

PHILIPPINE NATIONAL STANDARD

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Working Principles for Risk Analysis for Food Safety Application by Governments



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Working Principles for Risk Analysis for Food Safety Application by Governments

Foreword

The Philippine National Standard (PNS) on Working Principles for Risk Analysis for Food Safety Application by Governments was developed by the Bureau of Agriculture and Fisheries Standards with the guidance of the Technical Working Group. This document has been prepared by the Technical Working Group (TWG) for the development of the said standard as per Department of Agriculture Special Orders No. 585 and 789 series of 2017. The PNS has been approved by the Secretary of the Department of Agriculture in 2020.

In the development of the standard, the International Standard of the Codex Alimentarius Commission (CAC) *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) was adopted with modifications to suit the local conditions in the Philippines.

This document was drafted in accordance with the editorial rules of the BPS Directives Part 2.

Table of contents

Foreword.....	ii
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 General aspects.....	3
5 Risk assessment policy.....	4
6 Risk assessment.....	4
7 Risk management.....	6
8 Risk communication.....	7
Bibliography.....	8

Working Principles for Risk Analysis for Food Safety Application by Governments

1 Scope

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

2 Normative references

There are no normative references for this standard.

3 Terms and definitions

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

3.1**dose-response assessment**

determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response)

3.2**exposure assessment**

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

3.3**hazard**

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

3.4**hazard characterization**

qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For identified hazards, a dose-response assessment should be performed.

3.5**hazard identification**

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

3.6**responsible competent authority**

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

3.7**risk**

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

3.8**risk analysis**

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

3.8.1**risk assessment**

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

3.8.2**risk management**

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

3.8.3**risk communication**

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

3.9**risk assessment policy**

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

3.10**risk characterization**

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 hazard identification, hazard characterization and exposure assessment

3.11**risk estimate**

qualitative and/or quantitative estimation of risk resulting from risk characterization

3.12**risk profile**

description of the food safety problem and its context

4 General aspects

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

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

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

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

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

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

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

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

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

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

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

Working Principles for Risk Analysis for Food Safety Application by Governments

4.11 Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty, and the characteristics of the hazard.

4.12 The responsible competent authority should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by CAC, Food and Agriculture Organization (FAO), World Health Organization (WHO) and other relevant international inter-governmental organizations, including Oficina Internacional de Epizootias or World Organisation for Animal Health (OIE) and International Plant Protection Convention (IPPC).

4.13 With the support of international organizations where appropriate, the responsible competent authority should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.

4.14 The responsible competent authority should share information and experiences on risk analysis with relevant international organizations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent application of risk analysis.

5 Risk assessment policy

5.1 Determination of risk assessment policy should be included as a specific component of risk management.

5.2 Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased, and transparent.

5.3 The mandate given by risk managers to risk assessors should be as clear as possible.

5.4 When necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

6 Risk assessment

6.1 Each risk assessment should be fit for its intended purpose.

Working Principles for Risk Analysis for Food Safety Application by Governments

6.2 The scope and purpose of the risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

6.3 Experts involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

6.4 Risk assessment should incorporate the four steps, i.e. hazard identification, hazard characterization, exposure assessment, and risk characterization.

6.5 Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

6.6 Risk assessment should take into account relevant production, storage, and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, and the prevalence of specific adverse health effects.

6.7 Constraints, uncertainties, and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative but should be quantified to the extent that is scientifically achievable.

6.8 Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

6.9 The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

6.10 The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

7 Risk management

7.1 The responsible competent authority's decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.

7.2 Risk management should follow a structured approach including preliminary risk management activities (identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk 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.

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. The decisions may be 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.

7.4 In achieving agreed outcomes, risk management should take into account relevant production, processing, storage, transport, handling, and distribution 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.

7.5 Risk management should take into account the economic consequences of the feasibility of risk management options.

7.6 The risk management process should be transparent, consistent, and fully documented. Decisions on risk management should be documented to facilitate a wider understanding of the risk management process by all interested parties.

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.

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.

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

Working Principles for Risk Analysis for Food Safety Application by Governments

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.

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

8 Risk communication

8.1 Risk communication should:

- 8.1.1** promote awareness and understanding of the specific issues under consideration during the risk analysis;
- 8.1.2** promote consistency and transparency in formulating risk management options/recommendations;
- 8.1.3** provide a sound basis for understanding the risk management decisions proposed;
- 8.1.4** improve the overall effectiveness and efficiency of the risk analysis;
- 8.1.5** strengthen the working relationships among interested parties;
- 8.1.6** foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
- 8.1.7** promote the appropriate involvement of all interested parties;
- 8.1.8** exchange information in relation to the concerns of interested parties about the risks associated with food; and
- 8.1.9** respect the legitimate concern to preserve confidentiality where applicable.

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

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

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

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Bibliography

Codex Alimentarius Commission. (2007). *Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)*. Retrieved from http://www.fao.org/in put/download/standards/10751/CXG_062e.pdf

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