Microbiological Risk Assessment in Southeast Asia:

Current Gaps, Emerging Opportunities, and the Role of Whole Genome Sequencing in Strengthening Evidence-Based Food Safety

SUNWAY UNIVERSITY

Chai Lay Ching, PhD
Professor of Microbiology

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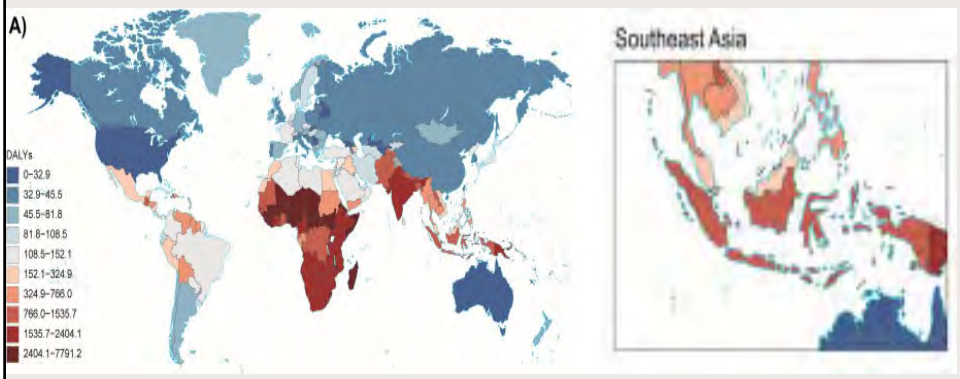
Foodborne Disease Burden and the Cost of Inaction



- 600 million illnesses & 420,000 deaths annually (WHO, 2015).
- SEA & Western Pacific: among top 3 regions for burden.
- ASEAN losses ≈ USD 15 billion/year.
- Under-reporting → underestimation of true risk.

Global burden of diseases due to enteric infections in 2021. A: Age-standardized DALY rates in 2021.

Li, T., *et al.* (2024). *Global burden of enteric infections related foodborne diseases, 1990–2021: Findings from the Global Burden of Disease Study 2021. Science in One Health, 3*, 100075. https://doi.org/10.1016/j.soh.2024.100075

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CODEX Alimentarius Food Safety Risk Analysis Framework

Codex and JEMRA define MRA as a structured, scientific process for quantifying risk.

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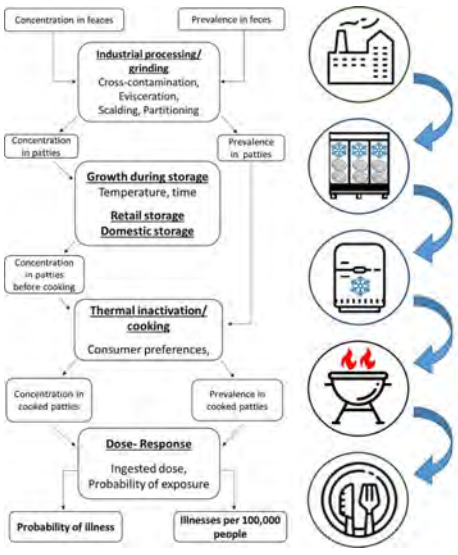

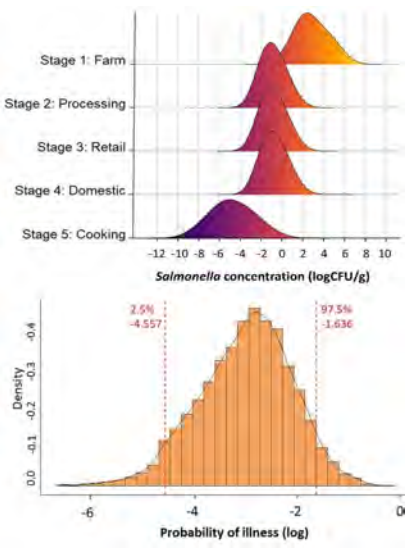

Stathas, L., *et al.* (2024). *Quantitative microbial risk assessment of Salmonella in fresh chicken patties. Food Research International, 178,* 113960. https://doi.org/10.1016/j.foodres.2024.113960

Quantitative MRA

- provides a numerical basis for managing risk.
- It moves us beyond statements like *"this pathogen is risky"* to *"this level of contamination will result in X cases of illness per million servings."*
- guides performance objectives and microbial criteria and support cost–benefit decisions

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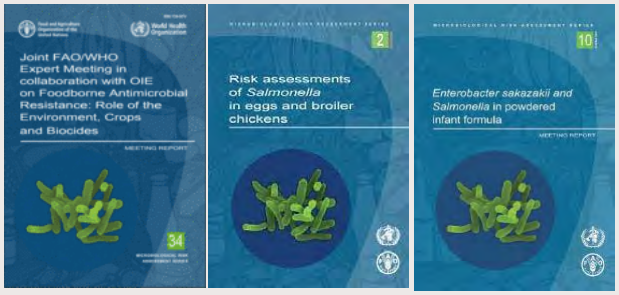
Global Best Practices

Globally, several agencies have embedded MRA into their decision-making:



Global trend toward predictive, data-driven, and genomics-enhanced MRAs.

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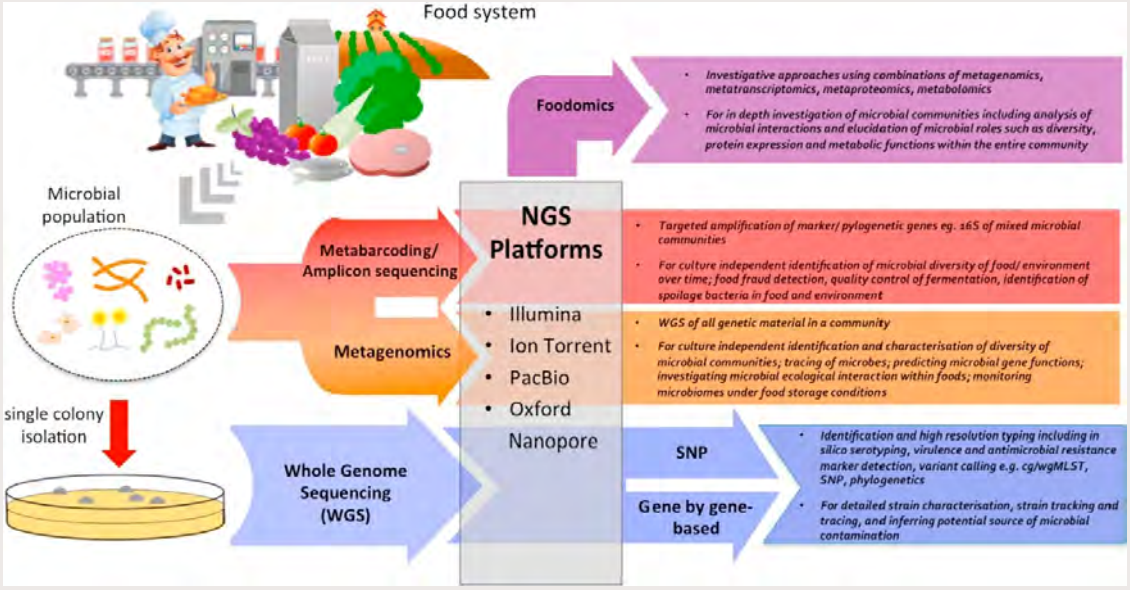
Next Generation Sequencing (NGS)



Jagadeesan, B., Gerner-Smidt, P., Allard, M. W., Leuillet, S., Winkler, A., Xiao, Y., … Chai, L. C., & Grant, K. (2019). *The use of next generation sequencing for improving food safety: Translation into practice.* Food Microbiology, 79, 96–115. [ILSI Europe, Open Access].

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Whole Genome Sequencing (WGS)

- WGS provides the complete genetic fingerprint of an organism.
- It enables:
  - Strain-level identification, separating pathogenic from harmless variants;
  - Detection of virulence and antimicrobial-resistance genes, strengthening hazard characterization;
  - Source attribution, linking human, food, and environmental isolates across the supply chain; and
  - Real-time outbreak detection and quantitative estimation of transmission pathways.
- Industrial Applications:
  - WGS helps industries perform root cause analysis for contamination events and identify persistent factory strains.
  - It allows tracing whether contamination is new or recurrent, enabling targeted hygiene interventions.
- WGS reduces uncertainty at every stage of the MRA pipeline, creating a seamless connection between *microbiology, epidemiology, and risk science*.

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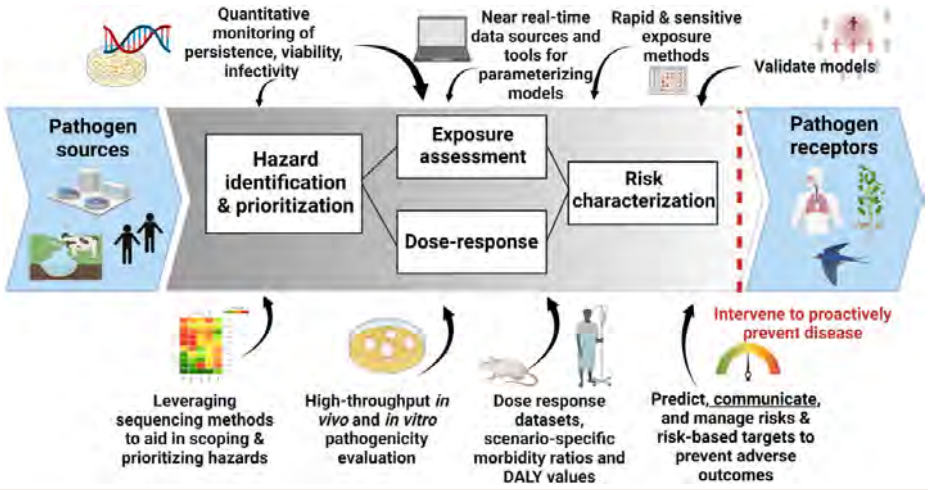
Path forward in QMRA to leverage advanced technologies to intervene and prevent disease.



Hamilton, K. A., *et al.* (2024). *Research gaps and priorities for quantitative microbial risk assessment (QMRA). Risk Analysis.* https://doi.org/10.1111/risa.14318

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Evidence from EU and US: GenomeTrakr and EFSA

FDA's GenomeTrakr network

- The world's largest open-access foodborne pathogen genome database, with over 250,000 sequenced isolates.
- It connects food, clinical, and environmental samples, allowing regulators to trace outbreaks to their exact source within days instead of weeks.

European Food Safety Authority (EFSA)

- Integrates WGS into quantitative MRAs for *Listeria monocytogenes* and *Salmonella enterica*.
- This has improved outbreak attribution and informed risk-based revisions of EU microbiological criteria.

When genomic data are linked to risk-modelling frameworks, public-health responses become faster, cheaper, and more accurate.

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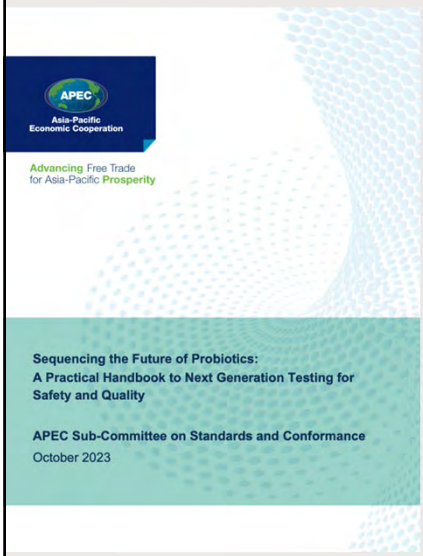

https://www.apec.org/publications/2023/10/sequencing-the-future-of-probiotics-a-practical-handbook-to-next-generation-testing-for-safety-and-quality

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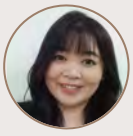
Expert Committee on Application of Next-Generation-Sequencing in Probiotics Testing for Quality and Safety Assurance

Lee Hui Key
Project Manager



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Dr Kim Yun-Gi
Keio University
(Republic of Korea)

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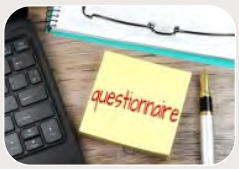
Methodology



Online Survey

Online Interviews

Expert Group Discussion

Workshop - Stakeholder engagement

Netherlands 3%

New Zealand 3%

Denmark 3%

US 18%

Germany 3%

Switzerland 3%

PRC 15%

Republic of Korea 10%

Chinese Taipei 8%

Japan 8%

India 5%

Malaysia 5%

Singapore 8%

Indonesia 3%

Viet Nam 8%

Thailand 3%

40 Food Testing Laboratories from 16 economies

Commercial labs (n=11)
Government labs (n=11)
Industry In-house labs (n=12)
R&D labs (n=6)

Challenges in implementing NGS for Probiotic testing

Asia	US, EU
- Limited **demand** for NGS - Challenges in **method validation** - **Regulation** requires only total viable count in mixed probiotic concoctions - Unclear **bioinformatics** analysis - Lack of **standards** for NGS-based probiotics testing	- No **standards** available for NGS-based probiotics testing - **Matrix complexity,** especially the mix due to strain competition and different proportion of strains → difficult to verify the assay. - Species-level identification vs strain-level identification - A lot of vertical and local methods are focusing on species - level and how that relates to internal methods are focusing on strain-level.

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Further Discussion- implementation of NGS for probiotics testing

What is the definition of 'strain'?	**One SNP/ Two SNPs, or it should also take phenotypic characteristics into consideration?**
Viability and stability of cells	**If a comparable molecular-based quantification method is chosen, the viability/stability of cells must be taken into consideration as well.**
Standard reference materials	**Lack of reference control.**
Database of the genome	• **Are the probiotics companies ready to deposit their genome in the database?** • **Who will manage of the database? Notwithstanding country regulations.**

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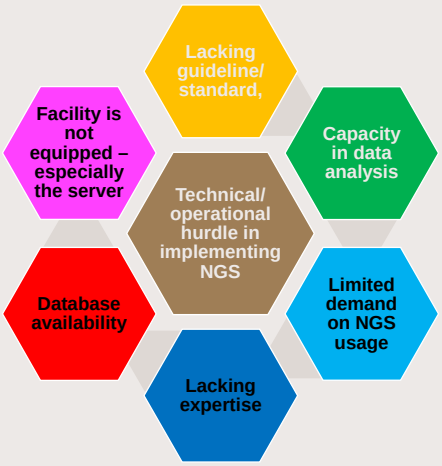
Gaps, Challenges & Way Forwards



Can be overcome by

- **Continuous discussion among the relevant stakeholders**
- **Collaboration between the public and industry**
- **Capacity building**
- **Raising awareness**
- **Standards/ regulatory development**

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The ASEAN Landscape

https://asean.org/wp-content/uploads/2024/09/ASCC-RD_Flagship-Report_Health4-2024.pdf

- FBDs are estimated to cause 175,000 deaths and 12 million disability-adjusted life years (DALYs) annually in ASEAN (WHO, 2016).
- The World Bank categorizes the condition of a country's food safety lifecycle into four stages according to FBDs' financial burden and the incentives for enhancing food safety management capacities:

Cambodia
Indonesia
Lao PDR
Myanmar
Philippines
Viet Nam

Brunei
Malaysia
Singapore
Thailand

(Nadarajan, 2021)

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The ASEAN Landscape

https://asean.org/wp-content/uploads/2024/09/ASCC-RD_Flagship-Report_Health4-2024.pdf

List of Several ASEAN Initiatives and Working Groups for Food Safety

ASEAN Consultative Committee on Standards and Quality (ACCSQ)	Harmonize national standards with international standards and implement mutual recognition agreements on conformity assessment. ACCSQ includes three working groups, two sectoral committees, six product working groups, and task forces established under Product Working Groups (PWGs).
ASEAN Health Cluster 4: Ensuring Food Safety (AHC4)	- Address food safety issues based on farm to table approach to ensure the protection of consumer's health - Provide assistance to ASEAN governments to develop and strengthen food safety infrastructures and programs in regional and international trade
ASEAN Food Reference Laboratory (AFRL)	Support the regional laboratory networks through government testing laboratories competent in the specific areas of expertise designed by ACCSQ and PFPWG
ASEAN Food Safety Regulatory Framework (AFSR) Agreement	- Provide a coherent and integrated approach and link initiatives into new legal frameworks, closing gaps and ensure that food safety is implemented across the food chain - Facilitate the free flow of safe food through; (i) harmonizing sanitary and phytosanitary measures and standards; (ii) reducing technical barriers to intra-ASEAN trade; (iii) reducing gaps of AMS' national food control systems
ASEAN Food Safety Network (AFSN)	Provide a platform for information exchange and dissemination related to food safety
ASEAN Food Testing Laboratory Committee (AFTLC)	- Monitor, guide, and review the implementation of AFRL - Provide support to promote and ensure the capacity of National Food Laboratories in AMS - Provide support to other regional initiatives related to food safety - Promote conformity assessment and accreditation of laboratories based on international standards
ASEAN Risk Assessment Center for Food Safety (ARAC)	Provide an independent scientific opinion on food safety issues in ASEAN through pooling and utilizing of scientific expertise
ASEAN Rapid Alert System for Food and Feed (ARASFF)	Provide a platform to assist competent authorities of the member states to exchange notifications and information about food or feed safety incidents promptly
ASEAN Task Force on Codex	Harmonize and strengthen ASEAN position at international food safety standard setting forums, Codex Alimentarius Commission, and its relevant bodies
Prepared Foodstuff Products Working Group (PFPWG)	- Harmonize food safety national standards with international standards - Develop Mutual Recognition Arrangements (MRAs)— ASEAN Sectoral MRA for Inspection and Certification Systems on Food Hygiene for Prepared Foodstuff Products—for prepared foodstuff

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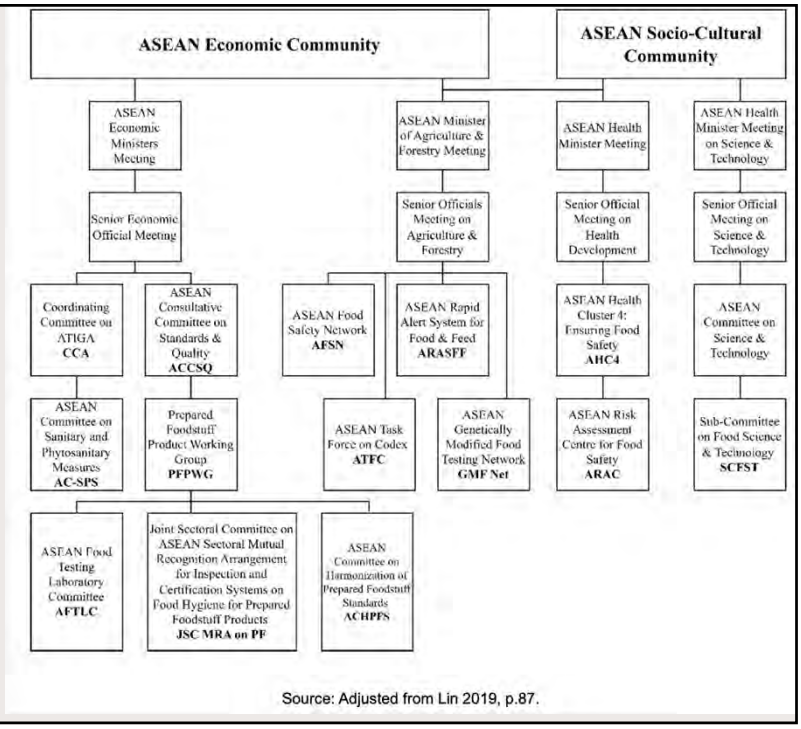
Food Safety Governance Framework in ASEAN

Unlike in the EU, ASEAN does not have the power to force AMS to comply with rules set by it, as ASEAN practices consensus decision-making and non-interference in internal affairs.



Source: Adjusted from Lin 2019, p.87.

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Risk Assessment Process

1. **Request for Risk Assessment**
   Any ASEAN sectoral body or individual AMS may submit a request
2. **Evaluation by Scientific Committee**
   The request is evaluated for adequacy suitability
3. **Scientific Panel Convened**
   A scientific panel is established and convened
4. **Assess Risk**
   The Panel undertakes the assessment of food safety risk
5. **Provide Scientific Opinion on Risk and Recommendations**
   The Panel provides its scientific opinion to the Scientific Committee
6. **Adoption of Scientific Opinion by Scientific Committee**
   The scientific opinion is put to the Scientific Committee for adoption
7. **Dissemination of Scientific Opinion and Recommendations**
   The scientific opinion and recommendations are provided to ASEAN sectoral body or individual AMS

How to propose risk assessment request for ARAC?

ARAC is a regional facility available to food safety regulatory bodies from all AMS and all relevant ASEAN sectoral bodies under the ASEAN Health Ministers, ASEAN Agriculture and Forestry Ministers and the ASEAN Economic Ministers.

Request for risk assessment work should be submitted to ARAC. Please email to arac@moh.gov.my for required form or download from the ARAC website **www.arac-asean.org**.

For more information, please contact as details shown below:

ARAC | ASEAN RISK ASSESSMENT CENTRE FOR FOOD SAFETY

ASEAN Risk Assessment Centre for Food Safety (ARAC),
Food Safety and Quality Division,
Ministry of Health Malaysia,
Level 4, Menara Prisma,
No 26, Persiaran Perdana, Presint 3,
62675 Putrajaya, Malaysia.
Phone +603-88850797
Fax +603-88850798
Email arac@moh.gov.my
Website www.arac-asean.org

ARISE
This is supported by the European Union through the ASEAN Regional Integration Support from the EU (ARISE).

ARAC | ASEAN RISK ASSESSMENT CENTRE FOR FOOD SAFETY

ASEAN Health Cluster 4
↓
ARAC
↓
Scientific Committee
↓
Scientific Panel

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Microbiological Risk Assessment of Salmonella in Cooked Chicken Dishes in Southeast Asia

ARAC | ASEAN RISK ASSESSMENT CENTRE FOR FOOD SAFETY

RISK ASSESSMENT REQUEST

Requesting Body	ASEAN Health Cluster 4: Ensuring Food Safety (AHC 4) Lead Country: Malaysia
Hazard Name	*Salmonella spp.*
Food Product	Cooked Chicken Dishes
Purpose	To provide information on the risk of *salmonella* in cooked chicken dishes to the ASEAN population, which will be used by the risk manager **to develop risk management options** for reducing the risk of *Salmonella spp.* infections.

Prof. Dr. Chai Lay Ching
Chair

Prof. Dr. Ratih Dewanti
Vice Chair

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Existing Capacity & Strengths of ASEAN

Building Foundations for risk-based Food Safety

Regional Framework
- ASEAN Risk Assessment Centre (ARAC) based in Malaysia serves as the regional coordination hub for food-safety risk assessment.
- ARAC's mandate: coordinate scientific assessments, strengthen national capacity, and provide a pool of qualified risk assessors across ASEAN.

Early Achievements
- First regional risk assessment completed on Total Aflatoxins and Aflatoxin B1 via consumption of peanuts and corn in Indonesia, Malaysia, Philippines, and Thailand.
- Developed common methodologies for data collection and exposure estimation — a major step toward harmonized MRA practice.

Capacity-Building Efforts
- Regular training workshops organized by ARAC, ILSI Southeast Asia, and FAO/WHO on Microbiological Risk Assessment principles and practice.
- Ongoing mentoring for risk managers to formulate risk assessment requests and interpret MRA results for policy use.

Policy & Governance
- The ASEAN Food Safety Policy and ASEAN Food Safety Regulatory Framework (AFSRF) anchor the region's shift toward science- and risk-based decision-making.
- Risk assessment formally embedded as the scientific pillar supporting risk management and communication.

Country-Level Strengths
- Singapore and Malaysia have established surveillance and laboratory systems capable of supporting QMRA.
- Thailand, Vietnam, and Philippines actively participate in regional training and ARAC projects, contributing local data and expertise.

ARAC ASEAN RISK ASSESSMENT CENTRE FOR FOOD SAFETY

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Key Gaps and Challenges in ASEAN

- People Gaps
- Data Gaps
- Linkage Gaps
- Platform Gaps

- **While ARAC provides regional coordination, national capacity varies greatly among Member States**
- **QMRA is still limited; Capacity building for QMRA is still at early stages.**
- **Data and metadata are lacking for robust MRA**
  - ***e.g., local prevalence and concentration data, dose–response relationships applicable to local food systems. This weakens hazard characterisation and exposure assessment***
- **Linkage of scientific risk assessment to regulatory decision-making remains underdeveloped**
- **Bioinformatics, genomics integration (e.g., WGS data) and advanced modelling skills are still nascent in many Member States.**
- **Sharing and interoperability of data (across AMS) is limited; coordination among labs and harmonisation of methods is still in progress.**

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Opportunities and the Road Ahead

From fragmented initiatives to a connected, data-driven ASEAN Food Safety Ecosystem

Strengthen Regional Capability

- Strengthen **ASEAN Risk Assessment Centre (ARAC)** as the regional hub for evidence-based food safety.
- Form stronger partnersgip with national centers.

Standardization & Process Improvement

- Harmonize **SOPs, data templates, and protocols** for microbial and chemical risk assessment.
- Establish **common terminology and metadata standards** for regional interoperability.

Capacity & Talent Development

- Identify and train **risk assessors** in each ASEAN Member State.
- Implement a **structured competency framework** and certification pathway to sustain expertise.

Science–Policy Linkage

- Strengthen the **connection between risk assessors and risk managers** to ensure translation of MRA outputs into regulation and standards.
- Institutionalize **science-policy dialogues** and joint interpretation workshops.

Data Infrastructure & Integration

- Create an **ASEAN-wide WGS and MRA data platform** for secure data sharing and joint analysis.
- Develop an **ASEAN Shared Laboratory Network** for genomic surveillance and source tracking.

Technology & Tools

- Deploy **simplified modelling tools** for data-poor countries to perform basic QMRA.
- Integrate **bioinformatics pipelines** for WGS-based risk assessment.

Collaboration & Governance

- Foster **public–private partnerships** for data contribution, validation, and use.
- Establish **regional agreements or MOUs** for data sharing and capacity exchange.

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Thank you

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