WORKING PRINCIPLES FOR RISK ANALYSIS

National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives

ICS 01.120 ISBN 974-403-335-5
UNOFFICIAL TRANSLATION

THAI AGRICULTURAL STANDARD

TAS 9006-2005

WORKING PRINCIPLES FOR RISK ANALYSIS

National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
50 Phaholyothin Road, Ladyao, Chatuchak, Bangkok 10900
Telephone (662) 561 2277 www.acfs.go.th

Published in the Royal Gazette Vol.122 Section 122D,
dated 22 December B.E.2548
The establishment of national standards or regulations is for the benefit of management of food safety. It is necessary to follow a scientific systematic approach with clear structure and transparent process based on the international risk analysis. Therefore, it is appropriate to establish the Thai Agricultural Standard on Working Principles for Risk Analysis based on the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius issued by the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme.

The establishment of this standard is based on the following document:


**Remark:**

The standard title has been revised from “Thai Agricultural Commodity and Food Standard (TACFS)” to “Thai Agricultural Standard (TAS)” in accordance with the enforcement of the Agricultural Standards Act B.E. 2551 (2008).
NOTIFICATION OF THE NATIONAL COMMITTEE ON
AGRICULTURAL COMMODITY AND FOOD STANDARDS
SUBJECT: THAI AGRICULTURAL COMMODITY AND FOOD STANDARD:
WORKING PRINCIPLES FOR RISK ANALYSIS
B.E.2548 (2005)

The resolution of the 2/2548 session of the National Committee on Agricultural Commodity and Food Standards dated 29 August B.E. 2548 (2005) endorsed the Thai Agricultural Commodity and Food Standard entitled Working Principles for Risk Analysis. This standard would be of benefits for quality improvement, facilitating trade and protecting consumers.

By virtue of the Cabinet Resolution on Appointment and Authorization of the National Committee on Agricultural Commodity and Food Standards dated 19 November B.E. 2545 (2002), the Notification on Thai Agricultural Commodity and Food Standard entitled Working Principles for Risk Analysis is hereby issued as voluntary standard, the details of which are attached herewith.

Notified on 29 September B.E.2548 (2005)

Khunying Sudarat Keyuraphan
Minister of Agriculture and Cooperatives
Chairperson of the National Committee on Agricultural Commodity and Food Standards
THAI AGRICULTURAL STANDARD
WORKING PRINCIPLES FOR RISK ANALYSIS

1 SCOPE

This standard establishes working principles for risk analysis to be used as a guideline for risk managers, risk assessors and risk communicators involved in food safety standards or requirements establishment process according to risk analysis principles.

2 DEFINITIONS

For the purpose of this standard:

2.1 Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

2.2 Hazard means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

2.3 Hazard identification means the identification of hazard (2.2) and which may be present in a particular food or group of foods.

2.4 Hazard characterization means the 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 chemical agents, a dose response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

2.5 Dose response assessment means the 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).

2.6 Exposure assessment means the 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.

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

2.8 Risk analysis means a process consisting of three components: risk assessment, risk management and risk communication.

2.9 Risk assessment means a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.
2.10 **Risk assessment policy** means documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

2.11 **Risk characterization** means 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 hazard identification, hazard characterization and exposure assessment.

2.12 **Risk communication** means the 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.

2.13 **Risk estimate** means the quantitative estimation of risk resulting from risk characterization.

2.14 **Risk management** means the 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.

2.15 **Risk profile** means the description of the food safety problem and its context.

2.16 **Interested parties** mean risk assessors, risk managers, consumers, industry, the academic community and other relevant parties and their representative organizations.

3 **RISK ANALYSIS - GENERAL ASPECTS**

3.1 The risk analysis should be:

(1) applied consistently;

(2) open, transparent and documented;

(3) conducted in accordance with Annex A when applied in the establishment of food standards, and guidelines and other recommendations; and

(4) evaluated and reviewed as appropriate in the light of newly generated scientific data.

3.2 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).

3.3 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.

3.4 Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
3.5 The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

3.6 There should be a functional separation of risk assessment and risk management, 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.

3.7 When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, standard establishment bodies 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.

3.8 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. Where there is sufficient scientific evidence to allow risk manager to proceed to elaborate a standard or related text, 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 RISK ASSESSMENT POLICY

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

4.2 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.

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

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

5 RISK ASSESSMENT

5.1 The scope and purpose of the particular 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.

5.2 Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented and open to public.

5.3 Risk Assessment should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.
Risk assessment should be based on science, documented, separated from risk management and emphasize on interactive communication.

5.4 Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

5.5 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.

5.6 Risk assessment should seek and incorporate relevant data from different parts of the world include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available risk assessor should cooperate with other agencies to conduct studies relevant to the objectives. The conduct of the risk assessment should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

5.7 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.

5.8 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.

5.9 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.

5.10 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.

6  RISK MANAGEMENT

6.1 While recognizing the dual purposes are protecting the health of consumers and ensuring fair practices in the food trade, decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

6.2 Risk management should follow a structured approach including preliminary risk management. For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile;
ranking of the hazard for risk assessment and risk management priority; monitoring and review of the decision taken. The decisions should be based on risk assessment, and 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 in Annex A (A.4) as appropriate.

6.3 Risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind the guidance given in section 3.7 of General Principles.

6.4 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.

6.5 The risk management process should be transparent, consistent and fully documented. Decisions and recommendations on risk management should be documented, and where appropriate clearly identified.

6.6 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.

6.7 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.

6.8 In order to avoid unjustified trade barriers, 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 should seek and take into consideration 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. Select measures that are no more trade-restrictive than necessary.

6.9 Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers’ health.

6.10 Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.
7 RISK COMMUNICATION

7.1 Risk communication should:

(1) promote awareness and understanding of the specific issues under consideration during the risk analysis;

(2) promote consistency and transparency in formulating risk management options/recommendations;

(3) provide a sound basis for understanding the risk management decisions proposed;

(4) improve the overall effectiveness and efficiency of the risk analysis;

(5) strengthen the working relationships among participants;

(6) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;

(7) promote the appropriate involvement of all interested parties; and

(8) exchange information in relation to the concerns of interested parties about the risks associated with food.

7.2 Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers, and reciprocal communication with all interested parties in all aspects of the process and need to be documented.

7.3 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.

7.4 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 need for specific standards or related texts and the procedures followed to determine 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 the risk assessment (see section 5.9).

7.5 The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentiality.
ANNEX A
THE ESTABLISHMENT OF FOOD STANDARDS, GUIDELINES AND OTHER RECOMMENDATIONS

A.1 The food standards, guidelines and other recommendations shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of efficiency relevant information, in order that the standards assure the quality and safety of the food supply.

A.2 When elaborating and deciding upon food standards will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

A.3 In this regard it is noted that food labelling plays an important role in furthering both of the health protection of consumers and for the promotion of fair practices in food trade.

A.4 Criteria for the consideration of the other factors in risk analysis should emphasize on consumer health and safety and take into account the following criteria.

A.4.1 when health and safety matters are concerned
A.4.2 other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
A.4.3 consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
A.4.4 some legitimate concerns of governments when establishing their national legislation are not generally applicable;
A.4.5 only those other factors which can be accepted on a world-wide basis, or on a regional basis;
A.4.6 the consideration of specific other factors in the development of risk management should be clearly documented, including the rationale for their integration, on a case-by-case basis;
A.4.7 the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
A.4.8 the integration of other legitimate factors in risk management should not create unjustified barriers to trade.