

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 3

CX/FH 03/3-Add ...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, U.S.A., 27 January – 1 February 2003

#### INDIA'S COMMENTS:

#### Endorsement of Hygiene Provisions in the Codex Standards and Codes of Practice

#### I. Code of Practice for Fish and Fishery Products – (step 8) –Appendix II

While appreciating the effects of CAC to streamline standards of code of practice of fish and fishery products, we would like to highlight the major concern of India and other developing countries, especially in framing the definition and the requirements of *fishing vessels*. In the General Definition the 'Vessels' are not defined properly but are included in the definition of "Facility". At section 3.1 the basic requirements for the design and construction of the fishing and harvesting vessel have been highlighted, which is very much detrimental to the interest of developing nations. As it is rightly pointed out in para I of section 3.1, "there are many different types of fishing vessels used throughout the world, which have involved in particular region to take account of the prevailing economics, environment and type of fish and shellfish caught". In India most of these vessels engaged in fish harvesting operations are small fishing boats / country vessels designed only for short term operations and they are meant only for the capture and transportation of fish with in a short stipulated time. No pre-processing and processing activities are taking place in these vessels. Considering their size and mode of operation it is practically impossible for these vessels to meet the requirements of section 3.1.2, 3.1.3 and 3.1.4. Therefore, it is strongly recommended that the requirement of the said sections are made compulsory only for freezer vessels / factory vessels where the fish is processed and packed.

As such the followings amendments are suggested.

## **Section 2.1 - General Definition**

In the definition for “Facility”, it is stated in vague manner that “Premises also include vessels”. The vessels as such are not defined properly. Therefore, it is suggested that vessels may be defined as “Fishing vessels” where fish is harvested, chilled / frozen, prepared, processed and packed or stored”.

## **Section 3.1 - (page 40)**

In the last sentence of para 1 the word “all vessels” should be replaced and read as, “all freezer vessels/ factory vessels should have”.

## **Section 3.1- (page 40)**

The Second para of the said section should be deleted and suitable written, as “the design and construction of the freezer vessels/ factory vessels should take in to consideration the following”.

## **Section 3.7 - Product tracing and recall procedures**

Recall procedure is a prerequisite of HACCP envisaging that no process is fail - safe. However, in Indian conditions product tracing from “water to table” is practically impossible due to the vastness of the area and due to the in-adequacy of the facility and the number of people involved in it. The matter has been discussed in previous codex meetings and amicable solution was not evolved, therefore the clause 3.7 may be deleted or suitably amended.

## **II. Proposed Draft Model Certificate for Fish and Fishery Products- Appendix X**

After elaborate discussion on 22<sup>nd</sup>, 23<sup>rd</sup> and 24<sup>th</sup> Sessions the Committee had agreed to advance the proposed draft of sanitary certificate to step 5 for adaptation by 25<sup>th</sup> Session of CAC and to return the other proposal draft model certificates to step 3. From India’s point of view, the following modification shall be made in the said sanitary and other certificates both in format and definition.

### **Section 5.1.2 - Model inspection certificate (page 140)**

The last sentence of the said section may be re-written as “an inspection of finished product has been conducted by an inspector of the competent authority or *an inspector authorised by the competent authority*” .

It is not always possible to inspect the consignment by the competent authority officials alone. Therefore, inspectors authorised / approved by the competent authority may be allowed to inspect the cargo.

### **Annexure II - Format of the certificate (page 142)**

The “Tel:, Fax:, E-mail:” mentioned at the right hand top of the format is confusing as to whether it is applicable for the competent authority or the inspection body.

Therefore, it should be made clear that those details are meant for competent authority only.

#### **Annexure II - Format of the certificate (page 142)**

Under the heading “ Details identifying the fishery products” in the column no. 1 “Description of species” (scientific name) may be changed as “Description of species” (Generic Name).

This is to avoid practical difficulties in identifying the species in frozen / processed condition. Moreover, instances are many where similar species are mixed together and are difficult to segregate due to their close resemblance.

#### **Annexure II - Format of the certificate (page 142)**

Under the head of “Details identify the fishery products” in the column 4 “lot identifier / date code” should be amended as “lot identifier / month code”.

In India most of the fish processing units are in small scale sector, having a production capacity less than 5 mt/day. Therefore, a 40 foot container may constitute 20-25 day codes, depending upon the availability of the material. This in turned crates inconvenience while issuing the certificates however, a month code will serve the purpose, as it indicates the period of production where, the material is processed in similar conditions. Health certificates specified by EU only envisage code “ (where available)”.

#### **Annexure II - Format of the certificate (page 143)**

Under IV- Attestation, the first sentence may be re written as “The undersigned official inspector or *official recognised inspector* hereby certifies that at the time of inspection”.

#### **Annexure II - Format of the certificate (page 143)**

At Sl.No. 2 “Under a competent HACCP” may be re-written as “Under a competent HACCP or *a similar plan*”.

#### **Annexure III - Statement concerning radio activity level in fish (page 144)**

The first sentence may be deleted since there is no relevance of the sentence in the certificate.

#### **Annexure III - Statement concerning radio activity level in fish (page 144)**

The last part of the second sentence starting from “And in no instances the level of radio activity has been found to exceed the natural background level” may be deleted, since any previous detection of radio activity even to a very small quantity above the limit will prevent the issuance of the certificate. Moreover, the present test levels of radio activity are recorded in the certificate.

**Annexure III - Statement concerning radio activity level in fish (page 144)**

Signature of the “*Director general of (name of the competent authority). Head of (name of division)*” may be deleted as the signature of the official inspector is sufficient.

**Annexure IV- Statement concerning trace elements in fish (page 145)**

“*Scientific name*” may be amended as “*generic name*”.

**Annexure IV- Statement concerning trace elements in fish (page 145)**

The first and second para may be deleted as these have no relevance in this certificate.

**Annexure IV- Statement concerning trace elements in fish (page 145)**

Signature of the “*Director general of (name of the competent authority). Head of (name of division)*” may be deleted as the signature of the official inspector is sufficient.

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Agenda Item 4

CX/FH 03/4-Add ...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, U.S.A., 27 January – 1 February 2003

#### INDIA'S COMMENTS:

#### **Draft Revised Guidelines for the Application of HACCP System**

#### **Consideration of the Obstacles to the Application of the HACCP Particularly in Small and Less Developed Businesses and Approaches to Overcome them.**

The proposed document was discussed by the Codex Committee on Food Hygiene (CCFH) in its 34<sup>th</sup> Session in October 2001 in Bangkok. The proposed document included two annexes, Annex 1 on "Proposed Revised Guidelines for the Application of HACCP System" and Annex 2 on "Obstacles to the Application of HACCP, particularly in SLDBs and Approaches to Overcome Them". The Committee decided that the Annex 1, after suitably revised, would be a revision to the current guidelines for the application of HACCP system which is a part of the "Recommended International Code of Practice, General Principles of Food Hygiene" CAC/RCP 1-1969, Revision 3 (1997, Amendment 1999). The Committee clarified that the proposed document was not intended to be adopted as a separate document and would replace the current HACCP document. It however did not specify the status of the Annex 2 whether it would be a part of the HACCP document or not. The Committee suggested that the Drafting Group should revise Annexes 1 & 2 suitably after incorporating the comments from different countries and present these to the next meeting for discussion.

It may, therefore, be noted that the Annex 1, i.e., the document on HACCP, is not specifically being developed for SLDBs, but the document may include the concerns of SLDBs suitably and would be used for all the businesses, small or big, alike. However, our efforts should be to have Annex 2 integrated with Annex 1.

## **Comments on Annex 1 : Agenda Item 4a)**

### **General Comments**

Scope of the guidelines to be included in the document.

1. **Para 1:**

Sentence 2 has already been covered in the document at different places and does not need to be over emphasised. Further, verification of prerequisite programmes including training would be difficult.

2. **Para 2:**

The wording “for all types of food business” may be deleted. It does not convey any additional value to SLDBs because it is well understood that the management awareness and commitment, in any case, is necessary for application of HACCP systems. The sentence “effectiveness will also rely upon management and employees having appropriate knowledge and skills” has already been identified as a constraint for implementation of HACCP for SLDBs. By putting it over here, there is no additional value provided to the SLDBs. Therefore, it should be deleted.

3. **Para 5:**

The second sentence does not have any meaning as CCPs are a part of HACCP and not GHPs and it has already been indicated that GHPs are a pre-requisite to HACCP. The sentence therefore needs to be deleted.

4. **Para 6**

As the seven principles of HACCP have been accepted for application on food businesses, hence, the first sentence is superfluous and should be deleted. Further we agree that the purpose of putting this para is to identify the need for giving flexibility to SLDBs in implementation of HACCP in light of obstacles faced by them. However, in the given formulation this aspect has not come out as intended. We suggest the following formulation:

“ It is recognised that HACCP in SLDBs is difficult due to the obstacles as referred in Annex II. Therefore, while applying HACCP principles in SLDBs flexibility should be allowed taking into account the nature and size of operations, including the human and financial resources, infrastructure, processes, knowledge and practical constraints”.

6. **Para 8:**

Para to be deleted as this aspect has already been included in para 2 and the para on training.

## APPLICATION

### 1. Step 1: Assemble HACCP team

In the third line "should" to be changed to “may” to read as "...expert advise **may** be obtained from other sources ...".

### 2. Step 2: Describe product

The last sentence to be modified as follows:

**"Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics, hazards or processing steps, for the purpose of development of the HACCP Plan.**

**Issues such as consumption pattern and target market are also crucial in designing the HACCP plan, therefore, it is proposed that these two may also be included in the para suitably.**

### 3. Step 4: Construct flow diagram

**Add the following at the end of the second sentence:**

***"/group of products" to read as “ the flow diagram should cover all steps in the operation for a specific product/group of products”.***

### 4. Step 6: List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards.

**Modify first para as follows:**

***"The HACCP team (see also para 1 above) should list all of the hazards that may be reasonably expected to occur at each step, according to the identified scope which may include one or more of the stages namely **primary production, processing, manufacture, or distribution until the point of consumption.*****

### 5. Step 8: Establish critical limits for each CCP

**Para 2:** The first sentence of the para may be modified as follows:

**“Where expertly developed HACCP guidance **or scientific literature** has been used to establish the critical limits-----”.**

The second sentence may not always to be true as under certain cases the critical limits may not be measurable and may be qualitative, for example, in the case the critical limit is boiling, the same would be observed visually and would not need to have any specific measurable value. The sentence may therefore be deleted.

6. Step 11: Establish verification procedures

Last para: **"where appropriate" to be modified to "where possible" as per the original version.**

**The following para to be added:**

**“Verification in SLDBs shall be limited to review of records and random testing of end products. However, the verification under regulation shall be designed as needed for the specific foods based on risk”.**

7. Step 12: Establish documentation and record keeping

Para 1: **The words “ and sufficient to assist the business to verify that the HACCP controls are in place and being maintained” are not necessary. The last sentence has already been given in the introduction of the document and is not necessary here.**

8. **Under Training, para 1:** Last sentence – “ As an aid in developing specific training support to HACCP Plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each critical point” to be deleted as the same is not relevant under this heading.

**Comments on Annex 2 : Agenda Item 4b)**

**General comments** – In order to give equal status to this document vis-à-vis the guidelines, it is essential that this document is referred in the main HACCP document and is appended to the same.

Further, there is also a need to include elaboration on how to apply the different steps for SLDBs in this document. This will be required to give clarity to the solutions proposed against each of obstacles while referring to the concerned principle of HACCP system. In addition, it has been observed that the following obstacles are still not addressed with regard to the application in SLDBs.

- Primary production – In most of the developing countries, the primary production of the produce is under unorganised sector. The processing unit procures raw material from a number of farmers. As a result of this, the processing unit has no control and it is very difficult to monitor the practices followed by the farmers during primary production. The processor has virtually no control over minimising the hazards at farm level and addresses the issue by controlling the entry of such contaminated primary produce at the stage of entry into the processing unit. Accordingly, India proposes that this problem should also be reflected in Annex-2 and approaches to overcome them.
- Seasonal nature of the production – In case of fresh fruits and vegetables, the availability of fresh produce is generally restricted to 3 – 4 months, due to which the processor has to depend upon the processing

of more than one product in his processing unit. It means that he has to develop HACCP Plans for each produce separately which not only requires resources in terms of finance but also requires technical expertise in the concerned area. It is, therefore, essential that obstacles faced due to seasonal of the produce are also reflected in Annex. – 2.

- Records – As record keeping has already been identified as an obstacle in implementation of HACCP in SLDBs due to different levels of education of workers. Hence, it is proposed that the minimum records that need to be maintained for SLDBs should be specified.
- Verification – Minimum verification of critical control points in SLDBs should be limited to review of records and random testing of end products. However, the verification under regulation shall be designed as needed for the specific foods based on the risk.

We have observed that there are several points mentioned in the document as obstacles which in fact are not specific to SLDBs and are general obstacles. In our view, such obstacles should not be included in this document. Our comments on Annex 2 are as follows:

- 1) Obstacle No.4: Perceived and real financial constraints. In our view the words 'perceived and real' are redundant and should be removed.

In the suggested measures, the 4<sup>th</sup> bullet point is "focusing implementation on a sector-by-sector basis". If the meaning is that one sector should be taken up at a time and after the completion of the HACCP in this sector another sector should be taken up, then the implementation in some sectors would take a long time. In our view this would not be prudent. Therefore, we suggest to delete this provision.

- 2) \* Obstacle No.5: Insufficient government infrastructure and commitment,  
\* Obstacle No.6: Absence of legal requirements,  
\* Obstacle No.8: Lack of customer awareness, including consumer awareness,  
and  
\* Obstacle No.12: Inadequate communications.

The obstacles mentioned above are not specific to SLDBs alone. They apply to large businesses as well. Therefore, they should be deleted.

- 3) Obstacle No.7: Lack of business awareness and positive attitude of industry and trade associations.

The first bullet point under recommendations is 'enforcement activities to promote HACCP, particularly in SLDBs'. The enforcement activities, **if undertaken**, should not be directed only to SLDBs alone, they should be directed to all businesses as a policy matter. Therefore, we propose to delete this bullet point.

- 4) Obstacle No.9: Lack of effective education and training programmes.

It is noted that this obstacle and the recommendation made are duplication of the Obstacles 2 and 3, and, therefore, it is recommended that this obstacle item be deleted. However, the recommendations made in 3<sup>rd</sup>, 5<sup>th</sup>, 7<sup>th</sup> and 8<sup>th</sup> bullet points be included in the recommendations of Obstacle 2.

- 5) Obstacle No.10: Lack of expertise, information and/or technical support

This obstacle and the recommendations made are repetitive of Obstacle 2 and, therefore, it is suggested that this be deleted.

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Agenda Item 5 a)

CX/FH 03/5-Add...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

**Thirty-fifty Session**  
**Orlando, Florida, USA, January 27 – February 1, 2003**

INDIA'S COMMENTS:

### **DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR SALMONELLA SSP. IN POULTRY**

#### **Para 2 – Risk Management Strategies in the Broiler Production Chain** **Sub-para 2.5 – Slaughter**

India acknowledges that GMP, GHP and HACCP are important pre-requisites for the slaughtering process. It is also acknowledged that chilling at the suggested temperatures is required to reduce risk from cross contamination. However, both methods of chilling, i.e., through air and water should be treated at par. Accordingly, the 4<sup>th</sup> indent in this sub-para may be modified as follows :

*“Chilling by air or water should be carried out to reduce risk from cross contamination.”*

#### **Sub-para 2.7 – Distribution and retail sale**

India acknowledges that GHP is important at the point of distribution and retail sale. However, it is impractical to adopt GMP at these points as this is implemented only at the manufacturing stage. Moreover, India is of the view that HACCP should not be made a pre-requisite at the distribution and retail sale points as it is difficult to implement in developing countries due to economic reasons. Accordingly, it is proposed that the words, “GMP” and “HACCP” should be deleted from the sub-para.

**Sub-para 2.8 – Catering**

India acknowledges that GHP is important for catering. However, it is impractical to adopt GMP for this purpose as this is implemented only at the manufacturing stage. Moreover, India is of the view that HACCP should not be made a pre-requisite for catering purposes as it is difficult to implement this in developing countries due to economic reasons. Accordingly, it is proposed that the words, “*GMP*” and “*HACCP*” should be deleted from the sub-para.

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Agenda Item 5 e)

CX/FH 03/6-Add ...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, U.S.A., 27 January – 1 February 2003

#### INDIA'S COMMENTS:

#### **Proposed Draft Process by which the Code Committee on Food Hygiene could undertake its work in Microbiological Risk Assessment/Risk Management" (CX/FH 03/06)**

India would like to compliment the USA for preparing this useful and reader-friendly document. The proposed draft clearly outlines the process through which the CCFH might undertake its activities related to microbiological risk assessment and risk management. While India, in general, supports the document, there are a few provisions included in the paper, which have caused some concerns. We would provide our comments on them when they are taken up.

#### **2. Section "Proposed Process"**

The 3<sup>rd</sup> bullet in the section 'Proposed Process' says that undertaking a microbiological risk assessment through the FAO/WHO Joint Expert Group on Microbiological Risk Assessment would be optional.

Risk assessment is an important and inevitable step in establishing science based standards. The statements 1 and 2 of the 'Statements of Principle Relating to the Role of Food Safety Risk Assessment' in the Codex Procedural Manual, 12<sup>th</sup> edition, clearly state that the Codex decisions and recommendations should be based on a risk assessment and that risk assessment be soundly based on science.

Therefore, India does not agree that the microbiological risk assessment by JEMRA would be 'optional' and stresses that the process of risk assessment must necessarily be undertaken by JEMRA (an expert body) for any standard elaboration exercise in order to ensure that the standards so elaborated are effective but not unnecessarily stringent or trade restrictive.

*It is, therefore, proposed to delete the word 'optional' at the end of the third bullet in the 'Proposed process'.*

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#### **1. Section 1: Proposal for Work- subsections 1.1 and 1.4**

In the **subsection 1.1** it is mentioned that 'international intergovernmental or non-governmental organizations' may propose new work related to microbiological risk assessment/ management. This is not acceptable because these organizations, which are not members of the Codex Alimentarius Commission, do not represent any country's concern. If the Committee entertains such proposals, it may lead to a situation wherein the proposals are put up by these organizations and then resisted by the governments of the member countries, thereby causing loss of valuable time and resources of the Committee. If these organizations have any useful proposal, they can convince any member country to make that proposal to the Commission or the appropriate Committee.

*India, therefore, proposes to delete the words 'or by a recognized international intergovernmental or non-governmental organization' from the subsection 1.1.*

Further, in consequence upon this proposal, India would also like to delete the word '**organization**' appearing in the penultimate sentence of the paragraph 1.4.

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#### **4. Sub-section 1.3**

India has two observations to make on the subsection 1.3. In the first bullet it is mentioned that availability of 'data' should be an additional criteria if the proposal for new work is going to include a recommendation for the conduct of an international risk assessment. Conducting a risk assessment at international level would require 'global data' for a meaningful outcome.

*We, therefore, propose to add the word 'Global' before the word 'data' in the first bullet of the subsection 1.3.*

Our second comment is on 3<sup>rd</sup> bullet. In the 3<sup>rd</sup> bullet it is mentioned that initiation of risk assessment at 'national level' should be an additional criteria for the conduct of an international risk assessment. However, it is not clear why international risk assessment should have been preceded by a similar exercise at national level. Since the process of 'international risk assessment' is to be carried out by the WHO/FAO Joint Expert Committee on Microbiological Risk Assessment, the need for initiation of risk assessment at national level seems to be unrelated and misplaced here.

*India, therefore, proposes to delete the third bullet.*

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**5. Section 3: Involvement of the FAO/WHO Joint Expert Group on Microbiological Risk Assessment (suggestions for addition of a new subsection 3.5)**

According to the approved Codex procedures, as stated in the Codex Procedural Manual, 12<sup>th</sup> Edition, page 165 under the heading 'Statement of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to which Other Factors are taken into Account', Codex decisions are required to be based on sound scientific analysis. Therefore, in order to ensure that the risk assessment forms an integral prerequisite to any output document of the Committee, it is proposed to add a subsection 3.5 as follows:

*"No output documents of the Committee should be advanced to step 5 without completion of the risk assessment by the WHO/FAO Joint Expert Group on Microbiological Risk Assessment and full data and details of its scientific evaluation should be made available to the member countries prior to its advancing to steps 5."*

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**6. Section 4: Iterative Process between CCFH and FAO/WHO Expert Group on Microbiological Risk Assessment**

The subsection 4.2 states that the Committee may utilize Working Groups to develop output documents and to provide for communication between the Committee and risk assessors between sessions of CCFH. However, a Working Group within a Committee includes only a few countries as members, and not necessarily risk assessment experts. Therefore, it would not be appropriate for such Groups to communicate with the risk assessors on matters that have not been discussed in the committee sessions. Any such Working Group can not be mandated to work independent of the Committee.

**We, therefore, propose to delete the portion "and to provide for communication.....of CCFH" from the paragraph.**

**Further, in accordance with our submission, the references to working groups in subsections 4.4 and 4.5 should also be deleted.**

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**7. Annex 1: Section 6**

There is a minor editorial correction needed in the last bullet of section 6. The word '**including**' in the sentence needs to be replaced by the word '**and**'. The sentence may be corrected as:

"Areas where major absence of information exist that could hamper risk management activities ~~including~~ and, if warranted, the conduct of a risk assessment "

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Agenda Item 6

CX/FH 03/7-Add ...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, U.S.A., 27 January – 1 February 2003

#### INDIA'S COMMENTS:

**Proposed Draft Principles and Guidelines for the conduct  
of Microbiological Risk Management at step 4 (CX/FH  
03/07).**

#### 1. General Statement

India appreciates the tremendous efforts of France and its drafting group partners in preparing this exhaustive, but useful document. The document outlines the different components of microbiological risk management and details what should be considered and what would be involved at each step of the process of microbiological risk management. The guidelines elaborated in the document would be useful to risk managers.

On studying the document, however, we have noted that it has attempted to embody certain approach and concepts that need very careful attention. We have four observations to make. First, it attempts to develop approach to application of microbiological risk management not only with respect to Codex, but also with respect to countries. India feels that Codex Committees should limit their work to Codex standards and Codex guidelines to be employed for the purpose of international trade of food, which, incidentally are also intended to be used by countries. We are of the opinion that the this document need not and should not include any portion separately for countries and hence all such references should be excluded from the document.

Our second general observation is that the document has attempted to introduce the doctrine of precautionary principle at several places in contradiction to the adoption of the 24<sup>th</sup> CAC. The Commission had adopted that in the absence of scientific evidence, Codex should not elaborate any standards, and instead should develop guidelines that are science-based. We should replace all references to precautionary principle in the document by the resolution of the Commission.

Our third observation is on the suggestion to the microbiological risk assessment by JEMRA being optional. As per Codex resolution , all Codex standards should be based on risk assessment. For matters related to microbiological risk, this is to be carried out by the JEMRA. Hence when needed, microbiological risk assessment must be carried out and it must be carried out by JEMRA.

Our last comment is on including non-safety issues in the document at various places. We may recall that Codex mandate is food safety. Therefore, this document should concentrate on matters related to human health, and all non-safety issues should be deleted. Accordingly the paper needs to be revised suitably.

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## **2. Section 1 : Scope**

The last paragraph mentions about recommendations applicable to countries only. As we have submitted earlier in our general comments, Codex document should primarily confine to recommendations for Codex only, there is no need for this paragraph and therefore we suggest that this be deleted.

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## **3. Section 2: Definitions**

In the definition of food safety objectives, India proposes that the square bracket for the word 'microbiological' be removed.

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## **4. Section 3: General Principles**

Our comments are on Principles 7 and 9.

**(a) Principle 7 :** The Principle 7 is put in square bracket. This principle says that when scientific knowledge of the risk is insufficient the risk managers can apply a precautionary approach through interim measures. Similar suggestion has been made elsewhere, such as in the last paragraph within square bracket in the section 5.2.2 and in the last paragraph after the last bullet point in section 5.2.4.

The principle, as it is stated, is likely to be misused. Since no scientific proof is required, countries may set arbitrary stringent standards and thus impose undue non-tariff barriers. For such situation, the 24<sup>th</sup> Session of the CAC has adopted the following decision on precautionary principle:

*"When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence."*

India, therefore, proposes that the existing paragraph in Principle 7 be replaced with the paragraph adopted by the CAC, as mentioned above.

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**(b) Principle 9 :** This principle refers to food tracing / traceability system as an example of appropriate food safety infrastructure. It may be recalled that food tracing or traceability has not yet been conceptualized and is still under consideration of different Codex committees. Therefore, food tracing / traceability should at best be put in square bracket if not deleted.

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## **5. Section 5.1.1 : Identification of Risk Managers**

The 3<sup>rd</sup> paragraph of the section 5.1.1 suggests that the risk assessment will 'normally' be the responsibility of the FAO/WHO joint expert group of microbiological risk assessment. Since the risk assessment is not 'normally' but 'always' the responsibility of the JEMRA, India proposes to delete the word 'normally' from the paragraph.

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## **6. Section 5.1.8 : Regional considerations**

In the 2<sup>nd</sup> bullet point, the sentence should be continued with the following :

“, technical feasibility and impact on food trade.”

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## **7. Section 5.2.1 : Determining the appropriate level of protection (ALOP)**

On section 5.2.1, India has three comments. **First comment** is on the first sentence of the 4<sup>th</sup> paragraph which says that "the ALOP / ALR applies equally to both domestic and imported food."

It is well recognized that ALOP / ALR applies to both domestic and imported food and therefore this statement is unnecessary and can be deleted.

**Our second comment** is on paragraph 7. The first sentence of the paragraph says that decisions on ALOP should be determined for the general population and any susceptible sub-populations. We are not comfortable with including the word 'susceptible sub-populations' in the scope of decisions on ALOP. The reason for making this suggestion is that the ALOP for susceptible sub-population would always be higher than the general population although the percent of such population may be very small. For susceptible sub-population separate ALOPs may be decided and food may be produced based on such ALOP for such population with suitable labelling provisions so that the general population is not taxed by paying higher price for food produced on the basis of higher ALOP.

India, therefore, proposes to delete the words "in susceptible sub-populations" from the first sentence.

**Our third comment** is on the first bullet point. After the first word ‘Technical’ add the words ‘and economic’.

---

## **8. Section 5.2.2:**

India would like to make three comments on the section 5.2.2.

**Our first comment** is on the third bullet point. The reference to primary production after ‘any stage in the food chain’ is not required as it is included in the food chain. Hence the portion after the word ‘chain’ in the sentence be deleted.

**Our second comment** is on the third paragraph including two bullet points from the last. As we have submitted earlier that this document should include recommendations only for the Codex, this entire paragraph should be deleted as it applies only to countries.

**Our third comment** is on the last paragraph of the section 5.2.2 says that in case scientific data are insufficient or incomplete, countries may adopt 'appropriate precautionary approach' for the risk management/risk assessment. This 'appropriate precautionary approach' may include setting up certain standards which goes against the adoption of the CAC according to which no standard can be set but only code of practice can be made. If retained the paragraph may lead to misuse by countries. Therefore, India proposes to delete the last paragraph.

---

## **9. Section 5.2.3 : Selection of preferred microbiological risk management options**

The penultimate paragraph of the section 5.2.3 recommends that other important elements should be considered in microbiological risk management options, and then includes some examples of such elements. These examples are not conclusive and are not required to be included. We, therefore, propose to delete the second sentence of the paragraph, which provide some such examples.

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## **10. Section 5.2.4: Final Management Decisions** (Fifth bullet point, last para after the last bullet and the sub-section on 'for national purposes')

Under the sub-section 5.2.4, we would like to make three submissions. **The first one** is on the fifth bullet point. The sentence should include reference to ‘economic consequences’ instead of ‘economic information’, and should therefore be revised as “*be based on the best available scientific and technical information and economic consequences*”.

**Our second comment** is on the last paragraph appearing after the last bullet point. This paragraph again recommends the precautionary approach in cases when scientific knowledge is insufficient in violation of the Commission's adoption in its 24<sup>th</sup> session in such cases as we spelt out earlier. We therefore propose that this paragraph be replaced by the provision adopted by the CAC as follows:

*"When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence."*

**Our third comment** is on the sub-section entitled "for national purposes." This sub-section permits countries to adopt precautionary measures to protect health of consumers in case scientific data are insufficient or incomplete. The current text clearly provides the scope to countries to set **standards** as against the decision of the CAC which says that the Codex should not set standards in case scientific data is insufficient or incomplete and instead elaborate code of practices. Codex documents should primarily concentrate on Codex standards / guidelines rather than detailing non-Codex matters. Therefore, we suggest that the entire text under and including 'for national purposes' be deleted.

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## **11. Section 6.3 : Role of Product Tracing / Traceability**

The section 6.3 is on product tracing. As India submitted earlier that the matter of product tracing is still under consideration of different Codex committees, the entire section should be put in square bracket.

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Agenda Item 7

CX/FH 03/8-Add ...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, U.S.A., 27 January – 1 February 2003

#### INDIA'S COMMENTS:

##### **Proposed Draft Guidelines for the Control of *Listeria Monocytogenes* In Foods at step 4 (CX/FH 03/8)**

#### **1. Statement on section 5.4.2, Figure 1 and Annex 2, question V**

Our comments are on the question V of decision tree given in figure 1 in section 5.4.2 and paragraphs 2 and 3 of question V in Annex 2 which are related to each other.

In the Figure 1 on 'decisions' tree for microbiological criteria for foods in international trade, if the answer to the question V is '**Yes or unknown**', 20 samples should be examined, and if the answer is '**No**', 10 samples should be examined. It appears that the recommended number of samples (10 or 20) are not related to the lot size of the food article in question. It would be advisable if the number of samples to be examined were given in relative terms as follows:

"If the answer is 'yes or unknown', examine '2x' samples and if the answer is 'No', examine 'x' samples, where 'x' is the number of samples to be analyzed as arrived at by the statistical sampling procedure considering the lot size."

***India, therefore, proposes to amend the decision tree and the related paragraphs 2 and 3 in question V of Annex 2 suitably.***

## 2. Statement on sub section 5.7

The 3<sup>rd</sup> bullet of the last paragraph in subsection 5.7 states that the consumer should be educated to avoid the special offers sold near the end of the shelf-life. This can lead to unnecessary fear in the consumers that the products nearing the end of shelf-life are unsafe which is not true because shelf-life of a product is established after scientific studies and includes a safety margin. Guidance to provide such education to the consumers, therefore, reflects unjust and unnecessary bias against the manufacturers.

***Therefore, we propose to modify the text in the last bullet to read as follows:***

*"to respect for dates and instructions written on food labeling (in particular the use-by- date) ~~and avoid the special offers sold near the end of shelf life.~~"*

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Agenda Item 8

CX/FH 03/9-Add ...

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, U.S.A., 27 January – 1 February 2003

#### INDIA'S COMMENTS:

##### **Proposed Draft Code of Hygienic Practice for Milk and Milk Products at Step-4**

The main concern of India and other developing countries was with regard to providing flexibility in application of certain requirements of primary production of milk in smallholder dairy farms. This has, by and large, been taken care of by use of phrases like “if used “ or “if applicable” etc. placed next to the provisions where the flexibility is needed. India appreciates this action of the Drafting Group.

However, use of similar phrases in a few more provisions appears necessary and has been left out, perhaps, due to oversight. These provisions are listed below:

#### **Annex I**

##### **Section: 3.2.1.1 Animal Holding Areas –**

In the Last paragraph of the section 3.2.1.1, the words “**where applicable** “ may be added after the word “designed”. The modified sentence would read as “Animal holding areas should be designed, **where applicable**, such that diseased animals can be isolated to prevent the transmission of disease to healthy animals.”

---

##### **Section 3.2.1.2 – Milking areas and related facilities –**

In the section 3.2.1.2, in the first bullet point the words “**if used**” may be added after the words “flooring constructed.” The modified sentence would read as :

“Flooring constructed, **if used**, to facilitate draining of liquids and adequate means of disposing of waste.”

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### **Section 3.2.2 Animal Health**

In section 3.2.2, in the second bullet point the words “**where applicable**” may be added after the word “in the herd.” The sentence would read as

“Management of other animal in the herd, **where applicable**, and other framed animal present (including the segregation of diseased animal from healthy animals)--“

---

*(Feed has to be stored in some manner, and that is ‘feed store’. It does not necessarily mean a room. Hence I propose we ignore this--Varshney)*

### **Section 3.2.3. 2– Treatment of pests.**

In the third sub-Para the words **where used** or **if used** may be added after the word ”feed stores” in the second sentence. The revised sentence would read as

Hence, any feed stores if used, would be located at a suitable place -----

---

### **Section 3.2.3.3 – Veterinary Drugs, paragraph 3**

In the section 3.2.3.3, the 3<sup>rd</sup> paragraph as written presently conveys wrong meaning. It should be revised as follows, so that it conveys correct meaning:

“Only those medicinal products and medicinal premixes that have been authorized by the national authority should be used for inclusion in animal feeds.”

---

### **Section 3.2.4.2 - Milking equipment design**

In the section 3.2.4.2. in the first sentence the word **where used** may be added after the words storage tanks.

The revised sentence would read as

“Milking equipment, utensils and storage tanks **where used** should be designed-----“

---

### **Section 3.3.1 Milking equipment**

In the first sentence of the section 3.3.1, the word ‘**where used**’ may be added after the term ‘milking equipment’. The modified sentence would then read as :

“The design of milking equipment, **where used**, should ensure there-----“

---

### Section 3.3.2 – Milk storage equipment

In the first sentence of the section 3.3.2 the word ‘**where used**’ may be added after the term ‘milk storage tanks’. The revised sentence would then read as under:

“Milk storage tanks **where used** and cans should be so -----“

---

*(These footnotes were mentioned only in the Drafting Group text, and the committee text did not have them. Hence Committee can not discuss this. A suggestion however can be made---Varshney)*

The following was earlier stated below section 3.2.2

NOTE: Add footnote to clarify herd / animal issue

There were similar footnotes below section 3.2.3.1 and section 3.2.3.3 . There do not appear in the final document now circulated. This may be clarified.

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## Annex II – Guidelines for the Management of Control Measures during and after Processing

### Section 5.1.2 Control Measures Selection, last paragraph

In the section 5.1.2 the second and third sentences imply that the higher level hazards due to microorganism and animal diseases present in herds are specific to small holder dairying, which is misleading. Small holder dairying does not provide any additional hazards due to micro-organism or due to animals diseases more than does the commercial dairy farming system. The flexibility needed in small holder dairying is only due to its different nature and system followed than the commercial dairying. High level of micro-organisms may occur in commercial dairying system also, for example due to improperly cleaned milking machines, and such cases have been reported also. Likewise, the animal diseases and resultant hazards in milk are more probable in commercial dairying where segregation of animals would be more difficult than in small holder dairying where animal management by producer owning 1-3 animals is more efficient. Therefore, the implications of these two sentences hold good for any kind of dairying. We therefore suggest that these two sentences be presented in a separate revised paragraph as follows:

“Attention should also be paid to the application of microbiocidal control measures with such purpose that they effectively eliminate any **additional** risks associated with the transfer of zoonotic hazards of the milk ~~as well as any limit of higher measures of microbiocidal risk hazards~~. Similarly, where certain animal diseases are prevalent in herds producing milk, particular attention should be drawn to the recommendations in the animal health code established by the World Animal Health Organisation(OIE) as specific microbiocidal control measures or purpose there of may be necessary to eliminate the animal health risks associated with these diseases”.

---

## **Appendix A- Microbiostatic Control Measures Lactoperoxidase system**

Our comment pertains to the control measure ‘lactoperoxidase system’. In its last meeting on 26-28 June 2002 the Executive Committee of the Codex Alimentarius Commission decided to refer the Lactoperoxidase system to JECFA for its re-evaluation from safety point of view. This fact needs to be stated in the footnote 12. Accordingly, an additional sentence in the footnote 12 be added as follows:

“Codex Executive Committee (Alinorm 03/03A) has referred the lactoperoxidase system to JECFA for re-evaluation of its safety when used in raw milk”.

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**Agenda Item 9**

**CX/FH 03/10 –Add...**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE**

**Thirty-fifty Session  
Orlando, Florida, USA, January 27 – February 1, 2003**

**INDIA'S COMMENTS:**

### **PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICES FOR EGG PRODUCTS (CAC/RCP 15-1976 (AMENDED 1978, 1985))**

#### **SECTION I - OBJECTIVES**

The proposed draft revised code intends to cover eggs in shell in addition egg products, meaning thereby, that primary production would also be covered under the code of hygienic practices for egg products. The code claims to achieve ALOP against hazards in egg and egg products by using an outcome based approach recognising that different set of scientifically validated control measures can be used. This would mean that the countries need not follow what has already been enumerated in the Code of International Hygiene Practices for egg and egg products. The condition of developing countries is such that poultry farming is done by small farmers who follow the guidelines provided by technical experts of various companies providing services to them. Hence, the approach proposed in this document is not practically implementable in developing countries.

#### **SECTION III – PRIMARY PRODUCTION**

Under the introductory part of this section, it is stated that the hazards may vary with the type of production system and, therefore, it is necessary to consider the complete agricultural practices for safe production of eggs, which may include both table eggs and braking eggs. In most developing countries egg farming does not segregate production of table eggs or those meant for braking. The production system and methods are also more or less the same except that the feeding formula may differ.

### 3.1 Environmental Hygiene

Under this para there is emphasis on evaluation of land prior to its use for free range birds in respect of risk to domesticated birds, periodic monitoring of the environment and the flocks as well as judicious selection and use of fertilisers and agriculture chemicals. In most of the developing countries poultry farming is done on an open house system (availability of enough ventilation and sunshine) and free range foraging (intensive and control housing environment) is economically impractical. Moreover, in developing countries, there are thousands of small farmers operating in different locations. For these reasons, it is not possible to evaluate the land or environment or the fertilisers used in the surrounding agriculture fields.

This para further emphasises on identification of potential source of contamination from egg laying establishment. It points out that primary production should not be carried out in areas where the presence of potentially harmful substances (agriculture chemicals, wastes, sewage treatment, mining extraction, faecal contamination and contamination from organic wastes) would lead to an unacceptable level of such contaminants in or on the eggs. It is further stated that access of domesticated and wild animals to the site and to the water source used for primary production should be identified for potential faecal contamination of the soil and water.

The above requirements are not possible to monitor in developing countries because of the presence of very small poultry farmers. In many cases, the farmers also do mixed farming, whereby, they keep the cattle on the ground floor and poultry birds on the floor above. Acceptance of requirements suggested in the draft code would mean that the small farmers would have to close down their business. It is only in the developing countries where there are very few farmers doing poultry farming on a large scale with automatic feeding, watering, collection and packaging systems.

India would further wish to point out that there is already a lot of controversy over free range foraging as this system leads to recurrence of many bacterial and parasitical diseases because of the fact that birds have a direct contact with the floor. Moreover, this system leads to low productivity of flocks compared to caged birds, and as per calculations, the cost increases by two times because the birds need more space and different nutritional requirements. Therefore, free-range foraging system will not be technically and economically viable in developing countries.

In view of the above, it is proposed that para 3.1 may be deleted.

### 3.2 Hygienic Production of Eggs

#### 3.2.1 Egg laying establishments

##### 3.2.1.1 Flock management

##### 3.2.1.1.3. Agricultural and Veterinary Chemicals

Under this para, it is stated that the producer should keep record of agricultural and chemical applications including date of application, chemicals used, concentration, methods, frequency and where applied. It also mentions the need for communication with adjacent farmers to control spray drift.

In the developing countries, where the number of farmers in a particular area is huge because of the fact that their size is extremely small, it is practically impossible to control spray drift. Moreover, because of the large number of farmers, they have hardly any communication of the nature intended under this para. Since such farmers are not so well educated, it is not possible for them to maintain records as proposed in the paragraph.

In view of the above, it is proposed that para 3.2.1.1.3 may be deleted.

### 3.2.1.2 Egg Laying Systems

In the developing countries, the egg laying establishments are primitive and not under environmentally controlled systems. The proposed requirements are not practically implementable, specially because the size of farm holding is very small. In view of this, the para may be suitably modified to allow for conditions prevailing in developing countries.

### 3.2.1.3 Egg Collection

#### 3.2.1.3.1 Egg Handling

In the second bullet, it is proposed that the eggs should be protected from surface moisture. In developing countries, especially those having a tropical climate, it would not be possible to prevent eggs from surface moisture during the winters because of wide variation in the temperature maintained in the storage room and that outside.

### 3.4 Cleaning, Maintenance and Personnel Hygiene at Primary Production

#### 3.4.1 Personal Hygiene

Under this para, all requirements of personal hygiene required in a processing plant for egg products is required to be followed also in the fields. The requirements proposed here are not possible to implement in tropical developing countries having very small poultry holdings and where the temperatures go as high as 48°C and there is general lack of sufficient water resources. This para may, therefore, need to modify suitably to take into account conditions prevailing tropical developing countries.

## SECTION V – CONTROL OF OPERATION

### 5.3 Incoming Material Requirements

It is proposed that the word “*may*” in the opening sentence may be replaced by the word “*shall*”.

## SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

### 9.1 Lot Identification

This para proposes introduction of traceability from eggs to the egg-laying establishment, and egg products to the processing establishments.

India would like to state that the concept of trace back is still under discussion in the CCGP and has not yet taken a final shape. Moreover, in view of the fact that the poultry farm holdings very small (5-8 birds) in developing countries because of which the concept of trace back is not possible to implement.

In view of the above, India proposes that para 9.1 may be deleted

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Agenda Item 10

CX/FH 03/11 Add...  
(CRD...)

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

**Thirty-fifty Session**  
**Orlando, Florida, USA, January 27 – February 1, 2003**

### INDIA'S COMMENTS

#### PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (at step 3 of the Procedure)

#### I. INTRODUCTION

Para – 1

The word “*required*” should be replaced by the word “*appropriate*”.

Para – 2

Similarly, the word “*appropriately*” should be added after the words “*....food hygiene control measures used to*”. Further, the word “*distribution*” in the last sentence should be deleted, because this cannot be under the direct control of the food processor and, hence, cannot be validated by the food processor.

#### II. SCOPE

Para – 4

In line with the above suggestion, the word “*distribution*” should be deleted from the first sentence.

#### **IV. NATURE OF CONTROL MEASURES**

Para – 5

While, it is the objective of food hygiene control to provide safe food to the consumer, it may be necessary for those engaged in distribution, storage, retail sale, etc., to follow good practices, it will not be possible for food processor to validate these elements, as these may not be under his direct control. Therefore, while these elements may find mention under this para, these should not get reflected in paras concerned with validation.

Good consumer handling practices should be limited to guiding the consumer through labeling or other published material. Beyond this, the food processor cannot do anything.

#### **VI. STEPS PRIOR TO VALIDATION**

Para – 18(1)

Impact of specific hazards at specific levels will vary from region to region and also between age groups. This requires extensive studies and data collection which is beyond the economic scope of primary producers and small scale manufacturers, especially in developing countries. It is, therefore, suggested that the second sentence may read as follows :

*“Evaluate, to the extent possible, their reasonable likelihood of occurrence.”*

Para – 18(2)

The applicable range of the elements of food safety system should not include primary production, product distribution, consumer handling practices and retail sale of the product as these activities are not under the direct control of the food processor and hence, cannot be validated by the food processor. The responsibility of the food processor can, at best, be limited to controlling or verifying the food hygiene control measures at these levels. In view of this, it is proposed that the following bullet points should be deleted :

- Primary production and transport to the processing facility
- Product distribution
- Retail sale of the product
- Consumer handling practices

With regard to the second paragraph of this sub-para, India would like to state that all elements of the food safety systems should not be required for validation. It is only those elements which are critical to food safety should be taken up for validation. Accordingly, the first sentence of this may be modified to read as follows :

*“Those elements of the food safety system which are critical to food safety should be considered for validating for food hygiene control measures”.*

Para – 18(3)

The words *“as well as target markets”* should be added after the word *“level”*.

Para – 18(4)

The most effective step for control of hazards should take into account the cost implications as is necessary for developing countries and recognised by the CAC. Therefore, it is proposed that this sub-para should read as follows :

*“Having regard to cost of implications to identify the most effective steps(s) for control of the hazard(s) in the food(s) and the control measures(s) capable of controlling the hazard to the specified level.”*

## **VII. APPROACHES TO VALIDATION**

### Identify Essential Control Measures

Para – 20

In the second last sentence of this para, it has been indicated that in some cases, on-farm practices would be essential food hygiene control measures and will need to be validated. India suggest that on-farm practices should be explicitly made clear in this paragraph for the purpose of validation to avoid any room for arbitrariness.

### Approaches to Validation

Para – 23

The approaches to validation suggested under this para are highly expensive & time consuming, and is difficult to be implemented in developing countries. Moreover, in line with the suggestions given earlier, reference to areas where the food processor does not have direct control should be deleted. Hence, this para may read as follows :

*“The approach to validation will have to take into account over what parts of the food safety system the organization undertaking the validation study (e.g., the food manufacturer) has control.”*

### Steps Involved in the Validation Process

Para – 24

In the first arrow, *“V”* should read as *“VI”*.

In the last arrow, “VIII” should read as “IX”.

In the last arrow concerning revalidation of food safety system in case of significant changes, it is suggested that a third bullet may be added as follows:

- o When changes take place in the ALOP or National Food Safety Regulations or those required in the target markets.

### **VIII. LIMITATIONS TO VALIDATION**

Para – 31

In view of problems faced by small producers and those in developing countries, it is proposed that an additional bullet may be added as follows:

- “Lack of technical expertise and information” ; Lack of technical expertise and information can also be a limitation to validation in case of small scale producers/manufacturers, especially those in the developing countries. Necessary assistance should be provided by national and international organisations.

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

This section may be renumbered as “IX”.

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