

ARAC Standard Operating Procedure No.1

Title:

PROCEDURES FOR COMMISSIONING RISK ASSESSMENT AND/ OR SCIENTIFIC OPINIONS

Version No: 2

Amended version as endorsed by the ASEAN Senior Officials' Meeting on the
Health Development (SOMHD), 31 January 2025

ASEAN Risk Assessment Centre for Food Safety (ARAC),
Food Safety and Quality Programme,
Ministry of Health Malaysia,
Level 4, Menara Prisma, No 26, Persiaran Perdana,
Presint 3, 62675 Putrajaya, Malaysia
Phone no: +603-88850797
Email: arac@moh.gov.my
Website: www.arac-asean.org

ABBREVIATION AND ACRONYMS	3
1. INTRODUCTION.....	4
2. OBJECTIVE.....	4
3. SCOPE	4
4. TERMINOLOGY	5
5. PROCEDURE DETAILS.....	6
5.1 Request of Risk Assessment/ Scientific Opinion	6
5.2 Commission of Risk Assessment and/ or Scientific opinion.....	7
5.3 Evaluation of Risk Assessment Request by the Scientific Committee .	9
5.4 Conduct of Risk Assessment and / or Scientific Opinion	9
5.5 Endorsement of Risk Assessment and/ or Scientific Opinion Report	10
5.6 Workflow of Risk Assessment / Scientific Opinion Process.....	11
6. REFERENCES.....	13
Annex I	14
Annex II	16

ABBREVIATION AND ACRONYMS

ACCSQ	ASEAN Consultative Committee on Standards and Quality
AHC4	ASEAN Health Cluster 4: Ensuring Food Safety
AMS	ASEAN Member State
ARAC	ASEAN Risk Assessment Centre for Food Safety
FAO	Food and Agriculture Organization
PFPWG	Prepared Foodstuff Products Working Group
SOM-AMAF	Senior Officials Meeting of ASEAN Ministerial Meeting on Agriculture and Forestry
SOMHD	Senior Officials Meeting on Health Development
SOP	Standard Operating Procedure
WHO	World Health Organization

1. INTRODUCTION

The establishment of the ASEAN Risk Assessment Centre for Food Safety (ARAC) located in Malaysia is one (1) of the most important milestones of ASEAN Health Cluster 4: Ensuring Food Safety (AHC4) in the application of an integrated risk assessment mechanism in ASEAN. The primary function of ARAC is to provide independent scientific input by pooling and utilising scientific expertise across ASEAN in developing evidence-based common food safety measures in ASEAN.

As the coordinating centre on risk assessment in the region, ARAC will serve to provide independent risk assessment output and scientific opinion to all relevant ASEAN sectoral bodies such as AHC4 under Senior Officials Meeting on Health Development (SOM-HD), Prepared Foodstuff Products Working Group (PFPWG) under ASEAN Consultative Committee on Standards and Quality (ACCSQ) and ASEAN Sectoral Working Groups under Senior Officials Meeting of ASEAN Ministerial Meeting on Agriculture and Forestry (SOM-AMAF).

ARAC operates in accordance with the endorsed ARAC work plan and relevant documents, such as standard operating procedures for conducting risk assessments and providing scientific opinion including its operational works.

2. OBJECTIVE

This standard operating procedure provides a systematic workflow for ARAC in conducting the food safety risk assessment and/or scientific opinion to ensure efficient operations and implementation of risk assessment.

3. SCOPE

This SOP provides an overview of the flow of conducting risk assessment from requesting new risk assessment to the endorsement of the report by the AHC4 and procedures for commissioning the risk assessment and/or scientific opinions.

4. TERMINOLOGY

ARAC Focal Point	An individual nominated by the AMS acts as a link between national food safety authorities and national risk assessment organisation (if available) with ARAC.
Governing Body	Refers to the AHC4 as an entity or authority responsible for making decisions related to food safety based on the outcomes of risk assessment.
Risk Assessment	The scientific evaluation on potential adverse effect resulting from human exposure to foodborne hazards. It consists of four steps as hazard identification, hazard characterisation, exposure assessment, and risk characterization.
Risk Assessment Report	A report that may comprise a background of the risk assessment work, hazard identification, hazard characterisation, exposure assessment and risk characterisation including limitation and risk management options.
Risk Assessment Request	Formal inquiry to conduct a risk assessment or scientific opinion towards the evaluation of potential risks associated with a specific hazard, foods and conditions. It includes detail of purpose and desired expectations from the Risk Managers/Requesting Body.
Risk Manager/ Requesting Body	Refers to the ASEAN Sectoral Working Groups under SOM-AMAF, AHC4 under SOM-HD, PFPWG under ACCSQ and AMSs (food safety competent authorities) which will request for risk assessment and/ or scientific opinion from ARAC.
Risk Profile	Description on hazard (hazard identification) and information on pathways by which consumers are exposed

	to the hazard; possible risks associated with that exposure; consumer perceptions of the risks; and the distribution of possible risks among different segments of the population (hazard characterisation).
Scientific Committee	Group of top scientists and experts, nominated by the AMS and appointed by the governing body.
Scientific Opinion	Expert judgement or conclusion provided by the scientific panel based on a thorough evaluation of existing evidence, risk assessment report, data and research.
Scientific Panel	Group of experts from various fields of expertise which will conduct the risk assessment/ scientific opinion.
Self-Tasking	Risk assessment request developed by ARAC which identify a particular issue that require further analysis and research during the course of its regular work

5. PROCEDURE DETAILS

5.1 Request of Risk Assessment/ Scientific Opinion

The ARAC initiates its activities by calling for new risk assessment request from all relevant risk managers/ requesting body. ARAC Secretariat through the ASEAN Secretariat, will circulate an email requesting proposals for risk assessment and/ or scientific opinion to all risk managers/ requesting body.

Interested risk manager/ requesting body wishes to propose ARAC to conduct risk assessment shall fill the Risk Assessment and/ or Scientific Opinion Request Form (**Annex I**) with all the required details as below;

- a. The specific hazard and related foods
- b. The risk management questions
- c. Objective, purpose and scope of the risk assessment
- d. AMS data availability
- e. Additional information if available

The completed Risk Assessment Request Form shall be submitted to ASEAN Secretariat prior to review by AHC4 as the governing body. The risk manager/ requesting body may also request assistance from the ARAC Secretariat in completing the request form.

In addition, the risk manager/ requesting body at any time may also submit a risk assessment request to ARAC to conduct risk assessment work and/ or scientific opinion. Meanwhile, in the case of risk assessment request in the event of food safety emergency, the risk manager/ requesting body shall use the form as in **Annex II**, Risk Assessment and/ or Scientific Opinion Request Form in The Event of Food Safety Emergency.

During the course of its regular work, ARAC might consider the urgency to any specific or emerging issue falling within its remit which it considers to pose an actual or potential risk to consumer. Therefore, ARAC Scientific Committee or Scientific Panel may also submit a risk assessment request to AHC4 (governing body) as a self-tasking.

5.2 Commission of Risk Assessment and/ or Scientific opinion

AHC4 as the governing body of ARAC will coordinate, prioritise and commission risk assessment based on request from the risk manager/ requesting body.

AHC4 acting as a governing body shall:

- a. Evaluate the submitted risk assessment request form based on but not limited to the following considerations:
 - I. Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade
 - II. The needs and concerns of AMS
 - III. The diversity of national legislations and any apparent impediments to international trade
 - IV. Work already undertaken by other international organisations
 - V. New information/data that would justify the need to review the existing

assessments or establish a new risk assessment

- VI. The prospect of completing the risk assessment according to the proposed timeline i.e., risk assessment will provide results that can assist in reaching risk management decisions related to control of the hazard without unduly delaying the adoption of the needed risk management guidance
 - VII. The impact on trade i.e., magnitude of the problem in international trade
 - VIII. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available
 - IX. Comply with the ARAC and AHC4 Terms of Reference
- b. Prioritise the risk assessment based on the information provided in proposal in order to establish the priority list.
 - c. Report the result of evaluation and prioritisation of the risk assessment work with rationale to the risk manager/requesting body via Chair of AHC4
 - d. Ensure protection of confidential information and transparency approach during the process of evaluation and prioritisation of the risk assessment work.
 - e. Update the priority list for risk assessment and/ or scientific opinion and communicate to risk manager/requesting body.

ARAC Secretariat will support and facilitate AHC4 to verify the completeness of Proposal for Risk Assessment Request on Food Safety for ASEAN Risk Assessment Centre (ARAC) for prioritisation purposes by AHC4. If the information in the proposal is incomplete, the ARAC Secretariat will request the requesting Risk Manager for further information / clarification.

The priority list for risk assessment shall be updated by the AHC4 and communicated to risk manager (s) and AMSs. Decision of AHC4 to commission risk assessment and/ or scientific opinion will be forwarded to ARAC for Scientific Committee evaluation.

5.3 Evaluation of Risk Assessment Request by the Scientific Committee

The Scientific Committee shall evaluate the requests in terms of completeness and clarity including the expected output based on availability of data and information.

Prior to the evaluation, ARAC Secretariat shall prepare a risk profile in consultation with ARAC Focal Point which should minimally contain the following relevant information:

- a. Information on the concentration data, consumption data and meta data (raw data/details of the sample/description of test result)
- b. Additional data available in addition to those listed in the risk assessment request form
- c. Identified data gap
- d. Other relevant information on hazard identification and hazard characterisation as supplementary information to the Risk Assessment Request Form to support the Scientific Committee in conducting a thorough and informed evaluation of the requests

When necessary, Scientific Committee can provide feedback on additional information required to the risk manager/ requesting body through the ARAC Secretariat. Upon agreement to conduct risk assessment and/ or scientific opinion, the Scientific Committee shall identify and appoint the Scientific Panel members. The Scientific Committee shall work consistently with the ARAC Standard Operating Procedure No. 2: Establishment and Operations of Scientific Committee.

5.4 Conduct of Risk Assessment and / or Scientific Opinion

The Scientific Panel shall conduct risk assessment and/ or scientific opinion based on the risk management questions provided in the Risk Assessment Request Form. The Scientific Panel may request additional scientific data and information from ARAC Focal Point through ARAC Secretariat.

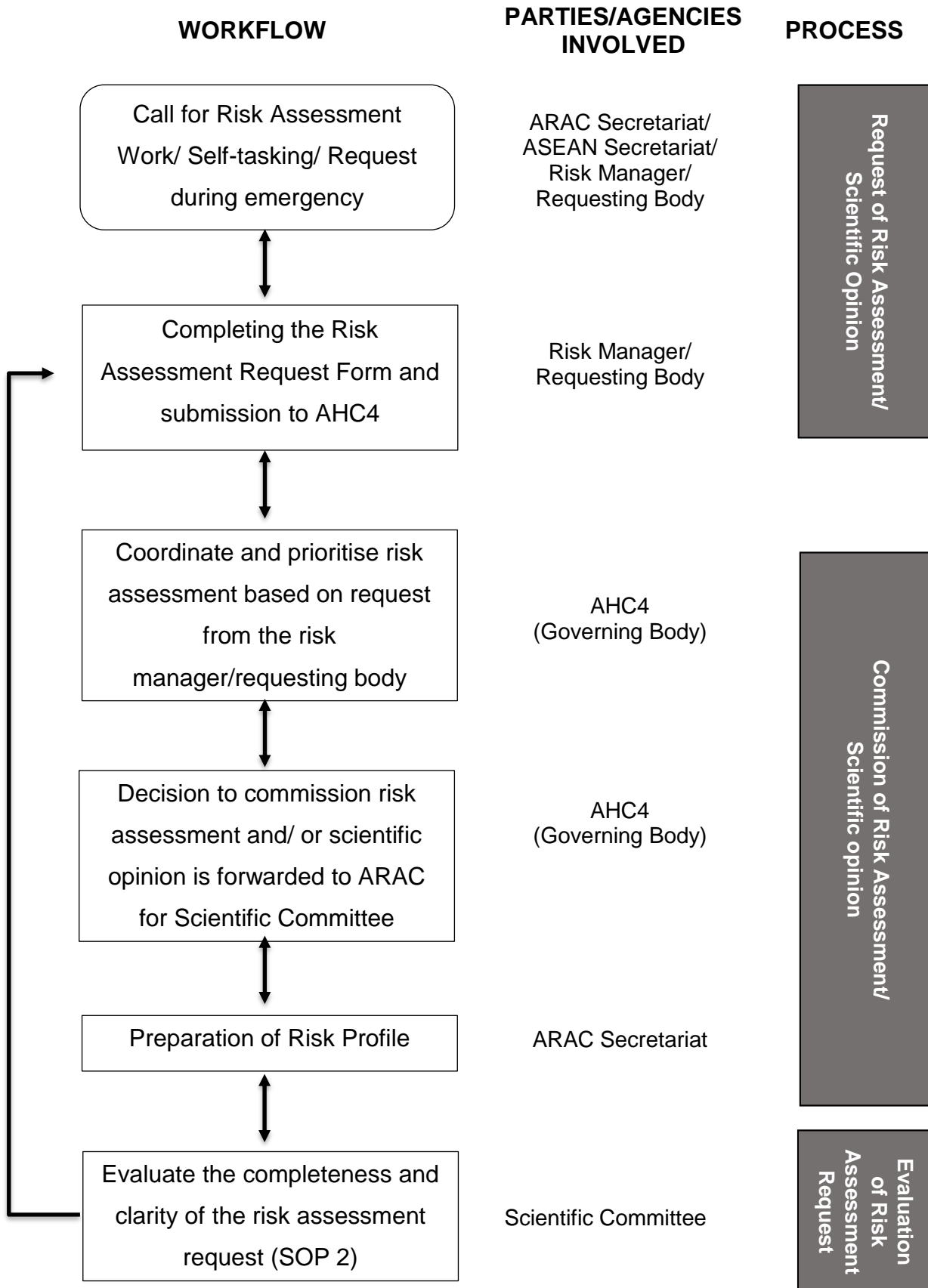
Upon completion of the risk assessment work, the risk assessment and/ or scientific opinion report will be submitted to the Scientific Committee for adoption. The

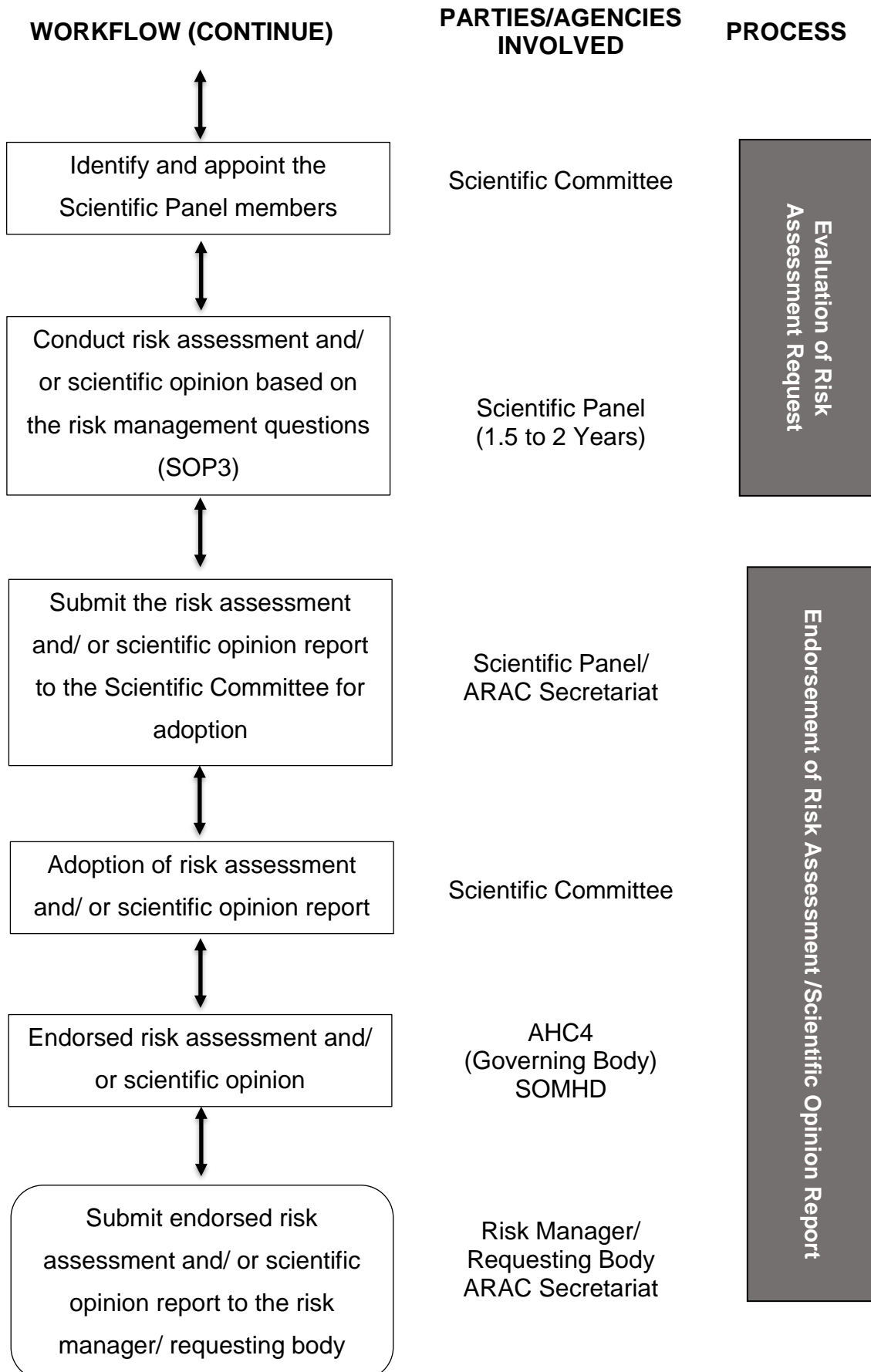
Scientific Committee may request for clarifications from the Scientific Panel through the ARAC Secretariat in regard to the finding from the risk assessment and/ or scientific opinion. The Scientific Panel shall work consistently with the ARAC Standard Operating Procedure No. 3: Scientific Panel.

5.5 Endorsement of Risk Assessment and/ or Scientific Opinion Report

The adopted risk assessment and/ or scientific opinion report by the Scientific Committee shall be submitted to the AHC4 as the governing body for endorsement and subsequently to SOMHD for further endorsement prior to forwarding it to the risk manager/requesting body. The risk manager/requesting body may request for clarifications from the Scientific Committee through AHC4 in regard to the finding from the risk assessment and/ or scientific opinion.

5.6 Workflow of Risk Assessment / Scientific Opinion Process





6. REFERENCES

FAO and WHO. 2023. Codex Alimentarius Commission Procedural Manual. Twenty-eighth edition, revised. Rome. <https://doi.org/10.4060/cc5042en>

FAO and WHO.2006. Food Safety Risk Analysis. A Guide for National Food Safety Authorities. Rome. <https://www.fao.org/4/a0822e/a0822e00.htm>

Annex I

RISK ASSESSMENT AND/ OR SCIENTIFIC OPINION REQUEST FORM

Email to: ASEAN Secretariat Health Division (health@asean.org)

Copy to: ARAC Secretariat (arac@moh.gov.my)

A. Information on the Risk Manager/Requesting Body

1. ASEAN Sectoral body:

2. Name of the Lead Country:

B. Information of the request

1. Types of requests. Tick (/) on the option below:

Risk Assessment:

Scientific Opinion:

2. Proposed title of the request:

a) Hazard Name: _____

b) Food Product: _____

3. Risk Management Questions

4. Background information covers concern of food safety issues, impact on health, economy and trade, including the problem statements and justification.

5. Objective, Purpose and Scope of the Proposed Risk Assessment Request

6. Data availability (Published data/monitoring and surveillance data from the competent authority, timeline for data availability) e.g.: concentration data, prevalence data, consumption data, raw data, details of the sample, description of test result.

7. Proposed timeline for completion of the risk assessment and/ or scientific opinion

8. AMS commitment to contribute required data for risk assessment. (Please specify the AMS which commit to contribute data)

9. Other relevant information:

10. Contact person for any clarification on this request:

Contact person 1: Name: Email: Telephone no: Address:	Contact person 2: Name: Email: Telephone no: Address:
---	---

Annex II

**RISK ASSESSMENT AND/ OR SCIENTIFIC OPINION REQUEST FORM IN THE
EVENT OF FOOD SAFETY EMERGENCY**

Email to: ARAC Secretariat (arac@moh.gov.my)

Copy to: ASEAN Secretariat Health Division (health@asean.org)

Risk Manager/Requesting Body: _____

1. Brief description of the situation (Food safety issues, impact on health, economy and trade, target population including the problem statements and justification)

2. Identified/possible hazard:

3. Implicated Food and product information (e.g., Raw/ RTE/ for further process, list of ingredients and product process flow, which ever relevant)

4. Risk Management Questions

5. Expected Output. Please tick (/) on the options below

Exposure Assessment (Depending on data provided)
Risk Characterisation
Recommendation for mitigation action
Others (Limited to ARAC TOR)

6. Data (e.g. Concentration data, prevalence) and Consumption Data (gram/day, average of population weight, target population)

7. Expected timeline for completion

8. Other relevant information

9. Contact person for any clarification on this request:

Contact person 1:	Contact person 2:
Name:	Name:
Email:	Email:
Telephone no:	Telephone no:
Address:	Address:

Important Note:

If new or updated information is available, the requester should inform the SC through ARAC Secretariat as soon as possible.

AMENDMENT LOG

Date of Revision	Version	Amendment Details	Endorsement Date
-	1	-	15 th September 2015
13-16 th August 2024	2	Refined scope of SOP, improvision of terminologies, description of procedures, and enhancement of the annexes, including the inclusion of a risk assessment form in the event of food safety emergencies.	TBC