
**NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS**

FINAL

**A REVIEW OF THE CODEX “DISCUSSION PAPER ON PROPOSED
DRAFT GUIDELINES FOR THE VALIDATION OF FOOD
HYGIENE CONTROL MEASURES”**

**Submitted with Technical Corrections and Edits
October 9, 2002
Washington, DC**

**THIS REPORT WAS ADOPTED BY NACMCF ON
AUGUST 28, 2002**

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF or Committee) was asked to review and comment on the proposed Codex Committee on Food Hygiene (CCFH) document entitled " Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures."

The Committee was provided the following charge:

In developing current codes of hygienic practice, the Codex Committee on Food Hygiene (CCFH) has moved towards a food safety outcomes approach that provides flexibility in the selection of control measures. In using this approach, CCFH has also recognized the increased need for validation of food safety control measures to demonstrate that they are capable of achieving the intended level of control of the hazard. In this regard, CCFH has used the term "validated control measures".

In addition to recognizing the increased importance of validation, the CCFH has also noted a lack of guidance on how the validation of food safety control measures should be conducted. CCFH has initiated the development of "Guidelines for the Validation of Food Hygiene Control Measures". The focus of this document is the validating of measures to control microbiological pathogens in food. The United States is the lead country for the development of this document, which in the parlance of Codex is referred to as a "Discussion Paper." A copy of the current Discussion Paper is attached.

The Discussion Paper speaks to several points including: the concept and definition of validation; prerequisites to validation; nature of control measures; approaches to validation; factors to consider in validation; and extent to which validation is needed, and when validation/re-validation is advisable.

Keeping in mind that the proposed new CCFH work on Guidelines for the Validation of Food Hygiene Control Measures is at the Discussion Paper stage and a complete technical document has yet to be developed, as guidance to the United States Delegation to the Codex Committee on Food Hygiene for the further development of the Discussion Paper, expert advice is requested from NACMCF on the following areas.

1. Are the stated prerequisites all necessary? Are there prerequisites that are critical, but that have not been adequately identified? Do all of the prerequisites have the same degree of importance?
2. Has the scientific basis for the approaches to validation been adequately justified? Are the approaches sufficient to permit the validation of food hygiene control measures? Are there alternative approaches to validation that should be considered?

3. With respect to the individual approaches to validation, what elements should be further elaborated?
4. Are the factors to be considered in validation complete? Are there additional factors that should be considered? Do all the factors have the same degree of importance?
5. Is the information presented on when validation or re-validation is needed sufficient and reasonable in relation to the simultaneous goals of being protective of public health, fostering scientifically based food safety systems, and developing practical advice on validation of control measures?

The Committee has the following comments on the overall document:

General Overview:

We recommend that a scope section is added that encompasses the following concepts:

SCOPE: The scope needs to clearly address and differentiate between validation activities and verification activities, and delineate differences between processing plant production procedures (i.e., thermal processes, chemical controls) which can be validated versus employee behavior practices, good hygienic practices, etc. which are difficult to validate, but should be verified. The scope should also address food control measures that are under a company's direct control versus those such as retail food service, consumer handling, storage, etc. that are beyond a company's direct control.

We also recommend that the following statement from the section entitled **Relationship of HACCP to validation of food hygiene control measures** be moved to the end of the scope section as follows: "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 effective implementation thereof, will help to ensure that a validated system continues to operate properly."

Under the section: **Prerequisites to Validation:**

The Committee recommends editing item 1) to read as "Identify specific hazards to be controlled, evaluate the reasonable likelihood of occurrence and the potential impact to the consumer. These include microbial, chemical and/or physical hazards."

The Committee recommends modifying item 2) to read as "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.”

The Committee recommends adding an item 3) “Identification/establishment of a performance criterion for the process , (i.e., the expected level of control of the hazard). ”

Under the section **Approaches to Validation:**

The Committee recommends that the following paragraph is moved from the end of this section to the beginning of the section: “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.”

Approach 1) requires additional clarification. The Committee concluded that data for validation can include sources beyond experimental trials (e.g., scientific literature, government regulations, equipment manufacturer’s validations, etc.). Approach number 1 needs to include a statement that indicates that control measures are plant specific, and must be validated on a plant by plant basis. Information on where/how to incorporate these control measures needs to be included. In addition, plant scale-up trials may be necessary using indicator organisms.

The Committee also concluded that Approaches 2 and 3 were written as verification activities rather than validation activities and thus should be rewritten to reflect validation related activities.

Under the section **Factors to be Considered:**

The Committee recommends the following edits and recommended wording.

Second full paragraph: “Constancy of Control Measures: The constancy of control measures varies by method. The greater the number of control measures that require validation, the greater the potential for variability in the validation process of the final product.”

Third full paragraph: “Process Variability occurs in each step of a food processing operation and must be considered when conducting a validation study.”

Forth full paragraph: “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. This paragraph on

sampling plans should also include information on the performance characteristics of the sampling plan(s).”

Fifth full paragraph: “Necessary Extent of Validation: 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 procedures with a single control measure that are well established and utilized such as the pasteurization of milk, the process has become so standardized that approval of parameter changes can be given by consulting a time/temperature chart. Novel processes with multiple control measures (e.g., potato salad) will require far greater resources for validation.”

Sixth full paragraph: “Control Measures: In certain cases, it may be important that control measures that lie beyond the responsibility of the producer or processor be revalidated , (e.g., cold chain distribution of ready-to-eat foods). The key point in this regard, is applying knowledge of these additional control measures to ensure that the safety of the product is maintained. As noted above, adequate additional control measures may require the use of other safety margins and/or verification activities applied elsewhere in the food chain, which are beyond the processor’s control to provide consumer protection. These additional control measures should be validated.”

Seventh full paragraph: “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.”

Under the section *Extent to which validation/revalidation is needed, when is validation required?*

The Committee recommends that the second paragraph be rewritten to more clearly explain the usefulness and limitations of historical data and experience as it is related to food safety issues.

“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. Care is needed, however, to avoid assuming that a food production or processing system is safe based solely on historical experience. (Note: This paragraph should be rewritten to more clearly explain the usefulness and limitations of historical data and experience as it is related to food safety issues).”

“Process innovations: 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 revalidation. 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, and require revalidation of the system. Any processing, packaging, distribution, or marketing innovations, or

scientific data indicating the emergence of new pathogens, etc., will require revalidation of the system.”

The Committee also recommends that the fifth paragraph under this section on focused validation be rewritten to clarify its meaning. The Committee agreed that focused validation efforts are effective, but the paragraph requires a rewrite to more clearly explain and describe focused validation activities.

The section **Relationship of HACCP to validation of food hygiene control measures** should be moved and included as the last paragraph of the scope section.

The Committee had the following answers to the questions presented:

- 1. Are the stated prerequisites all necessary? Are there prerequisites that are critical, but that have not been adequately identified? Do all of the prerequisites have the same degree of importance?**

The three stated prerequisites are necessary, with modifications. No other prerequisites were identified by the Committee. All of the prerequisites do not have the same degree of importance. Prerequisite number 1 is the most important, since if there are no identified specific hazards to be controlled, prerequisites numbers 2 and 3 do not apply. However, the general principles of food hygienic practices still apply even if no specific hazard is identified, and require verification rather than validation. If there is a specific hazard, the control measures must be validated.

- 2. Has the scientific basis for the approaches to validation been adequately justified? Are the approaches sufficient to permit the validation of food hygiene control measures? Are there alternative approaches to validation that should be considered?**

In the Committee’s opinion only approach number 1 is a scientifically based validation activity. Approach numbers 2 and 3, while important, are verification measures and not validation procedures. Nevertheless, approaches 2 and 3 may provide useful data for validation purposes. Numbers 2 and 3 should remain part of the document, but be reworded to reflect a role in validation. The Committee could not identify any other alternative approaches. In addition, the Committee concluded that data for validation can include sources beyond experimental trials (e.g., scientific literature, government regulations, equipment manufacturer’s validations, etc.). Approach number 1 also needs to include a statement that indicates that control measures are plant specific, and must be validated on a plant by plant basis. In addition, plant scale-up trials may be necessary using indicator organisms. Yes, there are alternative approaches for validation that should be considered. Alternative approaches to number 1 should be considered with appropriate scientific review to ensure that the attribute of performance evaluated is indicative of the status on the

control measure of interest. Consideration of alternate approaches to numbers 2 and 3 should be considered with caution since they relate to verification, not validation.

3. With respect to the individual approaches to validation, what elements should be further elaborated?

This question was answered in the subcommittee's response to question 2.

4. Are the factors to be considered in validation complete? Are there additional factors that should be considered? Do all the factors have the same degree of importance? Is the information presented on when validation or re-validation is needed sufficient and reasonable in relation to the simultaneous goals of being protective of public health, fostering scientifically based food safety systems, and developing practical advice on validation of control measures?

The factors to be considered in validation are not complete. The Committee recommends that the information in this section be revised. No additional factors could be identified by the Committee. All identified factors are interlinked, and it was not possible to rank the factors by degree of importance. All must be considered important, and the Committee could not separate any of them.

5. Is the information presented on when validation or re-validation is needed sufficient and reasonable in relation to the simultaneous goals of being protective of public health, fostering scientifically based food safety systems, and developing practical advice on validation of control measures?

Yes.

The Committee was provided three additional questions after receiving the original charge and has the following answers:

1. What role does verification and monitoring have in revalidation?

This question is circular in that validation (and, implicitly, revalidation) is defined as one process in verification (HACCP Principle 6). There is confusion in the use of the terms verification, validation and revalidation, requiring careful consideration and deliberation on the use and definitions of these terms.

2. How many failures need to occur before the system needs to be revalidated?

Assuming that "failure" means a deviation at a CCP that requires corrective action. "Repeated deviations" require a redesign of the product or process. However, the Committee is unsure how to quantify "repeated." Additionally, food safety systems must be revalidated, even if no process or product changes are made, and even if no deviations have occurred, as appropriate for a system of

control measures. This will provide auditors assurance that the food safety system is current (and accurate).

3. If the process is verified, does verification provide the baseline for validation?

This is a great question that deserves expansion and broad recognition. It is difficult to validate some commercial operations because of the size and hazardous nature of the process. Therefore, it is difficult to mimic these processes on a pilot plant or laboratory scale. Furthermore, it is not advisable or permitted to inoculate the raw material with pathogens in a commercial operation. Thus, in these situations, on-going verification activities can be used to help validate a system of control measures.