

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6

**CX/FH 00/6 - Add.1
September 2000**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-third Session

Washington, D.C., USA, 23 – 28 October 2000

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

In response to CX/FH 00/5, the following Governments and International Organisations submitted comments: Mexico, New Zealand, Poland, the United States of America, Commission of the European Communities (EC), and Consumers International.

General Comments

Mexico

As the document indicates, the technical administrative handling of risks should be preceded by a complete process of evaluation of risks in their different components. To attain this, it is essential to have ample and reliable information about the presence of pathogenic microorganisms in foods from their collection through their processing, in the environment, as well as information about the participation of each pathogen as a cause of illness through the consumption of food and the epidemiology of these ailments. Great vacuums of such information exist in developing countries, which may or may not participate in the international food trade. In this case, specialists will need to prepare themselves and experts will need to be developed to carry out a careful identification of each problem and develop a diagnostic profile for the risk based on the components that are identified within it.

A similar situation is presented in section 5.1.8, which says that the acceptable risk level should be identified. It is not known, for example, in what terms the maximum infectious dose (for the general population) of enterotoxogenic *Escherichia coli* differs from that which the population in industrialized countries exhibits, and how frequently Salmonellosis, Shigellosis and Campylobacteriosis are linked to food consumption.

The answer is fundamental to designing preventive measures for foodborne bacterial illnesses.

In virtue of the above, perhaps it would be necessary to develop a guidance document for said economies, considering the aforementioned deficiencies.

New Zealand

New Zealand strongly supports the work of France and the other members of the Working Group in continuing the development of CX/FH 00/6.

A considerable amount of the material currently presented in CX/FH 00/6 is generic in nature, and would more logically be presented in the work being undertaken by the CCGP on working principles for risk analysis, for use throughout the Codex system. As the document on microbiological risk management progresses through the step procedure, every opportunity should be taken to devolve generic principles and practices for risk management to the horizontal Codex guideline, and focus CX/FH 00/6 on particular application in the case of microbiological hazards in food.

Where references are made to public risk preferences, public values etc., a clear distinction should be made between risk management decision-making at the international level (Codex) compared with that at the national level. For foods in international trade, generic consideration of such factors should be debated and resolved by the CCGP rather than the CCFH.

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*. The document more clearly sets out the appropriate principles, processes and steps of microbiological risk management.

The United States believes there remain certain key areas of the document that require further attention. The United States encourages France, along with its drafting partners to further consider and elaborate the areas of FSOs and the TLR. A meeting of the Drafting Group to consider these subjects in-depth would seem appropriate. Additionally, the United States encourages careful consideration of the appropriate means to handle precaution and OLFs within the document.

European Communities

The European Community welcomes the document developed by the working group. It shows that the group has considered a variety of problems related to risk management, which are also discussed in the European Community. Most of the comments expressed by member countries and other participants have been taken into account. The CCFH has always been a committee that has been the helm of discussions concerning risk analysis related subjects. The European Community agrees that these principles and guidelines on microbiological risk management should be considered and interpreted in the light of current deliberations on risk analysis in other Codex Alimentarius Committees and in particular the Committee on General Principles (CCGP) which has been instructed to draw up "Working Principles for Risk Analysis".

Consumers International

Consumers International commends France for the preparation of this excellent document, CX/FH 00/6, Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management. We believe that the document has made considerable progress and is extremely valuable, and should be advanced to step 5.

INTRODUCTION

Mexico

In the first paragraph of the introduction change “La mundialización incrementada del comercio” //”the increased globalization of trade”// to “El incremento de la globalización del mercado de alimentos ...” //”The rise in globalization of the food market”//. In the last paragraph, next to last sentence after the phrase “risks that work in the industry,” add the phrase “y para otras partes interesadas” //“and for other interested parties”//.

New Zealand

Reference to “different elements of risk management” may be better expressed as “different components of risk management”, as elements have not been specifically defined.

2. DEFINITIONS

Mexico

We suggest that the definitions be listed in alphabetical order, with the following changes:

Microbiological Food Safety Objective: We suggest changing “riesgo en un alimento” //”risk in a food”// to “peligro microbiológico en un alimento” //”microbiological risk in a food”//.

Microbiological Risk: The probability of an adverse effect on health from the presence in foods of bacteria, viruses, yeasts, molds and algae, parasites, protozoa and helminthes, and their toxins or metabolites.

It is not necessary to indicate that the definition is for the purposes of the present document, since this was already stated at the beginning of the section.

Risk: We suggest changing “riesgo” //”risk”// to “peligro” //”hazard”//.

Risk Assessment: We suggest changing “evaluación de contacto” //”contact assessment”// to “evaluación de la exposición” //”exposure assessment”//.

Risk Characterization: We suggest the following text “El proceso de estimación cualitativa y/o cuantitativa, de la probabilidad de la incidencia y gravedad de efecto adversos en la salud en una población dada... , y evaluación de la exposición” //”The process of qualitative and/or quantitative estimation of the probability of occurrence and severity of adverse health effects on a given population... and exposure assessment”//.

Risk Communication: We suggest changing “evaluadores” //”evaluators”// to “especialistas en la evaluación del riesgo” //”specialists in risk evaluation”//.

New Zealand

Inclusion of risks due to helminths under the definition of microbiological risk is problematic, as some helminth hazards are grossly visible e.g. cysts of *Taenia saginata*.

European Communities

The definition of microbiological risk should be changed in order to acknowledge that biological and chemical agents have already been defined as hazards:

“A risk that is related to the presence of a microbiological hazard (such as bacteria, viruses, yeasts, moulds and algae, parasitic protozoa and helminths). This includes the chemical hazards they may produce (toxins and metabolites).”

3. GENERAL PRINCIPLES

Mexico

In the header (first paragraph in the Spanish version) for point 3, General Principles, we suggest eliminating “la aplicación de”.

Principle 5, “hacer” //”make”// to “tomar” //make/take”//.

Principle 8, “dirigirse al continuo total” //”address the whole continuum”// to “considerarse íntegramente desde la producción primaria hasta el consumidor” //”consider as a whole, from primary production to the consumer”//.

Principle 10 we suggest the following text: “Las decisiones de gestión de riesgos deberían ser revisadas mediante la información disponible” //”The risk management decisions should be reviewed based on the available information”//. And the rest of the definition starting with “Tal información...” //”Such information...”// should be eliminated, as it does not appear in the English version.

New Zealand

Principle 2 specifically refers to communication with consumers, yet effective risk communication must be inclusive of all stakeholders (interested parties) without a notion of priority. Further, it may not be appropriate or necessary to include all stakeholder groups in all “aspects” of the risk management process as currently stated (also refer to Section 4, paragraph 4). The principle could be rewritten as: “Risk management should include clear, iterative communication between interested parties during all aspects of the process, as appropriate”.

Although ideal, risk assessment policy cannot always be fully determined in advance of risk assessment. Recent experience with microbiological risk assessment has shown that interactions between risk managers and risk assessors often occur in an on-going, iterative manner as risk assessments evolve and progress. Therefore Principle 4 should be restated in a less prescriptive manner e.g. “clear determination of risk assessment policy, preferably before risk assessment commences”.

Principle 6 (in brackets) refers to adoption of risk management decisions “on an interim basis” as a reflection of a precautionary approach. However, all risk management decisions are subject to ongoing review, and in effect are always adopted on an interim basis.

Principle 7 refers to a specific step in the risk management process (risk management option assessment [5.2.1]). However, the current set of principles do not address application of other specific steps in the risk management process; i.e. Initial risk management activities [5.1], (referred to in the 1997 FAO/WHO Expert Consultation on Risk Management and Food Safety as “Risk evaluation”), Implementation [6], and

Monitoring and Review” [7]. There should be balanced representation of all these steps in the general principles.

The usefulness of Principle 8 is unclear. The scope and purpose of a microbiological risk management process will be different for different food safety issues, as will be the risk assessment process that provides the necessary data. If risk management is aimed at identifying and implementing optimal sanitary measures at any point(s) in the farm to table continuum where they will be most effective in mitigating risk, then risk management will need to “address the whole farm to table continuum”. However, applying a framework to manage risks throughout the whole farm to table continuum is a very resource-intensive task that will not always be possible. There are other situations where the purpose of the risk management process may obviate the need to address the whole farm to table continuum e.g. achieving specific food safety goals such as identifying equivalent sanitary measures for food in international trade, and establishing broad food safety policy by prioritising different food-borne risks to human health.

To properly address the scope and purpose of a range of microbiological risk management activities, Principle 8 could be rewritten as: “The scope and purpose of the risk management process should be clearly established, and should address the whole farm to table continuum or address specific sectors of that continuum as appropriate to the particular food safety issue under consideration”.

Principle 9 states that sanitary measures that are implemented should be proportionate to the risks identified”. However the generic application of this principle is unclear. “Proportionate” in what way? Without qualification, this principle exists in something of a vacuum and does not recognise that a number of factors operate in quite different ways when selecting risk management options.

In respect of principles 10 and 11, risk management decisions may need to be reviewed for a range of reasons e.g. changing societal expectations in terms of the appropriate level of protection, technological advances in sanitary measures, or epidemiological evidence that current sanitary measures are not effective in achieving the required level of protection. Principle 10 refers to review only in the context of “new information”, and principle 11 only refers to review of the “efficacy” of risk management measures. Further, the principles do not include reference to monitoring as an essential part of effective management of microbiological risks (see Section 7).

A new principle should be introduced to cover monitoring, and could be written as: “Monitoring and surveillance data should be gathered from appropriate parts of the farm to consumer continuum on an on-going basis so as to ensure effective management of food-borne microbiological risks”.

Principle 10 could be rewritten as “Risk management decisions should be considered as always open to review, and this should be undertaken on an on-going basis as appropriate to the circumstances”.

4. INVOLVEMENT OF STAKEHOLDERS

New Zealand

In the fourth paragraph, stakeholder involvement is described in terms of a “food safety problem”. However, microbiological risk management can have a variety of applications e.g. identification of a specific food safety problem, a need to develop a food safety standard, development of a food safety policy that achieves broad food safety goals, or development of sanitary measures that are necessary to achieve specified food safety goals such as the equivalence of a sanitary measure.

This paragraph would be better presented if it described the “nature, extent and complexity” of stakeholder involvement as being dependent on the nature and context of the particular food safety issue being addressed.

5. GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

New Zealand

“depending on the problem considered” should be replaced with “depending on the food safety issue considered”.

5.1.1 Identification of risk managers

New Zealand

There is repetition of material from earlier sections in 5.1.1, and this also goes beyond “identification of risk managers”. The final paragraph should be linked to the second paragraph.

5.1.2 Identification of a problem

New Zealand

Section 5.1.2 should be headed “Identification of food safety issue”, with consequential changes throughout the rest of the document to cover the different applications of microbiological risk management (as identified above).

Consumers International

The last paragraph in section 5.1.2. states that a formal risk management procedure as described in the document is not necessary to manage food hygiene problems which can be dealt with on a routine basis or managed directly by applying the “Recommended International Code of Practice – General Principles of Food Hygiene” or hygiene codes for specific foods. We find this wording somewhat confusing, particularly the phrase “formal risk management procedure”. Is this paragraph implying that the advice contained in the General Principles document and the hygiene codes are not risk management measures, or are “informal” risk management procedures? This paragraph should either be deleted, or edited to simply refer to these documents in managing food hygiene problems.

5.1.3 Risk profile

Mexico

In point 5.1.3 after the first paragraph, we suggest changing “problema microbiológico” //”microbiological problem”// to “riesgo microbiológico” //”microbiological risk”//.

- In the third bullet, we suggest the following text: “considerar... sobre la prevalencia y la concentración de los peligros microbiológicos en toda la cadena...” //”consider... the prevalence and concentration of microbiological hazards throughout the chain...”//.

European Community

The European Community recommends that the items referred to in the risk profile are classified into those that are likely to be further studied by risk assessors or those that are issues that risk managers should further consider themselves in close collaboration with interested parties. To this end the list in the paragraph might be divided into two groups as follows: 1) items that should later be addressed by risk assessors and 2) items that should be addressed by risk managers.

5.1.4 Defining goals

European Community

According to the opinion of the European Community the 5th paragraph should be deleted since the identification of risk managers has been dealt with under 5.1.1 and is not a goal of risk management.

5.1.5 Scope, range and risk assessment policy

Mexico

We suggest changing in the title of point 5.1.5 the phrase: “ámbito, extensión y política de gestión...” //”scope, range and {risk} management policy”// to “ámbito de aplicación de la gestión...” //”Scope of application of {risk} management”// and in the last paragraph we suggest changing the phrase “dirigirse a las cuestiones” //address the questions of”// to “llevarse a cabo bajo condiciones de consistencia, transparencia y racionalidad...” //”be carried out under conditions of consistence, transparency and reasonableness”// and eliminate the phrase “además de las cuestiones de claridad, consistencia y racionalidad en los productos de la evaluación de riesgos” //”as well as questions of clarity, consistency and reasonableness in the risk assessment products”//.

New Zealand

Section 5.1.5 is titled “Scope, range and risk assessment policy” but only addresses the latter. (Purpose and scope are again mentioned in 5.1.6). It is unclear what is meant by some of the supporting narrative describing risk assessment policy.

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

Mexico

In point 5.1.7 and particularly in bullet three, we suggest the following text: "Los estimados pueden ser un amplio intervalo de riesgos estimados, basados en diferentes datos y suposiciones, así como la evaluación científica en lugar de la presentación de un solo estimado. Las conclusiones deberían acompañar a la caracterización de riesgos y ser totalmente comunicados y/o explicados a los usuarios" //”Estimates may be a range of risk estimates based on different data and assumptions as judged by scientists rather than the presentation of a single risk estimate. Narratives should accompany risk characterizations and be fully communicated and/or explained to users”//.

New Zealand

Section 5.1.7 states that “All risk characterisations should explicitly address sources of variability and sources of uncertainties”. However, variability itself is often a major source of uncertainty.

5.1.8 Identifying the tolerable level of risk (TLR)

New Zealand

The placement of Section 5.1.8 under the general section on “Initial risk management activities” is different to that in the sequence of steps identified in the 1997 FAO/WHO Expert Consultation on Risk Management and Food Safety where it is part of “Risk management option assessment”. In most microbiological risk management situations, it will not be possible to predetermine the tolerable level of risk because all the factors listed in this section have yet to be considered in a systematic way. When considered under “Risk management option assessment”, they may have considerable impact on desired levels of protection. (The narrative in fact accepts this in the opening paragraph).

The second paragraph in 5.1.8 should be deleted. It implies that there will be a predetermined decision on tolerable level of risk, and control measures will flow from this. However, the tolerable level of risk that is agreed on during risk management option assessment will often be arrived at by some “balancing” process between public health goals and costs/technical feasibility of controls etc. (see final paragraph in 5.2.3).

The intent of the sixth bullet point in Section 5.1.8 for foods in international trade should be resolved generically at the level of the CAC.

United States of America

Tolerable Level of Risk: As with FSOs, the Tolerable Level of Risk (TLR) can be a useful concept in microbiological risk management. Again, as with FSOs, more development of the TLR concept is needed in this document, particularly with respect to the relationship between the TLR and the Appropriate Level of Protection.

Last bullet, [Other factors when appropriate]: The United States again notes that care is needed in this document in dealing with entities that can be included in the area of “Other Legitimate Factors”. As with the subject of precaution, the area of OLFs remains under discussion within the CCGP and the United States believes that it is inappropriate to finalize such OLFs in this paper until the CCGP has completed its discussion on the subject.

Consumers International

Regarding section 5.1.8, “Identifying the tolerable level of risk”, we believe that the first sentence of section 5.1.8, should not contain the word “should”. It is not necessary to identify a tolerable level of risk in situations where risks can easily be prevented.

We also believe that the square brackets around “public values” should be removed, in the third paragraph. It is appropriate in risk management to consider public values in determining a tolerable level of risk, and the term “public risk reduction preferences” alone is not sufficient. For example (and keeping in mind that this document is intended for both application in Codex and to provide advice to public authorities), public values regarding consumption of raw milk cheese differ in different countries, and the values in a given country may enter into the determination of a tolerable level of risk for that country. Those values include not just risk reduction preferences but also values having to do with cultural norms/traditions, values pertaining to rural agriculture, etc. Also, we believe that the square brackets around “other factors when appropriate” can be removed, since this is consistent with decisions already taken by the Commission.

5.2.1 Identification of Available options

Mexico

At the end of the last paragraph in point 5.2.1 we suggest changing the word “intermedias” //”intermediate”// to “provisionales” //”provisional”//.

New Zealand

The final paragraph in 5.2.1 should not include reference to precautionary “principle”, as no precautionary principle has been defined. Broader reference to precautionary “approach” is not problematic.

5.2.1.1 MICROBIOLOGICAL FOOD SAFETY OBJECTIVES

Mexico

In the 3rd paragraph of point 5.2.1.1 we suggest changing the phrase: " ... tipo de comida, peligro de preocupación ... " //”...type of food, hazard of concern”// to “...tipo de alimento, peligro relacionado...” //”...type of food, related hazard”//. After this phrase, in the English version of the document as well as in the Spanish, we suggest that it say “el nivel apropiado de protección respecto a ese peligro” //”the appropriate level of protection for that hazard”//.

New Zealand

New Zealand supports the inclusion of Section 5.2.1.1 on FSOs, and also looks to work elsewhere in Codex for continued development of this concept. Such work should lead to further development of the narrative currently presented in 5.2.1.1.

United States of America

Food Safety Objectives: Food Safety Objectives (FSOs) may be a useful concept and entity in microbiological risk management. However, the United States believes that substantially more work is needed on this section to clarify the specific nature and use of FSOs. In this regard, it should be made clear that FSOs should be viewed as a tool in microbiological risk management and not as a replacement/substitute for food safety control systems.

Consumers International

Regarding Microbiological Food Safety Objectives (MFSOs), Consumers International recommends the use of square brackets around the term throughout the document (e.g., add brackets in section 5.1.4 and retain brackets in sections 2, 5.2.1.1, and 6). We believe that examples of MFSOs, as suggested in footnote 7, are needed to clarify if this concept is useful or not, and if a unique new term is required. Concerning the current definition in square brackets, we strongly believe that a "tolerable" level of risk should not be an "objective." Rather, the objective in food safety and microbiological risk management is to prevent, eliminate or decrease risks to consumers as much as can reasonably be achieved. Indeed, section 5.1.4 states that the goals of risk management should be primarily aimed at preventing or reducing risks in order to protect human health, and section 5.2.1 states that the primary objective of microbiological risk management options assessment is an optimization of the interventions necessary to prevent and to control microbiological risk, and that it is aimed at selecting the option(s) that achieve the "chosen" level of public health protection.

5.2.1.2 Precautionary principle

New Zealand

The “Precautionary principle (Section 5.2.1.2) should be considered at the level of the CAC for foods in international trade.

United States of America

Precaution: The United States continues to believe that the document’s Principle 6 adequately handles the use of precaution in microbiological risk management and that a separate section dealing with precaution and particularly, the concepts articulated under the term Precautionary Principle, are unnecessary in this document. The United States believes it is unnecessary to pursue development of a section on precaution as currently structured; reference to the appropriate Codex documents on precaution (including those developed by the Codex Committee on General Principles) is sufficient. The United States believes that an annex on precaution, such as Annex 1, is unnecessary. Indeed, Annex 1 as currently presented is misleading, as the work on precaution by the CCGP is not yet concluded. If Section 5.2.1.2 is ultimately to remain in the document it should, at a minimum, be retitled as “The Use of Precaution in Microbiological Risk Management” and developed accordingly.

European Community

The European Community is convinced that is indispensable to allow risk managers to base temporary measures on the precautionary principle. We would therefore support further elaboration of this point in the Codex Committee on General Principles.

Consumers International

Consumers International supports inclusion of section 5.2.1.2 on the Precautionary Principle, and we can support the language currently in square brackets. However, we would prefer the following rewording (new words in CAPITALS):

A decision-making approach which may be applicable when there is REASON TO SUSPECT ~~a suspicion of~~ adverse effects but where there is ~~no evidence as to~~ NOT A SUFFICIENT SCIENTIFIC BASIS TO DETERMINE the existence, PRECISE NATURE, or extent of risks to human health, leading to protective measures without having to wait until the reality and seriousness of risks to human health becomes apparent.”

We believe that the wording “reason to suspect” is preferable to the word “suspicion”, since it implies a more rational basis. Also, we prefer “a sufficient scientific basis” to “no evidence”, since the latter may be too broad a phrase. There may be some limited evidence, and there should be some sound scientific reasoning, even in the absence of data, to suggest a risk.

5.2.2 *Selection of preferred microbiological risk management options*

New Zealand

The second paragraph in 5.2.2 is too restrictive. “Scientific understanding of primary production and processing” are not necessarily “primary considerations” in assessment of risk management options. There

are a range of food safety issues for management, and other parts of the food chain can be equally important.

The final bullet point in 5.2.2 covers societal choices / preferences and should be resolved at the CAC for foods in international trade. Thus it should be put in square brackets.

As mentioned in earlier comments, the final risk management decision (5.2.3) may not need to “address the whole farm to table continuum”.

5.2.3 Final Management decision

Mexico

In the second bullet in point 5.2.3. we suggest the following text: “Dirigirse desde la producción primaria hasta el consumidor” //”Address from primary production through to the consumer”//. Make this substitution in all occurrences.

New Zealand

The first paragraph in Section 5.3 could be amended to include “The risk profile should place the food safety issue within a particular food safety context, and provide as much information as possible to guide further action”.

For some applications of microbiological risk management, the goals will be well defined before risk profiling commences (Section 5.1.4). The final paragraph in 5.1.4 should be deleted (particularly the last part).

6. GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

Mexico

- In the first paragraph of point 6 we suggest the following text: “ ... puede efectuarse por un sector representativo de instituciones gubernamentales y de la industria alimentaria” //”may be effected by a sector representing government institutions and the food industry”//.

New Zealand

Section 6 should be subject to considerable further development, taking into account the particular implementation issues associated with microbiological hazards in the food supply. More generic material could be devolved to the working principles on risk analysis being developed by the CCGP. Similar comments apply to Section 7.

Consumers International

Paragraph 2, we recommend that the words "and the consumer" be deleted from the sentence "These systems place the burden of compliance with the regulatory authority rather than with the food manufacturer and the consumer." While we recognise that consumers have a role to play in ensuring food

safety, it is the producers of a product, not consumers that should bear the burden of ensuring that the product complies with relevant inspection or end product testing requirements.

7. MONITORING AND REVIEW

Consumers International

It should be clarified that monitoring is not only a tool to assess the effectiveness of the risk management decisions and measures taken, but also is a tool to re-evaluate them and to detect any newly emerging food hazards. We recommend that the following sentence be added to the end of the second paragraph: “On the basis of such data, risk management decisions may be re-evaluated to better address the microbiological public health problem, or to address newly identified problems.”

ANNEX I

Poland

We propose to accept second paragraph, number 34 with the paragraph 35 together.