

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 7

CX/FH 05/37/07 - Add.2

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-seventh Session

Buenos Aires, Argentina, 14- 19 March 2005

Comments on the

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF CONTROL MEASURES

Submitted by Argentina

ARGENTINA

General comments

The redrafting of the Proposed Draft—CX/FH 05/37/07—has taken into consideration the recommendations made by the Committee at its 36th session. In this respect, it is worth pointing out that the document has been simplified; its language is more direct and it now has a “guideline” format, which facilitates both its understanding and application.

Specific comments

The proposed draft clearly establishes the relationship between validation and the appropriate level of protection (ALOP), as well as the implications of this relationship.

IV. CONCEPT AND NATURE OF VALIDATION.

The last paragraph considers that “Validation of control measures or food safety control systems is performed **before** their actual implementation.” In some cases, there are bilateral agreements in which governments agree to conduct the assessment of the effectiveness of the measure through monitoring and verification of a certain number of shipments when marketing starts; the approach of accepting only the previous validation is not considered in these guidelines. With a view to taking this into account and to preventing agreements between two countries from being left out of international guidelines, Argentina proposes the following addition:

“Validation of control measures or food safety control systems is performed before their actual implementation, **unless agreements exist or are made on the matter between two or more countries at government level.**”

V. STEPS PRIOR TO VALIDATION OF CONTROL MEASURES

Argentina believes that item 1 should refer to risk assessment as a means or tool for the identification of (a) hazard(s) that can be controlled. We therefore propose the following addition:

1) Identify the hazard(s) that can be controlled, based on a risk assessment.

VI. THE VALIDATION PROCESS

A positive aspect we would like to highlight is that the process considers that where there is historical knowledge of the performance of the specific control measure—and it is effective for the control of a specific hazard—the measure will be considered validated.

Given the variety of measures applied historically, Argentina believes that this aspect should be stressed in the document and that special consideration should be given to knowledge of the failure to detect that the measure is not effective.

VII. PRIORITIES FOR VALIDATION

In addition to the fact that the acceptance—through validation—of measures that were not known, used or accepted may add some flexibility to the food control system, Argentina believes that it is of great importance to take into account that if the validation of all—or almost all—control measures used in the system was required, the system would become more rigid.

Considering the potential implications of their application—i.e. their requirement for most of the control measures applied—and the resources needed, these guidelines are very likely to have a negative effect on international trade in products coming from developing countries. Also, they could be easily used as barriers to trade in these products. Not only may these effects be due to the fact that developing countries’ producing sector and industry lack the resources needed for the validations required, but they may also reach competent authorities when establishing new regulatory requirements.

Therefore, special consideration should be given to the implications of validation, particularly on measures already in force and those which have been used historically.

The parameters used for the prioritization of control measures seem to be appropriate, as the risk level and the importance of the measure are the ones with the greatest impact on food hygiene control.

However, Argentina is of the opinion that care should be taken when stating that “In principle, **all** control measures used to control the various hazards potentially associated with a food product or product group should be validated.”

While the third item makes reference to it, historical experience is not considered a precedent that justifies the exemption of the evaluation given the historical use of the measure and the absence of detection of non-compliance with—or insufficient effectiveness—of the control measure. Hence, Argentina proposes to amend the text as follows:

“In principle, ~~all~~ control measures used to control the various hazards potentially associated with a food product or product group should be validated.”

The item Historical Experience should include:

- Historical experience: If experience and historical knowledge exists with respect to the performance of a control measure and there is reliable information on the absence of shortfalls in its effectiveness, these precedents will validate the measure. If little or no experience exists ... (the rest remains unchanged)