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APEC FOOD SAFETY MODERNISATION FRAMEWORK TO FACILITATE TRADE

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Advancing Free Trade for Asia-Pacific Prosperity

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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EXECUTIVE SUMMARY

This Framework advances the mandate of the APEC Food Safety Cooperation Forum to assist APEC economies in facilitating trade in food while protecting the health of consumers. The Framework provides guidance to economies in enhancing or modernising their food safety regulatory systems. The ten principles described in the Framework, such as transparency and risk-based decision making support food safety enhancement and modernisation of APEC member economies. The Framework recognises that APEC member economies are at different stages of economic development and have different needs in the enhancement or modernisation of their food safety regulatory systems.

INTRODUCTION

Foodborne disease incidents result in significant health and economic burden worldwide (WHO 2015; Box 1).

Serious transboundary food safety incidents are increasingly reported, for example, the outbreak of ***Escherichia coli* O104:H4 infection associated with consumption of sprouts** in 2011 spread over more than 15 economies in Europe and North America. In addition to domestic human health and economic consequences, food safety incidents can result in friction between trading partners over food safety requirements. Such issues can cause reputational and economical damage for the food industry, including loss of market access.

Box 1:

Estimates of the global burden of foodborne illnesses for 31 foodborne hazards for the year of 2010

about 600 million foodborne illness cases

420,000 deaths

Loss of 33 million disability adjusted life years

Estimates of the global burden of foodborne diseases: foodborne disease burden epidemiology reference group 2007-2015. World Health Organisation **(WHO, 2015)**.

Escherichia coli O104:H4 infection associated with consumption of sprouts

Data published by Food and Agricultural Organisation (FAO) indicates that global trade in food and agricultural products has grown almost three-fold in value terms over the past decade and is projected to continue rising.

Between 2000 and 2013, **the number of Regional Trade Agreements in force has more than doubled.** Greater participation in global trade is an integral part of APEC economies' strategies in securing a safe food supply and economic development.

Success in food export depends largely on the economy's ability to provide safe food consistently and the capacity to meet the importing economy's food safety regulatory requirements. Prominent food safety incidents have prompted enhancement or modernisation of food safety regulatory systems worldwide (Box 2) where a high-level of focus has been given to specific interventions targeting the cause of the food safety incident.

Box 2:

Food safety incidents prompting global modernisation of food safety regulatory systems

2002 — Bovine spongiform encephalopathy (BSE) incidents prompted the European Union to modernise their food safety regulatory system and to take a **whole of food supply chain approach** in managing food safety since 2002

2006 — Large outbreaks attributed to fresh produce prompted a number of economies worldwide to improve their food safety regulatory systems since 2006

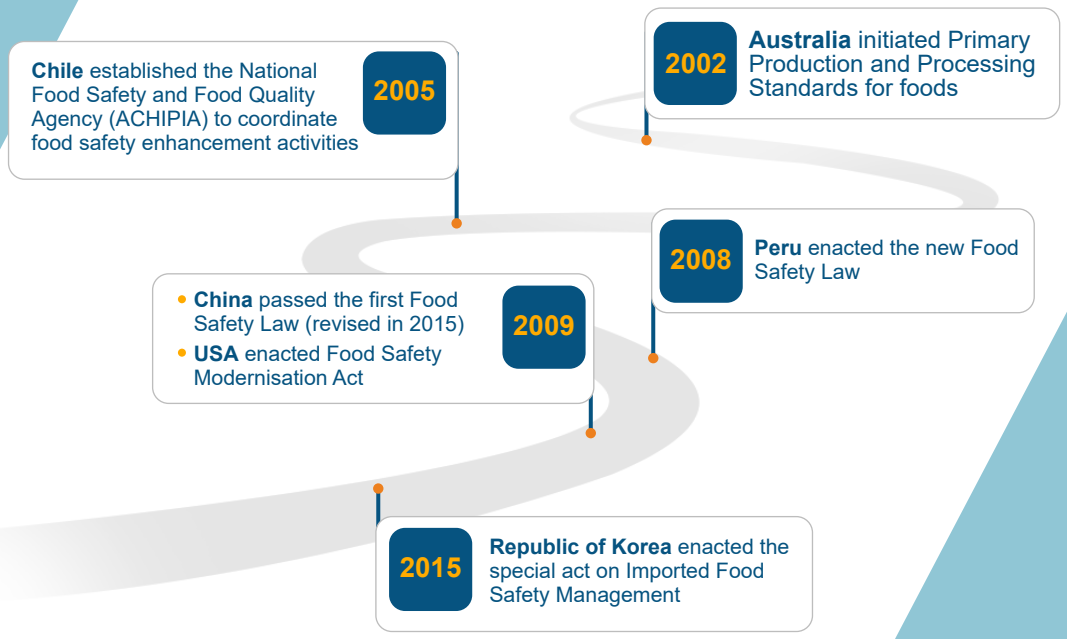
2008 — Food safety incidents resulting from consumption of 1,3,5-triazine-2,4,6-triamine contaminated dairy products prompted several APEC member economies to improve their food safety regulatory systems since 2008

Data published by Food and Agricultural Organisation (FAO)

The number of Regional Trade Agreements in force has more than doubled

Box 3:

Food safety modernisation across APEC



APEC economies took appropriate steps to deal with the increasing complexity in ensuring food safety in the region as well as the potential impact of new food safety regulatory measures on trade in the early 2000s (Box 3).

In 2007, the APEC Food Safety Cooperation Forum (FSCF) was established to address the need among APEC member economies to develop a more robust approach to strengthening food safety standards and practices without creating unnecessary impediments to trade.

In 2017, members of the FSCF agreed that APEC member economies should work together to further strengthen food safety regulatory systems. This included the harmonisation of food safety standards with internationally recognised food standards, based on available science, and ensuring member economies' food safety regulatory measures and their implementation are consistent with member obligations to the World Trade Organisation (WTO).

The purpose of this food safety modernisation framework (the Framework) is to progress the APEC FSCF mandate and to assist APEC member economies in enhancing or modernising their food safety regulatory systems where food safety regulatory measures and their implementation should be based on international standards, guidelines and principles adopted by Codex Alimentarius Commission. Harmonising food safety standards and ensuring consistency with the obligations described in the WTO's Agreements on Sanitary and Phytosanitary Measures (SPS Agreement) and Technical Barriers to Trade (TBT Agreement) based on available science to provide appropriate level of sanitary or phytosanitary protection, while ensuring that measures are no more trade restrictive than necessary, will secure a safer food supply and facilitate food trade in the APEC region.

The **scope** of this Framework is to ensure the safety of food for sale in the domestic market of APEC economies, regardless of whether that food is produced domestically or imported. The focus of this Framework is on food safety, including fraudulent and deceptive practices impacting on food safety. The Framework recognises that fraudulent and deceptive practices of a non-food safety nature can negatively impact consumers' confidence in the economy's food safety regulatory system.

FOOD SAFETY REGULATORY SYSTEMS AND DRIVERS OF FOOD SAFETY MODERNISATION

An economy's food safety regulatory system[1] is usually made up of food safety standards, regulations, laws, inspections, monitoring, enforcement, laboratory services, information, education, communications and emergency responses (Figure 1) to ensure food is safe for human consumption while not restricting food trade.

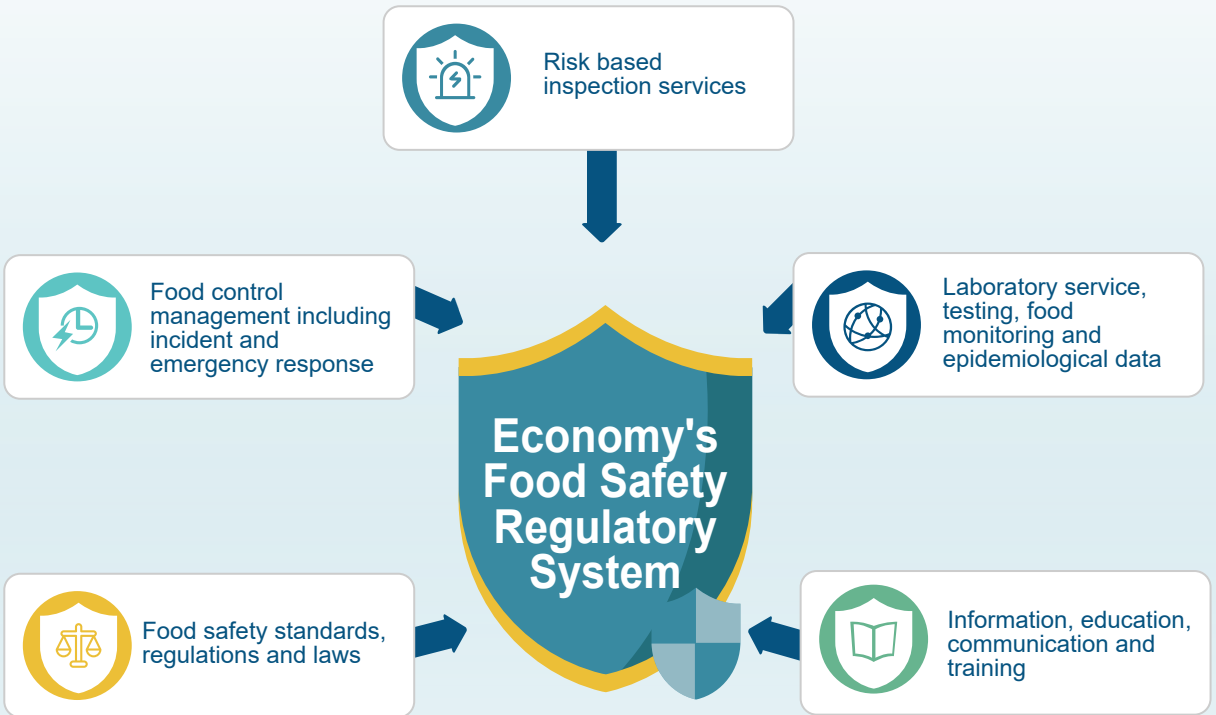


Figure 1 Building blocks to support food safety regulatory systems **(FAO and WHO, 2003)**

1. An economy's food safety regulatory system, which is an essential part of the economy's overall food control system, is made up of the relevant laws, policies, standards and processes that are employed by competent authorities to ensure food available for sale in the domestic market is safe to eat.

In the last decade, more than half of the APEC economies have been enhancing or modernising their food safety regulatory systems to improve food safety. APEC member economies at different stages of economic development have different needs in the enhancement or modernisation of their food safety regulatory systems. For example, some APEC member economies in recent years have focused their food safety enhancement or modernisation efforts on the control of specific microbiological pathogens associated with food, such as non-typhoidal *Salmonella* and *Campylobacter* in poultry meat and Shigatoxin-producing *Escherichia coli* in meat and dairy products.

Several other APEC member economies have focused their food safety enhancement or modernisation efforts on the prevention of food fraud impacting on food safety, such as unlicensed production of food, false labelling and claims, fraudulence in food sales and false advertising[2]. Specific food safety regulatory measures resulting from these food safety enhancement or modernisation activities have produced tangible food safety benefits for consumers in these economies. New Zealand, for example, has reduced foodborne *Campylobacter* illness by over 50% since the introduction of risk management strategies in 2006 to combat foodborne campylobacteriosis[3].

In the past, food safety standards, regulations and laws have tended to be reactive and enforcement driven. This approach has provided limited potential for longer term prevention of food safety problems and for building trust in an economy's food safety regulatory system. Modernised food safety regulatory systems recognise that food business operators have the primary responsibility for producing safe food and that, working together with food safety regulators, an economy can employ proactive and preventive measures to ensure safe food throughout the food supply chain.

2. APEC member economies have focused their food safety enhancement or modernisation efforts on the prevention of food fraud impacting on food safety.

3. Foodborne campylobacteriosis in New Zealand has been reduced by over 50% since the introduction of risk management strategies in 2006.

An economy's ability to effectively modernise its food safety system is influenced by a range of factors. This includes but is not limited to: globalisation of the food supply, obligations to the WTO's SPS and TBT Agreements, and consistency with international food standards and guidelines developed by the Codex Alimentarius Commission.

Modernisation or enhancement of food safety regulatory systems in APEC economies by applying risk analysis based on scientific evidence, as well as internationally agreed principles with transparent communication and harmonisation with international standards is expected to provide benefits for consumers, government, and stakeholders who are either directly or indirectly involved in food production, transportation, sales and handling (**CAC/GL 82-2013** and Box 4).

Box 4:

Benefits of food safety modernisation to stakeholders

- Prevent foodborne illnesses, ensure consumer confidence
- Contribute to the economy's health targets/objectives
- Reduce risks of economic loss including the loss of market access
- Target most effective intervention measures, and combine them with monitoring and enforcement actions to reduce health risk resulting from food consumption
- Reduced compliance and enforcement burdens for industry and government
- Improve the competitiveness of the economy's food industry
- Economies' food safety standards are harmonised with internationally recognised standards
- Facilitate equivalence
- Reduce procedural obstacles in trade
- Reduce costs and delays in shipping food
- Transparent, collaborative and cooperative

Modernisation or enhancement of APEC member economies' food safety regulatory systems in alignment with member obligations under the WTO's SPS and TBT Agreements, will result in more efficient cross border food trade and associated services by reducing operational burden. Modernisation or enhancement of food safety regulatory systems is expected to improve confidence of APEC economies in each other's food safety control, recognising that while food safety regulatory systems may be different among economies, they can achieve the same objectives of consumer health protection by ensuring safer food supply while facilitating trade (Box 5).

Box 5:

New Zealand: Developing recognition agreements

01 support modernisation of food safety systems

02 encourage adoption of agreed international frameworks & standards

03 create an enabling environment for equivalence assessment and system recognition

THE FRAMEWORK

Guidelines which can assist APEC member economies to develop their food safety regulatory systems are described by FAO **(1997, 2006, 2007)** and the Codex Alimentarius Commission **(2013, 2017)**. In addition, learning from the experiences of other economies is highly desirable.

This Framework does not seek to duplicate the work that has already been published by FAO and Codex but aims to provide specific guidance for APEC member economies to enhance or modernise their food safety regulatory systems. This Framework is underpinned by the application of the following internationally accepted principles (Box 6) described by **Codex** and WTO's SPS and TBT Agreements.

Box 6:

Food safety modernisation based on internationally accepted principles

1. Protection of consumers
2. Trade facilitation
3. Whole of food chain approach
4. Transparency
5. Preventive measures
6. Evidence and risk-based decision making
7. Shared responsibility: primarily rests with food business operators
8. Equivalence
9. Consistency and impartiality
10. Continuous improvement

FAO 1997 | 2006 | 2007

Codex Alimentarius Commission 2013 | 2017

Codex

PRINCIPLES

Codex text **CAC/GL 82-2013** provides comprehensive guidance to APEC member economies to develop their food safety regulatory systems. Principles described in this Codex text underpin this Framework.

PRINCIPLE 1
PROTECTION OF CONSUMERS

APEC member economies' food safety regulatory systems should be designed, implemented and maintained with the primary goal to ensure safe food for consumers. In the event of a conflict with other interests such as trade, the priority should always be given to protecting consumers from unsafe food.

PRINCIPLE 2
TRADE FACILITATION

APEC member economies' food safety regulatory systems should be least restrictive to trade while protecting the health of consumers.

PRINCIPLE 3
WHOLE OF FOOD CHAIN APPROACH

APEC member economies' food safety regulatory systems should address the control of risk along the entire food chain. Food safety regulatory measures[4] need to be established, applied in a consistent, impartial and coordinated manner and reviewed for all stages of food production and supply including primary production of food, food processing, packaging, storage, transport, and handling as well as sale of foods to the consumers.

Principles and Guidelines for National Food Control Systems – CAC/GL 82-2013

4. Food safety regulatory measures described in this document refer to sanitary and phytosanitary measures described in the WTO's SPS Agreement.

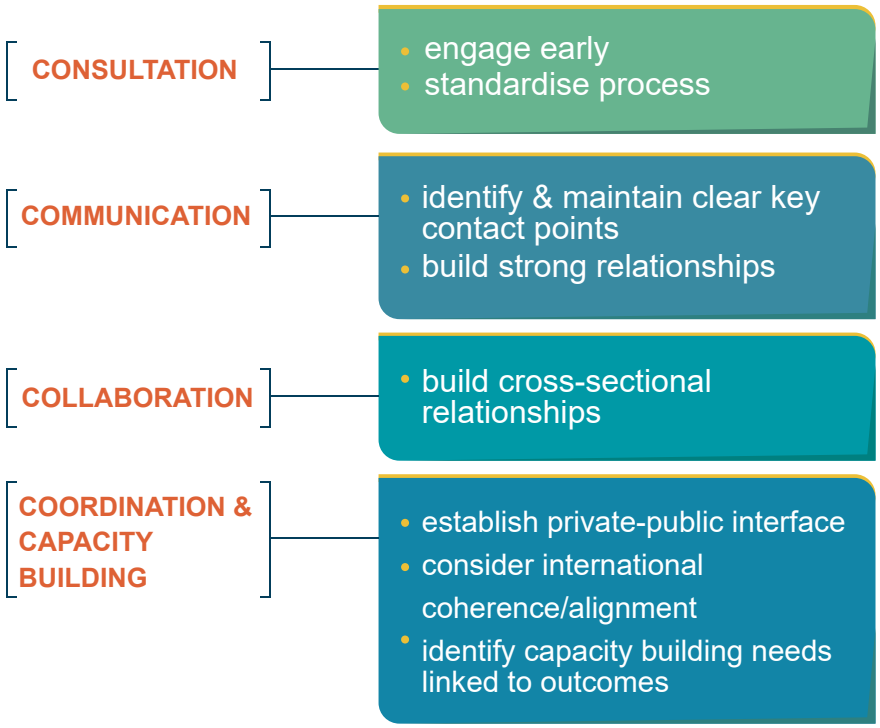
PRINCIPLE 4
TRANSPARENCY

All aspects of APEC member economies' food safety regulatory systems should be transparent and open to feedback from both domestic and international stakeholders, while respecting legal requirements to protect confidential information as appropriate.

Transparency[5] considerations should apply to all participants in the food chain including trading partners. This can be achieved through clear documentation and timely communication, as well as the exchange of information between trading partners to facilitate the conduct of corrective and preventive actions (Box 7).

Box 7:

Transparency: USA Rulemaking process core concepts



5. Transparency refers to operating in such a way that it is easy for others to see what actions are performed, and provides open access to information about how food is produced, its origin and measures that have been taken to reduce food safety risks.

PRINCIPLE 5
PREVENTIVE MEASURES

APEC member economies' food safety regulatory systems should have preventive measures such as Good Agricultural Practice[6], Good Manufacturing Practices, Good Hygiene Practices, and Hazard Analysis Critical Control Points (HACCP) principles among others. Robust policy and practical preventive measures should underpin an APEC member economy's food safety regulatory system. APEC member economies' food safety regulatory systems should include a reliable traceability system that enables targeted recalls of unsafe food products.

PRINCIPLE 6
EVIDENCE AND RISK BASED DECISION-MAKING

The application of specific food safety regulatory measures under an APEC member economy's food safety regulatory system should be based on the outcome of a risk analysis. APEC member economies are obligated, under the WTO SPS agreement, to ensure that the assessment of risk be based on the principles and guidelines as developed by Codex Alimentarius Commission.

The level of food safety regulatory requirements should be proportionate to the level of risk associated with the food or food ingredient.

PRINCIPLE 7
FOOD SAFETY IS A SHARED RESPONSIBILITY BUT THE PRIMARY RESPONSIBILITY RESTS WITH FOOD BUSINESS OPERATORS

All participants in an APEC member economy's food safety regulatory system should have their specific roles and responsibilities clearly defined. Food business operators have the primary role and responsibility for ensuring that their food products are safe, that is, it will not cause harm to the health of the consumer if it is prepared and/or consumed according to its intended use.

APEC member economies' governments are responsible for establishing and maintaining transparent up-to-date legal requirements of their food safety regulatory systems which enable effective enforcement, education and communication and are supported by adequate food safety controls and surveillance. The relevant competent authority has the responsibility to verify that food business operators comply with applicable food safety rules and regulations.

Consumers also have a role in managing food safety risks under their control by adhering to good food hygiene practices and by preventing food contamination in their homes. Where relevant, consumers should be provided with information on how to achieve this.

Academics and scientific institutions are a source of expertise to support the competent authorities' assessment of risk and the scientific foundation of the economies' food safety regulatory systems.

6. Good Agricultural Practice refers to the best practices in the production of crops, livestock and fishes as food.

PRINCIPLE 8
EQUIVALENCE AND RECOGNITION OF TRADING PARTNER'S SYSTEMS

APEC member economies' competent authorities should consider recognising food safety regulatory systems or components of the food safety regulatory systems of their counterpart economies should they be deemed to provide the same level of consumer protection. The concept of recognition of food safety regulatory systems, including the ability to recognise equivalence, should be provided for in APEC member economy's food safety regulatory system.

PRINCIPLE 9
CONSISTENCY AND IMPARTIALITY

All aspects of APEC member economies' food safety regulatory systems should be applied consistently and impartially without regard to whether food is produced domestically or is imported. The competent authority and all officials acting in official functions should be free of improper or undue influence or conflict of interests.

PRINCIPLE 10
CONTINUOUS IMPROVEMENT

APEC member economies should have the ability to undertake continuous improvement of their food safety regulatory system, and should regularly assess the effectiveness of the food safety regulatory system.

CREATING AN ENABLING ENVIRONMENT

APEC economies' food safety regulatory systems play a leading role in ensuring supply of safe food for consumers in APEC member economies and are underpinned by an enabling environment. In common with the overall government systems, they rely on the input from and collaboration with various sectors and stakeholders involved in the domestic and importing food supply chains, including government, industry and consumers.

An enabling environment supports the modernisation or enhancement of an APEC economy's food safety regulatory system. The common enabling factors include:

- **Leadership** that will create, champion and lead a common vision of enhancement or modernisation of the economy's food safety regulatory system, and take into consideration the triggers, drivers and needs, inclusive of the overall health policy and priorities of the government for enhancement or modernisation of food safety regulatory system from largely the domestic market;
- **Partnership** that has a broad basis of participation and consultation amongst government, industry and consumers, and delivers trust and confidence to stakeholders within and outside of the border;
- Provision of adequate **resources** in both human and financial aspects for enhancement or modernisation of the economy's food safety regulatory system
- Development of appropriate **competencies** for the enhancement or modernisation of the economy's food safety regulatory system through education and skill development.

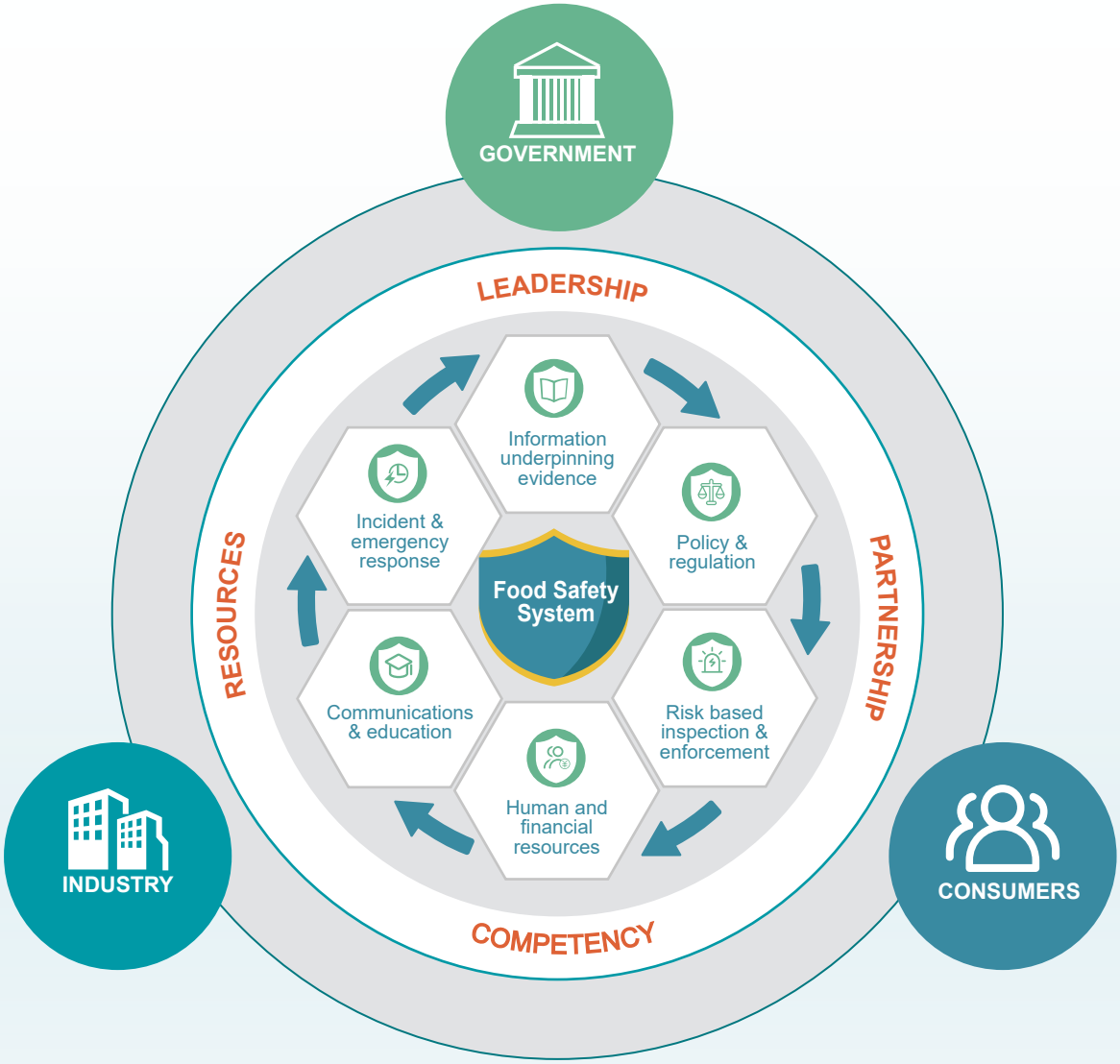


Figure 2 A dynamic food safety regulatory system that combines government food safety policy and leadership, technological innovation pushed by food businesses and demand from consumers. Together it creates an enabling environment and involves the appropriate stakeholders (Modified from **WHO, 2018**)

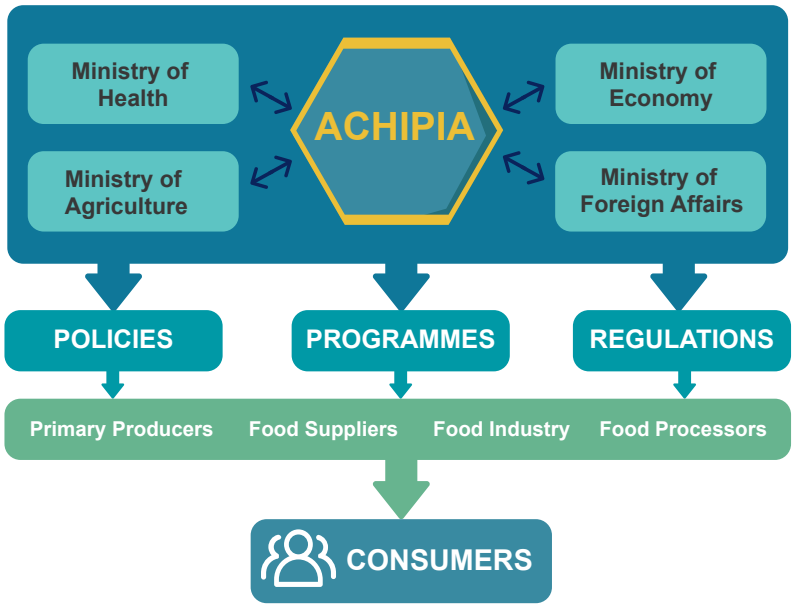
Regulatory authorities, food business operators and consumers need to interact in an enabling environment (Figure 2).

An integrated government food safety administration at the economy's highest level of government administration, if established, would aid the success of the development and implementation of the economy's food safety regulatory system. Such an integrated government administration should address food safety issues from farm-to-table and have the mandate to move resources to high priority areas without being involved in day-to- day food inspection responsibilities (**FAO, 1997**).

WHO, 2018 FAO, 1997

Box 8:

Chile: Coordinated Food Safety & Quality System

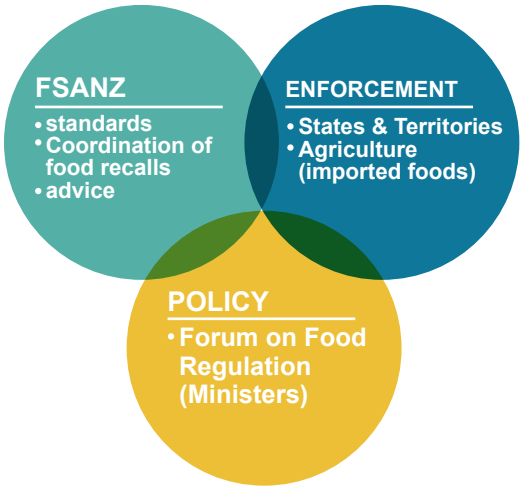


Organisational structures for an integrated government food safety administration differ among APEC economies. This is dependent on the stage of economic development or the mandate of the authorising jurisdiction of the economy's food safety regulatory system. Box 8 shows Chile's coordinated food safety and quality systems and Box 9 illustrates the Australian food regulatory framework.

Whatever the organisational structure may be, the functional components of the system such as policy initiatives, standards development, enforcement, and import controls should work together seamlessly to deliver the required outcomes. A policy body made up of competent authorities of the government with input from all relevant stakeholders can provide guidance on assessments, progress and reviews on the design and performance of an economy's food safety regulatory system.

Box 9:

Australian Food Regulatory Framework



ASSESSING THE NEEDS OF AN ECONOMY'S FOOD SAFETY REGULATORY SYSTEM

The capacity needs for APEC economies to reach the desired future status of their food safety regulatory systems vary as economies are at different stages of economic development. FAO recommends a systematic approach to prioritise and identify the needs in enhancing and modernising food safety regulatory systems and provides detailed guidance (FAO, **2006** and **2007**, Figure 3).

Figure 3 Key steps in identifying capacity building needs for food regulation (modified from **FAO, 2006**)

The support of relevant stakeholders is essential in the enhancement or modernisation of a member economy's food safety regulatory system. This can be facilitated by giving the stakeholders the opportunity to comment on draft regulations and for these comments to be taken into account in the final measure. Transparency, coordination, collaboration and consultation together with flexibility in approach are paramount in achieving consensus and the level of stakeholder input and support required for reaching the desired future status of the economy's food safety regulatory system.

FAO, 2006 FAO, 2007

Some guiding questions that can be considered in achieving coherence and consensus in modernising or enhancing an economy's food safety regulatory system include:

1. What is the scope and objective of the existing food safety regulatory system?
2. What additional benefits will an enhanced or modernised food safety regulatory system provide for consumer health and food trade?
3. What are the major gaps in the current food safety regulatory system that would inhibit the economy's harmonisation with internationally recognised principles in consumer protection and trade facilitation?
4. What are the requirements to create a coherent and modern food safety regulatory system that improve public health and discourages unfair and fraudulent practices in food trade?
5. How can food safety be achieved in a manner that does not create unjustified barriers to trade?

APPROACHES TO MODERNISING FOOD SAFETY REGULATORY SYSTEMS AND ADHERENCE TO GOOD REGULATORY PRACTICES

The approaches for modernising or enhancing an APEC member economy's food safety regulatory system can take various forms. For example:

- developing a new food safety policy and/or formulating a new food safety law or regulation
- harmonising and enhancing existing food safety laws, regulations and standards with internationally accepted principles
- moving to a risk and evidence-based approach in the development and implementation of food safety regulatory measures
- encouraging industry self-regulation and promoting consumer education
- changing enforcement approaches to focus resources on risk; and
- developing a new strategy to better engage stakeholders in decision-making for the development of food safety regulatory measures.

These approaches have different costs and benefits for the government and stakeholders involved. There are tools that can be used to assist in determining priorities and in adjusting and revising regulations to improve the outcome and effectiveness of enhancement or modernisation of an economy's food safety regulatory system. Regulatory Impact Analysis (RIA) is one such tool. RIA should be carried out before the modernisation or enhancement of an economy's food safety regulatory system is introduced. RIA is used to assess whether the intended enhancement or modernisation of the food safety regulatory system is likely to work in practice and achieve the desired objectives. RIA (Figure 4) considers alternate options, assesses the costs versus the benefits, and addresses improvements or modifications that could be made in the proposed enhancement or modernisation of the economy's food safety regulatory system. Wide consultation with all stakeholders including trade partners is necessary to add depth and rigour to the RIA and provide transparency.

Figure 4 Key steps in a regulatory impact analysis

RIA is an important element of the Good Regulatory Practices[7] (GRPs). The GRPs provide systems, tools and methods that competent authorities can employ to improve the quality of government regulations and ensure that regulatory measures are effective, transparent, inclusive and sustained. The three categories of GRPs identified in the **2011 APEC Leaders' Declaration** and elaborated in **2016 final report on good regulatory practices in APEC economies** are:

1. **Internal government coordination** of rulemaking activity, particularly the ability to manage regulatory reform, carry out regulatory reviews and coordinate with trade and competition officials
2. **RIA**, particularly the capacity to ensure that better policy options are chosen by establishing a systematic and consistent framework for assessing the potential impacts of government action, including impacts on trade
3. **Public consultation mechanisms**, particularly "publication for comment," use of central web portals for consultation, and other practices that allow wide access and the quality of consultation mechanisms.

Further use of other tools of GRPs such as stakeholder engagement and post implementation evaluation will ensure that a proposed enhancement or modernisation of the economy's food safety regulatory system is fit for purpose, will deliver what it is set out to achieve, and reduce unnecessary burdens to food businesses.

7. Good Regulatory Practices refer to internationally recognised processes, systems, tools and methods to improve the quality of regulations and ensure that regulatory outcomes are effective, transparent, inclusive and sustained (**World Bank, 2015**).

2011 APEC Leaders' Declaration

2016 final report on good regulatory practices in APEC economies

IMPLEMENTING ENHANCEMENT OR MODERNISATION OF ECONOMY'S FOOD SAFETY REGULATORY SYSTEM

Enhancing or modernising an economy's food safety regulatory system can be a major undertaking for an APEC economy, depending on the status of the existing food safety regulatory system, and the objectives of the enhancement or modernisation. Individual economies will want to customise the process to meet their identified needs. They will also need to consider the suitability and appropriateness for the change given the prevailing political, social and economic environment, stakeholder input and cost-benefit analyses.

In many cases, a stepwise approach is appropriate in the modernisation of a food safety regulatory system, as is building on the experience and support of other APEC economies which have enhanced or modernised their food safety regulatory systems. These steps (**WHO, 2018**) and outcomes could include the following:

Step 1 Strengthening the minimal food safety regulatory requirements with consideration given to food safety regulatory measures described in relevant standards and guidelines published by Codex.

Step 2 Adoption of a risk analysis approach in food safety regulation informed by evidence and scientific information. The ability to assess risk may depend on the development of the required competencies through education and training, and the support systems, e.g. analytical laboratory services and food and foodborne disease surveillance.

Step 3 Fully document and implement the measures enacted under the food safety regulatory system, incorporating periodical review and striving for continuous improvement.

WHO, 2018

MONITORING PROGRESS OF ENHANCEMENT OR MODERNISATION OF FOOD SAFETY REGULATORY SYSTEMS

APEC economies should regularly monitor and review the performance of their respective food safety regulatory systems to identify areas for ongoing improvement. This process should include review and evaluation of the overall strategy, the implementation plan as well as the specific regulatory measures to ensure that the system meets its objectives of protecting the health of consumers and is least restrictive to trade. As stated previously, Codex provides international standards and guidelines that are recognised by the WTO. In addition, Codex provides principles and guidelines for performance monitoring of economies' food safety regulatory systems. The review can be phased, or targeted. Regardless of the approach, the monitoring and review should be guided by relevance, transparency, efficiency and responsiveness.

Monitoring of indicators established in the design phase provide evidence and data for the purpose of monitoring and review.

Economies can use a variety of data relating to the performance of the food safety regulatory system, achievement of food safety objectives and feedback from stakeholders in the domestic food supply chain and among trading partners to monitor the performance of the progress of enhancement or modernisation. Data sources may include records of knowledge and compliance with regulatory requirements by industry, public health surveillance and risk based monitoring of food safety hazards.

Monitoring reports and actions taken to improve economies' food safety regulatory systems should be communicated effectively and efficiently to stakeholders.

SUMMARY

Global trade in food and agricultural products has increased greatly over the past decades which is predicted to continue. Foodborne disease incidents can potentially cause negative impacts on human health, economics and reputation. Greater participation in global trade assists in securing a safe food supply and economic development. Success in food export depends largely on the economy's ability to provide safe food consistently and the capacity to meet the trading partner economy's food safety regulatory requirements. This Framework is developed to assist APEC economies to enhance or modernise their food safety regulatory systems to protect consumer health from food consumption and facilitate food trade.