

1 **1 Scope**

2 This standard is intended to provide guidance to the responsible competent authority
3 for risk assessment, risk management and risk communication with regard to food
4 related risks to human health.

5 **2 Normative references**

6 The following referenced documents are indispensable for the application of this
7 document. For dated references, only the edition cited applies. For undated references,
8 the latest edition of the referenced document (including any amendments) applies.

9 CAC/GL 62-2007, *Working Principles for Risk Analysis for Food Safety for Application by*
10 *Governments*

11 **3 Terms and definitions**

12 For the purposes of this document, the following terms and definitions apply:

13 **3.1**

14 **exposure assessment**

15 qualitative and/or quantitative evaluation of the likely intake of biological, chemical,
16 and physical agents via food as well as exposures from other sources if relevant

17 **3.2**

18 **hazard**

19 biological, chemical and/or physical agent in, or condition of, food with the potential to
20 cause an adverse health effect

21 **3.3**

22 **hazard characterization**

23 qualitative and/or quantitative evaluation of the nature of the adverse health effects
24 associated with biological, chemical and physical agents which may be present in food.
25 For chemical agents, a dose-response assessment should be performed. For biological
26 or physical agents, a dose-response assessment should be performed if the data are
27 obtainable

28 **3.4**

29 **hazard identification**

30 identification of biological, chemical, and physical agents capable of causing adverse
31 health effects and which may be present in a particular food or group of foods

32 **3.5**

33 **responsible competent authority**

34 refers to the regulatory agency responsible for the implementation of official food
35 control system to ensure public health and safety across the food supply chain

36 **3.6**

50 risk

51 function of the probability of an adverse health effect and the severity of that effect,
52 consequential to a hazard(s) in food

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55 3.7**risk analysis**

56 process consisting of three components : risk assessment, risk management and risk
57 communication

58

59 3.8**risk assessment**

60 scientifically based process consisting of the following steps: (i) hazard identification,
61 (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization

62

63 3.9**risk assessment policy**

64 documented guidelines on the choice of options and associated judgements for their
65 application at appropriate decision points in the risk assessment such that the scientific
66 integrity of the process is maintained

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68 3.10**risk characterization**

69 qualitative and/or quantitative estimation, including attendant uncertainties, of the
70 probability of occurrence and severity of known or potential adverse health effects in a
71 given population based on hazard identification, hazard characterization and exposure
72 assessment

73

74 3.11**risk communication**

75 interactive exchange of information and opinions throughout the risk analysis process
76 concerning risk, risk-related factors and risk perceptions, among risk assessors, risk
77 managers, consumers, industry, the academic community and other interested parties,
78 including the explanation of risk assessment findings and the basis of risk management
79 decisions

80

81 3.12**risk estimate**

82 quantitative estimation of risk resulting from risk characterization

83

84 3.13**risk management**

85 process, distinct from risk assessment, of weighing policy alternatives, in consultation
86 with all interested parties, considering risk assessment and other factors relevant for
87 the health protection of consumers and for the promotion of fair trade practices, and, if
88 needed, selecting appropriate prevention and control options

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90 3.14**risk profile**

99 description of the food safety problem and its context

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102

103 **4 General aspects**

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105 4.1 The overall objective of risk analysis applied to food safety is to ensure human
106 health protection.

107

108 4.2 These principles apply equally to issues of national food control and food trade
109 situations and should be applied consistently and in a non-discriminatory manner.

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111 4.3 To the extent possible, the application of risk analysis should be established as
112 an integral part of a national food safety system.

113

114 4.4 Implementation of risk management decisions at the national level should be
115 supported by an adequately functioning food control system/program.

116

117 4.5 Risk analysis should be: applied consistently; open, transparent and
118 documented; and evaluated and reviewed as appropriate in the light of newly
119 generated scientific data.

120

121 4.6 The risk analysis should follow a structured approach comprising the three
122 distinct but closely linked components of risk analysis (risk assessment, risk
123 management and risk communication) as defined by the Codex Alimentarius
124 Commission, each component being integral to the overall risk analysis.

125

126 4.7 The three components of risk analysis should be documented fully and
127 systematically in a transparent manner. While respecting legitimate concerns to
128 preserve confidentiality, documentation should be accessible to all interested
129 parties (risk assessors, risk managers, consumers, industry, the academic
130 community and, as appropriate, other relevant parties and their representative
131 organizations).

132

133 4.8 Effective communication and consultation with all interested parties should be
134 ensured throughout the risk analysis.

135

136 4.9 The three components of risk analysis should be applied within an overarching
137 framework for management of food related risks to human health.

138

139 4.10 There should be a functional separation of risk assessment and risk management
140 to the degree practicable, in order to ensure the scientific integrity of the risk
141 assessment, to avoid confusion over the functions to be performed by risk
142 assessors and risk managers and to reduce any conflict of interest.

143

144 However, it is recognized that risk analysis is an iterative process, and
145 interaction between risk managers and risk assessors is essential for practical
146 application.

- 139 4.11 Precaution is an inherent element of risk analysis. Many sources of uncertainty
140 exist in the process of risk assessment and risk management of food related
141 hazards to human health. The degree of uncertainty and variability in the
142 available scientific information should be explicitly considered in the risk
143 analysis. The assumptions used for the risk assessment and the risk management
144 options selected should reflect the degree of uncertainty and the characteristics
145 of the hazard.
- 146 4.12 The responsible competent authority should take into account relevant guidance
147 and information obtained from risk analysis activities pertaining to human
148 health protection conducted by Codex, FAO, WHO and other relevant
149 international intergovernmental organizations, including OIE and IPPC.
- 150 4.13 With the support of international organizations where appropriate, the
151 responsible competent authority should design and/or apply appropriate
152 training, information and capacity building programs that are aimed to achieve
153 the effective application of risk analysis principles and techniques in their food
154 control systems.
- 155 4.14 The responsible competent authority should share information and experiences
156 on risk analysis with relevant international organizations, other national
157 governments (e.g. at the regional level through FAO/WHO Regional Coordinating
158 Committees) to promote and facilitate a broader and, where appropriate, more
159 consistent, application or risk analysis.

160 **5 Risk assessment policy**

- 161 5.1 Determination of risk assessment policy should be included as a specific
162 component of risk management.
- 163 5.2 Risk assessment policy should be established by risk managers in advance of risk
164 assessment, in consultation with risk assessors and all other interested parties.
165 This procedure aims at ensuring that the risk assessment is systematic,
166 complete, unbiased and transparent.
- 167 5.3 The mandate given by risk managers to risk assessors should be as clear as
168 possible.
- 169 5.4 When necessary, risk managers should ask risk assessors to evaluate the
170 potential changes in risk resulting from different risk management options.

171 **6 Risk assessment**

- 172 6.1 Each risk assessment should be fit for its intended purpose.
- 173 6.2 The scope and purpose of the risk assessment being carried out should be clearly
174 stated and in accordance with risk assessment policy. The output form and
175 possible alternative outputs of the risk assessment should be defined.

- 176 6.3 Experts involved in risk assessment including government officials and experts
177 from outside government should be objective in their scientific work and not be
178 subject to any conflict of interest that may compromise the integrity of the
179 assessment. Information on the identities of these experts, their individual
180 expertise and their professional experience should be publicly available, subject
181 to national considerations. These experts should be selected in a transparent
182 manner on the basis of their expertise and their independence with regard to the
183 interests involved, including disclosure of conflicts of interest in connection with
184 risk assessment.
- 185 6.4 Risk assessment should incorporate the four steps of risk assessment, i.e. hazard
186 identification, hazard characterization, exposure assessment and risk
187 characterization.
- 188 6.5 Risk assessment should be based on scientific data most relevant to the national
189 context. It should use available quantitative information to the greatest extent
190 possible. Risk assessment may also take into account qualitative information.
- 191 6.6 Risk assessment should take into account relevant production, storage and
192 handling practices used throughout the food chain including traditional
193 practices, methods of analysis, sampling and inspection and the prevalence of
194 specific adverse health effects.
- 195 6.7 Constraints, uncertainties and assumptions having an impact on the risk
196 assessment should be explicitly considered at each step in the risk assessment
197 and documented in a transparent manner. Expression of uncertainty or
198 variability in risk estimates may be qualitative or quantitative, but should be
199 quantified to the extent that is scientifically achievable.
- 200 6.8 Risk assessments should be based on realistic exposure scenarios, with
201 consideration of different situations being defined by risk assessment policy.
202 They should include consideration of susceptible and high-risk population
203 groups. Acute, chronic (including long-term), cumulative and/or combined
204 adverse health effects should be taken into account in carrying out risk
205 assessment, where relevant.
- 206 6.9 The report of the risk assessment should indicate any constraints, uncertainties,
207 assumptions and their impact on the risk assessment. Minority opinions should
208 also be recorded. The responsibility for resolving the impact of uncertainty on
209 the risk management decision lies with the risk manager, not the risk assessors.
- 211 6.10 The conclusion of the risk assessment including a risk estimate, if available,
212 should be presented in a readily understandable and useful form to risk
213 managers and made available to other risk assessors and interested parties so
214 that they can review the assessment.
- 215 7 **Risk management**
- 216 7.1 The responsible competent authority decisions on risk management, including
217 sanitary measures taken, should have as their primary objective the protection of

- 218 the health of consumers. Unjustified differences in the measures selected to
219 address similar risks in different situations should be avoided.
- 220 7.2 Risk management should follow a structured approach including preliminary
221 risk management activities (identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk
222 management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment), evaluation of risk management options, implementation, monitoring and review of the decision taken.
- 227 7.3 The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles as they relate to decisions at the national level. The responsible competent authority should base their sanitary measures on Codex standards and related texts, where available.
- 235 7.4 In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.
- 240 7.5 Risk management should take into account the economic consequences of the feasibility of risk management options.
- 242 7.6 The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.
- 246 7.7 The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.
- 249 7.8 Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.
- 252 7.9 Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade and select measures that are no more trade-restrictive than necessary.

260 7.10 Risk management should be a continuing process that takes into account all
261 newly generated data in the evaluation and review of risk management options.
262 The relevance, effectiveness, and impacts of risk management decisions and their
263 implementation should be regularly monitored and the decisions and/or their
264 implementation reviewed as necessary.

265 **8 Risk communication**

266 8.1 Risk communication should:

267 8.1.1 promote awareness and understanding of the specific issues under
268 consideration during the risk analysis;

269 8.1.2 promote consistency and transparency in formulating risk management
270 options/recommendations;

271 8.1.3 provide a sound basis for understanding the risk management decisions
272 proposed;

273 8.1.4 improve the overall effectiveness and efficiency of the risk analysis;

274 8.1.5 strengthen the working relationships among participants;

275 8.1.6 foster public understanding of the process, so as to enhance trust and
276 confidence in the safety of the food supply;

277 8.1.7 promote the appropriate involvement of all interested parties;

278 8.1.8 exchange information in relation to the concerns of interested parties about
279 the risks associated with food; and

280 8.1.9 respect the legitimate concern to preserve confidentiality where applicable.

281 8.2 Risk analysis should include clear, interactive and documented communication,
282 among risk assessors and risk managers and reciprocal communication with all
283 interested parties in all aspects of the process.

284 8.3 Risk communication should be more than the dissemination of information. Its
285 major function should be to ensure that all information and opinion required for
286 effective risk management is incorporated into the decision making process.

287 8.4 Risk communication involving interested parties should include a transparent
288 explanation of the risk assessment policy and of the assessment of risk, including
289 the uncertainty. The decisions taken and the procedures followed to reach them,
290 including how the uncertainty was dealt with, should also be clearly explained. It
291 should indicate any constraints, uncertainties, assumptions and their impact on
292 the risk analysis, and minority opinions that had been expressed in the course of
293 risk assessment (see 6.9).

294 **Bibliography**295 Codex Alimentarius Commission. 2013. *Codex Alimentarius Commission Procedural
296 Manual Twenty-first edition*. Rome: World Health Organization and Food and
297 Agriculture Organization of the United Nations.