

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 8

CX/GP 09/25/8

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-fifth Session

Paris, France, 30 March to 3 April 2009

### Proposed new Definitions of Risk Analysis Terms related to Food Safety Clarifying the Nature of “Risk Based” Standards

Discussion Paper Prepared by New Zealand in conjunction with the United Kingdom

#### 1. Background

The Procedural Manual of the CAC contains several definitions that describe aspects of risk analysis as applied throughout the Codex system and most Codex committees now incorporate risk analysis principles and approaches in their work. One aspect of this is the increasing use of the terms “risk-based” or “based on risk assessment” when describing a standard. These terms are also commonly used as qualifiers when Competent Authorities describe national standards.

Currently, there is no explanatory text in the Codex system on what these terms mean. This raises the question whether a Codex (or national) standard that is generic in nature e.g. a code of practice that does not have a specified outcome, should be considered as “risk-based”? Further, the Codex Committee on Meat Hygiene (CCMH) has strictly 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 Codex Committee on Food Hygiene (CCFH) suggest that this is not workable as a generic definition.

The 24<sup>th</sup> Session of the Codex Committee on General Principles (CCGP) invited a discussion paper from New Zealand and the United Kingdom on this topic, informed by discussions at an informal CCGP physical working group on risk analysis, held in Brussels in September 2006<sup>1</sup>. The Working Group (WG) supported further work on explanatory text to clarify the issues described in this discussion paper. This would help to position risk assessment as one of several options for developing Codex standards that are fit-for-purpose, and at the same time maintain the integrity and value of risk assessment to Codex.

#### 2. Purpose of this discussion paper

The CAC is committed to development of food safety standards based on risk assessment *where appropriate*<sup>2</sup>. Risk assessment is commonly referred to as a primary option in standards development<sup>3</sup>, even though a risk assessment as defined by Codex should have an outcome that is usually specific to a particular

<sup>1</sup> Report of the 23<sup>rd</sup> Session of the Codex Committee on General Principles, ALINORM 06/29/33, paragraphs 149-162

<sup>2</sup> “Health and safety aspects of Codex decisions and recommendations should be based on risk assessment, as appropriate to the circumstances”. 17<sup>th</sup> Edition of the CAC Procedural Manual, page 196

<sup>3</sup> “In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made....”. Codex Alimentarius. Food Hygiene Basic Texts. Third Edition 2003

hazard/food combination<sup>4</sup>. However, there will continue to be many situations where risk assessment is inappropriate, unavailable or of limited extent in the development of an international standard<sup>5</sup>.

It is essential to recognise that 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 or appropriate. Both types of text may be “fit for purpose”.

This discussion paper raises the question as to whether there is a need to further influence the way in which terminology relating to “risk-based” standards is used within Codex, in order to:

- Avoid misunderstanding of the positioning and use of risk analysis in the development of Codex standards
- Recognise the continuing importance of Codex standards that are not “risk-based” but that are fully appropriate in the context of their development
- Where relevant, facilitate recognition of Codex standards as “enabling” rather than necessarily incorporating decisions on an appropriate level of consumer protection; thus providing for national risk management decisions as appropriate
- Facilitate an OIE / Codex cross-sector understanding of the demands of a “risk-based” approach to standard-setting if food safety standards are to take the whole of the food chain into account

### **3. Development of an explanatory text**

#### **CCGP WG**

The informal CCGP WG meeting in September 2006 agreed that “risk-based standards” are formulated according to current scientific knowledge, whether quantitative or qualitative, on risks to human health and are aimed at achieving a specified level of human health protection. The informal WG recognised that there are several ways to gain sufficient scientific knowledge to develop standards that could be described as “risk-based”.

Codex can itself elaborate a “risk-based standard” that delivers a specified level of public health protection. This can be taken up intact by risk managers at the national level if the level of consumer protection therein is deemed acceptable.

The CCGP WG also noted that Codex develops “enabling” (guidance) standards incorporating risk analysis principles e.g. Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) guidance on design of import control systems, CCMH guidance on meat hygiene. Risk managers apply such guidelines to develop specific control measures for application at the national level. These national standards may be risk-based if appropriate national risk assessments are available.

#### **A possible explanatory text**

“Risk characterization” 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>6</sup>. Thus use of the term “risk” as a qualifier to a food safety standard clearly implies knowledge on the likely impacts of the standard in terms of public health protection when the standard is implemented. As long as a quantitative link is scientifically established between the standard

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<sup>4</sup>“A scientifically-based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization”. 17<sup>th</sup> Edition of the CAC Procedural Manual, page 4-5

<sup>5</sup> The CAC has also 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> 15<sup>th</sup> Edition of the CAC Procedural Manual, page 45

itself and the outcome – the appropriate level of consumer protection (ALOP) – it can be genuinely described and promulgated by Codex as “risk-based”.

A starting point for a possible explanatory text for a “risk-based standard” or a “standard based on risk assessment” is:

*“A standard that is based on specific knowledge of risks, is aimed at achieving an established level of health protection, and can be explained in these terms”*

As mentioned above, development of such an explanatory text should not in any way imply a hierarchy between different types of Codex standards. It is essential to recognise that Codex texts developed using risk assessment are not inherently better or worse than texts developed on the basis of the available science where risk assessment is not possible or appropriate; both types may be fully “fit for purpose” in the context of their application at the international level.

#### **4. Recommendations**

New Zealand in conjunction with the United Kingdom have revised the discussion paper as requested by the 30<sup>th</sup> Session of the CCGP and recommend that the 31st Session of CCGP:

1. Consider the content of the revised discussion paper
2. Acknowledge that the explanation of a “risk-based standard” or “standard based on risk assessment” is consistent with the body of provisions and definitions concerning risk analysis that is already agreed by the CAC
3. Decide whether new work should be initiated on an explanatory Codex text for appropriate use of the term “risk-based standards” or “standards based on risk assessment” so as to guide Codex in consistent use of such terms.