codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9 **CX/GP 06/23/9**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-third Session
Paris, France, 10 – 14 April 2006

PROPOSED NEW DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY (Proposal from New Zealand)

Background

The 22nd Session of the Committee on General Principles considered the information provided by the Committee on Meat Hygiene concerning risk analysis definitions, and the proposals for the definitions of "process criterion" and "risk based" included in the Draft Code of Hygienic Practice for Meat, subsequently adopted by the Commission (CX/GP 05/22/2).

The Delegation of New Zealand proposed to consider the development of Codex-wide definitions for "risk based" and "science based", since these terms were used frequently and some times imprecisely within the framework of Codex and elsewhere. The Delegation noted that some standards might be considered as "risk based" even though a complete risk analysis had not been carried out, and that such definitions would be especially relevant in relation to the provisions of the SPS Agreement.

The Committee noted that the definitions proposed by the Committee on Meat Hygiene were already included in the Draft Code of Hygienic Practice for Meat, submitted for adoption by the 28th Session of the Commission and would not be affected by the development of general definitions in the CCGP at this stage, but could be reviewed in the future if required.

After some discussion, the Committee agreed that it would be premature to decide on the need for new work on definitions at the present session and welcomed the offer of the Delegation of New Zealand to prepare a discussion paper providing the background to the proposed definitions, taking into account the recommendations of the last session of the CCMH, for consideration by the next session (ALINORM 05/28/33A, para. 22-24).

The Committee is invited to consider the discussion paper prepared by New Zealand on "risk based" standards and the need for further work in this area.

DISCUSSION PAPER

Clarifying the Nature of Risk-Based Standards

Prepared by New Zealand

1. Background

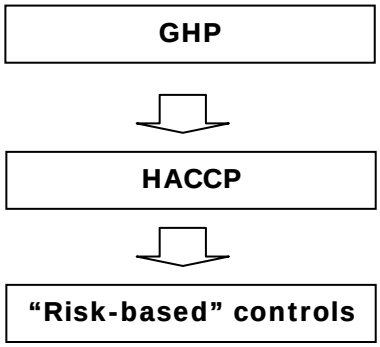
1.1. Changes in approach to establishing food safety standards

Establishment of food safety standards is a core activity of the Codex Alimentarius Commission.

"Traditional" approaches to establishing food safety standards have evolved in a time of limited knowledge on the relationship between the presence and level of hazards in the food chain and the actual risks to the consumer. Nevertheless, food safety controls based on empirical scientific knowledge have served government, industry and consumers well in limiting exposure to hazards of public health concern.

In an increasingly complex global food safety regulatory environment, three "waves of change" are evident. The early 1990's saw more rigorous science being applied in review of GHP-based controls. The mid-1990's brought more targeted food safety systems, particularly those based on Hazard Analysis Critical Control Point (HACCP), and the challenging of standards based on control of hazards to levels that were "as-low-as-reasonably-achievable" (ALARA). The late 1990's saw the need for risk-based controls emerge as an international goal.

Figure 1: Derivation of food safety controls since the early 1990's



1.2. Codex Alimentarius Commission

The CAC is now committed to development of food safety standards based on science[1] and risk assessment[2].

Food safety standards based on risk assessment are outcome-focused and provide considerable advantages to food safety risk managers at both the international and national level. However, their elaboration is demanding in terms of scientific inputs and decision-making processes. Risk managers should know the degree of health protection they are aiming to achieve and risk assessors will likely have examined the impact of different controls on minimising risks, providing the risk managers with data that allows them to more objectively reach decisions on the most appropriate controls. The overriding objective of risk management is to maximize risk reduction while ensuring the efficiency and effectiveness of the controls that are employed.

[1] "The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence…." - Procedural Manual 15th Edition, page 159

[2] "Health and safety aspects of Codex decisions and recommendations should be based on risk assessment, as appropriate to the circumstances" - Procedural Manual 15th Edition, page 161

As a result of the CAC procedural commitment to risk assessment in the development of food safety standards, a number of recent Codex documents commonly incorporate the term "risk-based". Despite this, there is little systematic understanding within the Codex system of what conditions need to be met before a standard can genuinely be regarded as "risk-based". In this vacuum, *individual* committees and ad hoc Codex groups are increasingly developing definitions and describing what constitutes a "risk-based" standard.

The CAC will increasingly strive to elaborate "risk-based" standards and implement "risk-based" approaches to more general aspects of food control e.g. the validation guidelines being developed by the Codex Committee on Food Hygiene. However, many situations will continue to exist where there is insufficient scientific information to genuinely develop Codex standards based on risk assessment. In this environment, it is essential that all stakeholders involved in food safety understand the difference and the relative merits of standards elaborated on the basis of risk assessment compared with standards elaborated using other approaches e.g. based on good hygienic practice (GHP) or HACCP. Without this understanding, there will be increasingly non-systematic (and inappropriate) use of the term "risk-based" in relation to Codex (and national government) standards. As well as creating confusion and inefficiency in the elaboration of new standards and guidelines by different Codex committees, this will undermine the integrity and value of risk assessment to the Codex system.

The CAC is also committed to collaborating with other international standard-setting organisations in areas of mutual interest. In this respect, the World Organisation for Animal Health (OIE) sets food safety standards related to zoonoses (human diseases arising from animals) at the live animal level. OIE similarly refers to the importance of risk assessment in the development of commodity import standards[3]. Both the CAC and OIE recognize that the *whole food chain* must be taken into account if food safety standards are to be based on an assessment of risks to human health and this further emphasizes the need for a common understanding of the demands of a "risk-based" approach to standard-setting.

In essence, all stakeholders in food safety need to clearly understand the difference between "managing hazards" and "managing risks".

2. "Risk-based" standards

2.1. Codex definitions

A hazard is defined by Codex as "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect".[4]

A risk is defined by Codex as "A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food".[4]

Many current Codex standards are formulated according to scientific information on relevant hazards. They are aimed at eliminating or reducing exposure to hazards, with the *expectation* that there will be a reduction in risk to human health. While standards arising from evaluation of all available scientific information on hazards will continue to be important food safety tools, the inability to link such standards to actual human health outcomes and their often inflexible nature are key drivers for the development of "risk-based" standards.

2.2. What constitutes a "risk-based standard"?

Food safety standards established by the CAC should be based on sound peer-reviewed science as a minimum. In the ideal situation, standards should also be based on risk assessment and a systematic process for reaching decisions on an appropriate level of consumer protection (ALOP).

In this context, "risk-based" standards are formulated according to current knowledge, whether quantitative or qualitative, on risks to human health. They are aimed at achieving an established level of human health protection (whether quantitative or qualitative) and should be able to be explained and validated in these terms.

[3] Guidelines for Import Risk Analysis. OIE Terrestrial Animal Health Code 2004, page 24
[4] CAC Procedural Manual 15th Edition, page 44

Description of a standard as "risk-based" should satisfy the above provisions. This obviously requires particular and robust scientific inputs and application of a systematic process by risk managers to reach a decision on an ALOP. An ALOP for food-borne illness can be expressed in a number of ways, for example:

- A broad public health goal related to risk reduction e.g. "50% reduction" in foodborne illness due to a prioritised group of hazards over 10 years
- A specific public health goal related to a particular hazard / food combination e.g. acceptable number of cases of illness due to *L. monocytogenes* in smoked salmon in the general population over a specified time period
- A specific public health goal related to a particular hazard and class of food e.g. acceptable number of cases of illness due to *L. monocytogenes* in refrigerated ready-to-eat foods in the general population over a specified time period
- A specific public health goal related to societal impact e.g. Disability-Adjusted Life Years resulting from health risks from a particular hazard
- A broad public health goal that accepts the current level of consumer protection e.g. as a benchmark when determining the equivalence of different food controls or food production technologies

As risk-based standards are outcome-driven, maximum flexibility can be provided to industry that has the primary responsibility for implementation.

3. Risk management framework

Elaboration and implementation of "risk-based" standards requires a systematic risk management process.

3.1. Codex definitions

Codex defines risk analysis as "a process consisting of three components: risk assessment, risk management and risk communication".[5]

While the CAC has not defined a specific *process* for implementing a "risk-based" approach to food safety, the working principles for risk analysis elaborated for application *within the framework of Codex* state "Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken".[6]

Following the guidelines established by a FAO/WHO Consultation on Food Safety Risk Management[7], the draft standard on microbiological risk management currently being elaborated by the CCFH *for application by governments* [8] describes a structured approach in terms of the following four steps: preliminary risk management activities, identification and selection of risk management options, implementation of risk management options, and monitoring and review.

3.2. A generic framework

FAO/WHO, CAC and individual countries have now made significant progress in the development of a generic risk management framework that identifies the different activities that need to be conducted in a structured, on going and iterative manner to manage microbiological food safety risks. It is a systematic *process* that uses the results of risk assessment and other scientific evaluations to develop risk management options for implementation at appropriate steps along the food chain.

During application of this process, types of risk management options that can be considered include:

[5] CAC Procedural Manual 14th Edition, page 45

[6] "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius" - CAC Procedural Manual 14th Edition, page 101

[7] "Risk Management and Food Safety". Report of a Joint FAO/WHO Consultation. FAO Food and Nutrition Paper 65 (1997)

[8] "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)" - ALINORM 05/28/13, App. III

- Development of specific quantitative microbiological metrics such as food safety objectives (FSOs), performance objectives (POs), and performance criteria (PCs) that are risk-based and that can be incorporated in regulation
- Determining the relative importance of different interventions throughout the food chain in reducing risk and developing controls on this basis
- Implementing non-regulated food safety measures such as consumer education or producer quality assurance programmes if indicated by risk assessment
- Jusifying the use of equivalent food technologies or control procedures where it is shown that equivalent levels of consumer protection can be achieved.

A risk management framework (RMF) provides a systematic process whereby knowledge on risk, and evaluation of other factors relevant to protecting human health and the promotion of non-discriminatory and least trade-restrictive practices, are used to choose and implement standards or other actions.

4. Recommendations

The Procedural Manual of the CAC already contains several definitions clarifying generic aspects of risk analysis as applied throughout the Codex system. The Procedural Manual should also include an explanation of the term "risk-based" so as to promote general understanding, avoid inappropriate use and facilitate efficiency in the elaboration of new standards and guidelines by different Codex committees.

1. CCGP should develop a clear and concise *generic* explanation of what is expected of a standard that is described as "risk-based" or is described as being "based on risk assessment". This should include development of a generic definition as it relates to development of "risk-based" standards throughout the Codex system. A starting point could be:

   A risk-based standard is "A standard that is based on specific knowledge of risks and has the objective of achieving an established level of health protection".

2. CCGP could also clarify the *generic* process whereby "risk-based" standards are elaborated and implemented. This explanation could include a generic description of a risk management framework (RMF) and the different components applied by Codex compared with national governments. A starting point could be the description of a RMF as:

   "A structured process for application of a risk-based approach to food safety that consists of four generic steps: preliminary risk management activities, identification and selection of risk management options, implementation of risk management options, monitoring and review".