

# codex alimentarius commission



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Agenda Item 8

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON GENERAL PRINCIPLES  
Twenty-fourth Session  
Paris, France, 2- 6 April 2007**

**PROPOSED NEW DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY:  
CLARIFYING THE NATURE OF RISK BASED STANDARDS**

**Discussion Paper Prepared by New Zealand and the United Kingdom**

## **1. Background**

### **1.1. Risk analysis and Codex**

“Risk-based” standards are identified in a number of Codex (and national government) documents as a highly desirable goal. Their establishment and implementation are instrumental to reaping the full benefits from application of risk analysis to food safety issues,. Such standards also give effect to the provisions and obligations of the WTO SPS Agreement for food in international trade.

No fewer than ten Codex committees are now involved in developing, or have developed, principles and guidelines to assist in setting of standards using risk analysis. The Procedural Manual of the CAC contains several definitions that describe generic aspects of risk analysis as applied throughout the Codex system.

We suggest that, in some areas, the use of risk analysis narrative and terminology in relation to standards development in Codex is running ahead of understanding and practice. The term “risk-based” or “based on risk assessment” is now commonly used at Codex and national government levels in relation to food safety standards. However, there is no general explanatory text in the Codex system as to what this means. For example, we would ask whether a Codex (or national) standard that is generic in nature e.g. a code of practice, and does not have a specified outcome, should be described as “risk-based”?

In contrast, there are many situations in standard development in Codex where a risk assessment is unnecessary<sup>1</sup> or unavailable – for example, where there is insufficient scientific information to develop standards based on risk assessment<sup>2</sup>. In these circumstances, “enabling” standards elaborated using GHP and HACCP approaches may have considerable value in providing an approach to the control of food risks that is “fit-for-purpose” yet not demand resource intensive, formal risk assessment.

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<sup>1</sup> This does not preclude incorporation of risk analysis principles and guidelines

<sup>2</sup> Where risk assessment (as defined by Codex) is not conducted, there are clear expectations that measures should be objective and proportionate, and based on scientific analysis and advice

## 1.2. Codex Committee on General Principles: Informal Working Group

The 23<sup>rd</sup> Session of the Codex Committee on General Principles (CCGP) considered a discussion paper which sought to clarify how a definition of the term “risk-based” might be considered for general use within the Codex framework. The Committee agreed that this issue should be considered further at its 24<sup>th</sup> Session in 2007, and invited a revised paper from New Zealand and the United Kingdom. This revised discussion paper was to be informed by the outcome of an informal CCGP physical working group on risk analysis, held in Brussels in September 2006<sup>3</sup>

The Informal Consultation sought to:

- Develop a general understanding of what constitutes a “risk-based” standard in the Codex setting, including criteria that might apply if a Codex standard was described/designated as “risk-based”
- Discuss the practical implications of Codex striving for “risk-based” standards, including the impact of differences in applying risk analysis principles at the international compared with the national level
- Discuss whether Codex should develop explanatory text, including the possibility of a definition of “risk-based” or “based on risk assessment” in the context of standard setting, so as to maintain the integrity and value of risk assessment to Codex and enhance the utility and flexibility of Codex standards.

## 2. Introduction

### 2.1. What are standards?

The CAC does not provide a definition of a Codex “standard”, however There seems to be a general understanding that there are two types of Codex “standards”:

- Quantitative standards such as MRLs as well as “related texts” are generally referred to as “standards” in the Procedural Manual<sup>4</sup>
- The Procedural Manual states that the Codex Alimentarius includes “provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures”<sup>5</sup>.

The CAC has noted advice from the WTO that the SPS Agreement “does not differentiate between the terms “standards”, “guidelines” or “recommendations””, and “a text would be applied depended on its substantive content rather than on category of the text”<sup>6</sup>. In the WTO SPS environment, the scientific conclusions that can be drawn from a risk assessment should reasonably support (and be reflected in) an SPS measure under examination.

### 2.2 What is the basis for developing a standard?

The CAC is committed to development of food safety standards based on sound science and risk assessment. It is similarly committed to basing its decisions on risk assessment, *where appropriate* (Box 1). Where food safety risk assessment is used, CAC has also defined its expectations in terms of risk assessment (Box 2).

***Box 1: CAC statements on the role of science and risk assessment***

<sup>3</sup> Report of the 23<sup>rd</sup> Session of the Codex Committee on General Principles, ALINORM 06/29/33, paragraphs 149-162.

<sup>4</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 19

<sup>5</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 31

<sup>6</sup> Report of the 23<sup>th</sup> Session of the Codex Alimentarius Commission. ALINORM 99/33

“The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence....”<sup>7</sup>  
“Health and safety aspects of Codex decisions and recommendations should be based on risk assessment, as appropriate to the circumstances”<sup>8</sup>  
“Where there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the CAC 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”.<sup>9</sup>

***Box 2: Codex definitions of risk assessment***

“Food safety risk assessment....should incorporate the four steps of the risk assessment process....”<sup>10</sup>  
“Risk assessment: A scientifically-based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization”<sup>11</sup>

### **2.3 Current uses of risk assessment terminology**

Risk assessment is commonly referred to as a component of standards development within a range of existing Codex texts (Box 3). However, this does not always reflect the inclusion of a risk assessment as defined by Codex, which is usually *specific to a hazard/food commodity/population*.

The Codex Committee on Meat Hygiene (CCMH) has defined “risk-based” in relation to a standard as “Containing any performance objective, performance criterion or process criterion developed according to risk analysis principles”. Recent discussions in the CCFH clearly indicate that this strict definition is not workable as a generic definition of a “risk-based” standard.

We have therefore asked whether there is a need to further develop the way in which terminology relating to “risk-based” standards is used within Codex, in order to avoid misunderstanding and recognise the value of enabling and fit-for-purpose standards not based on formal risk assessment.

***Box 3: Examples of the use of risk assessment terminology in standards development***

Food Hygiene Basic Texts<sup>12</sup>

“In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made....”

“Microbiological criteria should be ..... based on scientific analysis and advice, and, where sufficient data are available, a risk analysis appropriate to the food stuff and its use”

<sup>7</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 159

<sup>8</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 161

<sup>9</sup> Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, 15<sup>th</sup> Edition of the CAC Procedural Manual, page 101 - 107

<sup>10</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 161

<sup>11</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 45

<sup>12</sup> Codex Alimentarius. Food Hygiene Basic Texts. Third Edition 2003

### CCFICS<sup>13</sup>

“The extent and stringency of requirements applied in specific circumstances should be proportionate to the risk”

“The sanitary measure that the exporting country proposes as equivalent must be capable of achieving the importing country’s ALOP”

### CAC Principles for Risk Analysis and Guidelines for Safety Assessment of Foods derived from Modern Biotechnology<sup>14</sup>

“If a new or altered hazard .... is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health”

### OIE

“The principle aim of import risk analysis is to provide importing countries with an objective and defensible *method*<sup>15</sup> of assessing the disease risks associated with an importation....”<sup>16</sup>

The CAC is committed to collaborating with other international standard-setting bodies 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<sup>17,18</sup>. 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. This emphasises the need for a cross-sector understanding of the demands of a “risk-based” approach to standard-setting and appropriate use of terminology.

## **2.4 Challenges that arise**

The introductory passages above demonstrate the absolute commitment of the CAC to the development of food safety standards based on sound science and risk assessment. It also demonstrates the commitment of the CAC to basing its decisions on risk assessment, *where appropriate*, and to undertaking risk assessment in such cases following a prescribed methodology.

The corollary is that where it is *not* appropriate to use risk assessment, CAC would nevertheless use the available science and evidence in the process of generating a text. It is important to recognise that there is no presumed hierarchy, despite some of the current uses of risk assessment terminology within Codex. Texts developed using formal risk assessment are not inherently better or worse than texts developed on the basis of the available science where formal risk assessment is not possible. Both types of text may be “fit for purpose”. We therefore propose terminology that would allow us to differentiate between these texts, and in doing so would allow us to more fully recognise the value of texts developed on the basis of the available science where formal risk assessment is not possible.

## **3. Development of “risk-based” standards**

### **3.1. “Hazard-based” standards**

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<sup>13</sup> Codex Alimentarius. Food Import and Export Inspection and Certification Systems; Combined Texts. Second Edition, 2005

<sup>14</sup> Foods Derived from Biotechnology. Joint FAO/WHO Food Standards Programme, CAC 2004.

<sup>15</sup> Writers italics

<sup>16</sup> Section 1.3. Risk Analysis. OIE Terrestrial Animal Health Code. 2004.

<sup>17</sup> CAC/29 INF/4. Information on Activities of the World Organisation for Animal Health (OIE) Relevant to Codex Work, 29<sup>th</sup> Session of the CAC, June 2006.

<sup>18</sup> Guidelines for Import Risk Analysis. OIE Terrestrial Animal Health Code 2004, page 24

“Hazard-based” standards are based primarily on knowledge of hazards in the food supply and their reduction (Box 3), rather than reducing hazards in the food supply *according to specific knowledge on impacts on human health*. “Hazard-based” standards provide core prerequisites of a food control programme and offer a reasonable and pragmatic response to many food safety issues.

**Box 4: Codex definitions of “hazard” and “risk”**

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”<sup>19</sup>

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”<sup>4</sup>

### 3.2. “Risk-based” standards

General use of the term “risk” as a qualifier to a food safety standard infers knowledge on the likely impacts of the standard in terms of public health when the standard is implemented. “Risk characterization” (the last step in the risk assessment process) is defined by Codex as “The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects *in a given population...*”<sup>20</sup>. As long as a link of sufficient strength is established between the standard(s) itself and the outcome – the appropriate level of consumer protection (ALOP) – it can genuinely be considered to be “risk-based” (see following sections).

Codex standards incorporating “risk-based” *approaches* provide a framework, informed by the best available science, within which risk managers at the national level can elaborate actual and proportionate risk-based measures. On the other hand, Codex itself may fully elaborate a “risk-based” *standard* that delivers a specified level of public health protection and this can be taken up intact by governments if that level of consumer protection is deemed acceptable.<sup>21</sup>

The Codex 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”.<sup>22</sup> Implementation is an additional step that occurs at the national level, following evaluation of risk management options<sup>23</sup>. This framework uses the results of risk assessment and other scientific evaluations to develop “risk-based” standards for implementation at appropriate steps along the food chain.

In support of the explanation above, CCFICS states that judgement of equivalence should take into account “analysis of the strength of the relationship between the exporting country’s specified sanitary measure, and the achievement of the ALOP of the importing country as reflected in the objective basis of comparison”.<sup>24</sup>

### 3.3. Differences at the international and national levels

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<sup>19</sup>CAC Procedural Manual 14th Edition, page 44

<sup>20</sup> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 45

<sup>21</sup> This also requires that the inputs to the risk assessment that underpins the Codex “risk-based” standard also fit at the national level

<sup>22</sup> “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” - CAC Procedural Manual 14<sup>th</sup> Edition, page 101

<sup>23</sup> “Risk Management and Food Safety”. Report of a Joint FAO/WHO Consultation. FAO Food and Nutrition Paper 65 (1997)

<sup>24</sup> CAC/GL 53-2003

Unavoidable restrictions apply to risk analysis at the Codex level compared to the national government level:

- Codex has little experience in setting an appropriate level of consumer protection (a “global ALOP”) as the expected outcome of an international standard
- Unlike national governments, Codex is not empowered to propound specific public health goals, especially those that are quantitative in nature e.g. a reduction in the burden of gastrointestinal foodborne disease by 20% over five years in a particular population
- Codex does not implement standards nor monitor outcomes, therefore it cannot itself evaluate the impact of a standard in terms of risk reduction
- Attempting to set Codex standards that are proportionate to risk will likely have different implications - and possibly lead to different standards - in different countries

## 4. Outputs of the CCGP Informal Working Group

### 4.1. Technical discussions

The Informal Working Group (IWG) generally agreed that a clear understanding of the difference between “hazard-based” and “risk-based” standards and the appropriate use risk analysis terminology to reflect this difference would be of general benefit to Codex.

The IWG:

- Noted that the scientific basis for Codex standards can be different and this difference can be described as “hazard-based” or “risk-based”. This in no way represents a choice between standards but does describe different approaches to standard development.
- Acknowledged that the current Codex system incorporates adequate flexibility in developing “hazard-based” and/or “risk-based” standards.
- Generally agreed that “risk-based” standards are formulated according to current scientific knowledge, whether quantitative or qualitative, on risks to human health. They are aimed at achieving a specified level of human health protection (whether expressed quantitatively or qualitatively).
- Noted that there are several ways to gain sufficient scientific knowledge to develop standards that are “risk-based” i.e. a link of sufficient strength is established between the standard and the outcome to form the basis of risk management decisions. These approaches do not necessarily involve resource-intensive quantitative risk assessment modelling and include:
  - Qualitative risk assessment
  - Quantitative risk assessment
  - Risk profiling and ranking of relative risks
  - Epidemiology
  - Food attribution studies
- Agreed that as “risk-based” standards are outcome-driven; maximum flexibility can be provided to the industry that has the primary responsibility for implementation.
- Noted that challenges will remain in clarifying the relationship between the *sufficiency* of scientific evidence and the scientific uncertainty inherent to risk assessments, and in judging the appropriateness and substantive nature of the risk assessment that is used in particular standard-setting situations.

- Noted that Codex “*enabling*” standards incorporate risk analysis principles and promote the development of specific “risk-based” standards at the national level (e.g. CCFICS guidance on design of import control systems, CCMH guidance on meat hygiene).

The IWG noted that there is no implied hierarchy between “hazard-based” and “risk-based” standards and all Codex standards should be “fit-for-purpose” i.e. both may be effective and appropriate in ensuring public health protection for food in trade.

The IWG supported further work on explanatory text to clarify the issues presented in this discussion paper - to guide Codex in future application of risk analysis principles and to prevent unnecessary hurdles when developing standards that are “fit-for-purpose”.

The IWG considered that it would be premature to develop a Codex definition of “risk-based” at this time.

## **5. Recommendations**

New Zealand and the United Kingdom have revised the discussion paper as requested by the 29<sup>th</sup> Session of the CCGP and have included the outputs of the CCGP IWG.

It is recommended that the 30<sup>th</sup> Session of CCGP:

1. Consider the content of this discussion paper and the technical output of the IWG
2. Acknowledge that description of a Codex standard as “risk-based” should be consistent with the body of provisions and definitions concerning risk assessment that is already agreed by the CAC
3. Decide whether new work should be initiated on explanatory text on “risk-based” standards so as to guide Codex in future application of risk analysis principles and to prevent unnecessary hurdles when developing standards that are “fit-for-purpose”.