

codex alimentarius commission



FOOD AND AGRICULTURE
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PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (At Step 3 of the Procedure)

In response to CX/FH 01/7, comments were submitted by Argentina, Mexico, New Zealand, United States of America, Consumers International, and IFAH.

GENERAL

Argentina

Argentina would like to make known in advance its approval for the progress made in the preparation of this document, which is considered to be of extreme importance for the correct application of such an important instrument as the Analysis of Microbiological Risks in Food Control Programs.

Coinciding with what is stated on page 3 (Background) regarding the fact that the document needs more discussion in some areas, and as we indicated above, that this document has great value, so much so that as it is written now, it cannot be considered more than a basis for a discussion of the issue in the heart of the Committee.

The document also presents some problems of varying types and severity in its translation into Spanish; we are not going to go into detail, since if the English version is consulted, it can itself be understood. On the other hand if, after discussion in conference, a new version will be a certainty, special attention should be placed on the translation of that new version.

Mexico

Translation of the document into Spanish, Mexico reserves the possibility of making suggestions to improve the translation and reading of the document in Spanish, which will be presented later.

New Zealand

New Zealand strongly supports further development of this paper and offers the following general comments.

United States of America

The United States appreciates the work of France and its drafting partners in further revising the *Proposed Draft Principles for the Conduct of Microbiological Risk Management*. We believe that good progress has been made in revising the document. There are a number of areas, however, that will require substantial further work and recommend that the document be held at Step 3 for further work by the Drafting Group.

The United States concurs with the parenthetical note under the Scope Section that additional clarity is needed on the Scope of the document. More specifically, the United States believes that the document currently speaks to two areas, the process of developing a microbiological risk management program, and the implementation of and compliance with risk management measures. While the United States believes that it is appropriate for the document to address both of these areas, a clearer articulation of the two areas is needed, as is the likely need for some revision to the wording of the document in this regard.

The United States notes the decision of the Codex Alimentarius Commission, with respect to the work being undertaken on *Working Principles for Risk Analysis*, that Codex should develop separate texts, one for Codex and one for governments. The United States believes that the Drafting Group for this document should carefully consider the area of microbiological risk management with respect to the revised Terms of Reference of CCFH and with respect to governments and, both in the Scope and other sections of the document, clearly articulate the appropriate principles and guidelines of microbiological risk management for CCFH and for governments. The United States notes that this is likely to require substantial redrafting of the text.

With respect to the use of precaution, the United States notes the proposal put forward by the Commission in relationship to the use of interim measures in Codex (that is, “When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence”). The United States believes the Committee and the Drafting Group, in its further work on this document, should consider the area of the use of precaution both with respect to the Codex Committee on Food Hygiene and to governments, keeping in mind the comment made above on the Scope of the document.

With respect to Food Safety Objectives, the United States supports the inclusion of FSOs in this document. We believe that, while the general thrust of this section of the document is satisfactory, significant revision is needed as noted in our comments below.

Consumers International

Consumers International commends France and the Working Group for their work on this document. It is an important document that clearly lays out Principles and Guidelines for conducting risk management, and considerable progress is evident since the previous draft.

INTRODUCTION

United States of America

Second paragraph, first sentence, Change “The rise in globalisation of the foodmarket...” to “The increased globalization of trade in foods...” Trade in food is what creates the problem, not the market itself.

The United States suggests that a reference to the Kiel Consultation (*WHO Expert Consultation, The Interaction between Assessors and Managers of Microbiological Hazards in Food, Kiel, Germany, March 2000*) be added to the list of references appearing in Paragraph 2.

International Federation for Animal Health (IFAH)

Since this is a document concerning aspects of Risk Management, it seems appropriate that there should be some cross-reference to the equivalent document for Risk Assessment. Because of the close iterative linkage between these two steps, there should be some commentary on the preceding steps taken for Risk Assessment.

Similarly, one would expect some discussion on the subsequent stage of Risk Communication in accordance with the principles and guidelines for risk analysis as discussed by the CAC in July 2001.

In the first sentence of the document, it seems inappropriate to state that "risks from microbiological hazards are of immediate and serious concern to human health". This is contrary to the whole basis of the principles of risk analysis, whereby the whole purpose of the process is to determine the level of risk in order to determine whether indeed there is any negative impact on human health. Therefore, we suggest that the sentence is amended to state that "risks from microbiological hazards **may be** of immediate etc..."

1. SCOPE

Argentina

We are, obviously, in agreement that Point 1 (Scope) of the document should be broadened and clarified, since it will be the point of reference from which future guidelines should be developed. We believe, as is stated in the previous paragraph, that the guidelines will be useful both to managers that work in official organs and to those who work in private industry. We have some doubt that in both cases the same principles will be applicable, thus we consider a separate treatment of the guidelines according to the sector they address to be more appropriate, that is, we believe the preparation of separate guidelines to be advisable, one set for the official risk managers and another for those who manage risks in the private sector.

New Zealand

The Scope should include reference to the four steps that are involved in the risk management process i.e. risk evaluation (but excluding risk assessment), assessment of risk management options, implementation, and monitoring and review.

Consumers International

It should be clarified that these principles and guidelines, while developed within and for Codex, also are useful guidance for governments.

2 DEFINITIONS

Mexico

We suggest including the following definition: "*Risk manager, the entity responsible for making decisions regarding microbiological risks, based on the scientific information provided by the assessors.*"

New Zealand

A definition for process criterion should be added.

Acceptable level of risk -ALR

United States of America

The United States notes that the SPS Agreement indicates that the Acceptable Level of Protection (ALOP) is often referred to as the Acceptable Level of Risk (ALR). Thus, the ALR is equivalent to the ALOP, should not be defined differently, and may be deleted as a definition. The relationship between the ALOP and ALR is clearly articulated in Section 5.2.1.1 (Identifying the acceptable level of risk (ALR-refers to ALOP)).

Consumers International

Consumers International accepts the definition currently in the text but suggests amending it as follows to be consistent with the Statements of Principle Concerning the Role of Science in Codex Decision-Making and the Extent to which Other Factors are taken into Account:

"The level of risk proposed following consideration of public health impact AND OTHER LEGITIMATE FACTORS RELEVANT FOR THE HEALTH PROTECTION OF CONSUMERS AND FOR THE PROMOTION OF FAIR PRACTICES IN FOOD TRADE, INCLUDING technological feasibility, economic implications, and that which society regards as reasonable in the context of and in comparison with other risks in everyday life."

Food Safety Objective**New Zealand**

The definition for FSO should include reference to the point of consumption e.g. "The level of microbiological hazard that is tolerable in a food at the point of consumption, or at a specified point along the food chain, in order to provide the appropriate level of public health protection".

United States of America

The definition given in the document states that a FSO is "the level of microbiological hazard that is tolerable in a food at a specified point along the food chain in order to provide the appropriate level of public health protection". Specifying that an FSO applies at a specific point in the food chain results in the FSO being tantamount to a microbiological criterion. The United States believes a more appropriate definition for an FSO is the following: "The level of a hazard that is tolerable in a food in order to provide the appropriate level of public health protection".

Microbiological Hazard:**United States of America**

Change "concerning" to "arising from". Hazards arise from bacteria, viruses, etc.

Microbiological risk:**United States of America**

Delete this definition and move the wording down as narrative under the definition of Risk. A microbiological risk is a risk and should not have a different definition. It is better to clarify the relationship of microbiological risk to risk generally under the definition for risk.

Risk**United States of America**

Add the following narrative under Risk to clarify the relationship of microbiological risk to risk generally. "A *microbiological risk is a risk arising from the presence in food of bacteria, viruses, yeasts, molds and algae, parasitic protozoa and helminths, and their toxins or metabolites.*

Risk Profile**New Zealand**

The definition of a risk profile would gain clarity if it included reference to a particular hazard/food combination rather than the more generic “food safety problem”.

3 GENERAL PRINCIPLES

- PRINCIPLE 3:

Argentina

In reference to Point 3 (General Principles), it is not very clear to us what Principle 3 is referring to when it mentions processes. Is it referring to the risk analysis process? to the evaluation of the risk analysis?... to the management process?... or perhaps we are talking about the actions that define what should be done to control hazards and their risks? We believe that this clarification is fundamental. Nevertheless, this is not the most important thing to keep in mind in Point 3, in which, in our opinion, a transcendental aspect of risk management has been obviated, which is its impact on the food trade. In no way can we fail to take into consideration the way in which the actions developed in the risk management step can influence the fluid exchange of food.

- PRINCIPLE 4

Argentina

As regards Principle 4, we believe that the first sentence should include the concept of the independence of the evaluation process, as well as its scientific integrity, and therefore we propose that the wording be changed as follows: “Risk management should ensure the scientific integrity and total independence of the risk evaluation process...”

United States of America

Retain as the Principle the words; “Establish risk assessment policy is a responsibility of the risk manager.” Move the rest of the text to under the principle as an explanatory narrative. Thus the narrative would read: *“In particular risk managers should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment, while ensuring transparent and appropriate interaction between them. The objective of the risk assessment should be clearly defined before risk assessment begins.”* This change clearly states the principle and uses the narrative to explain the principle.

- PRINCIPLE 5:

Argentina

We disagree with Principle 5. We believe that consideration of uncertainty throughout the Risk Analysis process is implicit and obvious, therefore this principle, as it is written now, would appear to try to emphasize this uncertainty to justify the adoption of precautionary measures that may not only be unnecessary, but may also be disruptive to the fluid exchange of food products.

- [PRINCIPLE 6]

Consumers International

A distinction should be made in the text between how Codex uses precaution in its risk management role, and how government risk managers use precaution. The "Proposed Draft Working Principles for Risk Analysis" currently being considered by the CCGP and currently circulating for government comments (CL 2001/24-GP) contains two paragraphs which relate to precaution. Paragraph 10 (a new addition proposed by Australia) states:

"[Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate. Precaution should be

exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.]"

Paragraph 40 repeats what the Commission, at its 24th session, agreed: "When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence."

Consumers International can support the current language in Principle 6, and would support the removal of the square brackets, but suggests the following alternative text:

"When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the choice of risk management options (including interim measures) should reflect the confidence in the available scientific information, and the decisions/measures taken should be proportional to the potential extent of the health risk and should be supported by the available scientific evidence."

Then, the agreement from the Commission meeting would go in section 5.2.1.3 as a further elaboration of this general principle as it would apply to risk management decisions taken by Codex, as described later in these comments.

- PRINCIPLE 7:

New Zealand

Principle 7 refers to only one component part of the risk management process, whereas every component is essential to the structured process.

- PRINCIPLE 8:

Argentina

We consider Principle 8 to be too broad and unjustified, since the overall focus of the chain for management actions will depend on the hazard in question and the point on the chain at which the actions will be taken on the food. Lastly, Principle 10 should be re-written.

- PRINCIPLE 10

Argentina

Lastly, Principle 10 should be re-written.

United States of America

Retain as the Principle the words, "Risk management decisions should always be open to review". Move the rest of the text under to under the principle as an explanatory narrative. Thus the narrative would read: "*Risk management decision should be open to review when new information becomes available that substantively alters the conclusions of risk assessment including the associated degree of uncertainty, or as new risk management options become available.*"

- PRINCIPLE 11

New Zealand

Principles 10, 11 and 12 address different issues but there is insufficient clarity in the current text to differentiate the objectives. Explanatory material incorporated in Section 7 should be used to increase clarity; e.g., Principle 11 should include reference to monitoring and surveillance of the human

population to determine if risk management measures are effective in achieving the ALOP on an on-going basis. Principle 12 could be rewritten as; “Risk management goals should be periodically reassessed in order to achieve continuous improvements in reducing risks to human health”.

4 INVOLVEMENT OF STAKEHOLDERS

Argentina

In Point 4 (Participation of Stakeholder) in the third paragraph, agricultural producers should be included, since if the list of stakeholders is open, it goes without saying that this is one of the most important sectors.

Mexico

Bullet 5, we request that it be modified so that it indicates that the identification of the ALOP and establishment of the FSO take into consideration the epidemiological research from each country, and that it not indicate that these reflect the preferences of the society, thus the following text is suggested: "Identification of the ALOP and the establishment of the FSO, according to the results that are produced by the epidemiological outcome of the population".

United States of America

In the sentence just before the bullet points, change “exemple” to “example”.

Fifth bullet point: change “FSO” to “the FSO(s)”.

Seventh bullet point: insert the word “options” after “management” to clarify what is being reviewed.

Consumers International

Consumers International welcomes and supports this section of the text, including the portion in square brackets.

International Federation For Animal Health (IFAH)

We agree that there is a requirement to include stakeholders in the process. However, there appears to be some confusion here as to how for all stakeholders are involved in the Risk Management process and the importance of their role at the stage of Risk Communication. Is it intended to have a separate document to discuss the Risk Communication steps? Without these steps, it would seem to be partially complete.

5 GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

Argentina

Finally, we agree that there are aspects of point 5 that should be further discussed and clarified for a better understanding of the document. For example, if there is no doubt as to regional differences in the presence of pathogens and characteristics of the incidence or prevalence of illness that may affect a susceptible population, we understand that this does not mean that the FSO should be different depending on the region.

5.1.1 Identification of risk managers

Argentina

In point 5.1.1., fourth paragraph, it is not clear what is being established when it says that risk management should or could involve other stakeholders, since both terms have very different connotations. At the end of the next paragraph, we think that, for better clarity, the word “scientific” should be added at the end (...developments in the scientific area.).

United States of America

Move the last paragraph (beginning “In undertaking microbiological risk management activities,...” up to become the last sentence of paragraph 1, inserting the word, “However,” in front of the sentence. This will make clearer that, while a separation between risk assessment and risk management should be maintained, there is still the need for frequent and transparent communication between risk assessors and risk managers.

International Federation for Animal Health

IFAH would prefer to use the phrase "At the outset of a microbiological risk **analysis** activity, etc..." in the first sentence. The risk assessment process would be expected to proceed in advance of the risk management step.

New Zealand

Section 5.1.1 refers to public authorities playing a pivotal role in microbiological risk management, but this role is not well developed throughout the document.

5.1.2 Identification of a food safety issue**International Federation for Animal Health (IFAH)**

We suggest the insertion of the word **microbiological** between "a" and "food". There is a range of contaminants that can create a food safety issue but this document refers very specifically to those of microbiological origin.

5.1.3 Risk profile**Argentina**

In point 5.1.3, the first sentence reads: “Elaboration of a risk profile is essential for effective risk management”. We believe that, more than effective risk management; a risk profile is essential to defining the conduct of a risk evaluation.

New Zealand

Section 5.1.3 should include reference to the ways in which risk profiling can actually “guide further action”, e.g., qualitative ranking of different food safety problems for risk management and prioritisation of particular food safety problems for formal risk assessment.

5.1.4 Defining goals**New Zealand**

Section 5.1.4 should be expanded to better reflect what is involved in scoping a risk management process for an identified food safety issue. The Section should include reference to different food safety issues that may be subject to risk management, e.g., an immediate food safety problem, elaboration of food standards, judgement of equivalence etc.

5.1.5 Risk assessment policy**United States of America**

2nd paragraph, second sentence, Delete the words “On the other hand”, as the words are superfluous and not needed here.

5.1.6 Commissioning of microbiological risk assessment

New Zealand

Section 5.1.6 should recognise that not all food safety problems will proceed to a call for a quantitative risk assessment. A qualitative risk assessment embedded in a risk profiling process may be sufficient to guide further risk management action, especially on an interim basis.

5.1.7 Consideration of the process and the results of the microbiological risk assessment

New Zealand

It should be made clear that the activity involved in the final bullet, i.e., 5.1.7 should be under the direction of the risk managers, either through risk assessment policy or through an iterative process throughout risk management.

Risk management option assessment should clearly recognise that a decision on an ALOP represents an iterative decision that is often “arrived at” through appropriate stakeholder consultation and consideration of available control measures. The current text infers that the decision on ALOP will precede selection of risk management options.

United States of America

4th Bullet Point. The United States supports the use of a peer review process and recommends deletion of the brackets around this bullet point.

International Federation for Animal Health

Recent experiences of the review process for the use of Fluoroquinolones in the US in relation to microbiological hazards in food suggest that the brackets be removed from Bullet point number 4. IFAH supports the concept that the risk assessment is subject to peer review.

5.1.8 Identification of available options

New Zealand

Section 5.2.1 should make strong reference to the value of setting microbiological performance criteria (“targets”) that reflect the outcome of process control systems (either GHP- or HACCP- based). In the ideal situation, these performance criteria will be derived from a FSO. In contemporary food safety environments, competent authorities are increasingly utilising performance criteria as the basis for verification activities and assurances that process control systems meet regulatory requirements.

United States of America

Delete the last sentence of this sentence dealing with precaution since the use of precaution is included in Principle 6. If a section on precaution is necessary, a section on the “use of precaution in microbiological risk management” is recommended. Also see our General Comments above relating to precaution and our comments relating to Section 5.2.1.3 below.

Consumers International

The brackets around the last paragraph can be removed, and in addition reference should be made to section 5.2.1.3, since additional guidance on interim measures that are part of a precautionary approach will be provided there.

International Federation for Animal Health

Following discussions at the CAC July 2001 IFAH proposes the deletion of the final sentence in brackets at the end of this section. Precaution is a fundamental component of risk management.

5.1.8.1 Identifying the acceptable level of risk (ALR – refers to ALOP)

New Zealand

The discussion material on ALOP in Section 5.2.1.1 and FSOs in Section 5.2.1.2 is well prepared and New Zealand looks forward to further development and refinement. A clear understanding of both of these concepts is essential to an effective and transparent risk management process. Sub-sets of principles, explanatory narrative, and guidelines for application, are needed for the purpose of this draft document. In this respect, the practical realities of application that currently exist need to be addressed.

The ability to establish a FSO at a specified point along the food chain (as described in the definition) needs to be developed within the context of QRA and modelling of the whole food chain.

United States of America

Third paragraph, third sentence, Delete “The” and insert “One useful expression of the”. The ALOP and/or ALR is one description of the degree of public health protection but not necessarily the only one.

Fifth paragraph, second sentence. Insert “the Codex” before “*Criteria...*” . Additionally, the proper reference for the document should be inserted or footnoted.

Last paragraph, 6th bullet point. Delete the bracketed term “public values” as the term “public risk reduction preferences” is clearer and accomplishes the same intent.

Last paragraph, 8th (last) bullet point. Delete this bullet point as it is unclear as to meaning and is unneeded with the addition of the reference to the Codex guidance on establishing other legitimate factors.

Consumers International

In the first bullet point, we suggest the following rewording: "An assessment of risk including the magnitude, FREQUENCY, severity and reversibility of the health effects and attendant uncertainties FOR THE GENERAL POPULATION AND ANY SUSCEPTIBLE SUBPOPULATIONS."

5.1.8.2 Food Safety Objectives

United States of America

As noted above in our General Comments, the United States supports the inclusion of FSOs in this document. We recommend, however, that the following changes be made to this section to improve clarity and content.

Third paragraph. Second sentence. Put a “full stop” after “hazard” and delete the rest of the paragraph. Acceptable levels of a hazard are not normally established for CCPs; rather the entity monitored at CCPs are such items as time, temperature, pH, etc.

Fourth paragraph (beginning “It is also clear that certain foodborne pathogens...”). Delete this paragraph, as is superfluous narrative information not appropriate for a Codex Guideline document.

Fifth paragraph (beginning “FSOs should contain...”). Move this paragraph up to begin the third paragraph.

Sixth paragraph (beginning “The relationship between the microbiological hazard...”). Delete this paragraph, as it is superfluous narrative information not appropriate for a Codex Guideline document.

Seventh paragraph (beginning “Because significant differences...”). Move to become the last paragraph of the Section.

Tenth paragraph (beginning “It is also important to distinguish...”), first bullet point, first sentence. Delete the words “or to force change in industry and enhance the safety of certain products”. This wording is too strident and is redundant to the wording of the last paragraph.

Consumers International

In the view of Consumers International, the determination of the Appropriate Level of Protection (ALOP) and an Acceptable Level of Risk (ALR) are social judgments. While the establishment of the ALOP and ALR should be informed by science and scientific arguments, they are also appropriately influenced by economic, social, and ethical considerations. Indeed, the definition of ALOP in

the WTO/SPS agreement never even mentions science but instead refers to a level of protection "deemed appropriate" by a member country. Both ALR and ALOP are society's attempt to answer the question, "How safe is safe enough?" The level of safety that is "safe enough" will vary depending on how easy it is to reduce the risk, who is exposed to the risk, the benefits associated with the activity or substance that creates the risk, etc.

- Footnote 5: the term industry has previously been used in this document and other Codex documents and it is not necessary to define it here. If it is defined, the definition given needs to be edited. For example, the definition should be edited so that it is understood that cooks are just an example of an individual working professionally in the food chain. Furthermore, it should be clarified that an industry does not necessarily work throughout the entire food chain, but rather at some point(s) along the food chain.

5.1.8.3 Precautionary principle

Argentina

We consider that, from what was discussed and resolved in the Commission’s Session, the “Precaution Principle,” along with the section that includes the present draft guideline for this concept, should not continue to be discussed. We do believe, however, that even though it cannot be considered a “Principle”, precaution can be focused on as an alternative logic to be considered when facing the possibility of the presence of a hazard.

New Zealand

New Zealand believes that a separate section on the “Precautionary principle” (Section 5.2.1.3) is unwarranted in this document. A precautionary approach is inherent to many aspects of the risk assessment and risk management process, and reference should be made in this context where necessary, e.g., when risk managers take into account the range of uncertainty surrounding a risk estimate.

A precautionary approach is also reasonable and practical in the context of the WTO SPS Agreement provision for provisional measures when relevant scientific information is insufficient (Article 5.7). Reference to this approach should be made under “Risk profiling”, as it is the WTO SPS provision that “guides further action”.

United States of America

The United States believes this Section should be removed from the document in its current form and calls attention to our general comment above in relationship to the discussion of precaution in this

document. The United States believes that the use of precaution in microbiological risk management should be carefully and fully discussed by the Drafting Group and the Committee in light of the results of the discussion of the Codex Alimentarius Commission on this subject, and the document revised accordingly.

Consumers International

As noted in the text, this section needs to be considered in light of the discussion that occurred at the recently concluded 24th session of the Commission. This is one area where guidance to governments needs to be distinguished from guidance to Codex. The agreement from the Commission should be included in this section: "When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence."

We also suggest that the title of the section be changed to "Decisions When Scientific Data Are Insufficient." This would be consistent with the terminology used to frame the discussion at the recent session of the Commission. Additional language is needed in this section to provide guidance to member countries on how to appropriately apply precaution in risk management (i.e., not as a disguised trade barrier). The Agreement on the Application of Sanitary and Phytosanitary Measures clearly recognizes the right of countries to take precautionary measures (as stated in Article 5, paragraph 7):

"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

Consumers International suggests the following, based on language that has been under discussion at the Codex Committee on General Principles (CCGP):

[When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for a member government to exercise precaution by provisionally adopting measures to protect the health of consumers until additional pertinent scientific information is available and a more complete risk assessment can be performed. In such situations, member countries should take into account the following considerations:

- 1) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost-effectiveness considerations.
- 2) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.
- 3) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data.
- 4) The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information. The measures taken are the least trade restrictive to achieve protection of the health of consumers.
- 5) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.

6) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.] This language, which is based on language proposed by the CCGP working group in April, but not yet adopted by CCGP as a whole, is in square brackets in recognition of on-going discussions within CCGP. In light of the recent discussions at the Commission, which called for more detailed principles and guidelines to be spelled out by the relevant committees, it seems appropriate for CCFH to provide some detail for how precaution can appropriately be used by governments, and to use the discussions at CCGP as a starting point for doing this.

International Federation for Animal Health

Following discussions at the CAC July 2001 IFAH proposes the deletion of the final sentence in brackets at the end of this section. Precaution is a fundamental component of risk management.

For the same reason, **5.2.1.3 Precautionary Principle** can be deleted and cross-reference made to the CAC position adopted at its 24th Session in July 2001.

5.1.9 Selection of preferred microbiological risk management options

United States of America

For additional clarity, The United States suggests that the following paragraph from the Kiel Consultation Report be added as a new second paragraph to this section.

“Selection of a preferred risk management option(s) will primarily involve a systematic identification and evaluation of the likely impact of different sanitary measures on reducing or eliminating risk to human health.”

Additionally, to provide for new and innovative technology, the United States recommends that the following new paragraph be added to the end of this Section.

“Whenever possible, the preferred option(s) should be performance-based and not be a barrier to future innovations that will enhance public health (e.g., mandating that risk reduction can only be achieved via a specific technology).”

Consumers International

At its 24th session (in 1999), the CCFH "agreed that economic and technical feasibility, practical aspects of measures (especially for small businesses), the availability of expertise, sampling, consumer information, environmental impact and Good Agricultural Practice (GAP), Good Manufacturing Practice (GMP) were legitimate factors, which had been or were being taken into account in the decision process. The Committee could not come to a conclusion at this time on the reference to cultural aspects and consumer concerns." This discussion should be reflected in this section. Consumers International agrees (as stated in paragraph 2) that protection of human health should be the primary consideration. However, we recommend that paragraphs 3 and 4 be amended as follows:

"The relevant production and processing methods (GAP AND GMP), the inspection, sampling and analysis methods, the difficulties [or operations] involved in control, inspection and compliance with requirements [and approval procedures] should be taken into account. However, other important elements should be considered, as appropriate. These elements include OTHER FACTORS RELEVANT TO THE HEALTH PROTECTION OF CONSUMERS AND PROMOTION OF FAIR PRACTICES IN FOOD TRADE, taking into account preferences expressed by stakeholders, INCLUDING technical and economic feasibility, THE AVAILABILITY OF EXPERTISE, cost-

effectiveness of alternative approaches to limiting risk, CONSUMER INFORMATION, AND ENVIRONMENTAL IMPACT."

5.1.10 Final management decision

Consumers International

In our view, bullet 4 is too limiting with regards to the types of information that might be used in reaching a final risk management decision. For example, information on consumer perceptions might also be used. We suggest the following rewording: "be based on the best available information (e.g., scientific, technical, economic, relating to consumer perceptions)"

6 GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

New Zealand

Guidelines for implementation of microbiological risk management decisions (Section 6) would benefit from considerable expansion. There is insufficient information on the respective roles of the competent authority and industry, especially in relation to validation and verification of performance-driven outcomes for process control systems. Reference to other Codex documents would enhance a sub-set of principles developed for this Section.

United States of America

The United States believes a careful review of this section be carried out, particularly in relationship to the bullet points presented under Section 5.2.1 (Identification of available options). The United States believes that the information presented in this section is insufficient in relation to the implementation of the various options presented in Section 5.2.1. Additionally, consideration of the construct of this section may be necessary depending upon any changes that may be made to the Scope of this document (see General Comment above).

International Federation for Animal Health

A fundamental component of implementation is the Risk Communication procedure and IFAH is surprised that there is no reference to this in this section.

7 MONITORING AND REVIEW

Argentina

Perhaps the most appropriate place to define the guidelines intended to be developed in sections 6 and 7 is within the sphere of the Committee itself. Afterward, the guidelines could be circulated to the countries for their comments. It is possible that the issuance of a simple circular letter requesting comments on the issues in these two sections, without any instruction or orientation, could bring more confusion than solutions to those responsible for the creation of the document.

New Zealand

Monitoring and review is an essential part of a framework for the effective management of food-borne risks to consumers and as noted in the draft text, more work is needed on Section 7.

United States of America

The United States supports the further careful review and development of this Section to ensure its adequacy, especially with respect to any changes made in the Scope of the document.

Additionally, the United States has the following suggested changes to the current text.

First paragraph. For clarity, change the first sentence to read: “Risk managers should periodically determine the degree of implementation and compliance to the risk management measures that have been initiated.” Additionally, replace “Moreover” with “Additionally” in the last sentence.

Second paragraph. In the first sentence, replace “information” with “data” so that the first sentence agrees with the second sentence. Additionally, add the phrase “which may be obtained through monitoring and surveillance activities” after “Such data” in the first sentence to add clarity as to how data is to be obtained.

Consumers International

In paragraph 2, add "public expectations" to the list in the second sentence on the kinds of new information that might be relevant to reviewing risk management decisions. New information, which might be relevant to reviewing risk management decisions, can appropriately include cultural or other non-scientific considerations.

International Federation for Animal Health

The Risk Analysis procedures call for an iterative and ongoing process of all the steps in the chain and the role of Risk Assessors and Risk Communicators are of ongoing and critical importance in this process. It would be useful to see some direct reference to this process in this section which covers some of these points in detail. It should be recognised that all stakeholders are relevant in the monitoring process and can provide significant inputs to the Risk Managers in the ongoing evaluation of hazards that may be identified in a review.