codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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COMMENTS ON THE PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT SUBMITTED BY

Argentina, United States of America, European Community, Consumers International, International Council of Grocery Manufacturers Association, International Dairy Federation

GENERAL COMMENTS

ARGENTINA

We have no comments or objections regarding this document.

UNITED STATES OF AMERICA

The United States notes that the working group on the "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management" has made substantial progress on this Step 3 document in relation to reaching consensus on multiple complex issues that have been a challenge to moving this document forward. While significant progress has been achieved, the United States feels that the document would benefit from additional discussion on several substantive issues that need to be better articulated to ensure that this guidance can be effectively used by all member nations and by the food industry and other stakeholders. Until this discussion takes place and the remaining substantive issues are resolved, the United States believes this document is not ready for advancement to Step 5.

The United States will be providing drafting suggestions to CCFH membership and the drafting group, indicating specific changes that will enhance the effectiveness and usefulness of the document. The United

States will also be offering extensive comments of an editorial nature with the goal of clarifying points captured in the document.

EUROPEAN COMMUNITY

The European Community would like to thank France and the drafting group for the work done. The document has developed in a positive direction and the Community can in general support the approach taken. However, the Community has some general as well as detailed comments at this stage.

- There are clearly some overlapping issues between this risk management document and the discussion paper on process (CX/FH 03/6) by which the CCFH undertakes its work in microbiological risk assessment/ risk management. For example, both documents deal with elements of risk profile and the role of Codex in risk management. Therefore, the scope and link of both these documents should be discussed and clarified at the CCFH meeting.
- The European Community feels that the concept of FSO is not yet fully developed and accepted, and there is still need for a profound discussion by the Committee on this important issue. Therefore, the Community recommends that the concept of FSO and its application will be discussed thoroughly at this CCFH meeting. Especially the option of setting FSOs versus performance criteria to stages of the food chain other than the time of consumption should be reflected in this discussion.

The European Commission is missing from the list of countries and organisations, which have participated in the preparation of the draft document.

CONSUMERS INTERNATIONAL

Consumers International appreciates the opportunity to comment on this draft process and commends the working group for developing such a well prepared proposal. CI supports the advancement of the document to step 5.

ICGMA

ICGMA appreciates the opportunity to comment on the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.* We commend the working group led by France on the revision of this document, which provides a framework for the management of risks arising from the occurrence of microbiological hazards in foods.

INTERNATIONAL DAIRY FEDERATION

The International Dairy Federation wishes to congratulate the drafting group for a significantly improved document.

However, there is still room for improving individual sections and some of the phrasings used.

Throughout the text FIL/IDF recommends a clear distinction be made between measures taken:

- by the regulatory authority (risk management measures or options that address public health risks according to Risk Analysis definitions)
- by the industry (control measures that address hazards according to HACCP definitions).

As for Performance Criteria, FIL/IDF recommends the following definition: *'The required effect of one or more control measures, expressed as the change in the level of hazard(s) in a food.'* unless this expression would be ambiguously close to the FSO's definition.

Throughout the text, appropriate amendments should be made to accommodate the above recommendations.

THE TERMS "MEASURES" AND "OPTIONS"

Confusion occurs with the use of the terms "measure" and "option" in association with a number of different qualifiers. Further, the contexts in which some of these terms are used also mix "hazard (management)" and "risk (management)".

The various qualifiers used throughout the document, presumably without any pattern, are:

Measure: "risk management measure", "food safety measures", "control measures", "food safety control measures", "sanitary measures", "food control measures", "risk management control measures", or just "measures".

Option: "risk management option", "management option", "control option", "risk control option", "risk management control option" or just "option".

Some of these terms are defined by other documents, e.g. "control measure" and "sanitary measure".

We recommend that the document be scrutinized with regard to the use of the above terminology according to the following principles:

Only the terms "risk management measure", "risk management option" and "control measure should be used, with the understanding that the term "sanitary measure", as defined by the SPS Agreement is an over-arching term covering everything.

Risk management measures that are the general means to prepare and implement risk management strategies and risk management options to meet objectives and goals in risk management, such as:

- Preparation for and commissioning of specific risk assessments;
- Identifying goals for risk management activities;
- Codes of Practices specifying control measures; and
- Framework legislation to mandate the implementation of HACCP systems and prerequisite programs.
- Regulations that specify labelling requirements, etc.
- Regulations that specify ALOPS, FSOs, mandatory criteria (microbiological, performance)

Risk management options that are options applied by authorities to manage risks (not hazards), such as establishing output objectives (ALOPs, FSOs, performance criteria, microbiological criteria, process criteria, labelling requirements, banning of certain foods etc.)

Control measures that are the options (measures) applied by food businesses to control the hazards (e.g. treatment to destroy pathogens, adjusting pH, adding preservatives, prerequisite programmes etc.).

1. SCOPE

INTERNATIONAL DAIRY FEDERATION

We welcome the differentiation within the document between risk management at Codex level and in the national context, respectively.

With regard to the role of this document within the Codex context, we recommend that it is stated that the Guidelines are intended to be applied in the development of future hazard and commodity specific Codex Guidelines and Codes of Practices concerning management of microbiological risks and hazards.

2. DEFINITIONS

Food Safety Objective -

CONSUMERS INTERNATIONAL

We think that the definition of "**Food Safety Objectives**" should be in square brackets, since this was a temporary compromise solution reached at the last session of CCFH.

ICGMA

ICGMA recommends removing the brackets around the word "microbiological", deleting the words "at the time of consumption", and deleting the brackets *and* the term (ALOP) at the end of the definition; so that the definition would read:

"Food Safety Objective -The maximum frequency and/or concentration of a microbiological hazard in a food that provides the appropriate level of health protection.

Example of FSO: 100 *Listeria monocytogenes* per gram of ready- to-eat food."

ICGMA believes that microbiological hazards should be specified because these principles and guidelines relate to microbiological risk management. We further believe that a food safety objective should be able to be measured practically, and this would usually not be possible at the time of consumption.

INTERNATIONAL DAIRY FEDERATION

We agree with the definition. However, there is no need for the square bracketed words. We suggest including a second example to emphasize the difference between a microbiological criterion and an FSO.

Such an example could be "10^{-12} cfu/g of *Clostridium botulinum* in sterilized canned foods"

Performance criteria

INTERNATIONAL DAIRY FEDERATION

It is important that there is clear distinction between a FSO, a performance criterion and a microbiological criterion as these are different risk management options.

A FSO is an expression of the required (absolute) outcome of all control measures applied throughout the food chain.

A microbiological criteria is an analytical expression of the (absolute) outcome in terms of hazard levels at a specified point in the food chain. These specified points could be after applying a process step or combinations of process steps and as outcome expressions at various stages along the food chain (e.g. raw materials).

The draft definition of "performance criteria" also relate to (absolute) outcome and therefore expresses the same as FSOs and microbiological criteria, depending on at which stage within the food chain it applies.

Therefore, if this risk management option is to be of any value, a performance criteria must not relate to (absolute) outcome (result of control measure(s) in terms of hazard levels) but to the relative effect of control measure(s), such as minimum reduction rates.

We note that in section 5.2.2.2 (addressing performance criteria), it is indirectly emphasized that there is a need for a new type of criteria to express the required food safety outcome at stages in the food chain earlier than consumption, e.g. raw materials. Although we agree in principle with that need, the use of "performance criteria" for this purpose is not adequate. We suggest that another term is used for the specifications relating to such products – see our comments to section 5.2.2.2.

On the basis of the above, we suggest the following definition:

*"**Performance criteria** - The required effect of one or more control measures, expressed as the change in the level of hazard(s) in a food".*

[Risk Management Policy]–

CONSUMERS INTERNATIONAL

Regarding the new definition for "**risk management policy**," we see that this is very similar to the definition of risk assessment policy, and is taken from the 2000 Kiel Consultation, *"The Interaction between Assessors and Managers of Microbiological Hazards in Food* (Section 5.4, 2nd paragraph, p. 9). In reviewing this section of the Kiel report, we note that this term is embedded in a section on risk assessment policy. It is unclear whether the 2000 Kiel consultation intended to introduce this new term, or whether the section only refers to risk assessment policy and contains a typographical error. We welcome clarification on this point. If this definition is retained, we believe it should be improved to clarify how it differs from risk assessment policy, and to be more consistent with section 5.1.3.

Risk manager :

CONSUMERS INTERNATIONAL

The definition "Risk Manager", we think that it should be clarified that Codex is the risk manager at the international level, so we suggest

"**Risk manager:** The representative of government at a national level or regional level or [DELETE: representative of] international organization at the international level (E.G., CODEX) who has the responsibility of risk management."

[Product tracing/traceability:]

EUROPEAN COMMUNITY

Traceability is not only a risk management tool linked to microbiological risks, it is in fact an important framework that needs to be in place to manage all risks associated to foodstuffs. It would therefore be more appropriate to further await the results from the other Codex Committees, especially the CCGP and the CCFICS, where the concept and definition of traceability is being developed in separate documents, instead of giving a specific definition for this term in this document.

ICGMA

ICGMA agrees with the working group that this any definition should follow the work undertaken by CCFICS and other Committees in this area. Product tracing should be limited to one step forward and one step back and implemented for purposes of health and safety.

INTERNATIONAL DAIRY FEDERATION

In our understanding, "product tracing" is the action taken to trace a specific food lot, whereas "traceability" is the ability (or system implemented) to conduct product tracing.

We would like to emphasize, that in practice, the ability of product tracing within a food business is normally limited to one step backwards (the supplier) and one step forward (the customer) within the food chain. The last phrase of the draft definitions does not seem to recognize this.

3. GENERAL PRINCIPLES

- PRINCIPLE 5: The scientific integrity of the risk assessment process should maintain the functional separation of risk management and risk assessment, while ensuring transparent and appropriate interaction between them.

CONSUMERS INTERNATIONAL

The scientific integrity of the risk assessment process REQUIRES [DELETE: should maintain] the functional separation of risk management and risk assessment [DELETE: while ensuring] AND transparent and appropriate interaction between them.

- [PRINCIPLE 7: In the case where scientific knowledge of the risk is insufficient, it may be appropriate for risk managers to apply a precautionary approach, through interim measures].

EUROPEAN COMMUNITY

The following words should be added in the end of the sentence in order to make it fully in line with the precautionary principle: “pending further scientific information.” In general the European Community feels that it is very important that the use of the precautionary principle is included in this document.

COMSUMERS INTERNATIONAL

Regarding principle 7, the Commission has already decided that in cases where scientific data are insufficient that Codex will not establish standards but that it might establish codes of practice or related texts. These are not interim measures. Interim measures are taken primarily at the national level. Thus we think that PRINCIPLE 7 should be edited as follows:

[PRINCIPLE 7: In the case where scientific knowledge of the risk is insufficient, it may be appropriate for risk managers to apply a precautionary approach. {DELETE COMMA AND MAKE THIS THE END OF THE SENTENCE, THEN ADD:] THIS MAY BE ACCOMPLISHED AT THE NATIONAL LEVEL through interim measures].

ICGMA

ICGMA believes that Principle 7, which is bracketed, [PRINCIPLE 7: In the case where scientific knowledge of the risk is insufficient, it may be appropriate for risk managers to apply a precautionary approach, through interim measures.], should be removed. We believe that Principle 6, which states "Risk managers should take into account the uncertainty of the risk estimate when making risk management decisions." addresses uncertainty in microbiological risk management.

Further, with respect to the use of precaution, ICGMA notes that the 24th Session of the Commission, July 2001, adopted the position, in regards to the consideration of precaution, that "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."

4. INVOLVEMENT OF STAKEHOLDERS

CONSUMERS INTERNATIONAL

We would like to suggest removing the square brackets in the last paragraph in section **4. INVOLVMENT OF STAKEHOLDERS**. We strongly support this section, and the sentence is already qualified by saying "as appropriate" and should not be qualified or weakened any further.

5. GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

EUROPEAN COMMUNITY

Certain relevant steps are missing from the list of general steps in the microbiological risk management. For example “Preparation of risk profile” as well as “assessment and selection of risk management options” should be added on the list in order to keep it in line with the other parts of the document.

CONSUMERS INTERNATIONAL

Our remaining comments relate to an overall tendency for the document to characterize risk management too narrowly, and also include a suggestion for reorganizing the document. For example, the new language in the introduction to section 5 seems to be overly focused on a quantitative approach, and to have a limited view of risk management as something you do to control one pathogen at a time, when actually the risk management approach or action may impact the risk from multiple pathogens, and/or may be qualitative. In the previous version the steps were what was laid out in the subsequent sections. Thus we recommend deleting the existing bullet points and replacing them with the titles of the sections, slightly edited, as indicated below. Then the steps listed are consistent with the rest of the document.

Furthermore, risk management is characterized as having 4 steps:

- preliminary risk management activities
- risk management option assessment
- implementation of risk management
- monitoring and review

ALL of this is risk management. But currently the document has only the first 2 steps in section 5, “Guidelines for the Conduct of Microbiological Risk Management,” and then a separate section for each of the last 2 steps (sections 6 and 7). We think that either each step should be a separate section, or each step should be a subsection of section 5. We understand that the last two steps (sections 6 and 7) are primarily done at the national level. We would like to propose following rearrangement:

5. GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

5.1 PRELIMINARY RISK MANAGEMENT ACTIVITIES

5.1.1 Identification of risk managers

5.1.2 Identification of a microbiological food safety issue

5.1.3 ESTABLISHING Microbiological Risk Management Policy

5.1.4 DEVELOPING THE Microbiological risk profile

5.1.5 Defining goals

5.1.6 CONSIDERATION OF Microbiological risk assessment

5.1.6.1 ESTABLISHING Microbiological risk assessment policy

5.1.6.2 Commissioning of microbiological risk assessment

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

5.1.8 CONSIDERING Regional ASPECTS [DELETE: considerations]

5.2 ASSESSMENTOF RISK MANAGEMENT OPTIONS

5.2.1 Determining the appropriate level of protection (ALOP)

5.2.2 Identification of available options

5.2.2.1 Role of FSO

5.2.2.2 ROLE OF Performance criteria

5.2.2.3 ROLE OF Microbiological criteria

5.2.2.3 ROLE OF Other factors

5.2.3 Selection of preferred microbiological risk management options

5.2.4 Final management decision

5.3. [DELETE: GUIDELINES FOR] IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

5.3.1 IMPLEMENTATION OF STANDARDS, GUIDELINES AND RELATED TEXTS

5.3.2 IMPLEMENTATION OF FSOS AND PERFORMANCE CRITERIA

5.3.2.1 FSO

5.3.2.3 Performance criteria

5.3.3 ROLE OF PRODUCT TRACING/TRACEABILITY

5.4. MONITORING AND REVIEW

5.4.1 MONITORING

5.4.2 REVIEW

INTERNATIONAL DAIRY FEDERATION

3rd and 4th indents ("Establish the ALOP/a FSO ...")

An ALOP or a FSO does not necessarily have to be established for a specific commodity but can be established for food in general.

One of the problems involved in mandating that these have to relate to specific commodities is that the understandings of which foods belong to which categories differ from country to country/region to region.

Examples:

- Would a FSO applicable to milk powder also apply to skim milk powder with vegetable fat?
- Would a FSO for meat products apply to processed cheese with 20% ham?
- Would a FSO for sprouts also apply to mixed ready-to-eat salads?

We suggest that the opportunity is given to specify ALOPs and FSOs for pathogens in food in general, leaving it to the individual food business to identify whether control of that pathogen is relevant (through the hazard identifications step of the hazard analysis).

6th indent ("As appropriate, decide upon....")

We refer to our comments to CX/FH 03/11 (Draft Proposed Guidelines for the Validation of Control Measures) in which we state that it is important that the responsibility for using validated control measure (combinations) is of the individual food business, which implies that it is also the responsibility of the food business to ensure that validations will be carried out where such validations are not available. Control measure validations can be carried out both within and outside the auspices of that food business.

To achieve this objective, the phrase "decide upon and/or" should be deleted.

Last paragraph ("Risk communication.....")

We suggest to state that the food business HACCP teams are primary target groups for risk communication to enable the teams to promptly address new risk issues into their hazard management programmes (HACCP and prerequisites).

5.1.2 Identification of a microbiological food safety issue

ICGMA

ICGMA agrees with the proposition of the *USA* that "a key step in microbiological risk management is determining the available resources (human, fmancial, time) for addressing the food safety issue." A management plan will be implemented more effectively when appropriate resources have been incorporated into the plan.

5.1.4 Microbiological risk profile

INTERNATIONAL DAIRY FEDERATION

In the 3rd para. ("Preparing the profile...."), it would be advisable to include which body (CCFH?) has the responsibility to conclude the risk profile. The current text only states that the role of the CCFH is to discuss the draft prepared by individuals.

More generally, it is hard to see a difference between the microbiological risk profile as described here, and qualitative risk assessment.

5.1.2 Identification of a microbiological food safety issue

CONSUMERS INTERNATIONAL

Regarding section **5.2.1. "Identification of a microbiological food safety issues"**, we believe that food safety issues can be formulated in many ways: broadly or specifically, affecting one commodity or many commodities, involving one pathogen or multiple pathogens, involving an emerging problem or an endemic problem. The issue may come to the attention of the risk manager from a variety of sources e.g. disease surveillance, enquiry from a trading partner, consumer concerns, industry information. This view is consistent with the 2002 Kiel Consultation. The risk manager needs to decide whether to pursue the issue or not. In CCFH, the issue may be raised by a Member government or Observer organization, or through referral by another Codex committee or the Commission. The CCFH may request a Member country or group of countries to prepare a draft risk profile on a particular issue, which would then be considered as a potential topic of future work by the Committee. Along those lines, we would like to suggest editing the existing text in the first two paragraphs as follows:

"5.1.2 Identification of a microbiological food safety issue

A food safety issue CAN BE FORMULATED IN MANY WAYS: BROADLY OR SPECIFICALLY, AFFECTING ONE OR MANY COMMODITIES, OR INVOLVING ONE OR MULTIPLE PATHOGENS. [DELETE: is a situation where a public health hazard associated with a food (e.g., a pathogenic microorganism) creates a risk that needs to be managed.] A specific food safety problem should be clearly identified and communicated. A food safety problem may already be well recognized and or may be a new or latent problem. FOOD SAFETY ISSUES INCLUDE:

- SETTING PRIORITIES AMONGST DIFFERENT PUBLIC HEALTH PROBLEMS OR CONDUCTING A RISK RANKING;
- ADDRESSING A SPECIFIC PUBLIC HEALTH FOOD SAFETY PROBLEM
- JUSTIFYING OR EVALUATING A NEW OR ALTERNATIVE MEASURE, TECHNOLOGY, OR INSPECTION SYSTEM;
- MAKING AN EQUIVALENCY DETERMINATION.

Food safety issue identification may be performed by a single stakeholder (e.g. the public authority) or be a result of collaboration between different stakeholders. IN CCFH, THE ISSUE MAY BE RAISED BY A MEMBER GOVERNMENT OR OBSERVER ORGANIZATION OR THROUGH REFERRAL BY ANOTHER CODEX COMMITTEE OF THE COMMISSION."

5.1.5 Defining goals

CONSUMERS INTERNATIONAL

We have a comment on the section 5.1.5. **"Defining goals"**, third paragraph.

According to the approach taken in the 2002 Kiel consultation we think that the sentence, "For countries, the goal is in particular to develop preferred risk management measures to control a specific hazard(s) in a specific commodity(s)", is formulated too narrowly. Countries may have different goals which all relate to reducing risks. We think that sentence should be deleted, and the paragraph revised to read:

"For countries, THE GOAL CONCERNS REDUCTION OF RISKS. Goals may be directed by statute, policy or regulatory considerations. Goals may also be influenced by economic factors and the consumer's perception of the microbiological risk."

5.1.6.2 Commissioning of microbiological risk assessment

CONSUMERS INTERNATIONAL

In section 5.1.6.2, consistent with the 2002 Kiel Consultation, we suggest that the following be added:

Information that should be documented in the commissioning of a microbiological risk assessment includes:

- Description of the specific risk management issue;
- Scope and purpose of the mRA;
- The mRA question(s);
- The risk profile;
- The type of mRA to be conducted, expertise needed, and resources allocated;
- How the outputs of the mRA will be used by risk managers;
- Timelines, including those for milestone reporting, manager-assessor meetings, stakeholder fora, completion targets;
- Criteria to validate the risk model and outcomes, and assess "reasonableness";
- Criteria to determine scientific and technical adequacy of the mRA;
- Analysis of any future data needs.

5.2.1 Determining the appropriate level of protection (ALOP)

EUROPEAN COMMUNITY

The European Community has doubts about the statement that ALOP should be scientifically justifiable. In our understanding the SPS agreement does not require this, the agreement requires only that the sanitary measures taken to achieve the ALOP have scientific justification. In our opinion the setting of the ALOP is a policy decision, and the countries have the full right to set it at a level, which they consider most appropriate to their circumstances. Therefore the words "scientifically justifiable and" should be deleted from the second sentence in 4. paragraph.

CONSUMERS INTERNATIONAL

Section **5.2.1. Determining the ALOP** seems to cover most of the important issues, but there is repetition of the sentence "The ALOP/ALR applies equally to both domestic and imported food." in the second and at the beginning of the fourth paragraph. We think it should be in one place, e.g. the fourth paragraph should be the last sentence of the second paragraph.

ICGMA

ICGMA believes that sanitary measures used to establish an ALOP should be based on scientific criteria. To this end we support the removal of brackets from the words "scientifically justifiable and" in the third para in this section, so that the para reads:

"The ALOP/ALR applies equally to both domestic and imported food. The ALOP/ALR should be scientifically justifiable and clearly conveyed to the exporting country."

The seventh para in this section contains examples of other factors that may be involved in determination of ALOP. ICGMA believes that the inclusion of the fifth bullet point (public risk reduction preferences, public values) in the list of examples is problematic because these factors could serve as trade barriers. This example should also be removed from 5.2.2.3, Other factors. If these factors are considered in establishing a country's ALOP, they should be based on objective criteria and should not be used as trade barriers.

INTERNATIONAL DAIRY FEDERATION

5th para. ("Determining the ...."):

The text states that ALOPs are determined for particular hazard(s) in particular commodity(s). This makes ALOPs equal to FSOs and microbiological criteria which can hardly be the intention.

We suggest that "a particular hazard(s) in a specific commodity(ies)" is replaced with "a particular risk(s) associated with a specific hazard(s) or with a specific hazard(s)/commodity(s) combination."

5.2.2 Identification of available options

EUROPEAN COMMUNITY

The European Community wants to endorse in this context the possibility for the countries to use the precautionary principle when the scientific information available is insufficient and incomplete.

ICGMA

ICGMA supports deleting the last sentence, which is bracketed, from this section.

5.2.2.1 Role of FSO

INTERNATIONAL DAIRY FEDERATION

In general, we have great faith in the future role of the FSO-concept as a key instrument to ensure food safety and effective risk communication in supplementing more traditional instruments such as microbiological criteria, GHP codes, HACCP-guidelines, etc.

Focus in food safety regulation need to shift entirely from thinking in terms of prescribing control measures for hazard control (mandating specific treatments and prerequisite programmes) towards thinking in terms of proper design, implementation and maintenance of plant specific food safety control systems governed by assessments of hazards and control measure performances.

International and local regulations that address food safety aspects play a major role in achieving this. In particular, these should provide (i) clear FSOs that can be applied as references for the practical design of individual food safety control systems throughout the food chain and (ii) principles and guidelines for ensuring the effective combination of control measures specific to the individual plant/commodity combination.

With regard to the current text in section 5.2.2.1, we have the following observations and comments:

2nd para. ("A FSO is based...."):

In foot note no. 9, it is stated that it seems very important to complement this document by rating the different microbiological pathogens.

We wonder whether this is important due to the availability of a vast amount of scientific litterature and anticipated difficulties in comparing the severity of different hazard/commodity combinations in different regions of the world.

Further, a rating could lead to, for instance, that a highly severe microbiological hazard currently under full control could receive a lower rating than a less severe hazard not under control.

3rd para. ("FSOs are seldom....)

The second sentence states that FSOs need to be translated by the competent authority to performance, process and microbiological criteria further up the food chain.

It will not be effective, nor practical, if it is the intention that competent authorities take on this responsibility. Adequate translation into up-stream requirements and criteria requires specific and detailed knowledge of all individual production, processing, and distribution steps involved. These differ substantially according to:

- commodity type (including nature and quality of raw materials and ingredients);
- specific food characteristics (including specific intrinsic factors);
- specific control measure combination (including nature, intensity and validity of processing steps and prerequisite programmes);
- specific individual plant (including nature intensity and validity of monitoring systems, verification systems, and validation systems);
- specific distribution systems (including shelf life, destinations, and means of storage and transports)
- intended end use (further processing, retail, catering, specific consumer groups)

Within each of the above key parameters, thousands of scenarios need be taken into account, which can hardly be done without, on the one hand, enforcing over-kill measures and, on the other hand, making unintended omissions/gaps in the risk management.

The role of the competent authority should be to establish the objectives and to audit that the design, operation and verification of the individual control system is adequate and sufficient to meet the objectives ("system auditors" rather than "process prescribers and product auditors").

Further, the statement in the 3rd para. does not comply with the subsequent sentence referring to HACCP plans nor the content of the 1st indent in the 5th para. ("In countries FSOs can be used:")

In conclusion, we suggest that "competent authority" be replaced with "the individual food business".

6th para. ("FSOs implemented by ....."):

We consider that it is possible to establish international FSOs for some hazards (e.g. for *Listeria monocytogenes* in ready-to-eat foods), while recognizing that local conditions may provide the rationale for applying other FSOs according to specific ALOPs.

This would be similar to the establishment of Codex maximum residue levels (MRLs) and maximum levels (MLs).

The possibility for establishing Codex FSOs is also stated at the end of section 6.1 of CX/FH 02/7.

5.2.2.2 Performance criteria

INTERNATIONAL DAIRY FEDERATION

It is indirectly emphasized in this section´s text that there is a need for a new type of criteria to express the required food safety outcome at stages in the food chain earlier than consumption, e.g. raw materials.

Although we agree in principle with that need, the use of "performance criteria" for this purpose is not adequate. We refer to our comments to the definition of this term.

Within the food industry, the term "acceptance criteria" are often used to express the required level of food safety of the raw materials and ingredients supplied to the food manufacturing plant. It should be noted that when governments establish standards for raw materials they take a direct responsibility for the food safety since food manufacturers typically have difficulties in not accepting complying products although higher standards may be needed for certain foods (e.g. infant foods).

It should be noted that the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997) provides for the use of microbiological criteria for the verification of the control measures applied in primary production.

We see now need to develop a new type of criteria for that purpose.

In conclusion, we recommend:

- that section 5.2.2.2 is redrafted to address the use of performance criteria as a expression of the needed/required effect of one or more control measures, expressed as the change in the level of hazard(s) in a food"; and

- that the issue of raw materials is addressed in section 5.2.2.3 on microbiological criteria.

Section 5.2.2.3 – Microbiological criteria

INTERNATIONAL DAIRY FEDERATION

In order to be consistent with the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997), and with reference to our general comment on terms, replace the last phrasing of the 1st para., i.e. from "...as food safety measures using...approaches", with the following

"...to design and validate control systems (control measure combinations), to verify compliance with such systems, and to determine the acceptability of a food lot of unknown origin or history".

5.2.3 Selection of preferred microbiological risk management options

CONSUMERS INTERNATIONAL

We would like to comment on the penultimate paragraph of 5.2.3, it seems there are some commas missing that obscure the meaning. We suggest it should read, "These elements could 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 COMMA, cost effectiveness of alternative approaches to limiting risk COMMA, consumers information, environmental impact and public values."

5.2.4 Final management decision

CONSUMERS INTERNATIONAL

The following comments are on section **5.2.4. "Final Management decision",** bullet 5. We believe that it would be better to add the word 'consumer':

- "be based on the best available scientific, technical, CONSUMER and economic information

And the last paragraph in the same section, second sentence:

"When such knowledge is insufficient OR INCOMPLETE, more stringent control measures should be selected"

INTERNATIONAL DAIRY FEDERATION

Include additional option:

In addition to the options provided, we suggest a new indent as follows:

"• give priority to hazard control in the segments of the food chains where the hazard occur (source directed measures)."

For national purposes:

ICGMA

ICGMA does not believe that the subsection, "For National Purposes", should be included in the document. Risk management advice at the national level is outside of the scope of this Committee. As it is being addressed by the Committee on General Principles in its risk analysis document. We therefore suggest removal of this subsection.

6.2.1 FSO

INTERNATIONAL DAIRY FEDERATION

4th para. ("Ensuring the correct...."): The text should refer to the auditing role of the competent authority.

6.3 ROLE OF PRODUCT TRACING/TRACEABILITY:

ICGMA

ICGMA supports the role of product tracing to facilitate the rapid withdrawal of unsafe food products and food ingredients from the market place when there is a public health threat, and supports its incorporation into microbiological risk management programs, specifically as a component of food recall systems.

7.1 MONITORING

ICGMA

ICGMA agrees that monitoring is used to provide information on risks to human health from specific hazards and/or foods, and that surveillance of human populations includes investigation of food-borne disease outbreaks and product tracing to the source of the likely causal pathogen.

ANNEX 2

Figure: Decision chart for [preliminary] risk management activities in relation to an overall framework for managing food-borne risks to human health; taken from Kiel expert consultation of April 2002)

EUROPEAN COMMUNITY

In this figure "the risk management options assessment" and "the setting an ALOP" are only presented as steps following "the conduct of microbiological risk assessment (MRA)". However, risk management

options assessment and setting of ALOP can take place without a prior MRA. It is always possible, and even desirable, to assess different management options available before taking the final risk management decision. Similarly it is useful to formulate at least an implicit ALOP before taking the management decision. Therefore the figure needs to be modified.