

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-second Session

Kampala, Uganda, 29 November - 3 December 2010

PROPOSED DRAFT GUIDELINES FOR CONTROL OF CAMPYLOBACTER AND SALMONELLA SPP. IN CHICKEN MEAT

Draft India's Comments

Section 3 Scope and use of the Guideline

3.1 Scope

It states that the guidelines are specifically meant for “**typical industrial systems**”. We would like to delete these words from scope to include the wider group of meat processing units.

Rationale: In developing countries, most of the chicken meat producing units are in the small scale and cannot be categorized in any of the above mentioned systems. It excludes the larger group of the small stakeholders.

Section 4: Definitions

It is proposed to amend the definition of “Total depopulation” as follows:

“Total depopulation: **Complete** Full harvest of chickens from a growing flock.”

Rationale: To maintain consistency with the definition of “Partial depopulation”

Section 7: Primary production-to-consumption approach to control measures

7.1 Generic flow diagram for application of control measures

Process Flow Diagram 3: Step 15 – Dress

It is proposed to include the “**Re-hanging (Optional)**” as a new step in between the hock cutting and venting

Rationale: To carry out the subsequent evisceration process.

9.5.2 Hazard- based control measures

Para 67: It is proposed to amend paragraph as follows:

“Inside/outside washing using a carcass washing systems with 1 – 3 washers using water with 25 – 35ppm total chlorine have been shown to reduce levels of *Campylobacter* by about 0.5 log₁₀ CFU/ml of whole carcass rinse sample. Post –wash sprays using Acidified Sodium Chlorite (ASC) or TSP may further reduce *Campylobacter* levels by an average 1.3 log₁₀ CFU/ml or 1.0 log₁₀ CFU/ml of whole carcass rinse sample respectively”.

Rationale: For better application of sanitizer on the carcass.

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PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (AT STEP 3)

COMMENTS OF INDIA

(DRAFT)

The Committee is required to consider the draft guidelines presented in the Appendix I. Our comments on the same are provided below:

APPENDIX I: PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (AT STEP 3)

SECTION III - PRIMARY PRODUCTION/HARVESTING AREA

Subsection 3.4 Cleaning, Maintenance and Personnel Hygiene at Primary Production

The guidance in this sub-section is a duplication of the guidance provided in sub-section 7.2 *Illness and Injuries*, where it is more appropriately included. Therefore, the paragraph may be deleted to avoid unnecessary duplication.

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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Forty-second Session
Kampala, Uganda, 29 November – 3 December 2010

PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF
HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF
NATURAL MINERAL WATERS
(At Step 3)

COMMENTS ON REPORT OF THE PHYSICAL WORKING GROUP

Paragraph 13: Second sentence of this paragraph states that there was general agreement that microbiological criteria for NMW should only be set in one document, preferably in the Code of Hygienic Practice for NMW.

We propose that instead of being covered only in the code of hygienic practice for NMW, the microbiological criteria for NMW should be given in the *Codex STAN 108 - 1981 'Codex Standard for Natural Mineral Waters'* which lays down specifications for the end-product.

Rationale: Microbiological criteria for Natural Mineral Waters (NMW) are very significant from human health point of view. Codex STAN 108 - 1981 'Codex standard for Natural Mineral Waters' gives the end product specification of Natural Mineral Water and like chemical parameters, microbiological specifications of end product should also be part of end product specification given in Codex STAN 108 – 1981.

Paragraph 15 a): The WG agreed to delete the absence of pathogenic microorganisms from *Codex STAN 108 – 1981 'Codex Standard for Natural Mineral Waters'* and has proposed paragraphs 97 - 99.

We do not agree to the proposal of the working group to delete the requirement of absence of pathogenic microorganisms from *Codex STAN 108 - 1981*. NMW should be tested for absence of pathogenic microorganisms although may be at lower frequencies in comparison to indicator organisms.

Rationale: *As per definition of NMW given in Codex STAN 108 - 1981, it is collected under conditions that guarantee the original microbiological purity. Further, no treatment or processing that alters its microbiological composition is allowed. Since no disinfection treatment*

is allowed, the microbiological quality of NMW is critical. The microbiological criteria given in Annex I to Doc. No. CX/FH 10/42/6 are process hygiene criteria and are indicator of effectiveness of hygiene measures but may not always guarantee the absence of pathogenic microorganisms in the end product. Thus the requirement of absence of pathogenic microorganisms should not be altogether deleted from Codex Stan 108.

Paragraph 17: The WG **recommends** that once there is agreement on Annex I of the Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters, the Codex Committee on Food Hygiene should discuss the proposal to delete section 4.4 of the *Codex Standard for Natural Mineral Waters (Codex STAN 108-1981)*.

We do not agree to the proposed Annex I to *Doc. No. CX/FH 10/42/6*. We propose that Table 2 of Annex I to *Doc. No. CX/FH 10/42/6* which specifies microbiological criteria for end product should be deleted.

We do not agree to the recommendation of the WG to delete section 4.4 of the *Codex Standard for Natural Mineral Waters (Codex STAN 108-1981)* which specifies microbiological requirements for packaged NMW.

Rationale: The process hygiene criteria for microbiological monitoring of NMW at source and during production given in Table 1 of the proposed Annex I only should be part of the code of hygienic practice for NMW.

Table 2 which gives the microbiological criteria for end product i.e. packaged NMW should be given in the *Codex STAN 108 - 1981 'Codex Standard for Natural Mineral Waters'* which lays down specifications for the end-product and thus, section 4.4 of *Codex STAN 108-1981* should be retained.

COMMENTS ON APPENDIX I (CX/FH 10/42/6)

PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (CAC/RCP 33-1985)

GENERAL COMMENTS

CAC/RCP 1 lays down general principles of food hygiene; however, additional hygienic practices specifically relevant to the production of natural mineral water may to be laid down in this document. The provisions of this document need not be limited to those specified in *CAC/RCP 1* instead this document can lay down more specific and/or elaborated requirements.

Specific comments with respect to this observation are given at comments on respective paragraphs.

SPECIFIC COMMENTS

SECTION II - SCOPE, USE AND DEFINITION

2.3 DEFINITIONS

Paragraph 8: Replace the word ‘Aquifers’ with the word ‘Aquifer’.

Rationale: Editorial error

SECTION III - PRIMARY PRODUCTION

Paragraph 9: Replace the existing text with the following:

‘Hygienic practices at the primary production level should be as per Section III of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that hygienic practices at the primary production level should be as per Section III of CAC/RCP 1, instead of just referring to Section III of CAC/RCP 1.

3.1 ENVIRONMENTAL HYGIENE – PROTECTION OF AQUIFERS

3.1.3 Perimeter of protection

Paragraph 12, First Sentence: Add the words ‘by hydro-geological studies’ at the end of the first sentence so that the sentence reads as follows:

‘Areas, wherein natural mineral waters might be contaminated or its chemical, physical and microbiological qualities otherwise deteriorated, should be determined **by hydro-geological studies.**’

Rationale: This is necessary to maintain continuity with the other paragraphs under sub-sub-section 3.1.3 which talk about hydrogeological studies.

Paragraph 12, Second Sentence: Insert the words ‘and physical, chemical and biochemical reactions’ after the word ‘contamination’ in the second sentence so that the sentence reads as follows:

‘Where indicated by hydrogeological conditions and considering the risks of contamination and physical, chemical and biochemical reactions several perimeters with separate dimensions may be provided for.’

***Rationale:** Physical, chemical and biochemical reactions also affect quality of NMW. This is consistent with Subsection III of the existing CAC/RCP 33 reproduced below:*

‘Where indicated by hydrogeological conditions and considering the risks of pollution and physical, chemical and biochemical reactions, several perimeters with separate dimensions may be provided for.’

This is also necessary to maintain continuity with the first sentence of this paragraph which talks about deterioration of chemical, physical and microbiological quality of NMW.

Paragraph 14:

Paragraph 14, Third Bullet: In the third bullet, add the words ‘and recharge zone’ at the end so that it reads as follows:

‘location and extent of the catchment area and recharge zone’

***Rationale:** To bring consistence with paragraph 13 which states that hydrogeological studies should be carried out to describe the recharge zone and catchment area.*

Paragraph 14, Seventh Bullet: In the seventh bullet, insert the words ‘(physical, chemical and microbiological)’ after the word quality so that it reads as follows:

‘chemistry and quality (physical, chemical and microbiological) of the groundwater resource’

***Rationale:** To provide clarity to the text.*

Paragraph 14, New Bullet: Insert the following new bullet at the end:

‘constancy of its composition, and stability of its discharge and its temperature’

***Rationale:** As per the definition of natural mineral water given in Codex STAN 108 – 1981 ‘Codex standard for natural mineral waters’, NMW is characterized by constancy of its composition , stability of discharge and its temperature. Therefore, constancy of composition, stability of discharge and temperature are also to be studied during hydrogeological studies.*

3.2 HYGIENE EXTRACTION AND COLLECTION OF NATURAL MINERAL WATERS

3.2.1 Extraction

Paragraph 18: First sentence of this paragraph should be amended as follows:

‘The withdrawal of natural mineral waters (from springs, galleries, natural or drilled wells) ~~should~~ **shall** be performed in conformity with the hydro-geological conditions in such a manner as to prevent any water other than the natural mineral waters from entering or, should there be pumping facilities, prevent any extraneous water from entering by reducing the supply.’

Rationale: This is an important requirement and the word ‘should’ in first line should be replaced with the word ‘shall’ or ‘must’ as in sub-section III.5 of the existing CAC/RCP 33.

3.2.3 Materials

Paragraph 21: The paragraph may be amended as follows:

‘The pipes, pumps or other possible devices coming into contact with natural mineral waters and used for its collection should be made of ~~such material~~ **inert material approved for food contact such as stainless steel and ceramic** as to guarantee that the original characteristics and qualities of natural mineral waters will not be changed.’

Rationale: To avoid ambiguity and speculation. This is consistent with the provisions under paragraph 30 and paragraph 41 of this document (Doc. No. CX/FH 10/42/6).

3.2.4 Equipments and reservoirs

Paragraph 22: Insert the words ‘and quality’ at the end so that the paragraph reads as follows:

‘Equipment and reservoirs used for extraction of natural mineral waters should be designed and constructed in order to minimize all hazards to human health, to avoid contamination of natural mineral waters and to maintain their original characteristics **and quality**.’

Rationale: To provide bring in more clarity and to bring consistency with paragraph 21 of this document (Doc. No. CX/FH 10/42/6).

3.2.5 Extraction of natural mineral waters, monitoring

New Paragraph: In sub-sub-section 3.2.5, insert the following new paragraph after the existing paragraph 23:

‘The composition of natural mineral water at source shall not vary more than $\pm 5\%$ for individual components.’

Rationale: As per the definition of natural mineral water given in Codex STAN 108-1981 'Codex Standard for Natural Mineral Waters', NMW is characterized by constancy of its composition. For the purpose of monitoring the constancy of composition the above new paragraph is proposed.

3.3 HANDLING, STORAGE AND TRANSPORT OF NATURAL MINERAL WATERS INTENDED FOR BOTTLING

TITLE: Delete the word 'TRANSPORT' so that the title reads as follows:

'HANDLING AND STORAGE ~~AND TRANSPORT~~ OF NATURAL MINERAL WATERS INTENDED FOR BOTTLING'

Rationale: As per sub-sub-section 3.1.3 of Codex STAN 108-1981 'Codex Standard for Natural Mineral Waters', the transport of NMW in bulk containers for packaging or for any other process before packaging is prohibited.

Further, provisions regarding transport of natural mineral waters intended for bottling are not covered anywhere in the subsequent paragraphs (paragraph 27 to 31) under sub-section 3.3 of this document (Doc. No. CX/FH 10/42/6).

Therefore, the word 'TRANSPORT' should be deleted from the title of sub-section 3.3 to prevent confusion and speculation.

3.3.3 Transport, piping and reservoirs

TITLE: Delete the word 'transport' so that the title reads as follows:

'~~Transport~~, Piping and reservoirs'

Rationale: Since, Paragraph 31 which gives provisions regarding 'roadways, areas used by wheeled traffic and areas serving the establishment' should be a part of Section IV on 'Establishment- Design and Facilities' instead of Section III on 'Primary Production', it should be deleted from sub-sub-section 3.3.3 (elaborate rationale given in the next comment).

In view of above, the word 'Transport' may be deleted from the title of sub-sub-section 3.3.3.

Paragraph 31: This paragraph should be a part of Section IV 'Establishment- Design and Facilities' under sub-section 4.2 'Premises and Rooms'. This paragraph may be shifted below paragraph 39 under sub-section 4.2.

Rationale: Paragraph 31 does not give any provisions regarding Primary Production. Therefore it should not be covered under Section III on 'Primary Production'

Paragraph 31 gives provisions regarding ‘Roadways, areas used by wheeled traffic and areas serving the establishment which are within its boundaries or in its immediate vicinity’. Therefore, it should be a part of Section IV on ‘Establishment- Design and Facilities’ and should be shifted below paragraph 39 under 4.2 on ‘Premises and Rooms’.

Even in the existing CAC/RCP 33 similar provisions regarding ‘Roadways and areas used for wheeled traffic’ are given as sub-section IV.2 under Section IV on ‘Establishment for processing natural mineral waters – Design and Facilities’.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Paragraph 32: Replace the existing text with the following:

‘Cleaning, maintenance and personnel hygiene at the primary production should be as per sub-section 3.4 of Recommended International Code of Practice – General Principles of Food Hygiene.’

***Rationale:** To bring in more clarity, it would be more appropriate if it is clearly mentioned that cleaning, maintenance and personnel hygiene at the primary production should be as per sub-section 3.4 of CAC/RCP 1, instead of just referring to CAC/RCP 1.*

Paragraph 34: In third line, insert the word ‘flood’ after the word ‘earthquake’ so that the paragraph reads as follows:

‘A detailed contingency plan should also be developed in collaboration with appropriate experts and authorities in order to react as quickly as possible to exceptional events (e.g. contamination of the groundwater resource, earthquake, **flood**, forest fires, as appropriate for the specific location) so that consequences can be minimised. This plan should be part of the global crisis management system of the operating company.’

***Rationale:** Flood is also an exceptional event that requires a quick reaction and a detailed contingency plan to minimize the consequences. Therefore, it would be appropriate and helpful if flood is mentioned in the examples of such exceptional events listed in paragraph 34.*

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Paragraph 36: Replace the existing text with the following:

‘Design and facilities of the establishment for processing natural mineral waters should be as per Section IV of Recommended International Code of Practice – General Principles of Food Hygiene.’

***Rationale:** To bring in more clarity, it would be more appropriate if it is clearly mentioned that design and facilities of the establishment for processing natural mineral waters should be as per Section IV of CAC/RCP 1, instead of just referring to Section IV of CAC/RCP 1.*

4.1 LOCATION

Paragraph 37: Replace the existing text with the following:

‘Location of establishment and equipments should be as per sub-section 4.1 of Recommended International Code of Practice – General Principles of Food Hygiene.’

***Rationale:** To bring in more clarity, it would be more appropriate if it is clearly mentioned that location of establishment and equipments should be as per sub-section 4.1 of CAC/RCP 1, instead of just referring to CAC/RCP 1.*

4.2 PREMISES AND ROOMS

Paragraph 38: In the second sentence replace the word ‘bottle’ with the word ‘container’ so that the sentence reads as follows;

‘It is advised to restrict operations in this particular area to a minimum by confining it to the open ~~bottle~~ **container** activities of ~~bottle~~ **container** rinsing, filling and capping areas.’

***Rationale:** ‘Container’ is more appropriate and inclusive term than ‘bottle’.*

4.3 EQUIPMENT

Paragraph 41: The paragraph may be revised as follows:

‘Food-grade stainless steel is the most appropriate material for equipment in contact with water. If alternative materials are used, it is vitally important to ensure that they do not impart an odour or taste to the water or alter its composition in any way. **All the material which is to be used in direct contact with water – such as pips, tubings, couplings that may be of rubber/plastic material – should have valid food grade conformance certified by the supplier of such material. Such material should not show migration of any chemicals to water.**’

***Rationale:** To ensure that only food grade materials appropriate for contact with water are used in manufacturing of equipments.*

Paragraph 42: The paragraph may be revised as follows:

‘It is essential to verify that any lubricants used are not only suitable for food use, but that they specifically have no adverse effect on water or its containers. **Lubricants should not be allowed to come in contact with natural mineral waters and packaging materials.**’

Rationale: Lubricants if allowed to come in contact with natural mineral water or packaging materials will alter the characteristics and quality of NMW.

4.4 FACILITIES

4.4.2 Drainage and waste disposal

Paragraph 44: Paragraph 44 should be merged with paragraph 62 under Section V ‘Control of Operation’ and replace the word ‘bottles’ with the word ‘containers’.

Rationale: ‘Container’ is more appropriate and inclusive term than ‘bottle’. Paragraph 44 does not describe facilities needed for drainage and waste disposal instead describes the actions to be taken to prevent unauthorized use of rejected containers. In view of above, it would be more appropriate if the existing text of paragraph 44 is shifted to Section V on ‘Establishment - Control of Operation’ and merged with paragraph 62 that covers segregation and management of rejected containers.

Paragraph 44: Insert following text under sub-sub-section 4.4.2 ‘Drainage and waste disposal’ as paragraph 44:

‘44. Establishments should have an efficient effluent and waste disposal system which should at all times be maintained in good order and repair. All drainage lines (including sewer systems) should be large enough to carry peak loads and should be so constructed as to avoid contamination of potable water supplies.’

Rationale: To retain important provisions regarding effluent and waste disposal as given in sub-sub-section IV.4.2 of the existing CAC/RCP 33.

4.4.3 Cleaning

Paragraph 45: This paragraph refers to the Recommended International Code of Practice - General Principles of Food Hygiene.

Replace the existing text with the following:

‘Cleaning facilities as per sub-sub-section 4.4.3 of Recommended International Code of Practice – General Principles of Food Hygiene should be available.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that cleaning facilities as per sub-sub-section 4.4.3 of CAC/RCP 1 should be available, instead of just referring to CAC/RCP 1.

4.4.5 Temperature control

Paragraph 47: It is proposed to add following text in the paragraph:

‘Adequate facilities should be available for monitoring and controlling ambient temperature during storage and transport of packaged Natural Mineral Water.’

Rationale: Refer to our general comment

4.4.6 Air quality and ventilation

Paragraph 48: .Replace the existing text with the following:

‘Ventilation facilities as per sub-sub-section 4.4.6 of Recommended International Code of Practice – General Principles of Food Hygiene should be available.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that ventilation facilities as per sub-sub-section 4.4.6 of CAC/RCP 1 should be available, instead of just referring to CAC/RCP 1.

Proposed New Paragraphs: In sub-sub-section 4.4.6, insert the following new paragraph after paragraph 48:

‘Ventilation openings should be provided with a screen or other protecting enclosure of non-corrodible material. Screens should be easily removable for cleaning’

Rationale: To retain important provision regarding covering/screens for ventilation openings as given in sub-sub-section IV.4.7 of the existing CAC/RCP 33. This provision is not covered in CAC/RCP 1.

Also refer to our general comment.

4.4.7 Lighting

Paragraph 49: Replace existing text with the following:

‘Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colours and the intensity should not be less than:

- 540 lux (50 foot candles) at all inspection points

- 220 lux (20 foot candles) in work rooms

- 110 lux (10 foot candles) in other areas.

Light bulbs and fixtures suspended over natural mineral water in any stage of production should be of a safety type and protected to prevent contamination of natural mineral water in case of breakage.’

Rationale: Refer our general comments

4.4.8 Storage

Paragraph 50: Replace the word ‘bottle’ the word ‘container’ so that the paragraph reads as follows:

‘Materials storage should be separated into allocated areas for packaging materials, closures and ~~bottles~~ **containers** and, where possible also different types of ~~bottles~~ **containers** such as glass, PET, PE, PC and PVC.’

***Rationale:** ‘Container’ is more appropriate and inclusive term than ‘bottle’.*

Proposed New Paragraph: In sub-sub-section 4.4.8, insert the following new paragraph after paragraph 51:

‘Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of natural mineral water, potable water, equipment, buildings or roadways on the premises.’

***Rationale:** To retain important provisions regarding facilities for storage of waste and inedible material as given in sub-sub-section IV.4.8 of the existing CAC/RCP 33.*

Proposed New Sub-sub-section: In sub-section 4.4 on ‘facilities’ insert the following new sub-sub-section:

4.4.9 Disinfection facilities

- Where appropriate, adequate facilities for disinfection of working implements and equipment should be provided. These facilities should be constructed of corrosion resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying hot and cold water in sufficient quantities.’

***Rationale:** Disinfection facilities should also be available in establishment for processing of natural mineral waters. For this purpose sub-sub-section IV.4.5 of the existing CAC/RCP 33 as given above should be retained. This provision is not covered in CAC/RCP 1.*

Also refer to our general comment.

SECTION V - ESTABLISHMENT: CONTROL OF OPERATION

Paragraph 52: Replace the existing text with the following:

‘Control of operation in the establishment for processing natural mineral waters should be as per Section V of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that control of operation in the establishment for processing natural mineral waters should be as per Section V of CAC/RCP 1, instead of just referring to Section V of CAC/RCP 1.

5.1 CONTROL OF FOOD HAZARDS

Paragraph 53: Replace the existing text with the following:

‘Control of food hazards should be as per subsection 5.1 of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that control of food hazards should be as per subsection 5.1 of CAC/RCP 1, instead of just referring to CAC/RCP 1.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Paragraph 54: The paragraph shall be shifted under sub-sub-section 5.2.3 on ‘Microbiological and other specifications’ of this document (Doc. No. CX/FH 10/42/6) with following amendments:

‘Natural mineral waters ~~intended~~ **ready** for bottling should meet all standards (i.e. chemical, microbiological, physical, radiological) established by the official authority having jurisdiction’

Rationale: The term ‘intended for bottling’ is confusing as natural mineral waters right from point of extraction and during production up till bottling is actually intended for bottling ultimately. However, this paragraph pertains to natural mineral waters immediately before bottling which should meet the end product standards. Therefore, to prevent confusion and to provide more clarity, the word ‘intended’ should be replaced with the word ‘ready’. For appropriate positioning of this paragraph which talks about chemical, microbiological, physical and radiological specifications.

5.2.2.2 Treatment

Paragraph 58: Delete the paragraph.

Rationale: Since, paragraph 57 already mentions that NMW may not be subjected to any treatment other than those permitted in Codex STAN 108 – 1981 ‘Codex Standard for Natural Mineral Waters’, paragraph 58 is superfluous and may be deleted.

Further, as per its definition given in Codex STAN 108 – 1981, Natural Mineral Water is characterized by its content of certain mineral salts and their relative proportions and the presence of trace elements or of other constituents; constancy of its composition; it is collected

under conditions which guarantee the original microbiological purity and chemical composition of essential components.

In view of above, only treatments permitted in sub-section 3.1 of Codex STAN 108 – 1981 should be allowed to ensure that original microbiological quality and composition of essential constituents which give it its properties is maintained.

Paragraph 61: The paragraph should be amended as follows:

‘The ~~bottle~~ **container** design for refillable ~~bottles~~ **containers** should enable easy multiple cleaning and disinfecting through washer. Effective ~~bottle~~ **container** washers should be in place.’

Rationale: ‘Container’ is more appropriate and inclusive term than ‘bottle’.

Paragraph 62: The paragraph should be amended as follows:

‘Effective measures should be taken to prevent the unauthorized reuse of rejected ~~bottles~~ **containers** – particularly those bearing company logos and other identification. ‘Rejected ~~bottles~~ **containers** (contaminated or non-cleanable) should be segregated and then managed in a way to avoid the potential for putting the bottle back on the line by mistake. Effective measures should be taken to prevent the unauthorized reuse of rejected containers – particularly those bearing company logos and other identification. Rejected containers waiting disfigurement, destruction or authorized collection should be stored securely.’

Rationale: As proposed in Paragraph 44.

Paragraph 63: The paragraph should be amended as follows:

‘The outlet of the washer should be adequately protected. Conveyors from the outlet of the washing machine to the filling machine should be covered to protect the containers from contamination. Cleaned and disinfected ~~bottles~~ **containers** should be all the time protected by covers when on conveyors, loading tables etc. Conveyor covers should be so designed as to protect ~~bottles~~ **containers** from above and laterally from dust, sneezes etc.’

Rationale: ‘Container’ is more appropriate and inclusive term than ‘bottle’.

5.2.3 Microbiological and other specifications

Paragraph 65: Delete the paragraph.

Rationale: It is not clear for why CAC/GL 21 – 1997 is to be referred here. Since, paragraph 66 already specifies the microbiological criteria for natural mineral waters, paragraph 65 should be deleted.

Paragraph 66: The paragraph should be amended as follows:

‘Microbiological monitoring of natural mineral waters shall meet the specifications of **Tables 1 and 2** in Annex I of this document and should be performed at a frequency that enables the appropriate hygienic management.’

Rationale: Microbiological criteria for NMW are given not only in Table 1 and/or Table 2 but in entire Annex I.

5.2.4 Microbiological cross-contamination

Paragraph 67: Replace the existing text with the following:

‘Control of microbiological cross-contamination should be as per sub-sub-section 5.2.4 of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that control of microbiological cross-contamination should be as per sub-sub-section 5.2.4 of CAC/RCP 1, instead of just referring to CAC/RCP 1.

5.2.5 Physical and chemical contamination

Paragraph 69: The paragraph should be amended as follows:

‘Special measures should be taken when filling bottles with carbonated water to avoid explosion and to protect the product ~~and the workers from glass debris.~~’

Rationale: The provisions of this document (Doc. No. CX/FH 10/42/6) should be restricted to product hygiene only. Worker welfare and protection is out of scope of this document.

5.3 INCOMING MATERIAL REQUIREMENTS

Proposed New Paragraph: In sub-section 5.3, insert the following new paragraph after paragraph 72:

‘To guarantee a good and stable quality of natural mineral water, certain criteria should be monitored regularly, e.g. Spring discharge, temperature of the natural mineral water; Appearance of the natural mineral water; Odour and taste of the natural mineral water; The conductance of natural mineral water or any other adequate parameter; The microbiological flora.’

Rationale: Natural mineral water is the raw material for packaged natural mineral water. It is necessary to ensure good and stable quality of natural mineral water for which the above mentioned criteria as listed in sub-section VII.1 of CAC/RCP 33 should be monitored and should be retained in the revised version (Doc. No. CX/FH 10/42/6).

5.4 PACKAGING

Proposed New Paragraphs: In sub-section 5.4, insert the following new paragraphs after paragraph 75:

‘All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination. Only packaging material required for immediate use should be kept in the packing or filling area.’

‘Product containers should not have been used for any purpose that may lead to contamination of the product. Used containers, also new containers if there is a possibility that they have been contaminated, should be cleaned and disinfected. When chemicals are used for these purposes, the container should be rinsed as prescribed under 5.2.3. Containers should be well drained after rinsing. Used and, when necessary, unused containers should be inspected immediately before filling.’

‘Packaging should be done under conditions that preclude the introduction of contaminants into the product.’

‘The methods, equipment and material used for sealing should guarantee a tight and impervious sealing and not damage the containers nor deteriorate the chemical, bacteriological and organoleptic qualities of natural mineral water.’

‘Secondary packaging of containers should protect the later from contamination and damage and allow appropriate handling and storing.’

Rationale: Sub-section VII.4 of existing CAC/RCP 33 contains important provisions regarding packaging material and containers which are not covered in CAC/RCP 1. These provisions as given above should be retained in the revised version (Doc. No. CX/FH 10/42/6).

Sub-section VII.5 of CAC/RCP 33 contains important provisions regarding filling and sealing of containers which are not covered in CAC/RCP 1. These provisions as given above should be retained in the revised version (Doc. No. CX/FH 10/42/6).

Secondary packaging is also needed to be considered appropriately to prevent damage to containers and resulting contamination of NMW.

Also refer our general comment.

5.5 WATER

Paragraph 76: Replace the existing text with the following:

‘Steam used on surfaces in direct contact with natural mineral waters should be produced with potable water and should not constitute a threat to the safety and suitability of food.’

Rationale: This paragraph refers to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1).

The corresponding sub-section 5.5 of CAC/RCP 1 specifies quality of following three types of water:

- i) Water in contact with food (sub-sub-section. 5.5.1)
- ii) Water used as food ingredient (sub-sub-section 5.5.2)
- iii) Water used for steam and ice production (sub-sub-section 5.5.3)

Since, natural mineral water is itself a food and mixing/contact of natural mineral waters with any other water is prohibited, sub-sub-sections 5.5.1 and 5.5.2 of CAC/RCP 1 do not pertain to NMW.

Steam may be used in natural mineral water establishment for cleaning and disinfection of pipes and equipments and thus the above paragraph is proposed in place of the existing paragraph referring to entire sub-section 5.5 of CAC/RCP 1.

5.6 MANAGEMENT AND SUPERVISION

Paragraph 77: Replace the existing text with the following:

‘Management and supervision of hygiene control systems should be as per sub-section 5.6 of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that management and supervision of hygiene control systems should be as per sub-section 5.6 of CAC/RCP 1, instead of just referring to CAC/RCP 1.

Proposed New Paragraphs: In subsection 5.6, insert the following two new paragraphs after paragraph 77:

‘Responsibility for ensuring compliance by all personnel with all requirements of personal hygiene should be specifically allocated to competent supervisory personnel.’

‘use and storage of physical, chemical and biological means of pest control shall be under supervision of trained personnel.’

Rationale: As per sub-section 5.6 of CAC/RCP 1 ‘the type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved.’

In case of NMW appointment competent supervisory personal is specifically required to ensure compliance of all hygienic requirements by the personnel handling the NMW and to ensure compliance to all necessary precautions while using and storage of physical, chemical and

biological means of pest control. These need to be specifically addressed in the revised document (Doc. No. CX/FH 10/42/6). This provision is not specifically covered in CAC/RCP 1.

This is in line with sub-section VI.9 and V.7.1 of existing CAC/RCP 33.

Also refer to our general comments.

5.7 DOCUMENTATION AND RECORDS

Paragraph 78: Replace the existing text with the following:

‘Documentation and records of processing, production and distribution of natural mineral waters should be maintained as per sub-section 5.7 of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that documentation and records of processing, production and distribution of natural mineral waters should be as per sub-section 5.7 of CAC/RCP 1, instead of just referring to CAC/RCP 1.

5.8 RECALL PROCEDURES

Paragraph 79: Replace the existing text with the following:

‘Recall procedures as per sub-section 5.8 of Recommended International Code of Practice – General Principles of Food Hygiene should be in place.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that recall procedures as per sub-section 5.8 of CAC/RCP 1 should be in place, instead of just referring to CAC/RCP 1.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

Paragraph 80: Replace the existing text with the following:

‘Maintenance and sanitation of the establishment for processing natural mineral waters should be as per Section VI of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that maintenance and sanitation of the establishment for processing natural mineral waters should be as per Section VI of CAC/RCP 1, instead of just referring to CAC/RCP 1.

6.1 MAINTENANCE AND CLEANING

Paragraph 81: Last sentence of this paragraph should be amended as follows:

‘Residues of these agents on a surface which may come in contact with natural mineral waters should, unless otherwise authorized by the official authority having jurisdiction **unless the manufacturers’ instructions indicate on scientific basis that rinsing is not required,** be removed by thorough rinsing with potable water or preferably with natural mineral water.’

Rationale: To bring in line with sub-sub-section 6.1.2 of CAC/RCP 1 which states that ‘Cleaning procedures will involve where necessary, disinfection with subsequent rinsing unless the manufacturers’ instructions indicate on scientific basis that rinsing is not required.’

6.2 CLEANING PROGRAMS

TITLE: The title should be amended as follows:

‘CLEANING **AND DISINFECTION PROGRAMS PROGRAMMES**’

Rationale: More appropriate title.

Paragraph 85: Replace the existing text with the following:

‘Cleaning and disinfection programmes should be developed as per sub-section 6.2 of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that cleaning and disinfection programmes should be developed as per sub-section 6.2 of CAC/RCP 1, instead of just referring to CAC/RCP 1.

Proposed New Paragraph: In sub-section 6.2, insert the following two new paragraphs after paragraph 85:

‘To prevent contamination of natural mineral water, all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.’

‘A permanent cleaning and disinfection schedule should be drawn up for each establishment to ensure that all areas are appropriately cleaned and that critical areas, equipment and material are designated for special attention.’

Rationale: It is necessary to design a disinfection and cleaning regimen in order to facilitate cleaning and disinfection. Thus, provisions under sub-sub-section V.2.2 and sub-section V.3 of existing CAC/RCP 33 as given above should be retained in the revised version (Doc. No. CX/FH 10/42/6).

These provisions are not covered even in CAC/RCP 1.

This will also be in line with the text given under paragraph 33 of Doc. No. CX/FH 10/42/6.

Also refer to our general comments.

6.3 PEST CONTROL SYSTEMS

Proposed New Paragraphs: In sub-section 6.3, insert the following three new paragraphs before paragraph 86:

‘There should be an effective and continuous programme for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation.’

‘Should pests gain entrance to the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from the use of these agents, including those hazards which may arise from residues retained in the natural mineral water, such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.’

‘Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard natural mineral water, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.’

Rationale: To retain important provisions regarding pest control as given in sub-section V.6 of the existing CAC/RCP 33. These provisions are not covered even in CAC/RCP 1.

Also refer to our general comment.

Paragraph 87: The first sentence of this paragraph should be amended as follows:

‘Insect stunning devices, if and where used, should be carefully located so that stunned insects and fragments of them do not fall into open ~~bottles~~ **containers or closures.’**

Rationale: ‘Container’ is more appropriate and inclusive term than ‘bottle’.

6.4 WASTE MANAGEENT

Paragraph 88: Substitute existing text with the following;

‘Waste material should be handled in such a manner as to avoid contamination of natural mineral water or potable water. Care should be taken to prevent access to waste by pests. Waste should be removed from the natural mineral water handling and other working areas as often as necessary and at least daily. Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste

should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

Rationale: This paragraph refers to the Recommended International Code of Practice - General Principles of Food Hygiene.

Sub-section V.4. of the existing CAC/RCP 33 as given above is more appropriate and elaborate than sub-sub-section 6.4 of CAC/RCP 1 regarding waste management and should be retained in the revised version (Doc. No. CX/FH 10/42/6) instead of referring to CAC/RCP 1.

Also refer to our general comments.

6.5 MONITORING EFFECTIVENESS

Paragraph 89: Replace the existing text with the following:

‘Effectiveness of the sanitation systems should be monitored as per sub-section 6.5 of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that effectiveness of the sanitation systems should be monitored as per sub-section 6.5 of CAC/RCP 1, instead of just referring to CAC/RCP 1.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

Paragraph 90: Replace the existing text with the following:

‘Personal hygiene in the establishment for processing natural mineral waters should be as per Section VII of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that personal hygiene in the establishment for processing natural mineral waters should be as per Section VII of CAC/RCP 1, instead of just referring to CAC/RCP 1.

Proposed New Paragraphs: In Section VII, insert the following paragraphs after paragraph 90:

‘Persons who come into contact with natural mineral water in the course of their work should have a medical examination prior to employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, whether because of epidemiological considerations or the medical history of the prospective natural mineral water handler.’

‘Adequate first-aid facilities should be provided in the establishment.’

‘Hands should be washed with a suitable hand cleaning preparation.’

‘After handling any material capable of transmitting disease, hands should be washed and disinfected immediately using a suitable disinfectant.’

‘Notices requiring hand-washing should be displayed.’

‘The protective clothing, head covering and foot wear to be worn while handling NMW should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor.’

Rationale: The above mentioned aspects of personal hygiene and health are not covered in Section VII of CAC/RCP 1. These are covered in existing CAC/RCP 33 and should be retained in the revised version (Doc. No. CX/FH 10/42/6).

Also refer to our general comments.

SECTION VIII – TRANSPORTATION AND STORAGE OF BOTTLED NATURAL MINERAL WATERS

TITLE: The title should be amended as follows:

‘TRANSPORTATION AND STORAGE OF BOTTLED PACKAGED NATURAL MINERAL WATERS’

Rationale: Since, NMW may also be filled in other types of containers, such as cans.

Paragraph 91: Replace the existing text with the following:

‘Transportation of natural mineral waters should be as per Section VIII of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: Since, Section VIII of CAC/RCP 1 covers only ‘transport’. To bring in more clarity, it would be more appropriate if it is clearly mentioned that transportation of natural mineral waters should be as per Section VIII of CAC/RCP 1, instead of just referring to CAC/RCP 1.

Paragraph 92: This paragraph should be amended as follows:

‘Care should be taken during storage and transport of packaged natural mineral waters to ensure a minimum temperature to prevent freezing of natural mineral waters which, due to expansion, is liable to cause breakage and/or explosion of bottles containers and/or increase the potential for failure during distribution and consequent risk to the safety of the consumer. It should also be noted that following a severe cold spell there is an increased potential for condensation developing on bottles containers which can give rise to damaged/mouldy labels and damp secondary packaging.’

***Rationale:** Firstly, title of Section VIII mentions ‘transportation and storage of packaged natural mineral waters’. However, ‘storage’ aspect has not been addressed in the subsequent paragraphs.*

Provisions under paragraph 92 apply to storage of NMW also. Therefore, storage aspect should also be included in this paragraph.

Secondly, ‘container’ is more appropriate and inclusive term than ‘bottle’.

Paragraph 93: Replace the words ‘Transportation of’ with the words ‘Storage and transportation of packaged’ so that the paragraph reads as follows:

‘Storage and transportation of packaged natural mineral waters at excessive high or low temperatures should be avoided as it may result in quality reduction (e.g. risk of compound migration from primary packaging materials).’

***Rationale:** Firstly, as per sub-sub-section 3.1.3 of Codex STAN 108-1981 ‘Codex Standard for Natural Mineral Waters’, the transport of NMW in bulk containers for packaging or for any other process before packaging is prohibited. Thus, the word ‘packaged’ should be introduced before NMW.*

Further, storage of packaged NMW at excessive high or low temperature may also result in quality reduction, thus provision under this paragraph applies to storage also.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

Paragraph 94: Replace the existing text with the following:

‘Product information and consumer awareness should be provided as per Section IX of Recommended International Code of Practice – General Principles of Food Hygiene.’

***Rationale:** To bring in more clarity, it would be more appropriate if it is clearly mentioned that product information and consumer awareness should be provided as per Section IX of CAC/RCP 1, instead of just referring to CAC/RCP 1.*

Paragraph 95: Replace the existing text with the following:

‘Packaged Natural Mineral Water shall be labelled as per Section 6 of Codex Standard for Natural Mineral Waters.’

***Rationale:** To bring in more clarity.*

SECTION X - TRAINING

Paragraph 96: Replace the existing text with the following:

‘All personnels engaged in handling natural mineral waters should be trained as per Section X of Recommended International Code of Practice – General Principles of Food Hygiene.’

Rationale: To bring in more clarity, it would be more appropriate if it is clearly mentioned that those engaged in handling natural mineral waters should be trained as per Section X of CAC/RCP 1, instead of just referring to Section X of CAC/RCP 1.

ANNEX I: MICROBIOLOGICAL CRITERIA

Paragraph 98: Substitute the existing text with the following:

‘A high level of hygienic control should be maintained – from the protection of the aquifer, the extraction and up to the bottling and capping to ensure the production of microbiologically safe packaged natural mineral waters.’

Rationale: The existing paragraph 98 appears to be informative. The paragraph has been reworded to make it recommendatory.

Further, the word ‘bottled’ NMW has been substituted with the word ‘packaged’ NMW

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-second Session

Kampala, Uganda, 29 November - 3 December 2010

PROPOSED DRAFT REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS (AT STEP 3)

COMMENTS OF INDIA

REPORT OF THE PHYSICAL WORKING GROUP

The paragraphs 30-32 of the Report invite the Committee to provide comments/guidance on some aspects of the document and on Appendix I containing the proposed draft guidelines. We have noted that the sections referred in the paragraphs 30 and 31 do not appear in the Appendix I. Our comments on the points referred in paragraphs 30 and 31 and on Appendix I are provided below:

- I. PARAGRAPH 30:** The paragraph 30 invites the Committee to discuss whether the structure/elements of the examples in the Section 7.2 are sufficient, or need to be rearranged, so that this part could be further elaborated in a desirable format in future.

The proposed elements for the examples are indicated in the paragraph 28. These appear to be adequate.

- II. PARAGRAPH 31:** The paragraph 31 invites the Committee to provide direction and guidance on several aspects of the document for its further development. These and our comments on them are provided below:

- *Establishment of MC related to hygiene indicator microorganisms (in relation to paragraphs 11 -12 in Section 5.2.1)*

The guidance included in the paragraphs (11) and (12) in the Appendix I is adequate.

- *“Uncertainty” and “variability” of sampling (in relation to Section 5.2.4)*

The guidance included in paragraph (16) in the Appendix I is adequate.

- *Elaboration of the general process for establishing an MC and underlying statistical considerations (including elaboration of sampling plan using mathematical approaches as Annex I referred in paragraphs 17 and 20 of Section 5.2.5)*

Relevant useful guidance from the existing *Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21)* may also be retained as indicated in our comments on the Appendix I.

- *Further elaboration of practical examples for establishment of MC including a MC for a toxin (in Section 7.2)*

Aflatoxin M₁/*Staphylococcus aureus* enterotoxins in milk could be considered for providing a practical example of establishment of MC for a toxin.

- *Consideration of whether MC for animal feed should be covered*

MC for animal feed may be considered only where it relates to the safety of food resulting through use of such feed. Aflatoxin in feed could be considered as an example.

- *Consideration of a way forward to address MC for “processing” and “environment”*

Example of MC for ‘processing’ and ‘environment’ would form appropriate means of providing guidance. An example of *Coxiella burnetti*/*Mycobacterium avium* subsp. *paratuberculosis* in relation to pasteurization of milk (processing) and of *Listeria monocytogenes* / *Cronobacter sakazakii* (environment) could be considered for further development of the document.

- *How to feature the aspect of “communication” (in paragraph 9, point 6 in Section 4 and in Section 7.2.6), by use of MC, in the context of FSO/PO/PC needs to be further addressed*

The guidance to be developed on the aspect of communication, by use of MC, in respect of FSO/PO/PC should include a provision that

in such cases it should be clearly communicated that the MC is linked to FSO/PO/PC; these metrics should be invariably communicated along with the MC; and the associated risk assessment should be available for scrutiny on request.

- *New text relating to “frequency of applying a MC” needs to be elaborated (as Annex II referred in paragraph 23 of Section 7.1.2)*

The guidance on frequency of applying MC in general would be useful to decide a risk based frequency. It should also include guidance on the alterations required in the decided frequency of applying an MC on the basis of observations like repeated non-compliance and a history of compliance.

III. PARAGRAPH 32: It invites the Committee to consider the draft guidelines presented in the Appendix I. Our comments on the same are provided below:

APPENDIX I: PROPOSED DRAFT GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS

1. SECTION: INTRODUCTION

- Paragraph (1):** The last sentence should be deleted.

Rationale: The guidance in the last sentence of Paragraph (1), that use of food safety risk management (MRM) metrics allows establishment of a direct relationship between microbiological criteria and public health outcomes, is not entirely correct. A direct relationship between microbiological criteria and public health outcomes exists even in absence of MRM metrics. For example, the *Code of Hygienic Practice for Powdered Infant Formulae for Infant and Young Children (CAC/RCP-66)* specifies microbiological criteria to ensure public health in the context. The CAC/RCP-66 does not include MRM metrics.

Use of MRM metrics, however, allows a more objective and transparent relation between the level of stringency of control measures or entire food safety control systems to the required level of public health protection. This is already noted in the *Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63), Annex II Guidance on Microbiological Risk Management Metrics* and need not be repeated here.

- ii. **Paragraph (2):** The first sentence should be amended as follows:

*‘The microbiological safety implementation of **validated** control measures **that have been validated, where possible, and** ideally ranging’*

Rationale: To ensure that the importance of such control measures that facilitate food safety but cannot always be validated is not undermined. Control measures such as air locks to minimize cross contamination, hand washing procedures, and several other basic hygiene practices as described in the International Recommended Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969) are of such a nature that it is not feasible to determine their quantitative effect on specific hazards. That such control measures cannot always be validated has been recognized in the *Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 – 2008)*.

2. SECTION: COMPONENTS OF MICROBIOLOGICAL CRITERIA

Subsection *Microbiological aspects of criteria*

- i. **Paragraph (13):** The third sentence should be amended as follows:

*‘Although the methods used should be the most sensitive and reproducible for the purpose, ~~in certain cases~~ methods **used for in-plant testing** might sacrifice some degree of sensitivity and reproducibility in the interest of speed and simplicity.’*

Rationale: A clear indication of the specific conditions when such a sacrifice might be justified should be included in the text to avoid any potential of misuse of the guidance. The existing *Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21)* clearly indicate in the penultimate sentence in the sub-sub-section 5.2.1 that such sacrifice in sensitivity and reproducibility might be necessary for methods used for in-plant testing. This should be retained.

- ii. **Proposed new paragraphs:** In the sub-sub-section *Microbiological Methods*, after existing Paragraph 13, insert the following two paragraphs:

‘Methods used to determine the suitability for consumption of highly perishable foods, or foods with a short shelf-life, should be chosen wherever possible so that the results of microbiological examinations are available before the foods are consumed or exceed their shelf-life.’

‘The microbiological methods specified should be reasonable with regard to complexity, availability of media, equipment etc., ease of interpretation, time required and costs.’

Rationale: To retain useful guidance from the sub-sub-sections 5.2.1 and 5.2.2 of the CAC/GL-21.

- iii. **Proposed new paragraph:** In the sub-sub-section *Sampling Plans*, before existing Paragraph 17:

Sampling plans should be administratively and economically feasible.

Rationale: To retain useful guidance from the sub-sub-section 6.1 of the CAC/GL-21.

With the above proposed insertions to retain useful guidance from the existing CAC/GL-21, the affected paragraphs should be re-numbered appropriately.

3. SECTION: RELATIONSHIP BETWEEN MICROBIOLOGICAL CRITERIA AND OTHER MICROBIOLOGICAL RISK MANAGEMENT METRICS

- i. **Paragraph (21):** The Paragraph should be amended as follows:

*‘Where competent authorities have set an ALOP, and/or have **derived established** an FSO and/or a PO... ..’*

Rationale: The guidance in the document should be useful also to the countries that do not utilize ALOP but where other adequate food safety standards and control measures are generally in place and used as a means to meet and communicate their food safety requirements. This is mostly true in case of developing countries.

The reference to ALOP in this document, in a manner that conveys setting-up of ALOP as the pre-requisite for establishing

MRM metrics, if retained, would appear to limit application of the final document to those few countries that have established ALOP.

The proposed amendment is in line with the objective of this document, which is primarily to provide guidance on use of microbiological criteria in respect of the MRM metrics. The document is not required to provide guidance on the specific means to express a required level of public health protection by the countries.

ii. **Paragraph (22):** Amend the Paragraph as follows:

*'Before deriving a microbiological criterion from ~~an~~ **ALOP FSO and/or PO**, the need for such metrics should be clearly articulated. This is'*

Rationale: To reflect that technically the MC would actually be derived from FSO and/or PO, which are often established in absence of an ALOP as well.

4. SECTION: ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

i. **Paragraph (26):** The text in the Paragraph should be amended as follows:

*'A microbiological criterion the stated purpose. **Such need is demonstrated, for example, by epidemiological evidence that the food under consideration may represent a public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment. The criterion should be technically attainable by applying Good Manufacturing Practices.** Microbiological criteria for food safety should be applied to the extent necessary to protect human life or health and set at a level that is not more trade restrictive than required to achieve an importing member's **ALOP stated food safety requirement.**'*

Rationale: The guidance on the means to demonstrate a need for establishment of a microbiological criteria and its attainability with the implementation of Good Manufacturing Practices, included in sub-section 4.1 in the existing *Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21)*, is useful and should be retained. Also,

countries often use means other than ALOP to express their food safety requirements as explained in our comments on the Paragraph (21) above.

- ii. **Paragraph (27):** The first sentence should be amended as follows:

‘Mandatory microbiological criteria (i.e., standards written into national law or other governmental regulations) should apply to those products and/or points of the food chain where no other effective tools are available, and where they are ~~expected to improve the degree of protection offered to the consumer necessary to ensure public health.~~’

Rationale: It would be appropriate to link establishment of mandatory microbiological criteria with the necessity to ensure public health rather than with improvement in degree of protection offered. This is so because if the public health is ensured with the prevailing mandatory requirements, there need not be a requirement to apply mandatory microbiological criteria merely to further improve the degree of protection offered.

- iii. **Paragraph (34):** The paragraph should be amended as follows:

‘In situations and the product-type specified. These may include sorting, reprocessing, withdrawal and/or recall, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken. ~~The Other~~ actions by regulatory authorities or business operators taken in response to the discovery of non-compliance invariably entail economic implications. may include more frequent inspection and audits, fines, official suspension of operations, the loss of a contract with a large buyer, or de-certification by a private standard setting body. In addition, a firm’s compliance history may impact its liability exposure and insurance rates. These exposures to potential increased costs create economic incentives for food producing firms to limit the probability and degree of noncompliance.

Rationale: The reference to de-certification by a private standard setting body has been included which appears to undermine the importance of national mandatory standards and Codex standards. Also, the other actions by regulatory authorities or business operators in case of non-compliance to

microbiological criteria, included as examples, are obvious and need not be included in the document. Therefore, it is proposed to amend the third sentence, while retaining an indication of the economic implications of non-compliances.

- iv. Paragraph (36):** It is proposed to delete the text in the square brackets.

Rationale: It would be appropriate if no deviations from the sampling plans are allowed. Otherwise, it would be extremely difficult to objectively interpret the results making the sampling plan redundant.

- v. Proposed new paragraph:** Insert the following paragraph after the existing paragraph (39):

'The test report shall give the information needed for complete identification of the sample, the sampling plan, the test method, the results and, if appropriate, their interpretation.'

Rationale: The above guidance included in sub-section 7.1 in the existing *Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21)* is useful and should be retained.

- vi. Paragraph (40):** The phrase 'other governments' should be deleted.

Rationale: The phrase 'other governments' is superfluous in the context.

- vii. Paragraph (41):** It is proposed to amend the Paragraph as follows:

*'The risk management framework should be used to continuously improve, refine and adjust the component parts of the microbiological criterion in relation to improved scientific knowledge and the increasing knowledge of public health risk **(FSO, PO, PC)**. This should take place whenever relevant information becomes available. The goal should ultimately be to achieve a more quantifiable estimation of the linkages between microbiological criteria and other metrics, **where necessary.**'*

Rationale: In the **first sentence** the inclusion of the terms FSO, PO, PC is misplaced. These terms are used to express the required level of stringency of control measures and are not linked to increase in level of knowledge of public health risk. The guidance in the **last sentence**, indicating that the goal of the review should be to achieve a more quantifiable estimation of linkages between microbiological criteria and other metrics, is not justified. The extent of quantification of the linkages between the microbiological criteria and other metrics would primarily be dependent upon the need of such quantification. This should be so indicated in the guidance.

viii. Paragraphs (47) – 51): These paragraphs relate to the examples of the scenarios in which the microbiological criteria are used and it has been indicate earlier in the agenda item (paragraph 29) that these are yet to be developed. The terms used in the examples like ‘CA’ in the ‘*Microbiological criteria for verifying the performance of HACCP systems*’ and ‘H₀’ in the ‘*Microbiological criteria for verifying hygienic conditions for the primary production environment*’ should be appropriately explained during the further development of these sections.

Rationale: *For clear understanding of the reader.*

