codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FH 05/37/07 - Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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Comments on the

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF CONTROL MEASURES

Submitted by; Canada, Venezuela, and International Dairy Federation (IDF)

Canada would like to thank the United States of America for leading the working group and note the significant improvement to the document. We would like to offer the following comments:

GENERAL COMMENTS

CANADA

Although there has been significant progress made in this document, Canada still has some concerns regarding parts of the text describing the design of control measures, their validation and their application. In particular more rigor should be applied in describing the "Approaches for validating control measures" in Section VI (The Validation Process). In our view, some paragraphs provide examples illustrating approaches for establishing control measures rather than validating them. Other paragraphs present approaches whereby one can establish how well specific practices are being applied to control a hazard. These sections should be reviewed and modified as appropriate to improve the logical flow of this document.

IDF

IDF would like to congratulate the Codex CCFH Drafting Group under the leadership of United States for the excellent work done in revising the document. The draft has improved considerably

and become more user-friendly.

IDF is pleased to note the improved clarification with regard to the respective roles and responsibilities of industry and governments. However, some additional clarity is needed with regard to the use of terms "industry" and "manufacturer" as well as the formulation of specific texts addressing these roles (See further details in our specific comments to the various sections below).

The Guidelines should address to a greater extent how uncertainty should be handled, both the uncertainty involved in validation as such as well as the uncertainty in performance of control measures that validation will demonstrate in many cases. Currently, the Guidelines addresses this only briefly in section VIII (use of safety factors in performances and the mutual relationship between the certainty of validation results and the extent of verification needed).

INTRODUCTION

FIRST PARAGRAPH

IDF

In the last sentence, we suggest that the phrase "*control of hazards by the*" be inserted prior to "*selected control measures*". The current text states that validation demonstrates that the control measures are delivered appropriately, which does not make sense.

SECOND PARAGRAPH

CANADA

In paragraph 2, second sentence, we recommend that the text be changed for better consistency with the title regarding HACCP in Section IV Concept and Nature of Validation. It is our view that these guidelines should address the relationship of validation of food hygiene control measures to HACCP rather than the other way around:

> *These guidelines also address the difference between validation and verification and the relationship of **validation of food hygiene control measures to HACCP**.*

LAST PARAGRAPH

IDF

This paragraph outlines the respective roles of industry and government/authorities.

In order to avoid any confusion with regard to the understanding of the use of the term within this context, we recommend the insertion of a note similar to the note 6 to the draft MRM document (CX/FH 05/37/6), which reads:

> *"**Note**: For the purpose of this document, it is understood that **industry** includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius)."*

In addition, there is a need to review the entire document to ensure the consistent use of this term, where reference to industry is understood as above, and to revise the wording where this is not the case (see suggestions in this regard to the relevant sections below).

III. DEFINITIONS

CANADA

References to the General Principles of Food Hygiene should be updated to the most recent version: The Codex *Recommended International Code of Practice - General Principles of Food Hygiene*- CAC/RCP 1-1969, Rev. 4-2003.

Control Measure

VENEZUELA

Venezuela considers that it would be advisable to analyze that which concerns the application of control measures, since within the text these are established without distinction, both for industry hygiene (e.g., the application of GMPs) and for food safety (e.g., HACCP implementation). We present this comment because in the Definitions' section, control measure refers only to food safety hazards. Therefore, we propose to define this concept in a more specific fashion within the document in order to avoid confusion in the implementation of these guidelines. To that effect, we propose the following wording:

> Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level, including the measures aimed to achieve food hygiene.

Validation

CANADA

We recommend adding the word "proposed" before "control measure" to emphasise the fact that validation of control measures is performed before their actual implementation. We also recommend deleting "capable of being consistently" to harmonize with the HACCP definition and to clearly differentiate validation from monitoring and verification. Validation should provide scientific evidence that a proposed control measure will work under the expected conditions. Monitoring and verification will verify that the measure is implemented consistently. The definition should be amended as follows:

> *Validation: Obtaining evidence that* ***proposed*** *control measures are ~~capable of being consistently~~ effective.*

In Footnote # 7, we recommend amending the text as follows for more accuracy:

> *Derived from (…), but was ~~expanded because control measures can include more than HACCP controls~~* ***modified to apply to all situations, whether or not a HACCP system is***

IDF

We note that the definitions for validation, verification and monitoring included in the ISO Final Draft International Standard on Food Safety Management Systems (FDIS 22000) read as follows:

> **validation**: obtaining evidence that the control measures of the HACCP plan and of operational prerequisite programs are capable of being effective*
>
> **verification**: confirmation, through the provision of objective evidence that specified requirements have been fulfilled
>
> **monitoring**: conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended and meeting specified limits
>
> *) Note that the ISO FDIS requires that control measures selected to control identified hazards must be based on a hazard analysis, be validated and be included either in the HACCP plan or in operational PRPs. FDIS also requires the implementation of other prerequisite programs, which need not be validated.

The CCFH may consider these definitions with the objective to obtain consistency between international food safety documents.

IV CONCEPT AND NATURE OF VALIDATION:

Third Paragraph

IDF

First sentence, the word "can" should be replaced with "should". A control measure can (in practice) be implemented with or without being validated, but it <u>should</u> not.

Further, we recommend the bracketed example be reworded into "*(e.g. managed through GHP systems and HACCP, where applicable)*"

Fourth Paragraph

IDF

In the 2nd and 3rd sentences, we recommend a rewording of the phrase "*the expected outcome frequently will be expressed*" into "*such outcome can be expressed*". Very few PCs and POs have been established as yet, so the term "frequently" is not yet appropriate.

Further, the last sentence should be editorially rephrased as follows (suggested changes highlighted):

"<u>Demonstration of whether</u> ~~Validation on the basis of~~ a performance objective can <u>be met can</u>, under certain circumstances, be focused on <u>validation of</u> an important individual or a defined combination of control measures in the food safety control system."

Fifth Paragraph

CANADA

In the fifth paragraph, second sentence, we recommend amending the text to eliminate the word "consistently" which, in our view, refers to the consistent "application" of a measure. A control measure, when effective, should be robust enough to take account of anticipated variability. We proposed the following wording:

> *For some control measures, evidence that ~~a control measure is callable of being consistently~~ **they are** effective **under specified conditions** can be obtained through direct…*

IDF

We note that the last example (consideration of past observations), in reality is a thorough analysis of past verification and monitoring information. This could be mentioned, either here or in section VI, point 1.

Relationship of Validation to Verification and Monitoring

FIRST PARAGRAPH

CANADA

In the first paragraph, second sentence, we recommend replacing "if implemented" with "when correctly implemented". It is important to stress that the control measures will work if they are implemented correctly. Once that has been established, monitoring and verification will determine if the control measure is being applied appropriately and if the desired effect is still being achieved.

VENEZUELA

Delete the first sentence in its entirety.

[Applies to the Spanish version only], modify the second sentence as follows:

La validación se concentra en la recolección y evaluación de información científica, técnica y de observación, para determinar si las medidas de control, en caso de que se llegaran a implementar, están en capacidad de controlar el peligro y que este nivel de control pueda ser logrado constantemente.

IDF

First paragraph, second sentence, we suggest modifying the 2nd sentence as follows (suggested changes highlighted):

"Validation focuses on the collection and evaluation of scientific technical and observational information to determine whether the control measure~~s~~(s) are capable, if implemented, of controlling the hazard to the appropriate level ~~and that this level of control can be achieved consistently~~. This is in contrast to monitoring and verification, which both take place only after the validated control measures have been implemented to check whether they can be adhered to and to

demonstrate that the defined level of control is achieved consistently.

In our opinion and in practical terms, the concept of "consistently achieved" should be rather related to a control measure after it has been implemented, i.e. to monitoring and verification. It is only then that it becomes essential that the validated performance (e.g. a flow and a temperature) is achieved all the time, i.e. consistently. A perfectly validated control measure may be affected by the way it is implemented (e.g. a flow of product can be influenced by the type of pump chosen), and consistency can only be detected by monitoring/verification.

Second Paragraph

IDF

Second paragraph, first sentence, we suggest to replace "*...at the time the control measure is applied...*" by "*.... at the step the control measure is applied....*"

Third Paragraph

VENEZUELA

Third sentence, delete "establishment" and substitute with "the established"

Relationship of Validation to the Appropriate Level of Protection

CANADA

We are questioning the necessity of including this section. The concepts explained here are more adequately covered in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

IDF

First paragraph, fourth sentence, for consistency with other parts of the document, we suggest that the first part of the 4th sentence reads as follows (suggested changes highlighted):

"In practice, ~~countries may establish~~ an FSO, POs, and/or PCs may be established as a practical, measurable articulation of...etc"

Relationship of Validation to HACCP

First Paragraph

CANADA

In the first paragraph, the second sentence is not accurate as it identifies some of the steps that are part of HACCP as being part of validation. We recommend replacing the sentence with the following:

> *Validation activities should include actions to confirm the efficacy of all elements of the HACCP system.*

IDF

We have come to the conclusion that there is not need to validate other elements than the control measures themselves. Therefore, we see no need to point out that the HACCP system require additional validation exercises other than those that are already addressed by the current Guidelines and we suggest to delete the entire paragraph or at least the 2nd and 3rd sentences.

The rationale for this view is as follows:

Validation of CCPs: CCPs are steps where control measures are applied. One or more control measures may be applied at the same step (CCP). Consequently, validation of control measures or combinations thereof, is fully covered by these Guidelines, i.e. the Guidelines include validation of CCPs. Consequently, there is no need to address this as an additional validation exercise that is outside the scope of these Guidelines.

Validation of critical limits: These Guidelines concern quantitative validation. A critical limit is closely related to the performance (e.g. the PC) of a control measure (e.g. a CCP), wherefore validation of critical limits is an integrated part of the validation of the performance of a control measure. Consequently, there is no need to address this as an additional validation exercise that is outside the scope of these Guidelines.

Validation of corrective actions: corrective action includes two types of actions: (i) bringing the control measure back into control (=”corrective action” according to FDIS 22000), and (ii) managing or disposing the affected non-conforming product (= "correction” according to FDIS 22000).

Type (i) corrective action need not be validated as it concerns the re-establishment of compliance with the intended (i.e. pre-set and earlier validated) performance of a control measure(s).

Type (ii) corrective action (correction) will, if the non-conforming food stays within the food chain, always involve the application of (additional) control measures. According to these Guidelines, such control measures should be validated anyway, but it is still the control measures that are to be validated – not the correction itself.

If, however, the CCFH decides to retain the 3rd sentence, we would like to point out the inconsistency with the introduction to the Guidelines in regard of the role of competent authorities in validation of HACCP; the reference to authorities should be removed.

Second Paragraph

CANADA

In the second paragraph, we recommend deleting the two last sentences. The concepts brought forward are better explained in subsequent sections.

IDF

If the first para. of this sub-subsection is deleted (as recommended above), we suggest deleting the second para. as well. Most of the information is generic to carrying out validation and not

specifically related to HACCP. We believe that the generic information is already provided by other sections of the Guidelines.

V. STEPS PRIOR TO VALIDATION OF CONTROL MEASURES

Item Number 1

CANADA

We recommend modifying number 1 as follows:

> *Identify the hazards that ~~can~~* ***are intended to*** *be controlled* ***and the necessary control measures.***

Item Number 2

CANADA

Under number 2 the first two bullet points appear to present the same idea. We recommend deleting the first bullet point and amending the second as follows:

> *The importance of the control measure as it relates to achieving the expected outcome for control of the hazard* ***(e.g., PC or PO).***

We recommend deleting the fourth bullet point "feasibility of conducting the validation". If a control measure cannot be validated because it is not "feasible", then another control measure or set of control measures should be selected, either at the specified point or up-stream or down stream of that point.

Item Number 3

IDF

Second bullet, the uses of the term "industry" in the 2nd bullet point and in the last para. are not correct, considering footnote 6 to the MRM document. Instead, the term "individual food business operator (e.g. food manufacturer)" should be used.

VI THE VALIDATION PROCESS

IDF

The document would benefit from the inclusion of practical examples of validation exercises, demonstrating the various approaches.

Approaches for validating control measures:

3. Collection of data during normal operating conditions in the food operation

CANADA

This section should be deleted as it appears to be an approach for establishing control measures, not for validating them. The examples given are simply establishing the parameters associated with incoming materials for which specific control measures will be established. This information is useful to establish the appropriate control measure parameters, e.g., pasteurization time/temperature to effect an adequate log reduction in the level of pathogens.

4. Statistically designed surveys

FIRST PARAGRAPH

CANADA

This paragraph should be deleted or rewritten to more clearly reflect its intent. The first paragraph presents an approach whereby one can establish how well the consumer applies specific practices necessary to control a hazard after the product has been manufactured and transported to retail. Such survey would not validate the effectiveness of consumer practices; it would simply provide an estimate of their degree of application by the general public. It can provide additional information for industry or government when designing control measures for application during manufacture of the product (e.g., to include a safety factor in the overall measures to be applied).

IDF

In the sentence of the first para., starting with "In such instances, procedures...." (Fourth sentence) the term "food manufacturer" is too limiting, wherefore it should be replaced by "individual food business operator (e.g. food manufacturer)".

5. Mathematical modeling

CANADA

We recommend adding at the end of the paragraph the following sentence:

> *Scientifically valid experimental trials (approach # 2) may be necessary to confirm the predicted performance of the control measure from the model.*

VIII LIMITATIONS TO VALIDATION:

First Bullet, Performance Target

CANADA

This paragraph should be deleted or rewritten for clarity. Step 3 of Section V (Steps prior to validation of control measures), clearly establishes the need for a target to be established. Without a target, validation of a control measure cannot occur.

IDF

Adequate text should be added, for instance under "performance targets", explaining that if a food

business operator applies a PO or a PC established by a competent authority, the role of the operator will be limited to the validation of whether the PO or PC, respectively can be fulfilled. In such case, the operator cannot be held responsible for the validity of the PO or PC as such. In other words, if a 5D reduction of a specific pathogen is required by a competent authority, the operator can only validate the fact that a step or a combination of steps in the processing will indeed guarantee this reduction. In this case, the responsibility to validate whether the required 5D reduction will really ensure the safety of the product at the end of the food chain will be the responsibility of the competent authority in question.

Last Bullet, Steps beyond the Control of the Validating Establishment

CANADA

This paragraph should be deleted as the validating establishment does not validate an entire food safety control system. It simply validates the measures for which it is responsible.

Last Paragraph

CANADA

In the last paragraph, the first and second sentences are not accurate and should be deleted. Uncertainty around the ability of a selected control measure to control the hazard should be dealt with through safety factors or other approaches when setting up the control measure. It is not appropriate to rely only on end product testing to ensure that a product is safe. Similarly, if a control measure has been validated as effective to control a hazard, verification still needs to occur to confirm that the control measure is being applied as required.