codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/FH 06/38/08 - Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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Houston, Texas, United States of America, 4- 9 December 2006

Comments at Step 3 on the

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES

Submitted by Australia, New Zealand and International Dairy Federation (IDF)

COMMENTS

AUSTRALIA

Australia is acutely aware that food safety relies critically on the implementation of food safety measures that have been confirmed as being capable of achieving the expected level of hazard control.

Australia therefore supports the progress of the document and believes that the positive suggestions we are putting forward will assist this work to move to the next step in the process.

Australia suggests that the document should be pared down to its intended core topic: validation. Australia considers that the document has foundered because the content extends beyond the intended scope. The core of the work – that is: validation what it is, why and how it is done – appears to be comprehensive and well structured. The Sections are clearly within the scope of the document title, but the inclusion of information about verification and monitoring in a section titled Concept and Nature of Validation is confusing.

For example, the third paragraph in the part on verification and monitoring contains several sentences which could be interpreted as validation. This may have arisen as a result of trying to be

concise with text; e.g., 'environmental monitoring to assess that sanitation measures were effective'. Such assessment could be considered validation. Another difficulty with the text is that monitoring is only a part of verification so it is not clear why it would be singled out.

Because of the difficulties with this part, we believe that restructuring the document and only working on the information that directly relates to validation will provide CCFH with a way forward

This means continuing work on all Sections but removing the part in Section IV Concept and Nature of Validation on the Relationship of Validation to Monitoring and Verification. Australia recognizes that there remains uncertainty about the association of validation with verification and the text that is included would need considerable revision in order for Australia to support its continued inclusion in the document, particularly in its current context i.e. in Section IV.

However, Australia recognizes that verification is particularly important in ensuring food safety systems produce safe food. As such, a 'sister' guideline should be developed which explains what verification is and the verification process. This would clearly differentiate between the two functions, rather than attempt to compare validation with verification. Therefore, Australia will propose the development of a sister guideline covering verification as new work under the newly established process by which CCFH will consider possible future work at the 39th Session of CCFH. Australia is prepared to lead this work.

Australia is also of the view that the inclusion of an explanation of the nature of control measures is not necessary for this document. The document is dependant on an understanding of the HACCP system, including control measures in particular, so to focus on one element does not greatly assist the reader. In order to progress the document, Australia would prefer to see the Annex removed. Alternatively, as some control measures, because of their nature, are more difficult to validate, for example, pest control measures or animal production practices, there may be scope for including some discussion on these difficulties under Limitations to Validation.

In terms of detail, Australia has specific comments which it will raise, as appropriate, at the 38th session of CCFH in December 2006.

NEW ZEALAND

New Zealand strongly supports the concept of validation and its importance in relation to demonstrating the achievement of measurable outcomes, whether for "hazard-based" or "risk-based" food control measures.

New Zealand suggests that currently there is a degree of confusion at both the Codex level and national level on application of validation, verification (including audit) as food control activities that are necessary to successfully implement food control measures. This confusion is partly due to the "evolutionary" aspects of food safety risk analysis in the Codex system over the last ten years and the development of the above concepts in different committees, particularly CCFICS, CCFH and CCGP.

With the benefit of hindsight, New Zealand would like to see a general discussion on the terms validation, verification (including audit) which leads to working definitions that reflect the current,

practical world of food control. This is particularly important in respect of validation, as there are very few examples where the "risk-based" validation concepts put forward in the draft guidelines have a basis in practice.

New Zealand also feels that the scope of these guidelines is too wide and unfocused in trying to include validation guidelines for "entire sets of control measure combinations forming a food safety control system." How can this be done in objective terms and what is the value to competent authorities and food establishments? (Of particular concern is reference to GHP in a document such as this, which represents current practice and in most situations will not be able to be validated in terms of human health outcomes).This approach includes aspects of the equivalence texts of CCFICS and work is continuing on extending those guidelines so that they have practical application.

New Zealand suggests that for the guidelines to be meaningful, they would benefit from:

- Limiting the scope of the guidelines so that they have practical explanation

- Clearly positioning validation and verification (including audit) as food control implementation activities, with reference to work in other Codex committees where needed

- The provision of key principles for validation

- Explaining the differences between validation of "hazard-based" measures and "risk-based" measures

- Defining/full explanation of "process criteria" and "product criteria" including examples of application

- Clear explanation of the role of Competent Authorities and food establishments in relation to validation

- Practical examples of validation of "hazard-based" and "risk-based" food control measures

New Zealand suggests that with refocusing of the draft, it could be considerably reduced in volume

IDF

IDF would like to congratulate the chair of the CCFH Drafting Group revising the document. The draft guidelines are now in a state that should allow progress in the Codex step procedure

We would like to put forward the following comments for consideration by the Committee:

V. STEPS PRIOR TO VALIDATION OF CONTROL MEASURES

Step 2) – Identify the food safety outcome required

LAST PARAGRAPH

IDF

In the last Para, the phrase "*relevant to the intended use of the food*" should be inserted prior to the word "established". Intended use has a significant impact on target levels. If a specific intended use was not taken into account when targets were established by competent authorities etc. , the corresponding target specific to such use should also be established individual food business operator.

Step 3) - Identify ….Include:

THIRD DASH POINT

IDF

The example of on-farm practices includes some difficulty, as it is not expected that the individual farmer is capable of carrying out any validation. In practice, on-farm practices is (or should be) indirectly taken into account by the individual food manufacturer. This difficulty can be overcome by adding the following:

"On-farm practices that impact the stringency requirements of food safety control systems during subsequent processing and manufacture, should be included in validation studies carried out by the individual food manufacturer, for instance as assessments of hazard levels in received farm products in combination with verification activities (such as analytical testing, supplier audits, etc.)."

Step 5) – If necessary …..

IDF

The following parameter should be added as a new indent:

"Established knowledge about the quantitative effect of a control measure on hazard occurence and/or hazard levels: Control measures that are of such nature that it is not feasible to determine their quantitative effect on specific hazards should not be prioritized for validation. Examples of such control measures includes air locks to minimize cross contamination, hand washing procedures and good house keeping."

VI THE VALIDATION PROCESS

Approaches for validating control measures:

4. Statistically designed surveys

IDF

This approach is, as described, not validation of control measures but verification of the assumptions made when establishing control measures such as labelled shelf life and storage & handling conditions.

Those control measures that apply beyond the control of the manufacturer is under indirect control by the manufacturer to the extent that they are communicated to the user (i.e. the instructions on the label). Validation of these control measures (e.g. shelf life, storage instructions, etc) is adequately covered by the other approaches, in particular approach #5.

We therefore suggest that approach #4 is removed in its entirety.

5. Mathematical modeling

IDF

It should be stated that modeling is particular useful, when hazard levels are low and/or where hazards occur with low frequency, e.g. by adding the following at the end:

"Mathematical modeling may be the only approach that is feasible in the validation of control systems where a hazard occur with very low frequencies and/or where hazard levels are well below analytical detection limits."

VIII LIMITATIONS TO VALIDATION:

Last Bullet

IDF

The word "uncertainty" should be replaced with "decreased level of confidence; the last phrase would then read:

"....may decrease the level of confidence of the validation".