

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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Comments on the PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES AT STEP 3

Submitted by: Brazil, Islamic Republic of Iran, Peru, and International Dairy Federation (IDF)

GENERAL COMMENTS

BRAZIL

Brazil recognizes the efforts of the drafting group led by United States of America and the advances obtained in the document.

MEXICO

We don't have comments regarding the English document. However, we are waiting to see that the differences between validation, monitoring, and verification be clarified in the Spanish version.

PERU

Peru appreciates the opportunity to express its views regarding the information requested.

The document would be improved, and better understood, if practical examples of validation drills were included that demonstrated different approaches.

IDF

IDF would like to congratulate the chair of the CCFH Drafting Group for the work undertaken and for facilitating the revision the document. We consider that the document adequately covers the concept of validation.

INTRODUCTION**SECOND PARAGRAPH****ISLAMIC REPUBLIC OF IRAN**

In sentences 3 and 4, add the word *regional* after the word *government* .

III. DEFINITIONS**ISLAMIC REPUBLIC OF IRAN**

We suggest adding the definition of *hazard*.

IV. CONCEPT AND NATURE OF VALIDATION**SECOND PARAGRAPH****ISLAMIC REPUBLIC OF IRAN & IDF**

In the 1st sentence in the parentheses: change *VIII* to *VII*.

Boxed information on validation, verification and monitoring**ISLAMIC REPUBLIC OF IRAN**

add an explanation for *validation*.

IDF

The heading should reflect the order in the text, i.e. it should read:

“Validation, Monitoring and Verification”

In the second sentence of -Verification “... *and that the underlying parameters and assumptions (etc)...*” should be deleted.

Rationale

It is not really adding to the understanding of the differences to monitoring and validation and could be confusing, e.g. as the term “valid” is used.

V. TASKS PRIOR TO VALIDATION OF CONTROL MEASURES**ISLAMIC REPUBLIC OF IRAN**

Add a new item, as the first task: “Decide which food product”.

ITEM B**IDF**

In the second sentence **Identify the food safety outcome required**

In the second sentence, the phrase “*relevant to the intended use of the food*” should be moved so that it appears prior to the word “established”

Rationale

It refers to the outcomes/targets, not to the authority.

ITEM C

Identify the measures.....

ISLAMIC REPUBLIC OF IRAN

In the first sentence c) add the word *control* before the word *measure*.

add a new bullet after the bullet “adverse health effects”: *The section (size) of population and the age/sexgroups most at risk.*

SECOND PARAGRAPH**IDF**

The understanding could benefit from additional examples, such as

Holding the food at a specified temperature for a specified time (cold storage)

BRAZIL**HISTORICAL EXPERIENCE BULLET**

In the 1st sentence, It is proposed to correct the term food borne term should read as follows: “*foodborne*”,

VI THE VALIDATION PROCESS.**ITEM 2****PERU**

The following aspects should be mentioned on numeral 2: that laboratory methods must be validated according to national and international standards and be consistently monitored.

ITEM 3**PERU**

On numeral 3 on the same item, the types of statistical analyses to conduct depending on the sampling done and the type of food involved should be indicated, since it is not the same to perform a t-test, an ANOVA test or an ANOVA test with repeated measurements, etc. Otherwise, this could lead to incorrect interpretations.

ITEM 4**BRAZIL**

In sentence 3, It is suggested the term “Risk-based” be replaced with “based on risk”, in order to ensure consistency with the language that was already used in the Codex Alimentarius, as mentioned in paragraph 132, ALINORM 07/30/REP, as proposed below:

Rationale

Mathematical modelling is a means of mathematically integrating scientific data on how factors affecting the performance of a control measure or combination of control measures affect their ability to achieve the intended food safety outcome. Mathematical models, such as pathogen growth models to assess the impact of changes in pH and water activity on the control of pathogen growth or the use of z-value models to determine alternative thermal processing conditions, are used extensively by industry. This can also include the use of ~~risk-based~~ **models based on risk** that examine the impact of a control measure or combination of control measures further along the food chain. Effective use of mathematical modeling typically requires that a model be appropriately validated for a specific food application. This may require additional testing. Validation based on the use of mathematical modelling should take into consideration the uncertainty/variability limits associated with the models' predictions

PERU

On numeral 4, the different programs (software) that can be used to develop these models should also be indicated.

ITEM 5

On numeral 5, it should be mentioned that if surveys are used, these should be aimed at people of the age, race and gender representative of the group to which the food is destined. For instance, if the product is destined for children, this is the group to be surveyed, and within this group, different subgroups (6-8 years, 8-10 years, etc.).

Steps Involved in the Validation Process**FOURTH BULLETT****PERU**

Regarding the item on "Analyze the results", where it mentions that statistical analyses should be performed, it is necessary to obtain samples before, during, and after the process in order to have a control from which a statistically significant variation may be analyzed as a process of the Validation of the Quality Assurance System.

VII. NEED FOR RE-VALIDATION

SECOND PARAGRAPH

- **Process changes:**

BRAZIL

In the 2nd Sentence, It is proposed to include as example “*a new source of raw material*”, since a new source of raw material may result in the need for re-validation of control measures and could compromise the food safety

Sentence should read as follows:

The introduction in the food safety control system of a new control measure, technology or a piece of equipment that is likely to have a decisive impact on the control of the hazard may necessitate that the system or parts of it be re-validated. Similarly, changes made in product formulation, **a new source of raw material** or the application of current control measures (e.g., time/temperature changes) may result in the need for re-validation of control measures.

ANNEX I

IDF

The examples in Annex I was drafted within a short time and should therefore only be read as illustrative examples that are provided to enhance the understanding of the concept of validation.

Rationale:

In particular, we suggest that references to VTEC in Example Two is replaced by the term “**a pathogen**” (or “*the pathogen*”, as appropriate) in order to avoid any misunderstanding and/or misuse as regards safe levels, etc.