

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 4 (a)

CX/FH 06/38/4

October 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-Eight Session

Houston, Texas, December 4 - 9, 2006

COMMENTS ON THE:

DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

Comments submitted by: Australia, Brazil, European Community, Japan, Peru, Thailand, the United States of America, and ICMSF

GENERAL COMMENTS

AUTRALIA

The document retains text that is not entirely consistent with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*¹ (the *Working Principles*). This is particularly evident in section 3 (General Principles for MRM; see below).

The focus is heavily biased toward FSOs and related concepts, while scant regard is given to the other MRM options outlined in section 6.1.2. The elaboration of the FSO concept in section 6.2.2 (and subsections) hampers the flow of the document. It would be better to remove most, if not all, of section 6.2.2 to an annex (or even a separate document).

In general the document does not provide very much in the way of guidance to risk managers that cannot be gleaned from other sources. Specific guidance is often lost in the text, or its impact is diluted, by excessive verbiage.

The Guidelines would be more effective if tied in explicitly with the Principles. That is to say, an approach based on “here are the Principles and here is guidance on how to achieve MRM consistent with those Principles” should be adopted. This is not necessarily obvious in the current document, aside from some slight elaboration of the Principles in section 4 (General Considerations).

THAILAND

We are of the opinion that the overview of this paper as well as its principles be consistent with the contents existing in the main principle ones which are Working Principle for Risk analysis in the Framework of the Codex Alimentarius adopted by CAC, and Working Principle for Risk Analysis for Food Safety being under consideration by CCGP. CCGP and CCFH can work separately;

¹ Procedural Manual of the Codex Alimentarius Commission, 15th ed., pp 101-107.

however, once they have to work on the same aspect, a mechanism to ensure the consistency of their work should be considered. At this stage, some inconsistency between these two documents could occur such as the structure of risk management and the application of provisional measure. We suggest that this document should not be submitted to CAC for adoption before the one established by CCGP is adopted otherwise the major inconsistencies have been solved.

UNITED STATES OF AMERICA

The United States would like to thank and congratulate France and the other members of the drafting group for the significant progress shown in this document, resulting in the adoption of the Draft Principles and Guidelines by the Commission at Step 5 of the elaboration procedure. We are generally very pleased with and strongly support these Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).

In preparation for the upcoming deliberations on this document during the Committee's 38th Session, we appreciate the opportunity to provide the following comments on this important document. These comments are primarily of an editorial nature to provide additional clarity to the concepts that CCFH has developed by embracing risk analysis.

INTRODUCTION

FOOT NOTE

AUSTRALIA

The first footnote to paragraph 1 should read "*Foodborne microbial hazards include...*"

UNITED STATES OF AMERICA

In footnote 1, we recommend adding the word "microbiological" before "hazards", so the sentence begins "Foodborne microbiological hazards...."

2 DEFINITIONS

Risk Manager

THAILAND

The scope of this document identifies that the Guideline is used by Codex and countries, while the definition of risk manager defines risk management as a national or international governmental organization. The term "international governmental organization" is broader than 'Codex'. We propose these two terms to be consistently used by revising the definition of risk manager or adding an explanatory note to "international governmental organization".

3 GENERAL PRINCIPLES FOR MRM

AUSTRALIA

3. GENERAL PRINCIPLES FOR MRM

The document retains text that is not entirely consistent with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*² (the *Working Principles*):

² Procedural Manual of the Codex Alimentarius Commission, 15th ed., pp 101-107.

PRINCIPLE 3**AUSTRALIA**

This should reference para 28 of the *Working Principles* which gives further guidance on what is meant by a “structured approach.”

PRINCIPLE 4**AUSTRALIA**

This should begin “*The MRM process...*”

PRINCIPLE 8**AUSTRALIA**

To be consistent with para 28 of the *Working Principles* and with section 8 of the document this should read “*MRM decisions should be subject to **monitoring and review.***”

PERU

Peru suggests modifying the paragraph on PRINCIPLE 8 as follows:

MRM decisions should be subject to review and revision.

4 GENERAL CONSIDERATIONS**AUSTRALIA**

Australia recognizes the aim of keeping the Principles short and to the point. However, it might be better that each paragraph in section 4 is taken back into section 3 and used as explanatory text under the Principle it is designed to illuminate.

FIRST PARAGRAPH**AUSTRALIA**

In many situations, it is unlikely that ALOPs will be “expressed”. The use of the word “expressed” in paragraph 1 implies the need for a public statement of a country’s ALOP. Australia suggests that the sentence is best moved to the end of the first paragraph under section 6.1.

THAILAND

In order to cover the legitimate work of Codex, “to promote fair trade practices” should be added to the objective of this guideline. Therefore, we would rewrite the first sentence of the first paragraph as follows: “Codex and government decisions and recommendations have as their primary objective the protection of the health of consumers **and ensure fair practices in international food trade**”

SECOND PARAGRAPH**AUSTRALIA**

Australia suggests that the first sentence of paragraph 2 be amended to:

“MRM should address the food chains and this should typically include primary production...” (i.e. delete “as individual continuums, when considering means for controlling the public health risks associated with food.”)

A footnote should be added to “environmental conditions” to clarify the consideration of matters such as location of sites to mitigate the effects of irrigation run-off or effluent from industrial wastes etc.

FOURTH PARAGRAPH**AUSTRALIA**

Australia recommends deletion of the words “proportionate to the risk identified” and “or technological feasible” in paragraph 4.

FIFTH PARAGRAPH**UNITED STATES OF AMERICA**

In the first sentence of the fifth paragraph the word “and” should be deleted before the word “effective”. Also, in the seventh paragraph toward the end of the second sentence, we recommend replacing the phrase “consumer use patterns associated with food” to “consumer food use patterns.”

SIXTH PARAGRAPH**PERU**

Peru suggests modifying and joining paragraph 5 and part of paragraph 6 (second sentence) as follows:

Risk managers should ensure an effective and timely consultation with all relevant interested parties and provide a sound basis for understanding the MRM decision, its rationale and implications. The extent and nature of public consultation will depend on the urgency, complexity and uncertainties related to the risk and the management strategies being considered. Decisions and recommendations on MRM should be documented, and where appropriate clearly identified in Codex or national standards and regulations, so as to facilitate a wider understanding of the conduct of MRM. The mandate given by risk managers to risk assessors relating to the conduct of an MRA should be as clear as possible. Interaction should allow risk managers to be informed by risk assessors of any constraints, **lack of data**, uncertainties, assumptions and their impact on the MRA.

Where there is disagreement among the risk assessors, the risk managers should be informed of the minority opinions and these differences should be documented.

5.1 Identification of a microbiological food safety issues**FIRST PARAGRAPH****AUSTRALIA**

In the third sentence of paragraph 1, it is suggested that an identified food safety issue should be communicated to affected consumers at the start of the MRM process, before any assessment has been undertaken of the scope of the issue (eg as might be delivered by a risk profile). This might give rise to undue alarm amongst consumers and adversely affect industry given that, at best, the risk manager would be able only to say that there *might* be a public health issue. Australia believes that the last sentence of paragraph 1 be amended to:

“At the start of this process, the food safety issue should be clearly identified and communicated from the risk managers to risk assessors, **and where relevant**, to industry and affected consumers.”

FOURTH PARAGRAPH

EUROPEAN COMMUNITY

In the fourth paragraph of **section 5.1**, first line, the European Community supports the idea of referring to "emergency measure" and therefore suggests deleting the reference to "immediate decision" contained in the first text in square brackets.

The European Community also suggests removing both sets of square brackets in the fourth paragraph of section 5.1.

It should be noted that emergency measures may include "interim measures", this could be added to the text if it would facilitate the acceptance of this section and of the following section.

PERU

Peru suggests removing the square brackets

THAILAND

The term “**emergency measure**” is more preferable than “immediate decision”. Also, this term should be used in every section because it much clearly shows the need to do something in such that situation.

UNITED STATES OF AMERICA

In the fourth paragraph we recommend removing the square brackets around [immediate decision/emergency measure] and replacing with “immediate action” and consequently adding the word “requiring” before the example of withdrawal/recall within the parentheses. In the next sentence, we would recommend replacing the word [emergency] in square brackets with “an immediate” and replacing the word “immediate” later in that sentence with “imminent.” Since the word “emergency” raised some concerns in earlier discussions, perhaps the word “immediate” conveys the same message without triggering the concerns.

ICMSF

Section 5.1. (Fourth paragraph) Pg 71. Second paragraph. Contains some square brackets. First set: [immediate decision/emergency measure]. We would prefer “immediate decision”. In light of this preference, we would delete “[emergency]” further on in the paragraph. In this paragraph, the immediate decision is qualified with “without further scientific consideration”. It is better to delete these words as they are a cause of confusion. Also, taking a decision immediately is not only about science, but also about technical aspects, feasibility of measures to mitigate, and many more. It is also more that just consideration.

FIFTH PARAGRAPH

AUSTRALIA

If the square-bracketed text is to be retained in the last paragraph, the text should be amended to "Where relevant scientific evidence is insufficient, it may be appropriate to adopt provisional measures, consistent with existing international obligations."

EUROPEAN COMMUNITY

Precautionary approach

As regards the fifth paragraph of **section 5.1**, the European Community suggests the removal of the square brackets (ALINORM 05/28/13, para. 114), considering the provisions of the WTO Agreement on Sanitary and Phytosanitary measures (“SPS Agreement”), the Codex *Procedural Manual* and the outcome of Codex Committee on General Principles (CCGP) work.

The European Community welcomes and supports the indication of precaution as an inherent element in the risk analysis process which appears in paragraph 11 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex *Procedural Manual*, 15th edition, page 102). However, the EC considers that there is an essential difference between the application of the principles for risk analysis by Codex and by the governments: the Codex Alimentarius Commission decided at its 24th session not to carry out the development of a standard if the scientific data is incomplete.

This limitation transfers implicitly to the governments the responsibility for taking provisional measures to protect the consumers pending complete scientific data. Article 5 (7), of the SPS Agreement authorizes Members to adopt temporarily sanitary or phytosanitary measures if the relevant scientific evidence is insufficient.

THAILAND

As for the last paragraph under this section (5.1) involving “precautionary approach”, the contents mentioned are now being considered by CCGP. The use of suitable wording is under its revision process. This paragraph should then be kept in the square brackets awaiting for the decision of CCGP. Likewise, every text in the square brackets regarding provisional measure/ option should (wait) remain await.

UNITED STATES OF AMERICA

In the fifth paragraph, we recommend rewording the first sentence to read, “Where scientific knowledge is insufficient, it may be appropriate to select a provisional MRM option (i.e., “apply a provisional risk management measure”) while obtaining additional information that may inform and modify the provisional MRM decision.” We also recommend replacing the reference in footnote 14 to the Draft Working Principles for Risk Analysis under consideration by CCGP with a reference to Article 5, paragraph 7, of the SPS Agreement, which contains the use of provisional measures in cases where relevant scientific evidence is insufficient and the requirement to obtain additional information to make a more objective assessment of risk and review the measure within a reasonable period of time. The U.S. believes the approach of applying a provisional measure until additional scientific information becomes available is appropriate and, therefore, there is no need to include a reference to a “precautionary approach” and no need to retain the square brackets around the paragraph.

ICMSF

Section 5.1, Pg 71, third paragraph, completely in square brackets, we would prefer to delete the paragraph completely. The provisional decision eluded to is already covered by the “immediate decision” mentioned in the second paragraph. It merely gives yet another example of a type of action that can be decided on over and above the ones given in the 2nd paragraph.

5.2 MICROBIOLOGICAL RISK PROFILE

SECOND PARAGRAPH

EUROPEAN COMMUNITY

- The European Community suggests replacing the word "provisional" in square brackets with "interim". The European Community also suggests removing the said square brackets.
- The last sentence in the second paragraph now reads: “*In some cases, no further action may be needed*”. The European Community would propose that a new sentence is inserted as follows:

“In some cases, the risk profile could give enough information for identification and selection of MRM options. In other cases, no further action may be needed.”

UNITED STATES OF AMERICA

In the first sentence of the second paragraph we recommend removing the square brackets around the word [provisional] since use of the term is consistent with our suggested revisions for the preceding paragraphs.

ICMSF

Section 5.2, Pg 71, Second paragraph, contains “implementing an immediate and/or [provisional] decision”. We would prefer to delete the word in square brackets and change to “implementing an immediate decision”.

LAST PARAGRAPH

AUSTRALIA

In the last paragraph of Section 5.2, the second-last sentence seems to imply that the risk profile can lead to possible MRM options - without going through a further risk assessment process. This is a concern, as we believe that it is the risk assessment process that should lead to the identification of possible MRM options. A number of tools can be used during this process depending on the hazard/commodities and the availability of data e.g. quantitative risk assessment, qualitative risk assessment, risk profile, scientific evaluation.

5.3 RISK ASSESSMENT POLICY

JAPAN

Japan would like to propose the insertion of the following new paragraph after the existing 1st paragraph in 5.3.

Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors. Establishing a risk assessment policy protects the scientific integrity of the risk assessment and offers guidance to balance value judgments, policy choices, adverse health parameters for presenting risk to human health, source of data to be considered, and management of data gaps and uncertainties during the course of the assessment. The risk assessment policy could be generic nature or MRA- specific, and should be documented to ensure consistency, clarity and transparency.

Rational: Current text does not provide much information for both risk assessors and risk managers, and does not articulate the responsibility of establishing risk assessment policy and what the risk assessment policy is. Proposed text refer to the paragraph 2.6 of the *Report of a Joint FAO/WHO Consultation* (Kiel, Germany: 2002) and *Report of a Joint FAO/WHO Consultation on Food Safety Risk Analysis: An Overview and Framework Manual* (2004), 4.3.1 PRELIMINARY RISK MANAGEMENT ACTIVITIES, Step 4 Establish a risk assessment policy.

5.4 MICROBIOLOGICAL RISK ASSESSMENT

FIRST PARAGRAPH

JAPAN

Japan would like to propose the insertion of the following new paragraph after the existing 1st paragraph in 5.4 MRA.

(New 2nd paragraph)

An important first step is to clarify risk management goals, and formulate the specific questions that should be answered by the MRA. Questions posed by the risk manager for an individual MRA will depend on the particular risk management goals, the hazards involved, the food matrix, the exposure pathway, and the intended use of the information generated from the MRA.

Rational: Risk managers should know the degree of health protection they are aiming to achieve in the beginning of risk management activities, and share with risk assessors. Then, risk assessors will likely have examined the impact of different controls on minimizing risks, providing the risk managers with data that allows them to more objectively reach decisions on the most appropriate controls. The proposed texts are referred from Kiel II document, Section 2.5 para 2 & 3.

SECOND PARAGRAPH

UNITED STATES OF AMERICA

We recommend rewording the third sentence of the second paragraph as follows: “It is also important that the MRA be adequately reviewed by the scientific community and, if appropriate, the public.”

FOURTH PARAGRAPH

ICMSF

Section 5.4. Pg 72. Fourth paragraph. The last sentence is already a long one and difficult to read. The last part reads “options, [or deciding on provisional MRM options] if some elements of the MRA need further study.”. We would suggest to leave out the words in brackets so that the sentence ends “options, or if some elements of the MRA need further study.”

LAST PARAGRAPH

AUSTRALIA

Australia recommends that the square-bracketed text in the last paragraph of Section 5.4 be deleted.

6. IDENTIFICATION AND SELECTION OF MRM OPTIONS

AUSTRALIA

This section and its subsections should be reworked to provide guidance to risk managers on all of the various MRM options outlined, rather than just the FSO concept (see additional comments to sections 6.1.2 and 6.2.2).

6.1 Identification of the available MRM options for Codex and countries

FIRST PARAGRAPH

UNITED STATES OF AMERICA

In the first paragraph, second sentence, we recommend replacing the word “acceptable” with the word “appropriate” to be consistent with establishment of an ALOP. In the second paragraph, we also suggest inserting the word “potential” prior to MRM, so it reads “Examples of potential MRM options....”

LAST PARAGRAPH

ICMSF

The MRM doc introduces a number of new risk-based risk management options (FSO, PO) and explains how the hierarchy in terminology and concepts (ALOP, FSO, PO, PC) is thought to work in principle. By necessity, a large part of the document is devoted to these new options and readers may be under the impression that these new concepts are more important and maybe supersede the many alternative options already available to risk managers. In section 6.1. a good number of these existing options are listed. In section 6.2.2. the risk-based MRM options are introduced. To emphasise that the current MRM options will also be important options for risk managers in the future, it would be good to add some wording to the second paragraph (one sentence only now) under section 6.1. This paragraph now reads: “Examples of MRM options (used either alone or in combination) available for Codex or countries, as appropriate are listed below.”. This could for

instance be changed to “Risk managers have many important MRM options (used either alone or in combination) already available currently. Some available for Codex or countries, as appropriate, are listed below. In section 6.2.2. some additional risk-based MRM options available to countries will be introduced”.

6.1.1 Codex

AUSTRALIA

The dot points should be further (but briefly) elaborated, perhaps to a similar extent to the example provided by the final dot point which has subsidiary dot points providing further guidance.

6.1.2 Countries

AUSTRALIA

The dot points should be further (but briefly) elaborated, perhaps to a similar extent to the example provided by the final dot point which has subsidiary dot points providing further guidance.

SECOND BULLET (LAST BULLET, THIRD DASH POINT)

EUROPEAN COMMUNITY

Traceability / Product Tracing

Concerning all references to “traceability / product tracing” in square brackets (point 6.1.2, second bullet point.; point 6.1.2, third indent under eighth bullet point and section 7.3, fifth bullet point), the European Community wishes to refer to:

- the definition of “*Traceability/Product Tracing*” of the *Codex Procedural Manual*, 15th edition, page 44;
- the “*Principles for the Application of Traceability/Product Tracing*” discussed at the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

The European Community is of the opinion that terms defined in the *Codex Procedural Manual* should not be put in square brackets.

ICMSF

In three occasions (twice in section 6.1.2. an once in section 7.3) the following words in square brackets are used in the MRM doc: [traceability/product tracing]. In all cases the words give another example of what can be an appropriate action where other examples already have been given and also they refer to ongoing work of CCFICS. For clarity and to avoid confusion, the words in square brackets should best be deleted in all three instances.

THAILAND

Section 6.1.2 and 7.3

The terms “traceability/ product tracing” are thought to still be put in the square brackets to wait for the final conclusion from the CAC on the guidelines on traceability/ product tracing submitted by CCFICS.

FOURTH BULLET**UNITED STATES OF AMERICA**

We recommend adding “or PO” after “FSO” in the fourth bullet, since a competent authority may also set a PO. Also, in the eighth bullet, we recommend replacing the terms “enforce or stipulate” with “communicate” and we recommend modifying the three examples as follows:

- prevention of contamination and/or introduction of hazards should be addressed at all relevant stages in the food/feed chain;
- rapid withdrawal/recall of food procedures should be in place, including appropriate traceability/product tracing systems;
- proper labelling includes information that instructs the consumer regarding safe handling practices and, where appropriate, briefly informs the consumer of the food safety issue.

We recommend adding a footnote at the end of the second bullet referencing the CCFICS document *Proposed Draft Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (Alinorm 06/29/30, Appendix III) which is at the Commission for adoption.

6.2 Selection of MRM options**SECOND PARAGRAPH****UNITED STATES OF AMERICA**

In the second bullet under the second paragraph we recommend replacing the term “various” with the term “multiple.”

6.2.1. RESPONSIBILITY FOR SELECTING MRM OPTIONS**THIRD PARAGRAPH****UNITED STATES OF AMERICA**

In the third paragraph we recommend replacing the words “as far as possible” with “to the extent feasible.”

6.2.2 RISK-BASED MRM OPTIONS**AUSTRALIA**

This entire section should be removed to an annex, retaining only a summary of the concepts involved. The title to the section implies that other MRM options are *not* risk-based, and should be changed to more accurately reflect its content (eg Food Safety Objectives and Related MRM Options).

FIRST PARAGRAPH**ICMSF**

Paragraph mentions 2x MRM tools. Please change “tools” to “options” to avoid confusion about MRM tools being interpreted as yet a new concept.

SECOND PARAGRAPH**ICMSF**

Section 6.2.2. In principle, the FSO is the key new MRM option to be defined only by risk managers in national competent authorities. PO and PC are not exclusively defined by such risk managers but can (and will) in many cases be set by industry unless they wish to adopt PO/PC advised by governments as is mentioned in section 6.2.2.3. (2nd para) for PC. Maybe this fact should be introduced in the text more clearly. This could maybe be done by adding some wording to the 2nd paragraph under section 6.2.2. The second part of this paragraph now reads “Therefore the concept

of FSO has been introduced. Effective MRM typically requires that additional risk-based milestones be established at particular steps in the food chain to ensure the ultimate food safety outcome. As a means of addressing this need, PO and PC have been introduced.”. We would suggest the following new wording “Therefore the concept of FSO has been introduced as the key new risk-based MRM option available exclusively to risk managers. Effective MRM typically requires that additional risk-based milestones be established at particular steps in the food chain to ensure the ultimate food safety outcome. As a means of addressing this need, PO and PC have been introduced as options available for risk managers as well as to Industry.”

6.2.2.1 FOOD SAFETY OBJECTIVE (FSO)

THIRD PARAGRAPH

AUSTRALIA

In the second dot point to paragraph 3 it is suggested that FSOs could be used to encourage change in the behaviour of consumers. This would only be achieved in combination with associated communication and education strategies.

EUROPEAN COMMUNITY

Second bullet point: unless further elaboration of the text is made or an example is provided, it is difficult to imagine how an FSO on its own can encourage change in the behaviour of consumers.

JAPAN

Simply by reading this bullet, it is difficult to understand how establishing FSOs encourages change in industry systems or in consumer behaviors. At least, impact of introducing FSO on the changes in industry is already included in the 4th bullet. Therefore Japan suggests removing this bullet.

ICMSF

Page 74, 6.2.2.1, second bullet point, which reads “to encourage change in industry food safety control systems, or in the behaviour of consumers, in order to enhance the safety of certain products;”. As such a change is not necessary in all cases, please change this bullet point text to: “to, where necessary, encourage particular change in industry food safety control systems or in the behaviour of consumers, in order to further enhance the safety of certain food products;”

LAST SENTENCE OF THE SECTION

UNITED STATES OF AMERICA

We recommend adding “among countries” after “universally common” in the last sentence of that section.

6.2.2.2 Performance Objective (PO)

THIRD PARAGRAPH

UNITED STATES OF AMERICA

We recommend adding the sentence “An MRA can assist in determining the relationship between a PO and an FSO” at the beginning of the third paragraph. Also in 6.2.2.2, we recommend revising the last sentence and accompanying bullets of paragraph four as follows:

“Although compliance with a PO itself is not always verified by analytical means, verifying that a PO is being consistently met can be achieved by measures such as:

- monitoring and recording of pertinent validated control measures, including establishment of a statistically-based MC for end products;
- surveillance or screening programs on the prevalence of a microbial hazard in a food (especially relevant for POs established by competent authorities).”

FOURTH PARAGRAPH**ICMSF**

Section 6.2.2.2. Last sentence of the 2nd paragraph on page 75 now reads “Although POs are generally not intended to be verified by analytical means, compliance with POs may need to be verified by other means, such as:”. Please change “may need to be verified” to “may, where necessary, be verified”.

Section 6.2.2.2. pg 75, third bullet point. Includes the following “(especially relevant for POs established by competent authorities)”. Please delete this part of the sentence as the first part seems to describe a very generic activity and mentions only investigation of prevalence and does not connect to the text in parenthesis.

6.2.2.3 Performance Criterion (PC)**FIRST PARAGRAPH****ICMSF**

Section 6.2.2.3. As defined, the PC relates to “one or more control measures” but all examples in the section relate to PCs set to describe the expected effect of a single control measure. Maybe the first paragraph under the definition can be altered somewhat. It now reads “PCs are generally set by individual food business. However, PCs may be set by national governments, for a specific control measure, where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.” We would suggest the following new text: “PCs are generally set by individual food business to cover a whole step in a food chain or part thereof. PCs may relate to a single control measure achieving a particular effect but may also relate to a combination of control measures that achieve that effect jointly. Where appropriate, PCs may be set by national governments, where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.”

SECOND AND THIRD PARAGRAPHS**ICMSF**

We would favour some slight changes to the wording of paragraphs 2 and 3 (3 and 4) and joining them as follows: “The PC can express three types of effect. It may express a desired reduction in the concentration and/or frequency of a hazard, it may express a level that can stay as it is but no higher or it can express an increase that can be accepted. In the first case, the PC relates to a microbiocidal effect and states the reduced level of the microbial population that needs to be achieved using a suitable (combination of) control measures, e.g. a heat treatment. In the other two instances the PC specifies the maximum increase in the microbial population that is acceptable, i.e. no increase for a microbiostatic effect or an increase to a particular higher level. Such effects then need to be achieved using appropriate control measures, e.g. chilling.

LAST PARAGRAPH**THAILAND****Process criteria and product criteria (footnote 19th)**

We would like to ask for more consideration on the meaning of “process criteria and product criteria” appeared as the footnote 19 whether it should be moved to the definition section.

6.2.2.4 Microbiological Criterion (MC)

FIRST PARAGRAPH

UNITED STATES OF AMERICA

In the third sentence of the first paragraph we recommend inserting the phrase “where knowledge of manufacturing conditions are available” at the end of the sentence but prior to the (e.g. HACCP).third paragraph

THIRD PARAGRAPH

ICMSF

6.2.2.4, last paragraph. Please delete this paragraph completely. The first sentence now reads: "In general, an MC will have to be more stringent than the PO or PC upon which it is based, in order to assure that the PO is being met with a specified level of confidence". It is better to omit this statement as the relationship between MC and PO/PC is not a direct and simple one. It is subject to much scientific debate currently. The second sentence in the paragraph refers to indicator organisms being used regarding the MC. This is not relevant in the MRM as it is not specific to the new risk-based concepts.

7.2 Countries

THIRD PARAGRAPH

AUSTRALIA

Australia recommends that paragraph 3 and square-bracketed paragraph 4 are deleted.

FOURTH PARAGRAPH

PERU

Peru suggests removing the square brackets.

UNITED STATES OF AMERICA

We recommend deleting the square brackets around the fourth paragraph, since this text is consistent with changes we have suggested earlier in the document. We also suggest deleting the square brackets in the sixth paragraph around [particularly for provisional MRM options,] for the same reason.

ICMSF

Section 7.2, Contains wording in square brackets in paragraph 4 and 6. Please delete this wording (so completely delete paragraph 4 and omit “[, particularly for provisional MRM options,]” from paragraph 6).

7.3 Industry

ICMSF

The fourth bullet point does not seem to make sense in terms that applying a sampling plan in itself as an activity contributing to achieving the effect of an MRM option. The bullet point can best be deleted as the remaining 6 are sufficiently informative

7.4 Consumer

PERU

Peru suggests modifying the paragraph on item 7.4 with the following text: (second sentence) delete “date labels” and substitute “expiration date labels.”

UNITED STATES OF AMERICA

In the second sentence we recommend that “date labels” be changed to “best-before date labels” and reference be made to the Codex General Standard for Labelling of Prepackaged Foods (Codex STAN 1-1985 (Rev. 1-1991)), where section 4.7.1 refers to using this term to express the date of minimum durability.

ICMSF

The first sentence here needs some rewording to be better understood. It now reads “Consumers can enhance both their personal and the public’s health by being responsible for, adhering to, being informed of and following food safety-related instructions.” We would suggest a change to “Consumers can enhance both their personal and the general public’s health by making an effort to be informed of and follow food safety-related instructions.”

8.1 Monitoring**FIRST PARAGRAPH****AUSTRALIA**

The final sentence of para 1 implies continual improvement should be a goal of MRM, which is not necessarily consistent with the concept of ALOP.

UNITED STATES OF AMERICA

In the first paragraph we recommend adding a new sentence after the first sentence. We believe the new sentence, which would read “(The use of the term is distinct from and should not to be confused with monitoring in the context of the operation of a HACCP program.),” is needed to emphasize the difference between monitoring in a general risk management context and monitoring in a HACCP context.

THIRD PARAGRAPH**UNITED STATES OF AMERICA**

In the third paragraph of 8.1, we recommend revising the first sentence to read: “Monitoring activities respecting microbial hazards may be needed at multiple points along the entire food chain to identify food safety issues and to assess public health and food safety status and trends.” We do not believe that monitoring activities are always needed along the entire food chain, which the wording of the current sentence indicates.

8.2 Review of MRM options**SECOND PARAGRAPH****UNITED STATES OF AMERICA**

In the first sentence of the second paragraph we suggest adding the words “and their outcomes” after MRM options, as it is not just the review of the options themselves that is the best way to assess whether consumer health protection is delivered.

FIFTH PARAGRAPH**UNITED STATES OF AMERICA**

In the fifth paragraph of 8.2, we recommend rewording the sentence as follows: “The results of review and the associated actions that risk managers (including Codex) are considering to take as a consequence of the review should be made public and communicated to all interested parties.”

ANNEX I: Overall framework for managing foodborne risks

AUSTRALIA

In the flowchart there is an arrow going from the box that says "Evaluating the result of the risk profile; Recommendations for further actions" around the left-hand side of the chart to the box in the lower left-hand corner that says "Identification and Selection of MRM options". This indicates that you can by-pass the Risk Assessment step and go straight from evaluating a Risk Profile to the identification and selection of MRM options. As discussed above the risk assessment process is not optional, so this arrow should be deleted. Australia recommends that the term "risk assessment process" is used to accommodate the various tools (as outlined in section 5.2) that contain the essential elements of Codex.

BRAZIL

Brazil would like to suggest that the diagram in Attachment I of the document be excluded.

PERU

Peru suggests removing the square brackets from the text in the diagram.

UNITED STATES OF AMERICA

The current annex appears to be partially a decision tree and partially a flow chart. The chart should be redrafted so that a single style of presentation is employed. It should also be reviewed to ensure that the steps in the chart match the steps in the body of the text. There appear to be some differences.

ANNEX II: SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK PROFILE

JAPAN

Annex II, paragraph 2, 2nd black bullet point: 1st, 2nd, and 4th white bullet points include multiple bullet points, which should be separated. Total white bullet points should be seven, not four.

PERU

Peru suggests modifying the first paragraph of item 6 with the following text [Spanish version only]:

6. Información disponible y vacíos graves de conocimiento. Proporcionar, en la medida de lo posible, información acerca de los siguientes puntos: [Available Information and Major Knowledge Gaps. Provide, to the extent possible, information on the following:]

Also, Peru suggests substituting the text from the last bullet on item 6 with the following [Spanish version only]:

Zonas donde existen vacíos importantes de información que pudieran constituir un obstáculo para las actividades de GRM, incluida, si conviene, la realización de una ERM. [Areas where major absences of information exist that could hamper MRM activities including, if warranted, the conduct of an MRA].

UNITED STATES OF AMERICA

We recommend several modifications to this annex in the following text. We believe the annex would be more useful with some reorganizing of the sections and there are many places the text could be streamlined to increase clarity and avoid duplication. These suggestions are provided

based on the practical experience we have gained in developing risk profiles over the course of the past three years.

New section 1, Introduction: Intended purpose of the risk profile: We recommend that a new section 1 be added, with consequent renumbering of the other sections. Since a risk profile can serve several different functions (e.g., guidance to risk managers at a national level, a proposal for new work within CCFH) it should include a section at the beginning indicating the purpose of the specific document.

New section 2, Hazard-food commodity combinations of concern: We recommend in the second bullet removing the words “due to this hazard” and deleting the third bullet altogether.

New section 3, Description of the public health problem: We recommend combining information in the current second, third and fourth bullets since they all relate to characteristics of the disease and also adding information on dose-response data. Therefore, we suggest replacing the current text in the indented bullets under the second main bullet with the following text:

- Description of the disease and aetiology
- Annual incidence rate in humans attributable to foodborne transmission including, if possible, any differences between sub-populations (e.g., due to age, gender, or health (immunocompromised, pregnant women)) and differences attributable to regional, seasonal, and ethnic factors
- Severity of clinical manifestations (e.g., case-fatality rate, rate of hospitalisation)
- Nature and frequency of long-term complications
- Availability and nature of treatment
- Epidemiology of the foodborne disease including frequency and characteristics of foodborne cases and data from outbreak investigations
- Available study data on the relationship between dose and response (including human or animal data that could be used in model development, if needed).

And, we recommend deleting the current third and fourth main bullets and adding a new fourth bullet which would read “Existence of regional/international trade agreements and how they may affect the public health problem.”

New section 4: We recommend changing the title of the section to “Factors related to exposure including food production, processing, distribution and consumption” since the information in this section relates to exposure.

Also, in section 4 we recommend in the first bullet removing the words “that are involved” and replacing “impact on risk management” with “impact on the risk.” We also suggest putting the information in parentheses in the second bullet after the word “continuum” and then following the parentheses with the text “with a focus on the factors which may impact the microbiological safety of the commodity”. We believe this wording will improve the clarity and readability of the bullet. Finally, in section 4 we suggest deleting bullets 3, 4, and 5 since we do not believe they belong as subsections under exposure and adding a new third bullet which reads “Extent of international trade of the food commodity and the possible impact on the risk.”

New section 5, Risk management options including the factors that should be considered in evaluating the options: We believe this section should describe the available (i.e., currently in place) and potential (i.e., not in place, including technologies under development) risk management options. To achieve this, we suggest combining some elements of sections 5 and 7 into a new 5 entitled “Risk management options including the factors that should be considered in evaluating the options” and deleting the sections titled “Other Risk Profile Elements” and “Available Information and Major Knowledge Gaps Provide.” Much of the information in the two sections we are

recommending for deletion is too specific and implies that the outcome of the risk profile is a Codex MRM guidance document, which may not be the case. We recommend the following text for new section 5:

5. Risk management options, including the factors that should be considered in evaluating the options

- Extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines)
- Identification of additional risk management strategies that could be used to control the hazard
- Impact of other factors, including
 - Regional/international trade agreements and how they may affect the public health impact with respect to the specific hazard/commodity combination(s)
 - Public perceptions of the problem and the risk
 - Potential public health and economic consequences of establishing various options
- Existing Codex MRM guidance documents (including existing Codes of Hygienic Practice and/or Codes of Practice)
- International and/or national governmental and/or industry codes of hygienic practice and related information (e.g., microbiological criteria) that could be considered.

New section 6, Recommendations: Finally, we recommend deleting the current section entitled “Risk Assessment Needs and Questions” and replacing it with a new section “6 Recommendations” where next steps are discussed, including the possibility of conducting a risk assessment. New section 6 would include two bullets as follows:

6. Recommendations

- Include a discussion of sources (organisations, individuals) of information and scientific expertise that could be used in developing the recommended RM option and areas where major absences of information exist that could hamper MRM activities including, if warranted, the conduct of an MRA.
- If a risk assessment is recommended include a discussion of the benefits to be gained from requesting an MRA, the feasibility of such an assessment being accomplished within the required time frame, other relevant scientific knowledge and data that would facilitate the conduct of an MRA, the availability of national risk assessments or models, and the recommended questions that should be posed to the risk assessors.