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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
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**DISCUSSION PAPER ON 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 and the International Dairy Federation**

## INTRODUCTION

1. In the current environment of outcomes based codes of hygienic 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 validation that one is able to demonstrate that the selected control measures actually achieve the desired goal of controlling the food hazard(s).
2. Given the importance of validation of food safety control measures and the current lack of Codex guidelines on the subject, it would appropriate for the Codex Committee on Food Hygiene (CCFH) to consider the development of guidelines in this area.
3. This Paper discusses the subject of validation and presents a recommendation to the CCFH relating to the development of Guidelines for the Validation of Food Hygienic 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.

## CONCEPT AND DEFINITION OF VALIDATION

4. The safety of a food product depends upon the control of hazards that cause adverse health effects. Hazard control is accomplished by the use of a combination of properly operating control measures. When designing or revising a food safety system for a product or product group, it is essential to determine that the set of control measures are, indeed, effective in controlling the hazard to the level specified.

5. Validation, in the context of this Discussion Paper, is defined as the process of ensuring that a defined set of control measures is capable of achieving appropriate control over a specific hazard(s) in a specific food(s).

6. Validation of a defined set of control measures requires that their effectiveness be measured against an expected outcome, normally expressed in terms of a performance criterion (e.g., a heat treatment designed to reduce the level of Salmonella by 99.999% [5-log reduction] in a product). Thus, control measures should be validated to prove that they meet established performance criteria for controlling a specific hazard(s) in a food (s).

7. It is helpful to understand the relationships between validation 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). The SPS Agreement defines the ALOP as the “level of protection deemed appropriate by the Member establishing the sanitary or phytosanitary measure “ 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 exposure to a food-borne microbiological hazard that a society decides it can tolerate) to provide an objective means to describe 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.

## **VALIDATION VERSUS VERIFICATION/MONITORING**

8. Validation of food hygiene control measures is different from verification and routine monitoring. Validation is typically conducted prior to the initiation of a new food safety system to assure that it is capable of achieving the desired food safety outcome. Validation is repeated only infrequently when changes made to the food safety system are significant enough to require revalidation. Alternatively it could be required if there is 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) or the response of the hazard to control measures has changed (e.g., microbial adaptation) or there is the emergence of a previously unidentified hazard or concern related to a particular food (e.g., Enterohaemorrhagic *E. coli* in apple juice). In these situations, there is a need to reaffirm that the defined set of control measures are effective in controlling the hazard to the required level. Validation is not a process of monitoring 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 is not the ongoing process of verifying whether a HACCP plan is operating correctly.

## **PREREQUISITES TO VALIDATION**

9. 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:

i) Identification of the specific hazard(s) to be controlled, including microbial, chemical and physical hazards .

ii) Identification/establishment of a performance criterion for the process, i.e., the expected level of control of the hazard.

iii) Identification of the food hygiene control measures to be used for control of the food hazard. It is important to carefully assess the nature of the processing system to determine what specific measures will be the controlling ones. Where thermal processing is the primary means of controlling the hazard, the actual controlling measures may be few. Where hurdle technologies are employed as the sole means of control, there may be multiple control measures.

## **NATURE OF CONTROL MEASURES**

10. Because there are a large number 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 follows (with accompanying examples).

### **Controlling initial levels of a hazard**

- Require documentation attesting to microbiological, chemical and physical specifications.
- Use microbiological and chemical testing and appropriate criteria of specified sensitivity (and specificity) to reject unacceptable ingredients or products.

### **Preventing an unacceptable increase of the hazard**

- Prevent contamination (e.g., adopting good hygienic practices that minimize contamination during primary production or slaughter, separating raw from cooked ready-to-eat foods, implementing employee practices that minimize product contamination, using aseptic filling techniques).
- Prevent growth of pathogens (e.g., chilling and holding temperatures, pH, water activity, preservatives).

### **Reducing the level of a hazard**

- Destroy pathogens (e.g., freezing to kill certain parasites, disinfectants, pasteurization, irradiation).
- Remove pathogens (e.g., washing, ultra-filtration, centrifugation).
- Remove physical hazards.

## **APPROACHES TO VALIDATION**

11. Approaches or tools that can be used to validate food hygiene control measures would appear to be fundamentally three in nature.

i) Peer reviewed experimental trials that document the adequacy of the control measure(s). Laboratory challenge testing designed to mimic process conditions is such an approach. 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 lethality treatment) whose adequacy may be verified 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. 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). 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 could also 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.

ii) Collection of microbiological, chemical and physical contaminant data during normal operating conditions in the food operation. For example, when good veterinary practices and good hygienic practices constitute the food safety control system it will 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.

iii) Statistically designed surveys. This approach can be used to document critical practices that cannot otherwise be measured (e.g., inspection practices, consumer storage practices of temperature sensitive products). Included within this category are epidemiological surveys documenting the presence or absence of illness associated with a food manufacturing process.

12. The precise approach to the validation of a set of control measures will depend on the nature of the hazard, nature of the product, and the type of preventive measures selected to control the hazard. Usually a combination of approaches would be used since more than one preventive measure is normally employed to control a hazard (e.g., good hygienic practices, a microbiocidal kill step, refrigerated product storage). While the specific validation techniques employed may vary substantially, the goal remains the same across all products; i.e., documentation that the control measures employed are consistently able to provide the level of protection required to protect the public health.

#### **FACTORS TO CONSIDER IN VALIDATION**

13. 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. These factors include the following:

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 which include inspector based activities. The greater the number of control measures involved in the validation process, the greater the potential for variability in the validation process.

Process Variability (variability that occurs in each step 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 reliability of analytical testing is directly related to the precision parameters of the analytical methodology used and the statistical sampling plans employed. The use of appropriate validated analytical methodology and sampling plans is essential when validating food hygiene control measures.

Extent of Laboratory Validation of Control Measures such as Microbiocidal Treatments: For those processes where a single kill step can be used to judge, or primarily judge, the effectiveness of a set of food hygiene control measures, the extent of validation required will be a function of how well the science is established and the parameters affecting the process are known. For a procedure as well established and utilized as the pasteurization of milk, for example, the process has become so standardized that approval of parameter changes can be given by consulting a time/temperature chart. However, for other processes, such as non-traditional microbiocidal treatments like non-thermal processes, significantly more resources will be required.

Adequacy of Control Measures Requiring More Than Laboratory Validation: In certain cases, it may be important that control measures that lie beyond the responsibility of the producer or processor be validated. For example, it may be important to validate a "keep refrigerated" label on a food product. If refrigeration is strictly observed, the food's microbial or chemical constancy can be tested for by laboratory procedures. What cannot be determined readily in this manner is whether the warning is effective in transit, in the retail establishment and after sale to the consumer. If such an element is important to determine, special means to validate the control measure may be required. Such means can involve, for the example given, the use of statistical studies using time/temperature monitoring devices or consumer surveys. The key point in this regard, is understanding the limitation imposed by the potential lack of precision in the validation study and applying knowledge of this limitation to ensure that safety of the product is maintained. As noted below, uncertainties in validation of essential or important control measure steps require the use of additional safety margins elsewhere in the process to ensure adequate consumer protection.

Resource Constraints: The approaches to validation noted above 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.

Uncertainties associated with the validation of control measures: Uncertainties 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. For example, if there is no uncertainty in validating a control measure(s), a 5D kill may be employed. If there is high uncertainty in validating a control measure(s), then a 7D kill may be required.

## **EXTENT TO WHICH VALIDATION IS NEEDED. WHEN IS VALIDATION REQUIRED?**

14. 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? The following are some suggested parameters for decision-making:

Level of risk: 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 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 historical. The addition of new technology creates a new system. Minor changes may also result in a new system; multiple minor changes will certainly result in a new system that requires validation. Also, new data, such as new clinical information, and new detection methodology may indicate that the previously used food hygiene control measures were less effective than previously thought.

Focused validation: If a particular control measure (e.g., a microbiocidal treatment) is the clear determinant measure for ensuring the safety of the product, validation may focus on that measure. By focus, what is meant is that greater statistical assurity of the control of the hazard is obtained, in contrast to other control measures occurring in the system. Focused validation does not mean that other control measures are ignored. It is important to note that the reverse is also true. That is, if there are multiple measures that are critical to the control of the hazard, all such measures have equal importance in the validation process.

### **Relationship of HACCP to Validation of Food Hygiene Control Measures**

15. HACCP can be a helpful means of guiding the validation process. The application of HACCP permits the clear identification of both hazards and 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.

## **GUIDELINES FOR VALIDATION**

16. Based on the above discussion, a set of guidelines relating to validation of food hygiene control measures appears to be appropriate and can to be developed. These guidelines should encompass at least the following elements:

- Rationale for validation of food hygiene control measures.
- Concept and definition of validation.

- Prerequisites to undertaking validation.
- Approaches to validation.
- Factors to consider in validation.
- When and to what extent is validation needed?
- Relationship of validation of food hygiene control measures to HACCP.

## **RECOMMENDATION**

17. The Committee is invited to comment on the thoughts brought forward in this Discussion Paper and determine the appropriateness of developing a set of *Guidelines for the Validation of Food Hygiene Control Measures*.