codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FH 04/6 - Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

THIRTY-SIXTH SESSION
Washington DC (USA), March 29 – 3 April 2004

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

Comments at Step 3 submitted by Mexico, United States of America, and IDF

GENERAL COMMENTS

IDF

IDF wishes to congratulate France and members of the drafting group for the progress made in the development of the MRM principles and guidelines, in particular for the clarification provided in the description of stringency expressions, i.e. the FSO/PO/PC/MC approach. We consider the document as suitable for being progressed for adoption at Step 5, and are pleased to offer the few comments as specified below.

UNITED STATES OF AMERICA

The United States would like to congratulate France and its drafting partners on the significant enhancements that have been achieved in the "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management." A number of the issues that have hampered this document appear to have been effectively addressed. In particular, there seems to be a much clearer articulation of the role that microbial risk assessment plays in the risk management process, especially for Codex related activities.

While significant progress has been achieved, there are several areas that will require the Committee's attention in order to advance the document. In particular, there are several parts of the document, such as implementation and review of MRM decisions that have not received the same degree of conceptual evaluation that other parts of the document have received. This leaves the overall impression that the document is primarily focused on reaching initial risk management decisions, whereas the ongoing operation of risk management programs is often a challenge for member countries.

2. DEFINITIONS

IDF

Inclusion of those definitions reference would ease the understanding and reading of the document, in particular with regard to the confusion that often arises between:

- hazard >< risk

- MRM option >< control measure

Risk manager:

UNITED STATES OF AMEICA

There appears to be a paradox developing between this definition, which clearly states that the individuals who manage microbial food safety are government officials or their counterparts at international organizations, and principle #3, which clearly states that industry has the responsibility for producing a safe product, i.e., managing the microbiological risks associated with the product. In fact, both are managing the risks - the former establishing the stringency required of the control measures and verifying that level of protection has been achieved, and the latter actually managing the risk to that level of stringency. Either the definition of risk manager needs to be expanded so that it can include both activities or the drafting group needs to come up with another way to reflect the reality that the industry will be the group that will have to manage microbiological risks once the level of stringency has been established.

Definitions for the terms Process Criterion and Product Criterion need to be developed (see comments under Section 6.2.3 - Performance Criterion).

3. GENERAL PRINCIPLES

PRINCIPLE 2:

MEXICO

Third sentence, the term “farm to table” in this principle, and the term “farm to fork” in section 6.2 should be changed to “throughout the entire production chain”.

UNITED STATES OF AMERICA

The last sentence of the explanatory text suggests that MRM will enhance other food safety tools and infrastructure. It can be equally asserted that these activities are simply tools for MRM, i.e., MRM is the overarching activity.

[PRINCIPLE 6:]

MEXICO

At the beginning of the paragraph, add the text “As much as possible...” and remove the brackets.

UNITED STATES OF AMERICA

The second sentence of the explanatory text is too prescriptive. Furthermore, the information in the second and third sentences of the explanatory text is redundant to the material in the Codex “Principles and Guidelines *for the Conduct of a Microbiological Risk Assessment* (CAC/GL-30 (1999))”. We should simply cite the Risk Assessment document.

[PRINCIPLE 7:

MEXICO

Remove the brackets.

UNITED STATES OF AMERICA

The United States feels that the last sentence of the explanatory text should specifically include at statement that indicates that MRM policy should further assure that MRM options selected should not be more restrictive of technological innovation than is required to achieve an ALOP.

4. APPROPRIATE LEVEL OF PROTECTION

UNITED STATES OF AMERICA

Last paragraph, as a means of better understanding the relationship between FSO/PO and ALOP, it is recommended that the following statement be added to the last paragraph of this section:

"The articulation of a FSO or a PO in the absence of an explicit ALOP may serve as an implicit ALOP (see 6.2)."

5. PRELIMINARY MICROBIOLOGICAL RISK MANAGEMENT (MRM) ACTIVITIES

UNITED STATES OF AMERICA

The United States remains confused over what is meant by regional differences. If the intended interpretation is that a region is a geographical area that represents a portion of a country or a portion of several countries (which is consistent with the use of the term in the SPS agreement) then this represents a divergence from CCFH's usual focus on providing guidance to countries. Following this interpretation and using the United States as an example, each state within the United States would have the ability to establish their own requirements for imported foods. Alternatively, if the use of region refers to multiple countries agreeing to function as a single body (e.g., countries with formal or informal trading agreements), then we do not understand why the concept of region is needed since each country, alone or in consultation with other countries, has the right to establish its own ALOP and related MRM targets. Thus, the United States still does not feel that this concept has been clearly defined and articulated. Unless these questions can be answered, it is recommended that this section be deleted. If the concepts in the bullets are deemed to be pertinent, they should be moved to other sections of the document.

5.1 IDENTIFICATION OF A MICROBIOLOGICAL FOOD SAFETY ISSUE

MEXICO

In the fourth (last) paragraph, first sentence, change "will require" to "may require". In terms of the implementation of immediate decisions "without further scientific considerations", the need for a clear association between the consumption of a food and the appearance of adverse health effects should be taken into account, which in any case would consist of limited scientific information that could be explained to the extent possible by a risk profile, just as the document itself indicates in Annex I, after the diagram, in the second paragraph, which starts with "On the basis of the risk profile."

In this sense, the diagram in Annex I should reflect this situation.

5.2 MICROBIOLOGICAL RISK PROFILE

UNITED STATES OF AMERICA

Third paragraph, the parenthetical, "(possibly with a new risk profile)," should be deleted. If more information is needed, than the appropriate MRM option is to conduct research, conduct surveys, etc. The sequential revision of risk profiles seems to undermine the purpose of a risk profile which is to provide background information for reaching a decision.

5.3 MICROBIOLOGICAL RISK ASSESSMENT (MRA)

5.3.1 COMMISSIONING OF THE MRA

IDF

As this document is concerned with MRM, we consider a cross reference to the Codex MRA Guidelines would be more appropriate than an including an incomplete list of items. In particular, the review referred to in the last indent is better covered by the MRA Guidelines.

6.1 AVAILABLE MRM OPTIONS

IDF

In the first sentence of the first paragraph ("At national level, the..."), the phrase "...control a microbiological hazard to a degree...." should be amended into:

"...~~control~~ manage a microbiological ~~hazard~~ risk to a degree....".

Similarly, in the second sentence of the third paragraph ("There are generally a...."), the phrase "...can be used to prevent or eliminate a food safety hazard or reduce it to..." should be amended into

"...can be used to ensure the application of appropriate controls that prevent or eliminate a food safety hazard or reduce it to..."

The rationale for these suggestions is that MRM options manage the risk, whereas hazards are controlled by "control measures" (see current definitions of "control measure" and "risk manager") Risk managers do not apply the control measures.

6.2 COMMUNICATING THE STRINGENCY OF MRM SYSTEMS

6.2.1 Food Safety Objective (FSO)

UNITED STATES OF AMERICA

5th bullet. Separate into two bullets since it is describing two different thoughts. Delete "and regional" based on comment in comment on section 5 (see above).

6th bullet. This is an example where the earlier definition of risk managers leads to problems since this bullet clearly indicates that members of industry are risk managers.

IDF

Recognition of the following use of FSOs is considered to be important and should be addressed by an additional indent (to be inserted in between the 2nd and 3rd indents), as follows:

- *"by the food businesses to establish POs for end products to express operational targets for their individual food safety management system: the POs may not be universally common and will take into account the specific location of the business within the food chain and intended use of the end products"*

The above addition will enhance the compatibility with the text of section 6.3.2.

6.2.2 Performance Objective (PO)

UNITED STATES OF AMERICA

Second bullet, the explanatory text in the 2nd and 3rd sentence of the second bullet confuses more than it clarifies. These sentences should be separated as an indented section or moved to another location after the bullets.

The detailed discussion on the establishment of a safety-based shelf-life for foods is highly technical and does not seem appropriate for the current document. This is a highly complex topic, and articulation of the principles underlying the articulation of such values warrant a much more detailed consideration that can be achieved in the current document. The discussion on this subject should be deleted and CCFH should consider whether this should be a topic for future work.

The United States does not agree with the statement in the 5th that PO cannot be verified by analytical means. Furthermore, this statement is in direct conflict with the first sentence in the 6th paragraph that PO's are measurable and verifiable. It is recommended that the 5th paragraph be deleted.

IDF

Section 6.2.2 (not 6.3.2) - Performance Objective (PO)

The last two paragraphs, in particular the first sentence of both of them addressing verification, seem contradictory to each other.

In order to avoid any confusion on how to verify compliance with a PO, we suggest the following rewording of the last two paragraphs:

"Although POs are generally not intended to be verified by analytical means, compliance with POs may need to be verified by other means. Means to verify such compliance:

- *Establishment of a MC for end products that is used as a statistically based means for verifying within a stated degree of confidence that the PO is not being exceeded;*
- *Statistically based monitoring and records of pertinent process parameters or product parameters of validated control measures (especially relevant where measurement of microbiological hazard levels in a product is not practical); and/or*
- ***Surveillance or screening programs to monitor prevalence of a microbiological hazard in a food (especially relevant for risk managers in relation to generally applicable POs, e.g. those established by competent authorities)."***

6.2.3 Performance Criterion (PC)

UNITED STATES OF AMERICA

The implication that PCs are only established by industry seems inappropriate. There are numerous examples of PCs that have been established by national governments.

Consideration of process criteria (e.g. specific requirements for processing a food for a specific time and temperature) and product criteria (e.g., need for a product to have a specific pH/water activity combination), which had been included in past discussions has been dropped. Elimination of these concepts from the document is likely to cause problems since many regulatory requirements established by governments are indeed process criteria or product criteria. The United States would like these concepts to be reincorporated into the document and definitions for the terms developed.

6.3.3 Microbiological Criterion (MC)

IDF

There is a typo in the last paragraph, 1st line: "that" should be corrected into "than".

7 SELECTION OF MRM OPTIONS AND IMPLEMENTATION OF MRM DECISIONS

7.1 SELECTION OF MRM OPTIONS

MEXICO

The third bullet states "Other potential sources of the hazard and/or possible other **product** types...". I wonder, where it says "product," whether it should say "hazards", since when we speak of other sources, this could include other products.

7.2 IMPLEMENTATION OF MRM DECISIONS

UNITED STATES OF AMERICA

While the ultimate implementation of MRM decision is carried out by countries, it would seem appropriate for Codex to offer recommendations on "best practices," particularly in relation to how Principles 5 and 7 can be effectively met in relation to international trade.

8 MONITORING AND REVIEW OF MRM DECISIONS

8.1 MONITORING

UNITED STATES OF AMERICA

The section on monitoring appears to be largely focused on the acquisition of disease surveillance data. The United States agrees that this is an extremely important source of information for assessing the efficacy of MRM programs. We believe the document would be much improved if it included appropriate references to information that can be used to educate risk managers on how such programs can be most effectively operated.

It is also important to note in the text that public health surveillance data are not the only source of information and that other forms of data can be equally informative. For example, national baseline studies conducted by national governments, international agencies, or industry on the incidence of pathogens or surrogate microorganisms can be equally effective in assessing the level of control actually achieved, particularly when a FSO or a PO have been established. Such information is critical to assessing the overall verification of the efficacy of established control systems.

ANNEX I: OVERALL FRAMEWORK FOR MANAGING FOOD-BORNE RISKS

MEXICO

Modify the diagram to remove the arrow that goes from the identification of a microbiological risk issue to an immediate decision, since we think that there should at least exist a risk profile.

EDITORIAL COMMENTS

MEXICO

Apart from the translation aspect, we suggest modifying the terms to be defined that currently read “Objetivo de rendimiento” [Performance Objective] and “Criterio de rendimiento” [Performance Criterion], to terms that would be more clear in Spanish, such as “Objetivo de cumplimiento” [Performance Objective] and “Criterio de Cumplimiento” [Performance Criterion].