Appendix III. Relevant paragraphs within Codex documents referenced in IFT DRNCD Discussion Paper

Reference number	Paragraph number	Relevant text
2	**271-305**	***Codex Alimentarius Commission Procedural Manual - Thirtieth Edition***

Background

271. Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius hereinafter "working principles" establishes general guidance on risk analysis to Codex Alimentarius. These working principles were adopted in 2003 and published in this Codex Procedural Manual.

272. The objective of the working principles is "to provide guidance to the Commission and the Joint FAO/WHO expert bodies and consultations so that food safety and health aspects of Codex standards and related texts are based on risk analysis". By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Commission and its subsidiary bodies.

273. The nutritional risk analysis principles in Section 4.9 are established to guide the Commission and its subsidiary bodies – primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) – in applying nutritional risk analysis to their work. This guidance may be used for the work of other committees since CCNFSDU is also mandated, in accordance with its 4th term of reference: "to consider, amend if necessary, and endorse provisions on nutritional aspects" of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.

Introduction

274. Codex nutritional risk analysis addresses nutrients[xlii] and related substances[xliii] and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis (such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants, and allergens) nutrients and related substances are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.

[xlii] *Nutrient is defined by General Principles for the Addition of Essential Nutrients to Foods (CXG 9-1987)24 to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur. Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life, and which cannot be synthesized in adequate amounts by the body.*

[xliii] *A related substance is a constituent of food (other than a nutrient) that has a favourable physiological effect.*

275. The nutritional risk analysis principles and guidelines for application to the work of CCNFSDU hereinafter "nutritional risk analysis principles" are subsidiary to and should be read in conjunction with the working principles.

276. The nutritional risk analysis principles are framed within the three-component structure of the working principles, but with an added initial step to formally recognize problem formulation as an important preliminary risk management activity.

4.9 Nutritional risk analysis principles and guidelines for application to the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses

Scope and application

277. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management

strategies. In situations that address inadequate intakes, such a reduction in risk through addressing the inadequacy might be referred to as a nutritional benefit.

278. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food and are identified as:

a) nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; and/or

b) related substances that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake.

279. When favourable effects of the nutrient or related substance of primary interest are being assessed, consideration should be given to whether the food matrix could increase the risk of an adverse health effect.

280. Where appropriate, the application of quantitative nutritional risk assessment may guide decision-making on quantitative content provisions for nutrients and related substances in certain Codex texts.

281. Nutritional risk assessment should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:

a) formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);

b) formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;

c) managing risks by labelling advice in relation to consumption of foods of certain nutrient-related xliv compositions, including foods for special dietary use; and d) advising on risk-risk analysis (e.g. risk associated with significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food).

Definitions

282. Section 4.2: Definitions of risk analysis terms related to food safety in this Codex Procedural Manual provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by 'nutritional' and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below. [xliv] For the purpose of these nutritional risk analysis principles, the descriptive term 'nutrient-related' refers to one or more nutrients and/or related substances, as the case may be.

283. However, other definitions of risk analysis terms related to food safety have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. <u>The modified or newly developed subsidiary definitions are as follows:</u>

Adverse health effect[25] – A change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system, or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Bioavailability [26] – The proportion of the ingested nutrient or related substance that is absorbed and utilized through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, food processing/ preparation, and host-related intestinal and systemic factors.

Dose-response assessment – The determination of the relationship between the magnitude of intake of (or exposure to) (i.e. dose) a nutrient or related substance and the severity and/or frequency of associated adverse health effects (i.e. response).

Highest observed intake – the highest level of intake observed or administered as reported within a study(ies) of acceptable quality. It is derived only when no adverse health effects have been identified.

Homeostatic mechanism – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

Intake (exposure) assessment – The qualitative and/or quantitative evaluation of the likely intake of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

Nutrient-related hazard – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake. **Nutrient-related hazard characterization** – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a nutrient-related hazard.

Nutrient-related hazard identification – The identification of a nutrient related hazard in a particular food or group of foods.

Nutritional risk – A function of the probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

Nutrient-related risk characterization – 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 based on nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Upper level of intake – the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

284. Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of problem formulation as a key preliminary risk management activity. Preliminary nutritional risk management activities

285. Preliminary nutritional risk management activities should have regard to the particular sections in the working principles titled general aspects of risk analysis, and risk assessment policy. Nutritional problem formulation

286. Nutritional problem formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.

287. Such considerations should include whether a nutritional risk assessment is needed, and if so:

a) the priority it should be accorded;

b) who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;

c) the need for development of nutritional risk assessment policy;

d) how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;

e) whether data are available to embark on an evaluation of nutritional risks;

f) what level of resources are available; and g) the timeline for completing the assessment.

288. Specific information to be gathered for nutritional problem formulation may include:

a) a detailed inventory of prior knowledge;

b) identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;

c) relevant source(s) of intake; and

d) the health endpoints to be considered.

Nutritional risk assessment

289. The risk management section of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius is generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-related hazard identification and hazard characterization

290. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.

291. Nutritional risk assessment should take into consideration the nutrient related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.

292. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.

293. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.

294. Nutrient reference standards that may be used to characterize nutrient related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirements have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.

295. Nutrient reference standards that may be used to characterize nutrient related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations may be considered in the future. Some periodically updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.

296. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically-determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described. Nutrient-related intake assessment and risk characterization

297. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex Member Nations or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.

298. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements,[xlv] and in the case of certain minerals, water. It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed. Nutritional risk management

299. The risk management section of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.

300. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition,

consideration of the suitability of foods containing risk-increasing nutrients for certain purposes or subpopulations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.
301. Nutritional risk management decisions should take into account their impact on dietary patterns and consumer behaviour. Such information should be supported by relevant research.
302. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment. Nutritional risk communication
303. The risk communication section of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius is generally applicable to nutritional risk communication. Selection of risk assessor by CCNFSDU
304. Consistent with their important role in providing scientific advice to the Commission and its subsidiary bodies, FAO and/or WHO, including the FAO/ WHO Joint Expert Meeting on Nutrition (JEMNU), are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement, however, does not preclude the possible consideration of recommendations arising from other internationally-recognized expert bodies, as approved by the Commission.
305. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by CCNFSDU.
[xlv] Guidelines for Vitamin and Mineral Food Supplements (CXG 55–2005)27 define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solution, etc., that are designed to be taken in measured small unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

Reference number	**Paragraph number**	**Relevant text**
3	**3.4.4.3 – 3.4.7**	**CXG 2-1985 GUIDELINES ON NUTRITION LABELLING**

3.4.4.3 NRVs-NCD

<u>Intake levels not to exceed</u>

Saturated fatty acids	20 g[10,11]
Sodium	2,000 mg[12]

<u>Intake levels to achieve</u>

Potassium	3,500 mg[10]

[10]This value is based on the reference energy intake of 8 370 kilojoules/2 000 kilocalories. [11] The selection of this nutrient for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk as reported in the report Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 9 16. WHO, 2003.

[12] The selection of these nutrients for the establishment of an NRV was based on "high quality" evidence for a relationship with a biomarker for NCD risk in adults as reported in the respective 2012 WHO Guidelines on sodium and potassium intake for adults and children.

3.4.3 The following format should be used:

Total fat		...	g
	saturated fatty acids	...	g
of which	trans-fatty acids	...	g
	monounsaturated fatty acids	...	g
	polyunsaturated fatty acids	...	g
Cholesterol		...	mg

3.4.5 In countries where serving sizes are normally used, the information required by Sections 3.4.2, 3.4.3 and 3.4.4 may be given per serving only as quantified on the label or per portion provided that the number of portions contained in the package is stated.

3.4.6 The presence of available carbohydrates should be declared on the label as "carbohydrates". Where the type of carbohydrate is declared, this declaration should follow immediately the declaration of the total carbohydrate content in the following format:

"Carbohydrate ... g, of which sugars ... g".

This may be followed by the following: "x" ...g

where "x" represents the specific name of any other carbohydrate constituent.

3.4.7 Where the amount and/or type of fatty acids or the amount of cholesterol is declared, this declaration should follow immediately the declaration of the total fat in accordance with Section 3.4.3

Reference number	Paragraph number	Relevant text
7	**195-201**	**REP25/CAC Report of the 48th Session November 2025**

195. CAC48 in considering CRD26 (ADVANCING SCIENCE-BASED FOOD CLASSIFICATION: THE CASE FOR CODEX LEADERSHIP IN ADDRESSING THE "ULTRA-PROCESSED" DISCOURSE) shared the following views.

196. Members supporting the initiative underscored that the lack of clear, science-based, and globally harmonized definitions for UPFs was an emerging issue that could significantly impact global trade, food safety, and nutrition policy. They stressed that the issue was cross-cutting, relevant to multiple Codex subsidiary bodies, and that Codex, with its unique mandate covering health, trade, and standards, was the best forum to address it transparently.

197. Members expressing concerns about the initiative considered it premature to initiate new work at this stage, noting the ongoing work of WHO in this area, including the development of WHO guidelines and an operational definition for UPFs. These Members also suggested that existing active Codex committees were fully equipped to discuss various aspects of UPFs should a Member submit a specific proposal. Concerns were also raised that introducing the UPF concept into food regulations or standards before sufficient scientific consensus was reached could adversely affect current categorization, labelling, and risk assessment frameworks.

198. An Observer welcomed WHO guidance and urged Codex to consider both the health and environmental impacts of UPFs.

199. The proposer argued that current classification models, particularly those derived from the Nova food classification framework, overemphasized the extent of processing while overlooking formulation and compositional quality, which risked misclassification and the stigmatization of safe foods.

200. In response to a request for clarification, the WHO representative explained that work currently being undertaken by WHO involved establishing an operational definition, followed by the development of guidelines, both grounded in solid scientific evidence, collected through systematic reviews. Conclusion

201. CAC48 noted:

i. the general interest in this area of work;

ii. the ongoing work of WHO on ultra-processed foods (UPFs);
iii. the relevance of this issue to several Codex committees; and
iv. that if interested, Members could prepare a more detailed proposal for future discussion.

Reference number	Paragraph number	Relevant text
111	**91**	**ALINORM 95/26 CCNFSDU 19 Bonn-Bad Godesberg, Germany**

The Delegation of Australia proposed that the Committee consider dietary modelling, especially the methodology for forecasting the impact of change in food composition on the potential consumption of nutrients and non-nutrients in the diet, and the Committee agreed that Australia would prepare a paper for consideration by the 20th session. The Delegations of Germany and the United States also offered to provide data on their experience to assist Australia in this task.

Reference number	Paragraph number	Relevant text
112	**105-107**	**ALINORNI 97/26 CCNFSDU 20 Bonn-Bad Godesberg, Germany**

Dietary Modelling

105. The Committee recalled that its last session had agreed that Australia would prepare a paper on dietary modelling of nutrient intake. The 42nd Session of the CCEXEC had expressed the view that consideration of dietary models for nutrient intake did not appear to be consistent with the Commission's mandate and requested clarification from the CCNFSDU.

106. The Delegation of Australia introduced the paper (CRD 10) which covered current approaches to dietary modelling of intakes and its role in exposure assessment and risk assessment. The Committee took note of the forthcoming FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals (Geneva, 10 - 14 February 1997).

107. The Committee noted that dietary modelling could be relevant to its work, particularly in conjunction with the establishment of upper limits for supplementation and fortification, and agreed to circulate the paper for comments, in order to determine future work in this area at the next session.

Reference number	Paragraph number	Relevant text
113	**128 -131**	**ALINORM 01/26 CCNFSDU22, Berlin, Germany**

128. The Delegation of Australia, while introducing the working paper, recalled that the risk analysis approach was being integrated into the Codex decision-making process, on the basis of the recommendations of several FAO/WHO Expert Consultations.

The document considered how the recommendations of the FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals could be applied to the decision process of the Committee when considering nutrition issues. The Delegation proposed that the Committee consider the role of nutrient intake assessment in a risk based approach, which could be applied, for example, to assess the risk of exceeding a tolerable upper level of intake, especially when determining maximum levels of nutrient content in specific foods.

129. The Committee expressed its appreciation to the Delegation of Australia for this interesting paper on complex issues and had a general discussion on how to proceed further in this area. The Chairman noted the specificity of the risks associated with nutrients, especially problems related to malnutrition or over nutrition, and that they would require a relevant methodology.

130. The Delegation of Norway pointed out that such complex issues would need further consideration before deciding what further action was required in the Committee. Some delegations stressed the fundamental difference between risk assessment for chemicals and for nutrients, and expressed the view that approach taken for nutrients should not be exclusively toxicological but should also be related to nutrition. Some delegations noted that there were no guidelines for risk assessment for nutrients, but that it

would be useful to develop models and methods in this area, especially for the purpose of considering novel foods, and upper limits for nutrients.

131. The Committee agreed that a Circular Letter would invite governments to provide information on their experience with risk assessment for nutrition issues at the national level, including methodology and principles. The Delegation of Australia, in co-operation with interested delegations, would proceed with the development of a methodology for the application of risk assessment, in the light of the comments received, for consideration by the next session.

Reference number	Paragraph number	Relevant text
114	**138 -143**	**ALINORM 03/26 CCNFSDU23, Berlin, Germany**

138. The Committee recalled that following earlier discussions, it had been agreed at the last session that the Delegation of Australia would revise its initial discussion paper on the basis of the comments received on risk assessment for nutrition issues. The Delegation of Australia recalled the recommendations of the Commission concerning the application of risk analysis principles in the development of Codex food safety standards and noted the work undertaken by several committees on risk analysis. Several aspects of the Committee's work were related to food safety, as it appeared from recent discussions on the safe levels of vitamins and minerals and these issues should be addressed on the basis of scientific risk assessment. The Delegation recalled that several countries followed a risk-based approach for nutrient assessment at the national level, and some studies were underway to establish safe upper levels of consumption for vitamins and minerals (United States, EC). It was therefore proposed that the Committee should request FAO/WHO to extend their current work on Reference recommended nutrient intakes to include ULs for vitamins and minerals.

139. The Representative of FAO indicated that FAO had already decided to call an Expert Consultation to update the scientific developments related to some vitamins and minerals since the Bangkok meeting in 1998. As a part of this exercise the remit of this expert group would be broadened to the extent possible to consider the possibility to look into the issue of Upper Limits and safety with regard to some micronutrients.

140. The Observer form the EC informed the Committee of the work of the Scientific Committee for Food on the establishment of upper limits for vitamins and minerals and stressed that this was a long term exercise and that it might not be possible to address this question through an international consultation.

141. The Representative of FAO indicated that the Expert Consultation would consult and draw upon the experiences of the Food and Nutrition Board/US National Academy of Sciences and the European Community SCF's work in this area, in order to develop recommendations that could provide the scientific basis for further work in the Committee.

142. The Observer from CRN, referring to its written comments supported further work on risk assessment taking into account the most updated scientific data in order to ensure the scientific basic of decision making.

143. The Committee expressed its appreciation to the Delegation of Australia for its work in this important area and agreed that a risk-based approach should be followed for the establishment of upper limits for micronutrients. It agreed that the next session should be kept informed of the progress achieved by FAO/WHO and national scientific bodies in this area, in order to facilitate its further work on vitamins and minerals.

Reference number	Paragraph number	Relevant text
115	**10**	**CX/NFSDU 01/10: DISCUSSION PAPER ON THE APPLICATION OF METHODOLOGY OF RISK ASSESSMENT FOR NUTRITION ISSUES: THE INCORPORATION OF NUTRIENT INTAKE ASSESSMENT IN A RISK-BASED APPROACH TO ASSIST DECISION MAKING PROCESSES OF CCNFSDU, Berlin, Germany**

10. A risk assessment approach to setting standards for nutrients may be of increasing importance as all governments and Codex address controversial topics such as the use of non-nutritive ingredients (fat, oil and sugar replacements) and different dietary fibres in foods, increased use of novel foods or ingredients, foods derived by biotechnology, dietary supplements and food fortification. An associated issue is the assessment and scientific validation of nutrition and health claims.

Reference number	Paragraph number	Relevant text
116	**Agenda Item 9 at the 2002 CCNFSDU meeting**	**CX/NFSDU 02/9: DISCUSSION PAPER ON THE PROGRESS OF WORK BY FAO/WHO AND NATIONAL SCIENTIFIC BODIES IN RELATION TO RISK-BASED APPROACH FOR THE ESTABLISHMENT OF UPPER LIMITS FOR NUTRIENTS**

12. The approach to be followed would be the one laid out in the proposed draft working principles for risk analysis for application in the framework of the Codex Alimentarius (Appendix II, ALINORM 03/33) with the responsibility for risk assessment being the responsibility of the FAO/WHO Expert bodies and Consultations (risk assessors). According to these working principles, risk assessment should be based on all the available scientific data; predominantly quantitative but also takes into account qualitative information. The need to obtain information wherever possible from developing countries and based on realistic exposure scenarios is also emphasized.

Reference number	Paragraph number	Relevant text
117	**145-149**	**ALINORM 03/27/26 CCNFSDU23, Bonn, Germany**

145. The Delegation of Australia introduced the document and recalled that the CCNFSDU first considered the matter of dietary modelling to inform a risk-based approach for its decision making at its 20th session in 1996. After discussion of the potential to incorporate nutrient intake (dietary exposure) assessments within a risk-based approach at its 22nd Session in 2000, it was agreed that CCNFSDU would proceed with the development of a methodology for the application of risk assessment to relevant Codex standards and related texts. It also noted that while adopting the Working Principles for Risk Analysis, the Commission requested that relevant Codex committees develop or complete specific guidelines on risk analysis in their respective areas, consistent with the overarching Working Principles for inclusion in the Procedural Manual, as recommended in the Action Plan.

146. The Delegation highlighted ramifications of these developments to the work of the CCNFSDU and presented two recommendations in relation to the future work of the Committee in this area:

- to acknowledge that Working Principles for Risk Analysis are highly relevant to the Committee' s work and
- to elaborate specific principles and guidelines for Risk Analysis relevant to the work of the Committee.

147. The Delegation of the United States supported these proposals and indicated that risk analysis principles should acknowledge the unique characteristics of nutrients.

148. Some other delegations and observers also supported the above recommendations. It was noted that scientific process should be part of risk management decisions and that some guiding principles and guidelines were necessary especially for the establishment of safe upper levels of nutrients.

149. The Committee agreed that the Delegation of Australia14 would lead an electronic working group and invited Member Countries to submit their proposals to the Delegation of Australia with the understanding that an outline of specific guidelines prepared on the basis of Working Principles for Risk Analysis adopted by the Commission would aim to be prepared for consideration at the next session of the Committee.

Reference number	Paragraph number	Relevant text
118	**142-148**	**https://www.fao.org/4/y4800e/y4800e0o.htm#bm24**

SCOPE

1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
2) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
3) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

Reference number	Paragraph number	Relevant text
119	**3.4.4.3**	**GUIDELINES ON NUTRITION LABELLING CXG 2-1985**

3.4.4.2 NRVs-NCD

Intake levels not to exceed	
Saturated fatty acids	20 g[8,9]
Sodium	2 000 mg[10]
Intake levels to achieve	
Potassium	3 500 mg[10]

[8] This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories.
[9] The selection of this nutrient for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk as reported in the report Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916. WHO, 2003.
[10] The selection of these nutrients for the establishment of an NRV was based on "high quality" evidence for a relationship with a biomarker for NCD risk in adults as reported in the respective 2012 WHO Guidelines on sodium and potassium intake for adults and children.

Reference number	Paragraph number	Relevant text
120	**10- 46 pages**	***CXS 192-1995, Annex B***

https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B192-1995%252FCXS_192e.pdf.

Reference number	Paragraph number	Relevant text
123	**Entire document**	**WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS**

Scope:
1. These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
2. The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
3. Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).
https://www.fao.org/4/y5817e/y5817e04.htm.