codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FH 05/37/6 – Add.1**

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

Comments submitted by: Canada, the United States of America, Venezuela, Consumers International and International Dairy Federation (IDF)

GENERAL COMMENTS

CANADA

Canada would like to congratulate France for leading the working group and improving the document significantly. We are generally in agreement with the document and would like to offer comments to improve clarity of some sections.

UNITED STATES OF AMERICA

The delegation from France and its drafting partners are to be congratulated on significant progress that they achieved during the past year in the development of the *PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)*. Many of the previous conceptual hurdles to providing a consistent, practical framework for the conduct of microbial risk management have been successfully addressed. Likewise, the draft has been effectively integrated into the Commission overall framework for risk analysis.

The Delegation of the United States feels that despite this excellent progress there are still several areas within the document that would benefit from further clarification or examples relating to MRM principles and guidelines. The United States has provided below specific points that the Committee may wish to consider to further strengthen the document. The United States will also provide at the time of the meeting an annotated copy of the draft document with additional suggestions of an editorial nature.

Throughout the document there is reference to food/feed systems. CCFH's mandate of CCFH is the safety of food for human consumption. As such, in those instances where the presence of hazards in feed affect the safety of foods derived from an animal, the microbiological profile of feed should be considered. However, in those instances where the feed does not directly impact human health, but only that of the animal, then guidance developed for such feed should be undertaken by the appropriate committee within Codex.

VENEZUELA

- We recommend changing the term “safety issue” (“cuestión de la inocuidad”) to “safety problem” (“problema de la inocuidad”.) We believe that the proposed term is more accurate in regards to the issues at hand in this Proposed Draft.

- Regarding the term “industry” (“industria”), we recommend that it be used in future Codex texts, in order to not create confusion.

CI

Consumers International commends the working group for the excellent work done on this document and preparing such a well-prepared proposal. CI supports the advancement of the document to step 5. The entire document is reorganized in a better way compared to previous drafts, taking into account all of the stakeholders and steps involved in the process.

IDF

IDF would like to congratulate the Codex CCFH Drafting Group under the leadership of France for the excellent work done in revising the document. CX/FH 05/31/6 constitute a considerably improved document.

INTRODUCTION

SECOND PARAGRAPH

CI

We have only one comment on the INTRODUCTION, which is to clarify that the risk analysis approach has been adopted primarily to ensure protection of consumers, while also recognizing that it has other (secondary) uses, such as in demonstrating the equivalence of food safety control systems. Thus we suggest the following slight modification to the last sentence of paragraph 2:

Recently, risk analysis, involving its component parts of risk assessment, risk management and risk communication, has been introduced as a new approach in evaluating and controlling microbial hazards to help ensure the protection of consumers. IT ALSO CAN BE USEFUL FOR {delete:, while} facilitating the judgment of equivalence of food safety control systems.

1 SCOPE

VENEZUELA

[Applies to the Spanish version only], modify the 3rd sentence of this paragraph as follows:

Cuando ~~recomendaciones específicas~~ se apliquen recomendaciones específicas ~~solamente~~ al CODEX, o ~~solamente~~ a los países, esto será debidamente indicado en el texto.

2 DEFINITIONS

NOTE

UNITED STATES OF AMERICA

The following paragraph should be modified to read “risk manager” instead of “risk management.”

Note: it is realized that the definition of Risk Manager~~ment~~ does not include all of the individuals who are involved in the implementation phase and related activities associated with ~~various aspects of~~ MRM, i.e., MRM decisions are largely ~~are considered and~~ implemented by industry and other interested parties. The focus of the definition for ~~but~~ risk manager~~s~~ is restricted ~~would only be~~

~~associated~~ to governmental organizations with authority to decide on the acceptability of risk levels associated to foodborne hazards.

Risk manager

CI

CI supports the definition for Risk Manager. To clarify, is the Codex Alimentarius Commission and its subsidiary committees considered to be Risk Managers? If so, this should be noted.

3 GENERAL PRINCIPLES FOR MRM

PRINCIPLE 1

CI

Regarding PRINCIPLE 1 (Protection of human health should be the primary consideration in MRM), CI is on the opinion that "should" should be changed to "must."

PRINCIPLE 7

UNITED STATES OF AMERICA

The clarity of Principle 7 may benefit from being modified to read as follows:

PRINCIPLE 7: Risk managers ~~MRM~~ should consider regional differences in ~~take account of~~ risks ~~resulting~~ and risk management options. ~~from regional[1] differences in hazards in the food chain.~~

PRINCIPLE 8

CI

Regarding PRINCIPLE 8 (MRM decisions should be subject to review and revision), Consumers International believes it is important to keep in mind that, as stated on pages 6 and 13, MRM is a continuous process, and further improvements in public health are desirable and can be taken. In fact, risk reduction is a goal of this review and revision process, and that should be stated. We suggest that the principle be reworded as follows:

MRM decisions should be subject to review and revision, WITH A GOAL TOWARDS FURTHER RISK REDUCTION AND PUBLIC HEALTH IMPROVEMENT.

4 GENERAL CONSIDERATIONS

FIRST PARAGRAPH

CI

First sentence, "Codex and governments decisions and recommendations (delete: should) MUST have as their primary objective the protection of the health of consumers....."

SECOND PARAGRAPH

UNITED STATES OF AMERICA

The second paragraph should be modified to eliminate the comments related to ecological and environmental conditions. As currently written, this statement is much too broad to be useful in terms of guidance and will likely lead to non-tariff trade barriers resulting as a variety of issue only peripherally related to food safety are included in discussions of international trade in food.

"MRM should address the entire food chain when considering means for controlling the public health risks associated with food. This should typically include primary production (including feeds, agricultural practices, and environmental conditions leading to the contamination of crops and animals), product design and processing, transport, storage, distribution, marketing, preparation, and consumption ~~handling practices used throughout the food chain, including~~ This should include both domestic and imported products to the extent feasible."

FOURTH PARAGRAPH

CANADA

In paragraph 4, second sentence, the term "MRM program" is not clear. Is it meant to be the "MRM process" or the food control program itself? Also in the same sentence, the words "the factors" should be changed to "other factors" to be more accurate and consistent with the text referenced in footnote #12.

CI

Third sentence, seems to be too prescriptive, and does not adequately take into account the fact that managing risk and protecting public is not always an exact science, there is some uncertainty, and that the primary goal is to ensure protection of health, while at the same time not posing restrictions on trade or innovation that are not warranted, considering the ALOP. There needs to be more flexibility to ensure protection of public health. CI suggests that the sentence be revised as follows:

> They should ensure that the options selected PROTECT THE HEALTH OF CONSUMERS, are scientifically justifiable, proportionate to the risk identified, and not UNDULY more restrictive of trade or technological innovation, TAKING than required to achieve the ALOP INTO ACCOUNT.

FIFTH PARAGRAPH

UNITED STATES OF AMERICA

The implementation phase of MRM requires not only consultation but also outreach and education. Accordingly, the first sentence of the 5th paragraph should be modified to read:

~~"Since various~~ Most aspects of MRM are implemented by industry, ~~and~~ other interested parties, or consumers. Accordingly, risk managers should ensure ~~an~~ effective and timely consultation with all relevant interested parties before an MRM decision is taken, and effective consultation, outreach, and education after the MRM decision is taken. ~~with all relevant interested parties.~~ "

SIXTH PARAGRAPH

UNITED STATES OF AMERICA

The phrase ", and to the extent possible these differences should be documented" should be added to the end of the last sentence of the 6th paragraph.

SEVENTH PARAGRAPH

CANADA

In paragraph 7, the first sentence suggests that acceptable risk levels vary with microbial load which does not appropriately describe most regional situations. We recommend amending the first sentence as follows:

> *"~~Acceptable risk levels for~~* ***MRM decisions regarding*** *foodborne hazards will vary according to the regional microbial conditions* ***and regional ALOPs****".*

UNITED STATES OF AMERICA

The 7th paragraph needs additional work. It is mixing two different attributes, differences in microbial risks in different regions and difference in the acceptance of those risks in different regions. The latter is something that CCFH can provide guidance on in terms of accounting for the differences in those risks in both risk assessment and risk management activities. However, the acceptance of risk is a country issue and it is an area where the embracing of different "acceptable levels of risk" for different regions is a societal decision to be reached by a country. The paragraph sentence should be modified as depicted below so that only the former is being discussed.

> ~~"Acceptable~~ R~~r~~isk ~~levels for~~ associated with foodborne hazards can ~~will~~ vary according to ~~the~~ regional ~~microbial~~ conditions. MRM should take into account the diversity of production methods and processes, inspection, monitoring and verifications systems, sampling and testing methods, distribution and marketing systems, consumer use patterns associated with food, the country's stated national public health goals (ALOP), and the consumers' susceptibility to the hazard. ~~consumers' perception and the prevalence of specific adverse health effects."~~

EIGHT PARAGRAPH

CANADA

In paragraph 8, first sentence, we recommend changing "a continuous process" to "an iterative process". Countries cannot continuously apply the MRM process, however, once the MRM process has been applied to a situation, part or all of it should be repeated within a reasonable period of time to ensure that decisions made are still relevant given any new knowledge that has emerged since the completion of the initial process.

CI

In the view of Consumers International, the last paragraph of this section should read as follows:

> MRM should be independent, systematic, unbiased, complete and continuous. The process and decisions made should be subject to timely review, taking into account all relevant newly generated data.

The words "be independent, systematic, unbiased, complete," were in previous versions of this document, but it seems they are missing in this one, and CI believes they are the right words to use in a description of the process.

5.1 Identification of a microbiological food safety issues

FIRST PARAGRAPH

UNITED STATES OF AMERICA

Since the first sentence indicates that management may include issues where it is not definite that a hazard is foodborne, then the second sentence needs to be modified to the following: "The risk manager follows the MRM process to evaluate and if necessary manage the associated risk."

CI

Last sentence should clarify to whom the food safety issue should be clearly identified and communicated, keeping in mind that communication is a two-way process. CI recommends the following simple revision:

> At the start of this process, the food safety issue should be clearly identified and communicated WITH THE RELEVANT RISK MANAGERS AND RISK ASSESSORS, AS WELL AS AFFECTED CONSUMERS AND THE AFFECTED INDUSTRY.

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

Paragraph 4 and paragraph 5 should be combined, and the first sentence of paragraph 4 should be modified to read "…an immediate public health ~~concern and when they have to face up to a crisis situation~~." This phrase is redundant to the preceding part of the sentence.

The brackets should be removed from the second sentence.

The third sentence should be modified to read:

> In those instances, the provisional nature of the decision should be communicated to all interested parties and ~~Whenever possible,~~ the timeframe or circumstances under which the ~~[~~provisional~~]~~ decision will be reconsidered (e.g. reconsideration after the completion of a MRA) should be articulated when the decision is communicated initially.

5.2 Microbiological risk profile

IDF

The content of these two sections is not fully in line with Annex I "Overall framework for managing foodborne risks".

For example, the possibility to move directly from the step "Identification of microbiological food safety issue" to the step "Risk assessment" is not considered in Annex 1.

In our opinion, the technical differences between the risk profile and the risk assessment are not sufficiently spelled out in the respective sections and the flow of activities leading to the definition and implementation seem to be different. In fact it seems as if the approach through a full MRA is much more cautious than through a risk profiling. For example, it is indicated in section 5.3 that in the case of an MRA, the risk managers should be "fully informed of the strength and limitations of the MRA study" and " to decide whether the MRA is adequate to proceed further in developing and/or evaluating and deciding on suitable MRM options".

Such recommendations are missing in section 5.2, on the contrary, even though the uncertainties related to an risk profiling may be more important than in a full MRA, it is clearly indicated that decisions and MRM options can be made or implemented immediately. The necessary care required in the interpretation is not addressed.

This is probably not the intention, but we recommend reviewing the two sections and aligning them better with Annex 1. Explanations on the technical content of both risk profiles and MRA would be useful as an introduction to the sections (or references to existing document), followed by indications on the interpretation of the two types of approaches and finally a description of the steps leading to the implementation of management options.

SECOND PARAGRAPH

VENEZUELA

Delete "commissioning" and substitute "implementing." We recommend changing the term "commissioning" throughout the text to "implementing" (e.g., Annex 1.)

LAST PARAGRAPH

CANADA

In the last paragraph, we feel the last sentence is not clear as it leads the reader to believe that the risk profile itself would be introduced into the Codex step process. We recommend re-wording as follows:

The MRM options will typically take the form of draft MRM guidance document to be introduced into the Codex step process (e.g., codes of practice, guidance documents, microbiological specifications, etc.).

6.1 Identification of the available MRM options for Codex and countries

CANADA

In the first paragraph, first sentence, we recommend amending as follows:

The risk manager needs to ensure that MRM options are identified and the most appropriate one(s) selected for subsequent implementation by relevant interested parties.

Identifying MRM options in complex issues is best left to a multi-disciplinary team who might also provide input into decision criteria for selection of the most appropriate option(s). While the Risk Manager has the final responsibility for making the selection, an interactive approach involving relevant interested parties will provide key information required by the Risk Manager to ensure the selected option is appropriate to the situation.

6.1.2 Countries

UNITED STATES OF AMERICA

The 8th bulleted item should be modified to read:

- establish requirements for ~~public~~ inspection and audit procedures, certification or approval procedures;

As written, this implies that the consumer would be conducting the inspection.

The 10th bullet may need to be reconsidered since it appears to be mixing two different thoughts. The first is the development of awareness and training programs to inform the public and the other is training programs to educate inspectors in what needs to be done to enforce regulatory requirements. It would be better to separate these thoughts into two different bullets.

CI

The last sentence (Dash), the sentence needs editing. We suggest:

properly labelling with consumer information that either instructs THE CONSUMER regarding safe handling practices AND, WHERE APPROPRIATE, BRIEFLY INFORMS THE CONSUMER OF THE FOOD SAFETY ISSUE

6.2 Selection of MRM options

SECOND PARAGRAPH

IDF

We recommend that “control of hazards” in the first bullet be replaced with “planned control of hazards”.

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

The 4th paragraph should be modified to read:

"Whenever feasible, both Codex and countries should attempt to specify the level of control or risk reduction that is necessary (i.e. establish the stringency required for food safety control systems), while providing as much flexibility as possible in options that the industry can use to achieve the desired level of control.

6.2.1. Food Safety Objective (FSO)

FIRST PARAGRAPH

IDF

In the first para (last sentence) an in the last bullet, the references to "industry", as understood in footnote 6, are not entirely correct. Instead, "the individual food business operator (e.g. food manufacturer)" should be used. It is not the "sectors" that will/should establish these targets.

SECOND PARAGRAPH

CANADA

Paragraph 2 needs to be more clearly articulated, particularly, how the epidemiological survey relates to the ALOP. We recommend a change to sentences two and three as follows:

> *One is based on an observation of the public health status, mainly with the help of epidemiological surveys,* ***to obtain a dose-response relationship with implicated foods.*** *The other is based on* ***experimental or other scientific evidence to develop a*** *dose response curve~~s~~ linking hazard levels to disease ~~incidents~~* ***incidence*** *(risk characterization).*

UNITED STATES OF AMERICA

It would be more accurate to modify the second sentence to that it reads:

> The other is based on ~~dose response~~ risk characterization curves linking hazard levels to disease incidents ~~(risk characterizations)~~.

THIRD PARAGRAPH

UNITED STATES OF AMERICA

In the third bullet of the third paragraph the phrase, "Notably, FSOs may not be universally common and may take into account regional differences**,"** does not fit in that location and should be moved to the end of the paragraph. Furthermore, it should be modified to be consistent with the SPS Agreement.

6.2.2 Performance Objective (PO)

FIRST PARAGRAPH

UNITED STATES OF AMERICA

The 2nd bullet of the first paragraph should be modified to read "If it can be demonstrated and validated ~~(e.g. through validation)~~ that the level of the hazard will…"

The 3rd bullet of the first paragraph should be modified to read "…the PO and the FSO w~~e~~ould ~~theoretically~~ be the same.

THIRD PARAGRAPH

CANADA

Canada recommends modifying the third and fourth paragraph of this section to more clearly reflect the relationship of PO with food safety control systems and microbiological targets. In the third paragraph, Canada recommends deleting the third sentence and modifying the last sentence to incorporate the concept of margin of safety into the food safety control system, as follows:

"~~This knowledge can be the basis for considering a margin of safety in the PO/FSO level~~. *In designing their food safety control system such that* ***the PO (set by government or industry) and the FSO (set by government)*** *are met, industry will have to make provisions* ~~*in accord to*~~ ***respecting*** *their ability to consistently meet these standards in operational practice,* ***including consideration of a margin of safety****."*

IDF

In the 3rd para., reference is made to MRA, only. There is a need to address also quantitative hazard analysis and validation, as these will be the primary tools applied by industry in establishing appropriate relationships between FSOs (established on the basis of MRA) and the specific POs, as well as in establishing appropriate relationships between POs and PCs.

FOURTH PARAGRAPH

CANADA

Canada also recommends replacing the last two sentences of paragraph 4 with the following:

Countries may establish a generic PO for a food when subsequent steps in the food chain are generally uniform. Countries may also establish a microbiological requirement (e.g., a safe harbour) for application by those food businesses that are not capable of establishing a PO themselves. Where the same food is marketed in multiple countries having different levels of protection (articulated as FSOs), industry may wish to establish a microbiological requirement corresponding to the most stringent PO which ensures that the FSO within all countries may be achieved.

IDF

In the 4th para, the reference to "industry" as understood in footnote 6 is not entirely correct. Instead, "the individual food business (e.g. food manufacturer)" should be used.

6.2.3 Performance Criterion (PC)

SECOND PARAGRAPH

CANADA

In the 2nd paragraph, last sentence, we recommend adding the words "frequency and/or" to reflect the fact that both frequency and concentration may be modified by application of the control measure.

The PC can be expressed, e.g., in terms of a desired reduction (or acceptable increase) in the ***frequency and/or*** *concentration of a hazard...*

6.2.4 Microbiological Criterion (MC)

SECOND PARAGRAPH

UNITED STATES OF AMERICA

The second paragraph should be modified to read "…control of the hazard, the degree of confidence required, and the statistical methods…"

THIRD PARAGRAPH

CANADA

In the 3rd paragraph, last sentence, the example should not simply reflect on the relationship between *E. coli* levels and fecal contamination. The real issue is the presence of pathogens which may be associated with fecal contamination. The example should be modified to reflect the

relationship between the presence and extent of contamination with *E. coli* being directly related to the presence of specific pathogens, e.g., *E. coli* O157:H7 or *Salmonella* spp.

7 IMPLEMENTATION OF MRM OPTIONS

FIRST PARAGRAPH

UNITED STATES OF AMERICA

The last sentence in the first paragraph, "Codex does not implement MRM options.", is a very broad, strong statement. While Codex does not implement traditional regulatory programs, it does implement, in conjunction with it parent organizations (FAO & WHO), both the development and dissemination of commodity standards and related outreach and guidance programs. One would question with some degree of justification whether Codex Alimentarius fulfills the definition of a risk manager if it does not participate in the all four phases of risk management. While this is not a question for the working group or even CCFH, it is a question that appears to be causing some confusion.

7.2 Countries

CANADA

As included in the text in section 7.3 relating to Industry, it should be clearly indicated that part of the responsibilities of governments is to ensure that consumers are provided with appropriate information, education, etc., to understand their role in food safety. Programs might include evaluation of the performance of consumers in the delivery of their responsibilities related to MRM.

FIRST PARAGRAPH

UNITED STATES OF AMERICA

In the last sentence of the first paragraph, the phrase "and consumers" should be added. This reflects the fact that some options may be educational programs intended to the final consumer.

THIRD PARAGRAPH

UNITED STATES OF AMERICA

At the end of the first sentence in the 3rd paragraph replace "comply" with "implement". Not all options will involve compliance.

CI

First sentence, the point of view of consumers that are affected by the MRM option but do not have any duty to comply does not seem to have been taken into account. We suggest the sentence be revised as follows:

> To ensure transparency, risk managers should communicate decisions on MRM options to all interested parties, including the rationale, and how those affected will be expected to comply, WHERE APPROPRIATE

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

Remove the brackets from provisional.

CI

Since MRM is already defined as a continuous process, use of the term "provisional" should either be deleted or clarified.

SIXTH PARAGRAPH

UNITED STATES OF AMERICA

The 6th paragraph is actually describing a monitoring and review activity which is more appropriate for section 8.2. This paragraph should be moved. It is not apparent why modification of implementation plans is less important for long term activities compared to provisional plans. One could make the opposite argument that provisional plans are of short duration so the ability to modify a program is less critical.

7.4 Consumer

UNITED STATES OF AMERICA

This paragraph should be modified to read:

"Consumers can enhance both their personal and the public's health by ~~are responsible for~~ being informed of and following ~~adhering to~~ food safety-related instructions. Multiple means of providing this information to consumers should be undertaken, such as ~~This includes (e.g.~~ public education programs, safe handling labels, date labels, and public interest messages~~. prevention of cross contamination)~~ Consumer organizations can play a significant role in getting this information to consumers."

VENEZUELA

Delete "safe" and substitute "hygienic"

IDF

While the responsibilities of the countries and industry are elaborated in details, this section on consumers is very general and vague. We would welcome more specific comments, e.g. on different types of consumers, e.g. individuals or household as opposed to communities or catering activities such as in hospitals and similar. In particular for institutions, the application of GHP and HACCP like activities are needed and several of the bullets included under 7.3 would apply as well. In the case of individual consumers, the adherence to handling labels and instructions of manufacturers is essential.

8.1 Monitoring

FIRST PARAGRAPH

UNITED STATES OF AMERICA

The first paragraph of this section should be modified to read as below. The rationale of the modification is that not all improvements will lead to improved public health. A desirable improvement in the food control system could feasibly maintain the status quo in terms of public health but reduce substantially the cost of achieving that level of control.

"An essential part of the MRM process is the on-going gathering, analyzing, and interpreting of data related to the performance of food control systems, which in this context is referred to as monitoring. Monitoring is the basis on which the risk manager evaluates how well MRM options perform, and may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the

~~status of~~ extent or efficiency of risk mitigation and public health. Risk management programs should strive for continual improvement in public health."

SECOND PARAGRAPH

UNITED STATES OF AMERICA

The second paragraph should be modified to read as: "Monitoring activities related to measuring the state of public health is in most cases the responsibility of national governments. For instance, surveillance of human populations and the analysis of human health data on a national level is generally conducted by countries. International organizations such as WHO provide guidance for establishing and implementing public health monitoring programs."

THIRD PARAGRAPH

UNITED STATES OF AMERICA

The third paragraph appears to be calling for an overall surveillance program to evaluate all foods for public health concerns. While highly desirable, it would be more beneficial for the current document to provide guidance for establishing monitoring systems designed to specifically evaluate the performance for a specific risk management program. Practical guidance on how risk managers can design into their risk management programs a monitoring component is needed.

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

The 3rd bullet of the 4th paragraph should be modified as indicated below. In addition to a change in order, the final phrase was deleted since it is repeated again in the subsequent bullet.

"-laboratory-based surveillance of ~~hazards isolated from~~ humans, plants, animals, foods, and food processing environments for pertinent foodborne hazards; ~~environmental health data on practices and procedures;~~"

VENEZUELA

Delete "laboratory based" and substitute "based on laboratory tests"

SIXTH PARAGRAPH

UNITED STATES OF AMERICA

The 6th paragraph is focused on redesigning the entire surveillance systems within countries. It would be more practical to provide advice on how their current surveillance system can be utilized or modified to a small degree to monitor the effectiveness of a specific risk management program.

The United States still has concerns that the use of monitoring will be confused with the definition as employed in conjunction with HACCP.

8.2 Review of MRM options

UNITED STATES OF AMERICA

This section would benefit from practical guidance and examples of how countries and Codex design a review process into their MRM activities. Identification of "triggers" that should be employed to indicate when it is time to conduct a review would be beneficial. Who should have the ability to request a review is a pertinent question that is often debated. Should an international trading partner be able to request a review? When should Codex review its Codes of Hygienic Practices? This is particularly pertinent when there are new options for controlling the risk of concern.

Annex I.

CANADA

The explanatory text that accompanied this diagram in earlier documents is no longer present. It should be included as it helped to guide the reader through this complex diagram.

The box entitled “Selection of MRM” should be modified to “Identification and Selection of MRM options”.

An arrow should be present between “Implementation of MRM options” and “Monitoring and review of MRM options”.

UNITED STATES OF AMERICA

The current annex is 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.

IDF

As outlined in our comments to sections 5.2 and 5.3 above, the flow diagram does not fully reflect the text.

In addition, we suggest deleting the arrow between "Selection of MRM" and "No action" as the absence of action is hardly a management option. Instead, we recommend an arrow from "Evaluating the results of the MRA" to the "No Action".

It is also not clear what is meant by "Initiation of experimental work". Nothing is mentioned about experimental work, neither in the text nor in the annex 2, and we believe it should read "Initiation of the data gathering process". It would also be important to include the monitoring step and appropriate arrows indicating the need, for example, to revise management options if they are not appropriate.

Annex II.

UNITED STATES OF AMERICA

In moving this annex back to the MRM documents from the “process” document, it appears that some of its attributes as a means for introducing material into the CCFH process have been lost. The two working groups should get together (prior to the meeting if at all possible) and be sure that the current annex meets the needs of both documents.

IDF

Section 5.2 describes the risk profile as a "decision making tool", whereas the purpose section of Annex 2 describes it as an "abbreviated discussion paper". This does not seem to be consistent.

2. Description of the public health problem

VENEZUELA

Modify the title to read “Documentation and description of the public health problem”

Annex III.

GENERAL

UNITED STATES OF AMERICA

This annex is early in its development and requires further work. The United States realizes that this section is new and that a number of the concepts and procedures for being able to provide meaningful examples are still be developing by both this working group and the working group on *Listeria monocytogenes* which

provided even more detailed examples in an annex to their document. It may be beneficial in terms of accelerating both working groups for the Committee to consider transmitting a request to FAO/WHO for an expert consultation on the concepts and procedures that could be used to link these measures of stringency.

IDF

These examples could benefit from being further developed. For instance, it would be very helpful to illustrate how the mutually dependent cascade of targets and criteria can be established.

Further, it is important that the information in this Annex is consistent with the information provided in Annex II to the listeria document – and vice versa.

1. PASTEURIZED PERISHABLE PRODUCT

CANADA

As this is an example, we recommend using "may" as opposed to "will" in the first sentence or otherwise make reference to other destructive interventions rather than just heat.

FIRST BULLET

CANADA

Once again, the setting of "safe harbour" criteria should be applied to those industries unable to establish specific process criteria to meet a PC. However, there should be provisions in the food safety system to permit an industry to develop PCs and associated process criteria which differ from the "safe harbour" criteria, provided that the industry can demonstrate significant differences in handling of the product either upstream or downstream such that subsequent POs or FSOs are attained. Therefore, Canada suggests the following change:

> *"Safe harbour" criteria can be set by a manufacturer or competent authority which will consistently deliver a given PC (e.g., 6 log reduction in hazard level). Food businesses may default to the use of these criteria or they may establish specific process criteria to achieve a different PC depending on their needs.*

VENEZUELA

- We consider the term "safe harbor" ("refugio") to be confusing. Therefore, we propose taking into account the possibility of using an alternative term.

2. Raw fermented product kept at ambient temperature in which the hazard cannot grow:

CANADA

In the third sentence, while an MC establishes the analytical method and sampling plans to be applied, it is still the responsibility of either the industry or the competent authority to verify compliance. We therefore recommend a modification as follows:

> *Provided no recontamination can occur, for example, if the product is **not** sliced before sale, an MC may be established **for the product** and used to ensure compliance to the PO.*

3. Raw product kept at low temperature in which the hazard can grow:

CANADA

For clarity, we recommend rewriting as follows:

> *As growth of the hazard is possible between the sale to the consumer and the time of consumption, it is relevant to first set a PO for application at the retail level. This PO should take into account the potential for growth such that, at the time of consumption, the hazard amount in servings does not exceed the FSO. An MC could be established and used*

to ensure compliance to the PO, or a standard relevant to other measurable indicators may be established, provided a clear relationship between the level of the indicator and the relevant PO is established.

Since growth is possible between the time the product is manufactured and the time it is sold to the consumer, another PO, stricter than the one applied at the retail level, should be established. Once again, an MC for the product may be established and applied to verify compliance to this PO by the manufacturer.

Other MC should be set for raw ingredients where appropriate.