hygiene control measures is extensive and encompasses measures applied through the food continuum, from primary production, through processing, to consumption. Food hygiene control measures include: good agricultural practices; good manufacturing practices; HACCP; measures applied during distribution (including transport), storage and retail sale; and, good consumer handling practices. Food hygiene control measures can also encompass inspectional procedures including product sampling and testing and certain types of product labeling. 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, which include examples.

Controlling initial levels of hazard(s)

- Employing good agricultural practices to minimize contamination during primary production.
- Requiring auditable/verifiable documentation attesting to biological, chemical and physical specifications.
- Sampling and analyses using microbiological, chemical and physical methods of specified sensitivity and specificity to reject unacceptable ingredients or products based on established criteria.

Preventing an unacceptable increase of hazard(s)

- Limiting growth of pathogens through chilling, use of proper holding temperatures, pH, water activity levels, use of preservatives, use of competitive exclusion, etc.
- Employing good sanitation and disinfection practices to minimize microbial or chemical loads in facilities and/or on processing equipment that would otherwise contaminate the product.
- Using packaging techniques and materials to protect food from contamination.
- Implementing employee practices that minimize product contamination.

Reducing the level of hazard(s)

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

V CONCEPT AND NATURE OF VALIDATION.

6. The safety of a food product depends upon the prevention and control of hazards. Hazard prevention and control, if available to a particular sector of the food chain, may be accomplished by the use of a properly operating single food control measure or combination of control measures. When designing or revising a food safety 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.

7. The spectrum of food hygiene control measures includes both those for which effectiveness can be shown through direct experimental scientific studies and data collection and those whose effectiveness must be inferred through indirect observations, behavior studies or surveys. Food hygiene control measures include those that are under the direct control of food producers and manufacturers and those which occur in other steps of the food chain over which the producer/manufacturer has no direct control (e.g., measures that occur during distribution, retail sale and consumer handling practices).

Validation vs. Verification and Monitoring

8. Validation of food hygiene control measures is different from verification or routine monitoring.

9. As noted above, for the purposes of these Guidelines, validation is the obtaining of evidence that the food hygiene control measures selected to control a specific hazard(s) in a specific food(s) are consistently capable of controlling the hazard to the level specified.

10. Monitoring is the on-going collection of "real-time" information on a step of a food safety system or attribute of a food that is critical for the control of a specific hazard that establishes that the step or attribute is functioning within established limits, i.e., is under control.

11. Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine that the food hygiene control measures are being properly delivered as intended and thus are achieving the level of hazard control required.

12. Validation of a defined set of control measures requires that their effectiveness be measured against an expected outcome, preferably 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).

13. Validation is performed at the time a new food safety system is designed/implemented, or when changes are made to the food safety system that are significant enough to require re-validation. Examples of the changes that could lead to a need to re-validate a food safety system are: a change in the level of the hazard (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); reliance on a new control measure, technology or a piece of equipment that has not previously been validated. The need to re-validate may also arise as a result of the food safety system failing to meet monitoring or verification criteria at a rate or a manner that is indicative of a change in the parameters used to develop the initial hazard analysis. In these situations, there is a need to investigate and, if necessary reaffirm, that the defined set of control measures are effective in controlling the hazard to the required level.

14. 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. Additionally, it should not be confused with the verification activities of HACCP.

15. When an essential control measure in a food safety system (e.g., a thermal process that includes a substantial margin of safety) is historically known to be effective in controlling a specified hazard, additional validation through product testing may not be required.

Relationship of Validation to the Appropriate Level of Protection

16. 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 has 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). From an operational standpoint, countries may utilize a performance criterion (the required outcome, expressed in terms of the degree of hazard control expected) or a food safety objective [the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides the appropriate level of health protection] to provide an objective means to implement the ALOP for a particular hazard in a particular commodity(ies). A performance criterion is always associated with the application of one or more control measures. The process of validation will ensure that the selected set of control measures are effective in reaching the performance criterion and the underlying FSO, and thus in ensuring that the ALOP is achieved.

Relationship of HACCP to Validation of Food Hygiene Control Measures

17. HACCP can be a helpful means of guiding the validation process. The application of HACCP permits the clear identification of both hazards and essential control measures. Further, the identification of HACCP Critical Control Points and Critical Limits, and their effective implementation will help to ensure that validated system continues to operate properly. The monitoring and verification activities associated with a HACCP system will help to define when a food safety system requires re-validation.

VI. STEPS PRIOR TO VALIDATION

18. Prior to validation, the basis of a food safety system used to control a particular hazard(s) in a particular product(s) must be clearly known. This requires the following to be done.

1) Identify specific hazard(s) to be controlled and the specified level of the hazard that is acceptable. Evaluate their reasonable likelihood of occurrence and the potential impact to the consumer. These include biological, chemical and physical hazards.

2) Identify the applicable range of food safety system elements. These elements may include:

    - Primary production and transport to the processing facility
    - Product manufacture
    - Product storage
    - Product distribution
    - Retail sale of the product
    - Consumer handling practices
    - Effectiveness of plant and/or government inspectors
    - Product sampling and testing

    Preferably, all elements of the food safety system should be considered in validating food hygiene control measures. In some situations, some elements of the food safety 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 approach to validation (see below).

3) Identify whether there is an ALOP, FSO or performance criterion established at a national level for the particular hazard/food combination.

4) Identify the most effective step(s) for control of the hazard(s) in the food(s) and the control measure(s) capable of controlling the hazard to the specified level.

5) Identify/establish the essential control measures. Emphasis must be given to ensure effective control of the hazard(s) given the scope of application of the food safety system.

6) Identify whether any of the essential 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. APPROACHES TO VALIDATION

19. 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 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 microbiocidal 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.

Identify Essential Control Measures

20. 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 what specific control measures must be validated. It is normally not necessary to validate all control measures that comprise an entire food safety system. Where thermal processing 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 sole means of control, there will be multiple control measures. In some cases, on-farm practices will be essential food hygiene control measures and will need to be validated. The control measures used at critical control points are among the essential ones to be validated.

Approaches to Validation

21. Approaches or tools that can be used to validate food hygiene control measures are the following.

1. Reference to previous validation studies or historical knowledge of the effectiveness of the essential control measure(s). For certain well-established processes, 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).

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 the 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., a packaged 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 thermal processes 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 below 0.85 to prevent growth of Staphylococcus aureus.

   Pilot plant work-up of experimental trials 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 contaminant 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. A similar approach will be needed when hurdle technology is employed and no microbiocidal treatment is used. 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 essential control measures that cannot otherwise be measured (e.g., inspection practices, consumer storage practices of temperature sensitive products). 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 an essential control measure that otherwise cannot measured, the impact of the control measure must be taken into account elsewhere in validating those aspects of the process over which control is maintained (see below).

22. As noted above, validation through the conduct of experimental trials and direct collection of analytical and related information may not be necessary in those instances where the efficacy of a control measure has been well established and its application to the food is without complicating factors. In such instances, scientific literature, government regulations, equipment manufacturer's validations, etc. may provide the scientific information needed to validate the control measures. However, in such instances care must be taken to ensure that the conditions of application in a new food safety system are consistent with those identified in the scientific information examined. When there is any question regarding the efficacy of an essential control measure in the context of the

specific processing application, it is essential to verify its effectiveness, either through verification or re-validation.

23. The approach to validation will have to take into account over what parts of the food safety system the organization undertaking the validation study (e.g., the food manufacturer) has control. In instances where the organization undertaking the study does not have direct control over one or more of the food safety control measures that must be validated (e.g., the control measure occurs at the primary production level or in the product distribution chain), then appropriate data (e.g., statistically sound analytical testing results) will have to be obtained indicating that control measures are effective in controlling the hazard. In such instances procedures should be put into place upon which to base 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, post-manufacturing conditions) can be reasonably estimated. If such information cannot be obtained, this lack of information, and the uncertainty which arises in the knowledge of whether or not the hazard is controlled, must be taken into consideration when designing and validating those aspects of the process over which control is maintained.

Steps Involved in the Validation Process

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

- Carry out the necessary steps prior to validation presented in Section V above.
- Select the approach(es) to use in validating the controlling measures.
- Conduct the validation studies.
- Assess the findings of the validation studies against the performance criterion/criteria, food safety objective or other selected outcome.
- If the validation studies do not demonstrate that the expected level of hazard control has been achieved, adjust the control measures as appropriate and repeat the validation studies. If validation still cannot be demonstrated, redesign of the food safety system must be done, or the food product should not be produced/manufactured.
- Periodically review the food safety control system to ensure that the set of control measures selected to control the hazard has not changed.
- Re-validate the food safety system as needed if significant changes occur (see also Section VIII). For example, re-validate:

    - When new processing technology is introduced; when new information becomes available indicating that the current food safety system is not adequate to ensure the chosen level of protection (e.g., epidemiological findings confirm an increase in food borne illness from the hazard in the food); when a new pathogen is identified that cannot be controlled with existing food hygiene measures.
    - When repeated monitoring or verification identifies failures for which a process deviation cause cannot be identified; or when other information indicates that the food hygiene control measures are not adequate to control the hazard to the level specified.

25. As noted above, it is important to separate validation from verification. If there is an indication that the hazard is not being controlled to the level specified, prior to considering re-validation of the food hygiene control measures (including the selection of new measures), it is important to verify that all food hygiene control measures are being delivered properly. 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 system including re-validation.

Additional considerations

26. 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 and/or verification can be focused on these measures.

27. When a single food hygiene 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 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. The reverse is also true. That is, 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.

28. 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. For procedures with a single control measure that are well known and established such as the pasteurization of milk, 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.

29. When validating control measures, it is important to determine whether the measures will be processing plant specific. If they are, validation must be carried out on a plant- by- plant basis.

30. In some cases, it may not be possible to validate certain control measures that would otherwise be subject to validation (e.g., the organization undertaking the validation does not have control over the measure and cannot obtain appropriate analytical or other data that can demonstrate the effectiveness of the measure). In such cases, it is important that to verify, through statistically designed ingredient and/or end-product testing, that the controlling food safety measures have been implemented. If verification is not possible or practical (e.g., consumer handling practices) the potential impact of such measures should be taken into account in the use of other safety margins and/or validation/verification activities applied elsewhere in the food chain.

VIII. LIMITATIONS TO VALIDATION

31. 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 include the following.

- Lack of an ALOP, an FSO, or a performance criterion: The lack of clearly defined ALOPs, FSOs and/or performance criteria limit the ability to clearly establish that validation 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 behavioral measures that include inspector-based activities.

- Number of control measures: Since variability occurs with each control measure, the greater the number of control measures 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.

- 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.

32. These and other factors create uncertainties associated with the validation of control measures. To the extent possible, control measures should be selected such that uncertainties are minimized. However, the uncertainties that do exist in the ability to validate food hygiene control measures must be taken into account when establishing performance or related criteria. If the uncertainty in validating a control measure is such that the reliability of the control measure to effect a safe product is in doubt, then a greater margin of safety must be applied elsewhere in the process where the control measure can be meaningfully validated or verified. For example, if there is no uncertainty in validating a control measure(s), a 5D kill may be employed if the performance required is a 5D kill. If there is high uncertainty in validating a control measure(s), then a 7D kill may be required instead.

XI. EXTENT TO WHICH VALIDATION/RE-VALIDATION IS REQUIRED?

33. 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. Choices do have to be made. Given this situation, how should priorities be determined and when is validation required? When is re-validation required? The following are some suggested parameters for decision-making.

- Essential nature of a control measure(s): Validation priority should be given to the essential control measures in a food safety 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 system.

- Level of risk: The higher the potential for 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 for its control are effective.

- Historical experience: If little or no experience exists with respect to the control of a hazard, validation of control measures to control the hazard must 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. Safe foods are produced. There is no need to validate what prior experience has shown to be effective if 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 must be considered when determining whether or not historical information is still valid.

- Process innovations: The addition of new technology to a process may require re-validation of control measures originally established for the food safety 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, such as new clinical or epidemiological information, or new analytical methodology may demonstrate that the original control measures are inadequate and that new control measures may need to be designed and implemented. This will also result in the need to re-validate the food safety system.