codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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**Agenda Item 10** **CX/FH 03/11 Add.1**
**December 2002**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD HYGIENE**

**Thirty-fifth Session**
**Orlando, Florida, United States of America, 27 January – 1 February 2003**

**COMMENTS ON THE**

# PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES

**BY**

**Argentina, Canada, Egypt, Peru, Poland, Mexico, the United States of America, European Community, and International Dairy Federation**

## GENERAL COMMENTS:

**ARGENTINA**

This is considered an important document that seeks to establish the philosophy and methodology for the validation of control measures linked to food hygiene. We understand that this is a step forward in measuring the efficacy of the systems related to food safety, in which the entire food chain is taken into account, including transportation, sales and domestic handling. There are no comments at this stage to make regarding this transintional document, but given its recognized importance, we will follow it permanently during the entire approval process.

**CANADA**

Canada would like to thank the United States for the drafting of these guidelines and is pleased to offer the following comments:

Design/development of food safety control system versus validation:

It should be made clear in the text that there is a need to develop/design a food safety control system before validating the control measures. Once the control measures are established, then validation is required to ensure that the selected control measures result in the level of hazard control required. Control measures should be adequately robust to deal with the variability inherent in food systems. If

the control measures are not consistent in their effect, if the number of control measures adds significant variability, or if there is significant process variability, then these factors should dictate the incorporation of "safety margins" into the control measures. Such safety margins should be taken into account during the design/developmental stages of control measures, not during validation. To clarify this concept in the document, Canada recommends the creation of a section on the "Design of Food Safety Control Systems" which would follow the section on "Steps Prior to Validation".

Structure of the document:

The structure of the document should be re-organized to follow a logical flow and avoid repeating the same notions in several sections. As noted above, Canada recommends the creation of a section on the design of food safety control systems. The section should describe how to design a food safety control system and explain the essential elements of the system. The section should include a description of systems with a few essential control measures, systems with multiple control measures that have an effect when taken as a whole, and how to address the areas for which a food establishment has no control. This would allow the grouping of all paragraphs covering these aspects into one section.

We also recommend grouping all paragraphs pertaining to the need for re-validation into one single section as this idea is inappropriately repeated in various sections of the document.

Definitions:

The terms defined should be used consistently throughout the document. We found discrepancies regarding the terms "food safety control system" (e.g. the terms "food safety system" and "food safety management system" are used) and "control measure" (e.g. the terms "food control measure", "food hygiene measure", "food hygiene control measure" and "food safety measure" are used).

**MEXICO**

Given that examples are included in the document, we recommend using a single example, wherever possible, throughout the document, identifying the various characteristics or steps that are being shown.

**PERU**

Peru recognizes the importance of this draft for use by governments and the food industry and considers it to be quite clear and well structured. However, some comments have been formulated, the majority of them on form, a product of a translation that is not the most adequate.

**UNITED STATES OF AMERICA**

The United States strongly supports the development of Guidelines for the Validation of Food Hygiene Control Measures.

It is widely understood that there are many different kinds of food safety control measures that can be applied in food production and processing situations. Until recently, relatively little attention has been given in Codex to establishing a means for evaluating food safety control measures to determine if they are indeed effective. Modern food safety systems that use HACCP principles and current Codes of Hygienic Practice focus principally on food safety outcomes rather than on prescriptive sets of control measures. This increasing focus on achieving food safety outcomes necessitates a demonstration at some point in time that the selected control measures actually achieve the anticipated or desired food safety outcomes. Therefore, guidelines for the validation of food hygiene control measures would

prove extremely useful in the establishment and evaluation of contemporary food safety control systems.

The United States looks forward to a discussion of this extremely relevant and much-needed document during the 35th Session.

**EUROPEAN COMMUNITY**

The European Community would like to thank the United States and its drafting partners for the work done. The document is clear, easy to read and as such an improvement compared to the discussion paper discussed at the 34th Session. There is however still some overlap, especially concerning Chapter VII, the part on additional considerations (overlap with previous Chapters). The European Community has one general comment and some detailed comments.

In the document, too much emphasis is placed on situations where the validation of a set of food hygiene control measures may be narrowed to validation of a single essential control measure, for example where a pathogen reduction step is employed whose adequacy may be confirmed and used to validate the entire set of measures. In many cases however, a pathogen reduction step will have only a limited effect in reducing pathogen contamination, this effect depending directly on the initial level of contamination. This should be better reflected in the text, and more attention should be given to the integrated chain approach.

**INTERNATIONAL DAIRY FEDERATION**

Validation is an evaluation tool not limited to evaluation of control measures!

1. Validation is a tool used in the evaluation of various types of activities, including but not limited to:
2. Validation of individual control measures, such as the D and z-values for specific microorganisms
3. Validation of combined control measures, such as D-values for the combination of various pH, $a_w$, nutrient profiles, antagonistic flora etc. (for instance, in cheese ripening) for specific microorganism
4. Validation of control systems, such as the efficacy of HACCP systems
5. Validation of monitoring equipment, such as the calibration of a thermometer
6. Validation of verification methodology, such as ring trials of analytical methods

The draft Guidelines, as proposed in CX/FH 03/11, only address the first two applications of validation, but individual parts of the document seem to address validation in a broader sense which leads to confusion. The document needs to be much clearer with regard to the type of validations that are covered. This fact needs to be clearly spelled out in the scope of the document. The specific comments made to CX/FH 03/11 are submitted with the understanding that the content of the document is to be in line with the title (i.e. validation of control measures)

Various definitions of validation and verification already exists!

The definitions below are available in other international texts. These definitions can be grouped into two types: general definitions of validation (ISO and FDA) and definitions for control system validation (Codex and NACMSF).

| Source: | Verification | Validation |
|---|---|---|
| **ISO 9000:2000** | Conformation, through the provision of objective evidence that specific requirements have been fulfilled | Conformation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled |
| **Codex (Annex to CAC/RCP 1-1969, Rev. 3 (1997), Ammended 1999** | The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan. | Obtaining evidence that the elements of the HACCP plan are effective. |
| **US FDA** | Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled | Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. |
| **NACMSF** | Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. | That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards. |

Validation of control measures is the responsibility of the food industry!

In general, will be concerned if the target group for these guidelines would be governmental agencies and not individual food businesses responsible for designing specific HACCP systems for specific product/process combinations. Otherwise, these guidelines can lead to the establishment of regulatory "positive lists" of control measure combinations.

It is therefore important that it is clear from the guidelines, that the responsibility for using validated control measure (combinations) is the responsibility of the individual food business, which implies that it is also the responsibility of the food business to ensure that validations will be carried out where such validations are not available. Control measure validations can be carried out both within and outside the auspices of that food business.

Where control measure validation is carried out, it should be done in a uniform manner, and in this context the Guidelines will play an important role.

On the other hand, control system validations (e.g. validation of the efficacy of a HACCP system) are to be carried out both by the food business itself and by a independent third party (whether governmental or non-governmental).

The role of governmental food inspection is to audit the control systems, i.e. evaluation of the documentation for system design, including the control measure validations and system validations carried out/used.

## I. INTRODUCTION

**PARAGRAPH 1**

**INTERNATIONAL DAIRY FEDERATION**

It is stated that validation is about demonstrating that the control measures are capable of achieving the required level of food hazard(s) control. The term "required" may trigger some confusion, as it may be

perceived as requirements by law/authorities having jurisdiction. In many countries/cases, such requirements are not specified to the degree needed for the purpose of control measure validation (in most cases, such specification relates to the final outcome, i.e. relevant for control system validation, only). Further, the level of control needed/required depends on many factors, including the food and processing plant in question, the degree of management skills, hazard levels in raw materials and effect of additional control measures (including GHP). Therefore, we suggest that the text is phrased in a way that related the outcome to the initially (planning phase) intended level of control. See also ISO definitions in our comments to section V.

**PARAGRAPH 2**

**CANADA**

Paragraph 2 should be amended as follows and paragraph 3 deleted to reflect the fact that the document is not specific in nature:

> *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 **validation of the** full range of food hygiene control measures used in food production, processing, distribution and storage of foods **for the control of microbial, chemical and physical hazards**.*

**INTERNATIONAL DAIRY FEDERATION**

The last sentence should state that these guidelines are applicable to all types of foods (in addition to all types of control measures).

**PARAGRAPH 3**

**NEW ZEALAND**

New Zealand suggests adding *"microbiological"* hazards to be consistent within the document.

## II. SCOPE

**EUROPEAN COMMUNITY**

The scope of the document should be elaborated somewhat more in Chapter II.

**PARAGRAPH 4**

**CANADA**

Reference is made in the second sentence to "prerequisites to validation". This should be changed to "steps prior to validation" to be consistent with the title of Section VI.

## III. DEFINITIONS

### Control Measure:

**EGYPT**

In this section there are two overlapping definitions " Control Measure " and "Essential Control Measure. " The latter definition may indicate that there are " unessential " control measures which is technically and scientifically unacceptable'. Therefore, it is recommended to use this latter term in the plural form, "Control Measures " instead of " Essential Control Measure. "

**Essential Control Measure:**

**NEW ZEALAND**

New Zealand questions the need for this definition, given that *"control measures"* are defined and *"essential"* is self-explanatory.

**Food Safety Objective:**

**MEXICO**

We suggest that the definition for "Food Safety Objective" to read as follows: "Establish the maximum frequency and/or concentration of a hazard in a food at the point of consumption, to provide the appropriate level of health protection."

**PERFORMANCE CRITERIA:**

**NEW ZEALAND**

New Zealand suggests that consideration be given to using *"performance parameter"* as has been defined and used in the CCMPH document *Proposed Draft Code of Hygienic Practice for Fresh Meat (CX/MPH 3/4)*. This would avoid confusion with *"microbiological criterion"* and also ensure that the required level of hazard [controlled] can be defined appropriately. If this were accepted, then consequential changes would follow throughout this document.

**Monitoring:**

**CANADA**

The definitions for monitoring and verification include the phrase "operating properly". We believe these words are somewhat ambiguous, and could be taken to include aspects of validation. Therefore, we suggest it be replaced by "being implemented appropriately and/or performance criteria are being met".

**Validation:**

**NEW ZEALAND**

Suggest that *"the level specified"* is linked to what specifies it, i.e. *"performance criteria"*

**INTERNATIONAL DAIRY FEDERATION**

The definition used in this document should be aligned with those adopted by ISO, which encompass any type of validation and not only validation of control measures. ISO defines the concept as follows:

> Validation: Confirmation, through the provision of objective evidence, that the requirements* for a specific intended use or application have been fulfilled
>
> *) Need or expectation that is stated, generally implied or obligatory

**Verification:**

**CANADA**

We suggest that in the definition for verification, the phrase "food safety system" should read "food safety control system".

**INTERNATIONAL DAIRY FEDERATION**

The definition used in this document should be aligned with those adopted by ISO. ISO defines the concept as follows:

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

*) Need or expectation that is stated, generally implied or obligatory

## IV. NATURE OF CONTROL MEASURES

### PARAGRAPH 5

**CUBA**

Second sentence, should say: "good agricultural and animal production practices, good manufacturing practices, HACCP..."

**MEXICO**

Second sentence, at the beginning of the sentence, add "The range of"

**NEW ZEALAND**

Second bullet point – We suggest rewording to read "Requiring verifiable documentation attesting to the status of biological, chemical and physical hazards as appropriate, in the incoming raw material". "Auditable" should be "verifiable". It is also unclear what is meant by "biological, chemical and physical specifications".

Third bullet point – We suggest rewording to improve readability, as follows:

*"Sampling and analyses, as necessary, using appropriate tests based on established criteria, to reject unacceptable ingredients or products".*

**PERU**

Peru considers it appropriate to edit the first sentence in the following manner: "The range of food hygiene control measures is extensive and encompasses measures applied throughout the food continuum in an integral and sustained way, from primary production, through processing, to consumption."

In the second sentence and in other points in the document where it is used, we recommend changing the term "good consumer handling practices", to "good consumer practices during the handling and consumption of the food".

**INTERNATIONAL DAIRY FEDERATION**

In the 3rd line, HACCP is listed as a control measure. This is not entirely correct, as HACCP is a management system (i.e. used a risk management measure) that links individual control measures and control measure combinations. In order to avoid confusion, "HACCP" should be replaced by "measures applied prior to and during processing and distribution".

In the same paragraph, line 5-6, it is stated that control measures encompass inspectional procedures including sampling and testing. This statement is not entirely correct as these measures, at least within the HACCP concept, are monitoring and/or verification measures. Sampling and testing, but not

inspectional procedures, can only be used as a control measure if it is associated with a hold (test) and release base system. Consequently, we suggest the wording is corrected in this regard as follows:

*"Food hygiene control measures can also encompass sorting based upon inspectional procedures including product sampling and testing ~~and~~ as well as certain types of product labelling."*

## Controlling initial levels of hazard(s)

**CUBA**

In the first bullet, it should be modified to read: "Use good animal production and agricultural practices to minimize contamination during primary production."

**MEXICO**

In the 1st bullet point, after "Use" add "good animal production" and in Spanish version substitute the term "agropecuarios" // for "agrícolas" , since the former encompasses the aspects of both field agriculture and animal production.

In the 2nd bullet point, we suggest modifying the text in the following manner: "Requiring auditable/verifiable documentation attesting to microbiological, chemical and physical specifications of the raw materials."

In the 3rd bullet point, we recommend removing the word "specified" leaving the text as follows: "Carry out sampling and testing, using microbiological, chemical and physical methods with specificity and sensitivity to..."

**PERU**

The first bullet point should read: "Employing good agricultural and livestock practices to minimize contamination during primary production".

**INTERNATIONAL DAIRY FEDERATION**

The 2nd indent under "controlling initial levels of a hazard" lists documentation as a control measure. This is not correct: A control measure is defined as an action/activity that prevents, eliminates or reduces levels of hazards. Documentation is rather a general risk management measure. The indent should be deleted.

Similarly, the 3rd indent under "controlling initial levels of a hazard" should specify that testing should be used in combination with hold (test) and release based system.

## Preventing an unacceptable increase of hazard(s)

**CUBA**

In the third bullet, modify it to read: "Use packing techniques and materials that protect the food from contamination and that ensure their preservation."

**MEXICO**

In the 1st bullet, modify the text as follows:
"Restrict the growth of pathogens through refrigeration and preservation temperatures, pH, water activity levels, use of preservatives, microbial exclusion etc."

In the 2nd bullet, we suggest substituting “facilities” with "establishment."

**NEW ZEALAND**

New Zealand suggests adding a new bullet point:

- *“Preventing cross-contamination between raw and cooked product.”*

**PERU**

The first bullet point should say: “Limiting growth of pathogens through proper chilling and holding temperatures, pH, water activity levels, appropriate use of preservatives, use of competitive exclusion, etc.”

The second bullet point should read: “Employing good sanitation, cleaning and disinfection practices to minimize....”

In this section, a bullet point should be included on the measures carried out during the transportation and distribution, which form a part of the prevention of an increase in the hazard.

**Reducing the level of hazard(s)**

**MEXICO**

We suggest that the second bullet point begin with “Removing or eliminating”, in order to distinguish this from destruction.”

## V CONCEPT AND NATURE OF VALIDATION.

### PARAGRAPH 6

**CANADA**

First sentence, the phrase “properly operating single food control measure.” should be modified to “properly designed and implemented single food safety control measure....”.

### PARAGRAPH 7

**CANADA**

First sentence, end of the sentence, we suggest removing the reference to “behaviour studies” in the first sentence. Effectiveness of control measures cannot be measured, even indirectly, through “behaviour studies”. In the second sentence, we suggest to replace the two instances of “occur” with “are applied”. The word “occur” suggests that they just happen, as opposed to the need to specifically apply such measures at these steps.

Validation vs. Verification and Monitoring

### PARAGRAPHS 8 TO 15

**CANADA**

Considering that the words validation, verification and monitoring are already defined, this section should be re-written and include only one paragraph that establishes the links between validation, verification and monitoring. We believe that **paragraph 15** should be deleted as it does not belong in this section.

**EUROPEAN COMMUNITY**

In the document, the difference in meaning between the terms 'validation' and 'verification' should be explained more extensively.

**INTERNATIONAL DAIRY FEDERATION**

The text discussing validation vs. verification could benefit from the insertion of the fact that validation is, in principle, carried out prior to operation whereas verification is carried out during/after operation. This is also in line with the ISO definitions. The insertion of the following text is after the first para. is recommended:

> *"Simplified, "control measure validation" is an assessment carried out prior to operation to confirm that the control measures are capable of achieving the intended level of control, whereas "control measure verification" is an assessment carried out during and after the operation to confirm that the needed/required level of control has actually been achieved."*

## PARAGRAPH 10

**EUROPEAN COMMUNITY**

The words 'real time' are not appropriate and should be deleted.

**NEW ZEALAND**

New Zealand suggests some rewording of this paragraph to clarify, as follows:

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

## PARAGRAPH 12

**NEW ZEALAND**

New Zealand believes this example is one of a process criterion, not a performance criterion. This outcome does not tell us what level of hazard is left in the product and we would need this information to demonstrate that it can achieve or contribute to achieving a performance criterion and the food safety objective set for the particular hazard food combination.

**INTERNATIONAL DAIRY FEDERATION**

It should be stated that a performance criterion, when applicable, is established for a specific product/control measure combination wherefore, it is not automatically universally applicable to all foods or situations. Consequently, performance criteria are values that, in order to be valid, need be established (by the individual food business operator) within the context of a particular control system. Further, the term "criterion" should be avoided – it is redundant as "performance" alone carry the message in a sufficient way.

## PARAGRAPH 13

**CANADA**

Paragraph 13 should be amended as follows and moved to the section addressing the circumstances where re-validation is required (section XI):

In the second sentence, we suggest the reference to "reliance on a new control measure..." should be reworded as "introduction of a new control measure...".

The last words of the penultimate sentence reads "...parameters used to develop the initial hazard analysis." This should be changed to reflect the fact that we are more concerned about the "...parameters used to develop the current measures."

**NEW ZEALAND**

New Zealand is unsure as to what the second-to-last sentence actually means.
We suggest it be reworded to better express the intent.

**PERU**

The second last sentence, in order to be more easily understood, should read: "The need to re-validate may also arise as a result of non-compliance with monitoring or verification criteria, due to a change in the parameters used to develop the initial hazard analysis".

Relationship of Validation to the Appropriate Level of Protection

**PARAGRAPH 16**

**EUROPEAN COMMUNITY**

Third sentence, (after 'From an operational standpoint….') should be put between brackets as the concept of FSO has not yet definitively been defined within Codex.

Relationship of HACCP to Validation of Food Hygiene Control Measures

**PARAGRAPH 17**

**NEW ZEALAND**

New Zealand is unsure of what this paragraph is trying to say. Successful implementation of HACCP is dependent on validation of a HACCP plan as consistently achieving food safety outcomes for specific hazards. Therefore we would like to suggest a reworded paragraph to explain the intent:

*"Application of HACCP principles provides a good example of how validation works within the food chain. Successful implementation of HACCP is dependent on validation of a HACCP plan as consistently achieving food safety outcomes (performance criteria) for specific hazards. It also permits the clear identification of hazards, control measures available, Critical Control Points if any, and Critical Limits. The outcomes of monitoring and verification activities assist in determining when revalidation of the system may be necessary."*

**INTERNATIONAL DAIRY FEDERATION**

This sub-paragraph adds confusion to the document as it relates to control system validation (i.e. validation of entire HACCP systems) and to not control measure validation. The section should be deleted.

## VI. STEPS PRIOR TO VALIDATION

**PARAGRAPH 18 ITEM 1**

**NEW ZEALAND**

New Zealand suggests that the scope for the food safety system should be determined first as part of the basis of the food safety system. This would cover the range of steps in the food chain as mentioned in point 2.

**PARAGRAPH 18 ITEM 2**

**CANADA**

**Last paragraph,** there appears to be some confusion on establishing control measures versus validating them. It should be pointed out that much experimental work may be required to develop a set of control measures for some systems, and this would include consideration of the variability in control measures outside of the control of the entity establishing their own control measures. As explained in our General Comments, we recommend that a section on the "Design of Food Safety Control System" be created. The paragraph should be moved to this new section and amended as follows:

> *Preferably, all elements of the food safety system should be considered in ~~validating~~* ***establishing*** *food hygiene control measures. In some situations, some elements of the food safety* ***control*** *system (e.g., consumer handling practices) may lie outside of the control of the entity establishing these measures (e.g., food manufacturer), but these elements and their variability will need to be taken into consideration in the* ***establishment of the control measures****.*

**NEW ZEALAND**

New Zealand suggests that these *"elements"* of the food safety system would be covered by the scope, (see above). So the range relates to the scope. Whatever the scope of the system is, then validation will relate to that scope. Elements lying outside the control of the entity would be outside the scope.

**INTERNATIONAL DAIRY FEDERATION**

The following rewording of the introduction to the sequence is recommended (suggested changes highlighted with rationale explained in foot notes):

*"Prior to validation, the scope of the validation (i.e. which control measures to validate) as well as the application of the control measure(s) within the of ~~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."*

## VII. APPROACHES TO VALIDATION

**PARAGRAPH 19**

**PERU**

In the second sentence of Paragraph 19, where it says "a microbiocidal kill step" remove the word "kill" since it is redundant next to the term "microbiocidal".

**INTERNATIONAL DAIRY FEDERATION**

First sentence, iinsert "the purpose of the validation" after "will depend on" and at the end of the sentence, insert "intended/required" after "extent of control".

It would be appropriate additionally to insert a para. that addresses the different purposes of validation, as follows:

*"Validation may be carried out with the following objectives:*

- *To assess the total combination of control measures (control system) applied to a food, i.e. to provide an assessment that the resulting end product will be safe*

- *To assess the decisive control measures applied to a food, i.e. to provide an estimated validation result. In this case, uncertainties may have to be taken into account, e.g. by considering safety factors in the application of the control measures and/or taking into account historical experience.*
- *To assess a particular control measures, i.e. to provide an assessment of the effectiveness of a particular control measure. The result may not be directly related to the safety of the end product but can be used when designing a particular food safety system."*

**PARAGRAPH 20**

**EUROPEAN COMMUNITY**

The second to the last sentence, changed to read: "In ~~some~~ *many* cases, on farm practices…" and the last sentence of this paragraph should be deleted, as it is not appropriate.

**INTERNATIONAL DAIRY FEDERATION**

The heading of the first sub-section should be changed into "Identification of Food Safety Measures subject to validation" and the text need slight modification consequential to our comments above.

**PARAGRAPH 21 ITEM 2**

**CANADA**

The third sentence should be deleted as it does not describe an approach to validation rather it describes which control measures should be validated.

**NEW ZEALAND**

New Zealand suggests that these *"elements"* of the food safety system would be covered by the scope, (see above). So the range relates to the scope. Whatever the scope of the system is, then validation will relate to that scope. Elements lying outside the control of the entity would be outside the scope.

**PERU**

In point 2 of Paragraph 21 the term "Pruebas reto," //challenge testing// should be changed to "Pruebas de enfrentamiento," //challenge testing// which is a better term.

We recommend that the first sentence of the second paragraph of the same point read: "Conducting experimental tests in a pilot program may be necessary to ensure...."

**PARAGRAPH 21 ITEM 3**

**NEW ZEALAND**

First sentence - New Zealand suggests that "contaminant" be replaced by "hazard". Second sentence - New Zealand suggests that "inspection practices" can be routinely measured.

**INTERNATIONAL DAIRY FEDERATION**

3rd sentence: Delete the entire sentence as hurdle technology measures (which also includes microcidal measures) can also be validated according to indents 1 and 2.

**PARAGRAPH 21 ITEM 4**

**CANADA**

Unless this paragraph is rewritten to more clearly describe the concept and clarify the intent, this paragraph should be deleted. For example, consumer storage practices of temperature sensitive products is viewed as a "control measure" that cannot be measured. Storage temperatures can be

measured, and it is quite appropriate for regulatory agencies or industries to recommend control measures for consumers to apply, and to establish such measures as part of an overall "hurdle" approach to pathogen control. It should be noted that validation of the recommended storage temperature versus the actual implementation of this measure by the consumers are two different concepts.

**PERU**

First sentence, instead of saying "temperature sensitive products," it should say "perishable products".

**PARAGRAPH 22**

**CANADA**

This paragraph pertains to the approach to validation described in paragraph 21 -1 and should be grouped with it. We suggest replacing the last part of the last sentence with the following:

*When there is any question, it is essential to* ***establish its effectiveness through re-validation***.

**NEW ZEALAND**

Last sentence - New Zealand suggests changing *"verify"* to *"demonstrate"*.

**PERU**

In the last sentence, change the word "question" to "doubt.

**PARAGRAPH 23**

**CANADA**

We recommend the deletion of this paragraph. Similar to our comments on Paragraph 18(2), we believe it is not the approach to validation that should take into account what parts of the food safety system the organization undertaking the study has control. It is during the development or establishment of control measures that these issues should be taken into account. Assumptions will have to be made about factors such as pathogen levels in incoming product. These assumptions will be used to establish control measures to deal with expected hazard levels. Once control measures are established, it is these that are then validated. If there is concern about control of inputs, or if the manufacturer wishes to establish greater control, then the manufacturer may establish a control measure, such as testing on arrival, which will provide the necessary assurance that the other control measures established for the product will be adequate. Validation of such control measures may be considered, e.g., validating the degree to which the testing program will appropriately identify acceptable from unacceptable lots.

**NEW ZEALAND**

Last sentence - New Zealand suggests changing the last word from "maintained" to "essential".

**PARAGRAPH 24**

**CANADA**

The list of bullets in Paragraph 24 should stop after the fifth bullet point. A new introductory phrase should be added as follows: "Subsequent to initial validation, organizations should:" and then continue with the next two bullets. Regarding bullet point 1, referral should be to Section VI.

**NEW ZEALAND**

New Zealand suggests a new indent of *"Document the findings of the validation studies"* after indent 3. Indent 6 is a verification step and should be deleted.

**POLAND**

Point 24 – instead of "in Section V" it should be "in Section VI."

**INTERNATIONAL DAIRY FEDERATION**

5th indent: Often it is not the control measure that has to be adjusted but the intensity of application (i.e. higher time/temperature combination). Therefore, replace "control measure" with *"process parameters applied and/or the control measures used"*

7th indent: At the end of the first sub-indent, replace "that cannot be controlled with existing food hygiene measures" with *"and the efficiency of the control measure(s) against it is not known"*. Procedures that would provide indication that the current food safety system is not adequate (i.e. epidemiological findings, new pathogens, monitoring and verification results showing any systematic deviations and failures is included in control system validation and not in control measure validation.

**PARAGRAPH 25**

**NEW ZEALAND**

This paragraph relates to verification. New Zealand suggests that this may be better served under the heading *"Additional considerations"*. The second sentence of paragraph 25 is confusing and should be clarified. A re-arrangement of the sentence should also assist; we suggest the following rewording:

*"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, before consideration of re-validation (including the selection of new measures)."*

**PARAGRAPHS 26 AND 27**

**CANADA**

As per our General Comments, these paragraphs pertain to the design of food safety control systems and should be moved to a new section addressing the subject.

**PARAGRAPH 30**

**CANADA**

It appears that the intent of this paragraph is to impose on the manufacturer some need to validate control measures that are applied elsewhere. We believe this is neither appropriate, nor necessary. As is noted in the second and third sentence of this paragraph, control of hazards in inputs is either verified by the manufacturer or accounted for by the inclusion of safety factors in measures applied by the manufacturer. The first sentence really is not appropriate in this paragraph and should be deleted. The paragraph could then be moved into a section dealing with the design of food safety control systems.

**NEW ZEALAND**

Second sentence. New Zealand suggests that the sentence be reworded to assist clarification. Suggested new wording is *"In such cases, it is important to verify…"*

## VIII. LIMITATIONS TO VALIDATION

### PARAGRAPH 31

**CANADA**

**Introductory paragraph**

We have serious concern regarding the intent of this paragraph. The concept expressed in the second sentence is not appropriate - variation in validation methodology should not impact on control measures. It is necessary to first establish the parameters around a control measure and ensure that all factors noted in the second, third and fourth bullet points are accounted for (by, perhaps, including safety factors in the control measure). When it comes to validation, the variability in the test used to validate the control measure may result in the need to test a greater number of samples or perhaps test a larger sample size, etc., to have the level of confidence in the validation results. This results in greater cost, but should not be used to somehow adjust the control measure.

**First Bullet**

We suggest this bullet be deleted. Validation is about "obtaining evidence that food safety control measures....are capable of consistently controlling the hazard to the level specified." If a target does not exist, validation cannot be done.

**Bullets 2, 3 and 4**

We suggest this could be deleted or moved to a section dealing with the design of food safety control systems.

### PARAGRAPH 32

**CANADA**

We suggest to delete as per above comments

## IX. EXTENT TO WHICH VALIDATION/RE-VALIDATION IS REQUIRED?

**CANADA**

Reverse the number to IX (number 9) instead of XI.

**PERU**

Second bullet, Level of Risk, eliminate the underlined portion, as it is redundant: "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."

**Observations on the translation into Spanish**:

**MEXICO**

The general text of the document should be reviewed, as it is translated rather literally, which complicates the understanding and consequently the application of the document.

- In Section III on *Definitions*, we suggest that the abbreviations in Spanish be used in the definitions for "Appropriate Level of Protection" and "Food Safety Objective" and throughout the document.

- In Section VI, point 2, we recommend that the last sentence read as follows: "Toma de muestra de producto y aplicación de pruebas de laboratorio". //"The taking of product samples and application of laboratory tests"//. In the paragraph under the same point, we propose substituting the term "estar" //"is"// for "yacer" //"located"//.
- In Section VII, in the sub-heading "Focus/Validation Methods, paragraph 21, point 2, the second paragraph should read: "Una planta piloto para las pruebas experimentales puede ser necesaria para garantizar que las pruebas reflejan adecuadamente los parámetros y condiciones reales del proceso de elaboración. Es probable que la validación tenga que limitarse a un laboratorio o planta piloto si no hay disponibilidad de microorganismos sustitutos apropiados que puedan ser utilizados en la adquisición de datos sobre el peligro, bajo condiciones reales de producción, no se deben introducir microorganismos patógenos viables a un centro de producción de alimentos." // "A pilot plant for experimental tests may be necessary to guarantee that the tests adequately reflect the real parameters and conditions of the processing. The validation will probably need to be limited to one pilot laboratory or plant if there are not appropriate substitute microorganisms available that can be used in the acquisition of data on the hazard under the real production conditions; viable pathogenic microorganisms should not be introduced to a food production center."//

-In point 4, we suggest improving the text in the following manner: "Este enfoque puede ser usado para documentar medidas de control esenciales que no pueden ser calculadas o estimadas de ninguna otra manera (p.ej. prácticas de inspección, prácticas de almacenaje por parte del consumidor de productos susceptibles a la temperatura). Es importante enfatizar que este uso de encuestas estadísticas esta separado del uso de encuestas estadísticas que pueden ser empleadas en un monitoreo continuo. Cuando la validación estadística no pueda ser empleada para una medida de control esencial que no pueda ser calculada o estimada de ninguna otra manera, el impacto de dicha medida, de ser tomado en cuenta en alguna otra parte del proceso durante la validación de aquellos aspectos del proceso donde se mantenga el control (vease el siguiente texto)". //"This focus can be used to document essential control methods that cannot be calculated or estimated in any other way (e.g. inspection practices consumer storage practices for temperature-sensitive products). It is important to emphasize that this use of statistical survey is separate from the use of statistical surveys that can be used for continuous monitoring. When statistical validation cannot be used for an essential control measure that cannot be calculated or estimated in any other way, the impact of that measure, when taken into account in another part of the process during the validation of those aspects of the process where control is maintained (see the following text)" - //sic//.//

- In Section VIII, Limitations of the Validation, second bullet point, substitute the text in the second paragraph with: "...biológicas (p.ej. Antagonismo microbiano) y tendrá la mayor variabilidad para medidas de comportamiento las cuales incluyen actividades relacionadas con los inspectores". // "biological... (e.g., microbial antagonism) and will have greater variability for behavioral measures that can include activities related to the inspectors."//.

- In Section IX: Level at which validation/revalidation is needed, in the last bullet point, we suggest: "La aparición de nueva tecnologías en un proceso puede requerir

la revalidación de medidas de control establecidas... sistema de inocuidad de los alimentos." // "The appearance of new technologies in a process may require the re-validation of established control measures... food safety system."//.

**PERU**

In Paragraph 7 and everywhere else it is used, change the word "alimenticia" //food// to "alimentaria" //food//, which is more appropriate.