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Defining Risk in Food Safety in the Philippines

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Abstract

Food safety is a fundamental public health concern that is dependent on various factors such as changing global food production patterns, public expectations, and international trade policies.[1,2] As a member of the World Trade Organization, the Philippines has agreed to follow the Uruguay Round of Trade Organization, the Sanitary and Phytosanitary Agreement, and Technical Barriers to Trade that permits countries to take legitimate measures to protect the life and health of their consumers in relation to food safety matters while prohibiting them from using those measures in a way that unjustifiably restricts food trade.[3,4,5] The Philippines is also a member of the Codex Alimentarius Commission that aims to ensure consumer protection and to facilitate international trade.[6] With these objectives, Codex focuses on the development of food standards based on risk analysis and independent scientific advice provided by expert bodies organized by the Food and Agriculture Organization and the World Health Organization.[7] Risk analysis is a systematic and disciplined methodology that provides policymakers with the science-based information and evidence needed for effective and transparent decision-making, leading to improvements in food safety and public health.[8] In the Philippines, Republic Act No. 10611 or the Food Safety Act of 2013, serves as the framework for implementing the farm to fork food safety regulatory system which ensures a high level of consumer health protection, fair trade practices and global competitiveness of Philippine foods by controlling hazards in the food chain, adoption of precautionary measures based on scientific risk analysis, and adoption of international standards.[9]

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Introduction

Challenges in food safety are present throughout the food supply chain and it remains a growing concern globally.[10] Several factors contribute to the increased exposure of populations to more food hazards including but not limited to freer trade and globalization of food products.[11,12] To maintain a distinct relationship with its international trading partners, the Philippines has participated as a member of the World Trade Organization (WTO) since January 1, 1995, but has since recognized the multilateral trading system from the priorly imposed General Agreement on Tariffs and Trade (GATT) in 1979.[13] Included in the provisions of being a member of the WTO is the Sanitary and Phytosanitary Measures (SPS) Agreement.[15] The SPS Agreement states that member countries are permitted to impose legitimate measures that ensure food safety and the protection of human, animal, and plant health, provided that such measures are based on scientific knowledge and are not imposed to impede free trade.[16] This Agreement refers to the FAO/WHO Codex Alimentarius Commission (CAC) as the standard-setting body for food safety,14 the International Animal Health Organization (Office International des Epizooties) (OIE) for animal health; and, the FAO Secretariat of the International Plant Protection Convention (IPPC) for plant health.[14] The SPS Agreement entails all member countries to employ food safety risk analysis as basis for their respective SPS measures for trade.[17] Food safety refers to the protection of consumers from foodborne diseases and other health-related conditions brought about by the exposure to hazards present in food products.[12] The first recorded food- and water-borne disease outbreak in the Philippines was caused by *Vibrio cholerae* in 1583 during the Spanish colonization.[18] It was during the American period (1898-1918) that public health was given priority through building more hospitals and imposition of stricter measures to prevent the spread of diseases.[18] It was also during this period that the Department of Health (DOH)[19] and the Department of Agriculture (DA) and Natural Resources were established.[20] However, it was only in the enactment of the Republic Act No. 10611, otherwise known as the Food Safety Act of 2013 (FSA 2013), that a structured food safety regulatory system has been established. Provisions stated in the FSA 2013 delineates the mandates and responsibilities of specific government agencies to promote and ensure food safety from "farm to fork".[21] The FSA 2013, in Article IV General Principles, also stipulates the use of risk analysis as the scientific basis in the development of food safety policies to protect consumer health and to settle issues in the national food control and food trade.[22] The enactment of the FSA 2013 and the establishment of other food safety guidelines, such as the Code on Sanitation of the Philippines, and the Philippine National Codex Organization prove that it is imperative to prioritize the implementation of a stronger Philippine food safety regulatory system.[23]

To further the process of developing appropriate food safety control programs, defining food safety risks through risk profiling should be done as the initiating step in the preliminary risk management activity.[24] In view of this, this study was conducted to establish baseline information on how the Philippines defines risk through the current national food control system and provide suggestions that may further improve and strengthen the Philippine framework on food safety.

Materials and Methods

To establish baseline information on how the Philippines defines risk in food safety and provide suggestions which may further improve and strengthen the Philippine food safety framework, this study was conducted in three (3) phases:

- Review of available information relevant to food safety challenges and the existing food control system in the Philippines;
- Gap analysis of the implementation of food safety control strategies in the Philippines; and
- Provision of recommendations in defining risk which may further improve the Philippine framework on food safety.

Phase 1. Review of available information relevant to food safety challenges and the existing food control system in the Philippines

Potential factors such as geographic (i.e. topography, land area, etc.), atmospheric (i.e. climate and weather conditions), demographic (i.e. household food consumption and income), and economic (i.e. food trade and industry) profiles of the Philippines contributing to food safety challenges in the Philippines were gathered from electronic journals,

books, internet databases, government reports such as from the Philippine Atmospheric, Geophysical, and Astronomical Services Administration (PAGASA), the Department of Science and Technology - Food and Nutrition Research Institute (DOST-FNRI), Department of Trade and Industry (DTI), Philippine Statistics Authority (PSA), and the Department of Agriculture (DA), and other pertinent literature.

This study has also reviewed information relevant to the existing food control system in the Philippines including food laws, regulations, and policies, along with institutional responsibilities of government agencies mandated to strengthen the food safety framework of the Philippines from the online database of the Official Gazette of the Republic of the Philippines, the House of Representatives, the Food and Drug Administration (FDA), the Department of Health (DOH), the Department of Agriculture (DA), and other valid sources.

Phase 2. Gap analysis of the implementation of food safety control strategies in the

Philippines

This study has identified gaps in the implementation of farm-to-fork food safety control strategies by consolidating all gathered information on the Philippine national food control system from Phase 1 and identifying challenges encountered by the Philippines relating to food safety including (1) gaps in food laws specifically on food inspection, analytical capability, inadequacies of governance, and response to food safety issues of the country as reported and researched in relevant literature; (2) records of foodborne disease incidences and outbreaks requested from the Department of Health (DOH), as reported in the online reports of DOH, and as researched from relevant literature; and (3) food recall data requested from the Food and Drug Administration of the Philippines (FDA).

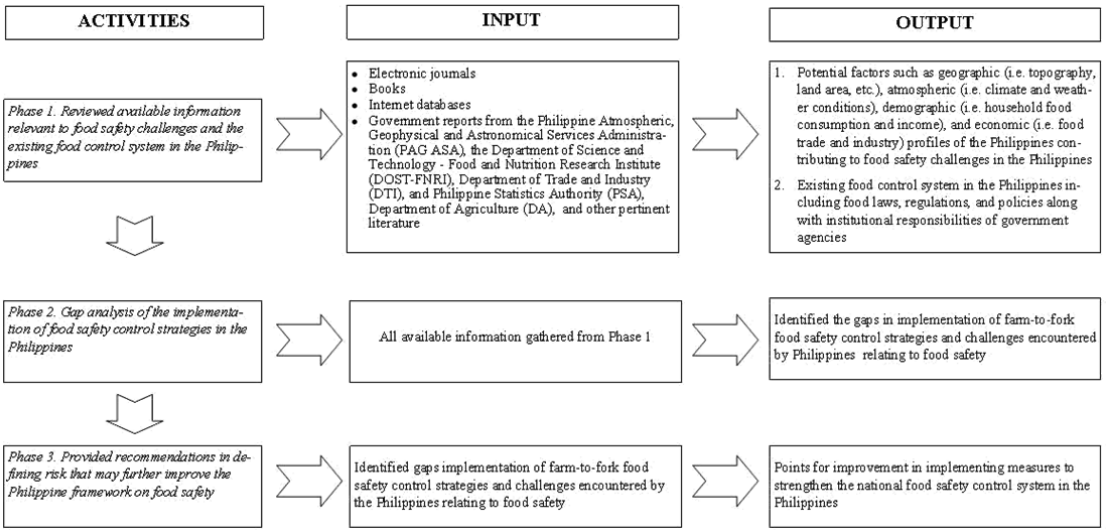

Fig. 1: Operational framework of the study

Phase 3.Provision of recommendations in defining risk which may further improve the Philippine framework on food safety

This study reviewed several approaches in defining risk in food safety that may be applied to strengthen the food safety control system of the Philippines based on journals, books, internet databases, government, and non-government organizational reports.

The study has established baseline information on how the Philippines currently defines risk and how the Philippines may define risk to potentially ensure protection of consumer health and minimize technical barriers to trade.

Results and Discussion

The food safety framework in the Philippines currently revolves around the enactment of the Philippine Food Safety Act of 2013 (FSA 2013). It

entails all concerned government agencies to take harmonized initiatives to impose measures to ensure consumer protection and promote food safety to the general public. One of these initiatives is the employment of risk analysis as the scientific basis in the development of necessary food safety policies and legislation not only to protect consumer health but also to clarify issues in the national food control and food trade.[25]

Definition of Risk

Risk, in general, deals with the possibility of the occurrence of a certain outcome which can result in an opportunity or a threat.[26] There are varying views on risk depending on causal factors such as the nature of the agent or the hazard of concern and its impact on a population.[27] It has become a challenge to harmonize its definition to allow the effective assessment, management, and communication of the identified risk.[27] In terms of food safety, the Codex Alimentarius Commission (CAC) has defined risk as a "function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food".[25]

The Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) led the development of food safety risk analysis which was later adopted by the CAC as a framework for a science-based food safety system that can be used by countries in dealing with food safety risks.[10,110] Following this, the Philippine Food Safety Act of 2013 (FSA 2013) stipulates the use of risk analysis as a scientific basis in the development of food safety policies and consumer protection measures to attain its objectives in protecting consumer health and ensuring fair trade practices.[9] The risk analysis framework consists of three distinct but interrelated aspects: risk assessment, risk management, and risk communication (Figure 2).[100]

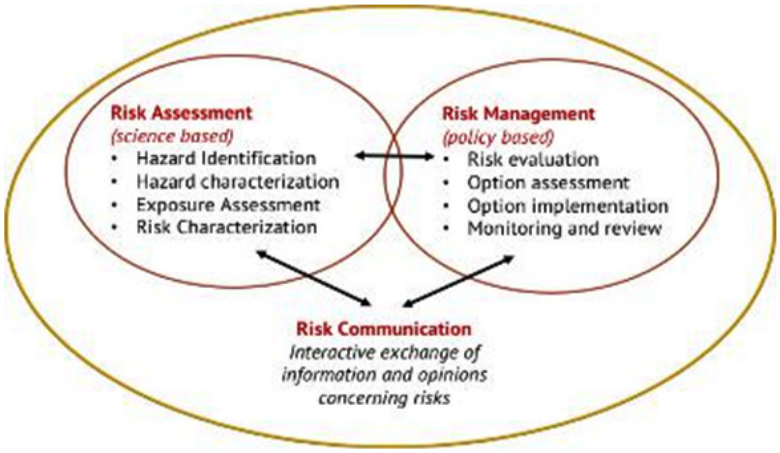

Fig. 2: The Risk Analysis Framework.[100]

Food safety risk assessment is the scientific process of understanding the food safety hazards that exist within a food system and the risks they pose for consumers.[100] Food safety risk management takes into account the details of an accurately accomplished risk assessment, the interests of all key players of a food system (producers, distributors, consumers, etc.), and other factors that are relevant for the protection of public health, economy, and other societal aspects affected by the food industry to weigh policy alternatives that could address the situation at hand.[100] Throughout the whole process of risk analysis, effective food safety risk communication must be in place as it is the interactive exchange of information and opinions between risk assessors and risk managers.[100]

With a scientific background, a risk-based approach on to food safety management will be able to determine where the risk is greatest and to direct the national resources in selecting suitable risk reduction measures to prioritized food safety issues.[99] The FAO/WHO emphasizes that a strong foundation on risk analysis is one of the key principles to

improve the food safety control system of a country.[10] This may be achieved through the generic risk management process that the FAO/WHO has provided to guide countries in the development of risk management systems on a national-level (Figure 3). 111 It starts with preliminary risk management activities intended to elucidate the food safety risks.[111] Defining food safety risks in the national setting, ideally through risk profiling, is a preliminary risk management step in developing a preemptive approach towards food safety.[28]

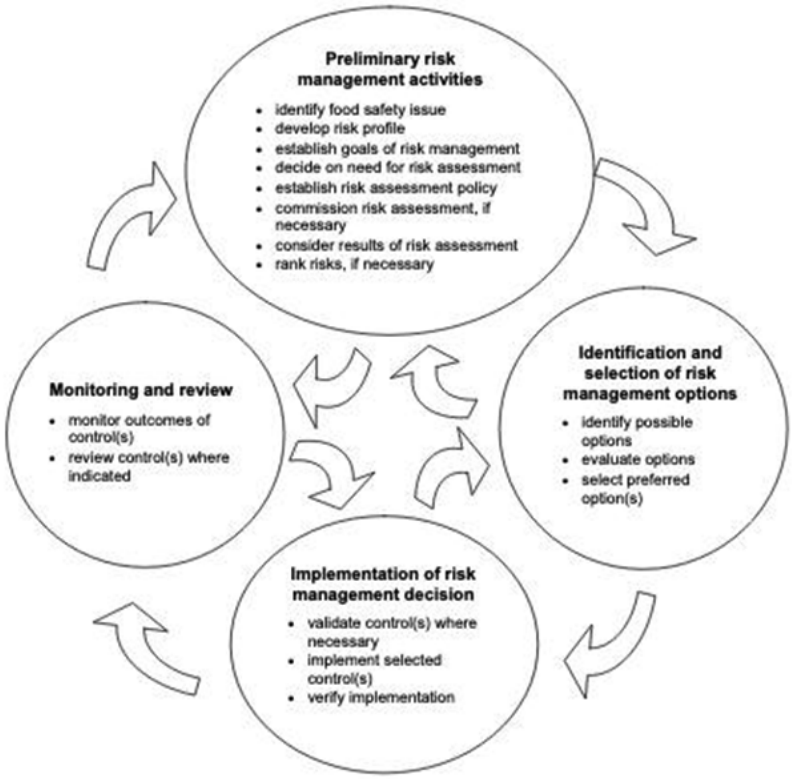

Fig. 3: Generic Process of Risk Management.[101]

Risk Profiling

The establishment of a risk profile (Figure 4)[100] is a preliminary risk management activity intended to provide risk managers a summary of what is currently known about the possible food safety risks and the current control measures, which consequently sheds light on the gaps in scientific information relevant to the risk, as a guide for setting work priorities, identifying possible risk management options, and determining if a formal risk assessment is necessary.[111]

Risk profiling involves risk assessors and risk managers who will determine the need for a formal risk assessment and its extent, through communication with other interested parties or stakeholders.109 A risk profile contains information, including: (1) a brief description of the food safety problem, (2) commodity or product involved and the pathways by which consumers may be exposed to the hazard, (3) possible effects or consequences of exposure to the society, (4) risk perception, (5) distribution of risks among different population sublevels, and (6) possible benefits regarding use of the chemical in food, which will determine the questions that need to be answered under risk characterization to meet the needs of the risk manager and will provide an overview of the available data, the lacking data, and the time frame for completing the assessment.[109,111]

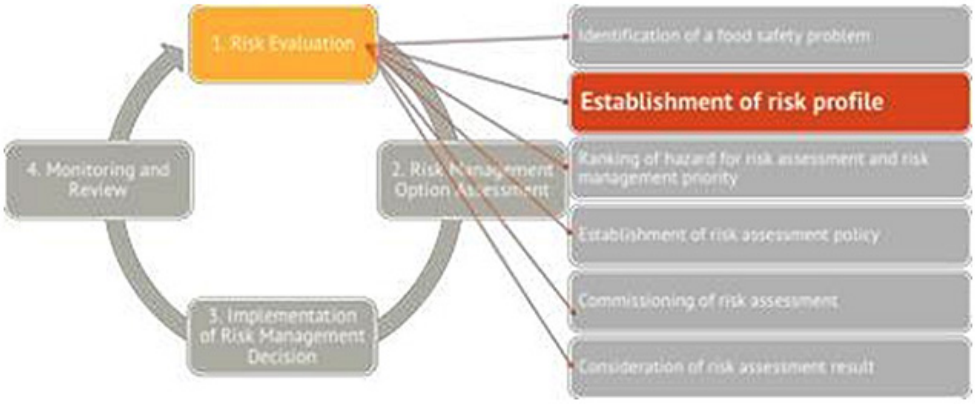

Fig. 4: Risk evaluation steps.[100]

To facilitate risk analysis and to evaluate the effectiveness of a food safety control system, risk profiling may be able to harmonize the definition of food safety risks that the country is facing.

To utilize this concept in the Philippines, this study identified the (1) factors affecting food safety in the Philippines, (2) Philippine food laws and regulations, and the (3) food safety issues and challenges in the Philippines in order to support and emphasize the need for risk profiling to strengthen the current food safety control system of the country.

Factors Affecting Food Safety in the Philippines

Food safety risk in the Philippines can be influenced by the vulnerability of the population against the hazard, their exposure to the hazard, and the nature of the food safety hazards.

These factors contribute to the different food safety challenges faced by the country.[27] They are considered when establishing health risks that concern food safety.

Population characteristics such as age, sex, income, and health status influence the vulnerability of the population to hazard exposure.[27] According to the US FDA.[29] among the population groups, the young children were found to be more at risk for foodborne diseases due to their still-developing immune systems. An estimate of 33.39% of the Filipino population is aged 0-14 years old.[30] This population group is considered the vulnerable or at-risk group, characterized by an increased susceptibility to acquiring foodborne diseases and is more likely to sustain a longer duration of disease that may eventually lead to hospitalization or even death.[31]

Several studies express the effects of sex-based differences in food choices and therefore, on exposure to food safety hazards.[32] A higher fraction of men were observed to eat meat and poultry than women, who were observed to eat more fruits and vegetables.[32] Reports also show that men are more likely to consume “high-risk” foods or food items that were usually linked to foodborne disease outbreaks such as runny eggs, pink hamburgers, and raw oysters.[32]

The variation in the income status of a population comes into play amidst the rising food costs, inducing differences in the ability to procure food commodities that result in a gradient across the population with regard to food safety.[33] Low-income households in developing countries such as the Philippines resort to consuming less food or food with lowered costs, trading assets of food important to health and wellbeing. They also tend to forego other essential expenditures such as health care or education as a result of their inability to procured food due to an increase in food costs of any magnitude.[33] Such practice would render these households vulnerable to health risks including foodborne diseases.

The nature and source of the food safety hazards are also considered when establishing health risks concerning food safety. Contaminants and pathogens that cause foodborne diseases may be naturally occurring in the environment or introduced in the food chain as a result of processing and

human activities.[34] Heavy metals such as mercury, cadmium, and arsenic among others, are chemical contaminants which can be attributed to volcanic emissions.[35] As the Philippines is located along the "Pacific Ring of Fire," a zone of violent volcanic and earthquake activities,36 the proximity of volcanoes make the soil, atmosphere, and water susceptible to heavy metal contamination which may affect people through biocontamination in the food chain.[37]

The climate of the Philippines can also bring about several factors that can affect food safety. As presented in Table 1, the ambient temperature range in the Philippines (25.5°C to 28.3°C) is within the temperature danger zone for food storage (4.44°C to 60°C) which is conducive to the log phase of growth of bacterial pathogens such as *Staphylococcus aureus, Salmonella enteritidis, Escherichia coli* O157:H7, and Campylobacter.[38,39]

Table 1: Atmospheric profile of the Philippines.[40]

Elements	Characteristics
Climate	Tropical and maritime characterized by relatively high temperature, high humidity, and abundant rainfall
Seasons	Rainy season from June to November Dry season from December to May
Temperature	Mean monthly range of 25.5°C (January) to the warmest of 28.3°C (May)
Relative humidity	Mean monthly range of 71% (March) to 85% (September) due to high temperature and surrounding bodies of water
Rainfall	Mean annual range of 965 to 4,064 mm varies from region to region depending upon thedirection of the moisture-bearing winds and the location of the mountain system. Also, frequent typhoons have a great influence on local rainfall, humidity, and cloudiness.

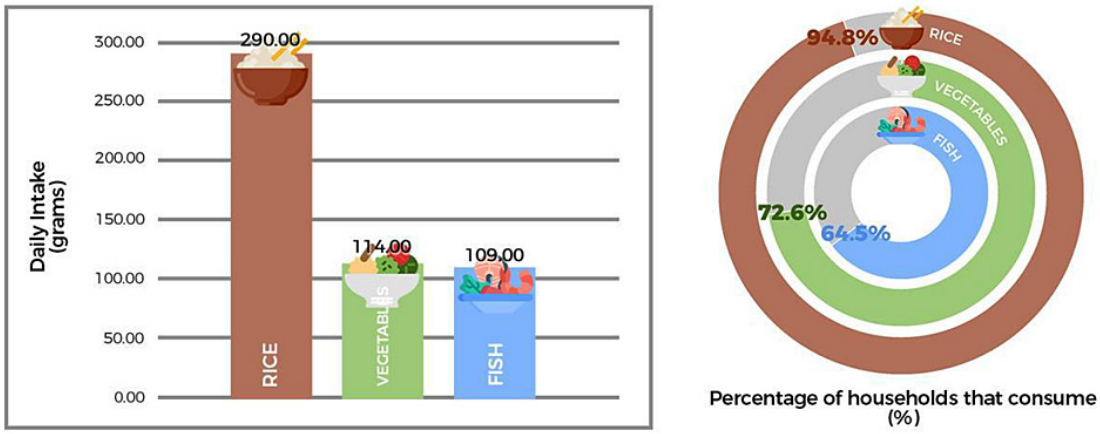

Fig. 5: A portion of the results of the 8th National Nutrition Survey showing (left) the average daily intake (in grams) per capita in the Philippines and (right) the most consumed items of Philippine households.[100]

The high relative humidity and heavy rainfall in the Philippines require local food processing businesses to maintain microorganism-inhibiting storage conditions and measures since the presence of moisture in food processing equipment or storage areas may accelerate the growth of spoilage microorganisms.[41] The impacts of these climate characteristics may both, directly and indirectly, affect the relationship between the survival and incidence probability of microorganisms and therefore the corresponding risk of foodborne diseases.[42] The Center for Disease Control and

Prevention prompted travel advisories for travelers to the Philippines to be wary in the consumption of food or water which may be contaminated and may consequently lead to the contraction of foodborne diseases.[43]

Consumption is a significant factor in the exposure to food safety hazards, and therefore in establishing the probability of the occurrence of adverse health effects.[44] Based on the National Nutrition Survey conducted by the Food and Nutrition Research Institute,[45] rice can be considered as a staple food as it is consumed by 94.8% of the households in the Philippines at 290 g per capita intake (Figure 5). FNRI (2015)[45] reported that most of the top consumed commodities such as rice, vegetables, and fish, need processing or a cook step prior to consumption. High consumption of a commodity suggests a higher exposure of the population to hazards associated with that commodity. The most common hazard associated with rice is the Bacillus cereus from which adverse health effects arise if the rice is not properly prepared, cooked, or reheated.[46]

Food Laws and Regulations in the Philippines

Food hygiene is an integral part of food safety, and supporting sanitation programs should be developed to ensure that food is safe and suitable for consumption.[47] In the Philippines, the Code on Sanitation of the Philippines (Presidential Decree No. 856, s. 1975)[48] had been established in 1975 as a reference and guide for the enforcement of sanitation requirements, especially for food establishments.[49] Provisions on Food Establishments can be found in Chapter III of the Code on Sanitation that includes sanitary permits, health certificates, quality and protection of food, structural requirements.[49]

However, the first Philippine Constitution that had concrete provisions on food safety was the 1987 Constitution of the Philippines[50] which included: (1) Article II, Section 15, "The State shall protect and promote the right to health of the people and instill health consciousness among them"; (2) Section 12 in Article XIII, "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems"; and (3) Article XVI Section 9, "the State shall protect consumers from trade malpractices and substandard or hazardous products." When the Department of Health (DOH) and the Department of Agriculture (DA), formerly joint with the Department of Environment and Natural Resources as the Department of Agriculture and Natural Resources, were established in 1898, several laws and regulations were implemented to protect consumer health and the agriculture and fisheries sectors of the country.[20,51] Additionally, Republic Act No. 7394, known as the Consumer Act of the Philippines, was enacted to protect the interests of the consumer, promote the general welfare, and establish standards of conduct for business and industry.[52] The law particularly provides authority to identified implementing agencies responsible for food product and quality investigation relevant to consumer concerns but the food safety initiatives and programs that the various government agencies and bureaus had implemented were not jointly planned, coordinated, and carried out which led to a fragmented food control system.[53,21,23]

As presented in Table 2, several Philippine food safety policies from farm-to-fork were established to ensure that the food supply is of good quality and is safe for public consumption.

Food Safety Issues and Challenges in the Philippines

As stipulated in Section 19 Article V of the FSA 2013,[9] the role of the Department of Interior and Local Government (DILG), in collaboration with the Department of Agriculture (DA), Department of Health (DOH) and other concerned agencies, is to enforce food safety and sanitary rules and regulations, inspection, and compliance of businesses rendering food services through the Code on Sanitation of the Philippines (Presidential Decree No. 856, 1975).[47] These government agencies shall be working hand-in-hand in conducting research, monitoring, and documentation of food-related diseases.

However, there are several indications which may imply that there are gaps in the Philippine food control system and these include (1) gaps in food laws specifically on food inspection, analytical capability, inadequacies of governance, and response to food safety issues of the country as reported and researched in relevant literature; (2) incidences of foodborne diseases (FBD) outbreaks; and (3) records of food recalls.

Table 2: Philippine food safety policies established to address food safety concerns from farm-to-fork.

Food safety concern	Corresponding policies
A. Fresh	
Food security and trade	RA 8435: Agriculture and Fisheries Modernization Act (1997)
B. Processed	
Pure and safe food supply	EO 175: Food, Drugs and Devices, and Cosmetics Act (1987)
Quality and safety of food products	AO 153: Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking or Holding Food (2004)
Meat inspection and hygiene	RA 9296: Meat Inspection Code of the Philippines (2005)
Regulatory system for processed foods	RA 9711: Food and Drug Administration Act of 2009
Food safety and quality defect	FDA Bureau Circular 12: Guidelines on Product Recall (2016)
Safety of drinking water	AO 2017-0010: Philippine National Standards for Drinking Water of 2017
C. Food Service	
Sanitation requirements for food	PD 856: The Code on Sanitation of the establishments Philippines (1975)
Breastmilk substitutes, breastmilk supplements, and Other Related Products	EO 51: National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Other Related Products-1986
D. Unified Food Safety Control System (Farm-to-Fork)	
Food safety, fair trade, and global competitiveness of Philippine foods and food products (Unified law for food safety)	RA 10611: Food Safety Act of 2013

RA - Republic Act; PD - Presidential Decree; EO - Executive Order; AO - Administrative Order

Food Inspection

Food inspectors are responsible for providing a line of defense against food adulteration by ensuring that food and food products are in accordance with the standards.[54] This is administered by the food inspector through regular coordination and communication with the food industry, trading, retailing, and the consumers.[54]

According to the Implementing Rules and Regulations of Republic Act No. 10611 (Sections 15, 18, and 29 Article VIII A.O. No. 2015-0007), food inspectors must have certification, have skills on risk-based inspection, undergo training, and perform their duties at the highest level of competence and integrity with the assurance that regular evaluation is conducted to verify continuing competence.[9] However, the study of the World Health Organization-Philippines in Cebu City by Magtibay[55] on "Developing Guidelines for Sanitary Inspection on Risk-Based Inspection for Food Establishments" reported the following gaps:

- Lack of professional control in food safety measures for both small- and micro- food processors;
- No determined standards for risks related to small- and micro- food processors, specifically the longganisa and chorizo industry;
- Absence of currently published comprehensive guidelines, procedures, and checklists for catering services;
- Lack of standardized risk-based training for food inspectors; and,
- No examination or certification process and trainings for food inspectors currently in place.

Analytical capability

The Food and Agriculture Organization (FAO) and World Health Organization (WHO)[54] stated that considerable investment for laboratory maintenance and operation is required to achieve optimum results in laboratory analyses. Common utilization of laboratory analysis in food risk assessment involves quantification tests, use of different assays in dose-response assessments, and metagenomics which aims to determine and estimate the level of hazard specifically found in the food commodity.[54] These analyses commonly involve sophisticated instruments that require regular calibration and facilities with controlled conditions, and skilled analysts which account for the total expense for the analysis.[56,57]

It was emphasized in a publication of DOH[58] on Health Policy Notes (Volume 3: Issue 4) that the identified main problem of the Bureau of Food and Drugs (BFAD), presently known as the Food and Drug Administration of the Philippines (FDA) in improving its analytical capability was not on the expertise of the laboratory employees performing the analyses, but the unavailability of laboratory infrastructure and equipment.

Gaps in technicalities involved in laboratory analyses were also identified as reported by Lustre[4] including:

- Improvement of research protocols for the importation and exportation of local food and food products;
- Lack of sufficient space area and number of quarantine pest areas for the exportation of major agricultural commodities of the Philippines (i.e. mango and fresh coconut); and
- Unavailability of scientific research data and studies on food safety and food safety issues in the country.

Table 3: Locations of foodborne disease outbreaks in the Philippines for 1995-2004 and 2005-2018.[60,61]

Location	Incidences in Inclusive Years (%)	
	1995-2004	2005-2018
Food Service Eating Facility (school, canteen, restaurants, hotels)	27	35.41
Household (single and multiple household involvement,community, fiestas, birthday celebrations)	43	48.80
Others(office, public gathering, orphanage facility, jail)	20	15.79
Unknown	10	-

Foodborne Disease Outbreaks

Implementation of stricter food safety policies and regulations from "farm to fork" focusing on raw food commodities, however, does not imply a decreased probability of foodborne disease cases as improper food handling practices in the household are not taken into account.[59] Studies by Azanza[60] and Azanza *et al*.[61] on Foodborne Disease (FBD) Outbreaks in the Philippines for the years 1995 to 2004 and 2005 to 2018, respectively, have reported the locations where incidences of FBD outbreaks were traced (Table 3); indicating that the leading location of FBD outbreak is in households, followed by food service eating facilities, for both periods.

Tables 4 and 5 present summaries of the food vehicles and the causative agents associated with FBD outbreaks in the country for the years 1995 to 2004 and 2005 to 2018.

The most common vehicle for FBD outbreaks in the country were meat-based dishes from the period of 1995 to 2004 and 2005 to 2018. However, in general, there was an observed decrease in the percentage of FBD outbreaks. This may be attributed in part to the implementation of food safety controls such as (1) RA 9296 or the Meat Inspection Code of the Philippines[62] that ensures the safety and quality of meat and meat products

involving proper preservation, inspection, and importation which may have influenced the decrease in the number of foodborne disease cases in meat-based dishes/products; (2) FDA Bureau Circular 12 or Guidelines on Product Recall (2016)[63] that ensures an effective and efficient recall strategy of distributed food products found and proved to be unsafe and hazardous to the consumers which may have reduced the occurrences of FBD cases; (3) AO 2017-0010 or the Philippine National Standards for Drinking Water of 201764 which sets safety and quality standards for drinking water both for direct consumption and for use in food production; and (4) AO 153 or the Revised Guidelines on Current Good Manufacturing Practice (GMP) in Manufacturing, Packing, Repacking or Holding Food (2004)[65] that aligns the current Good Manufacturing Practices (cGMP) of the country for human food products with international standards and strengthens the industry implementation and regulatory inspection which may also have contributed to the decrease of FBD cases especially in bakery and confectionery products.

The number of FBD outbreaks that resulted from the reported causative agents (Table 5) generally decreased on the periods reported by Azanza[60] and Azanza *et al*.,[61] except for unknown microbiological pathogens. Media reports may have prompted the alertness of food safety authorities to monitor and implement control measures to reduce the incidences.

In addition, according to the records provided by the Department of Health - Epidemiology Bureau (DOH-EB),[66] a total of 7,729 FBD cases were reported from 1988 to 2019 in the Field Epidemiology Training Program (FETP) Epidemiologic Studies Database, while 134 FBD outbreaks were investigated. According to the DOH-EB,[66] sources of these FBD include a wide range of food and water products, from fresh produce such as seafood, meat, mushrooms, and fresh vegetables and fruits, to processed foods such as spaghetti, chocolate cake, ice candy, soya milk, porridge, milk tea, and peanut butter. The availability of foodborne disease outbreaks epidemiology data is evidence that there is a working disease surveillance system in the country which is essential in making public health decisions.66 A surveillance system has been set up, not only for cases of foodborne disease outbreaks but also for issues surrounding food trade including food recalls and detention.[67]

Table 4: Food vehicles implicated in food borne disease outbreaks in the Philippines for 1995-2004 and 2005-2018.[60,61]

Food Vehicle	Incidences in Inclusive Years (%)	
	1995 to 2004	2005 to 2018
Meat-based dishes/ products	32	14.35
Fish and other seafood dishes	20	12.92[a]
Bakery and confectionery products	17	9.57
Toxin-containing or inedible materials	13	10.53
Other dishes (e.g. noodles and pasta dishes; rice and root crops)	10[b, c]	10.05[b] 7.18[c]
Beverages	8	NIR
Multiple implicated fooddishes	NIR	27.27

NIR – No information reported by Azanza[60] / Azanza *et al.*[61]
[a]Including manufactured products
[b]Noodles and pasta dishes
[c]Rice and root crop

Table 5: Reported causative agents in the Philippine foodborne disease outbreaks for 1995-2004 and 2005-2018.[60,61]

Causative Agents		Incidences in Inclusive Years (%)	
Microbiological	**Chemical/Toxin**	**1995-2004**	**2005-2018**
Unknown		15	87.97
Salmonella spp.		30	2.46
	Staphylococcal enterotoxin	23	1.24
	Carbamates	NIR	0.96
	PSP	4	1.14
Salmonella enteritidis		NIR	0.82
Henipavirus		NIR	0.75
Entamoeba histolytica		NIR	0.73
Vibrio parahaemolyticus		10	0.70
Vibrio cholerae		4	NIR
Aeromonas spp.		2	NIR
	Histamine	4	NIR
	Dioscorine	NIR	0.70
	Tetrodotoxin	1	0.68
	Cyanogenic glycoside	NIR	0.68
	Oxalic acid	NIR	0.35
	Toxalbumin curcin	NIR	0.30
	Ciguatoxin	1	0.29
	Nitrate	NIR	0.13
	Nitrite	1	NIR
	Psilocybin/Psilocin	1	NIR
	Jatropha curcas toxin	1	NIR
	Amatoxin	1	NIR
Escherichia coli		2	0.08

*NIR - No Information Reported by Azanza[60] / Azanza *et al.*[61]

Food Recalls

Imported food products are regulated as a food safety control measure for decreasing the health risk in the country. Regulating imported processed foods is tasked to the Department of Health (DOH) while regulating imported raw or fresh foods is assigned to the Department of Agriculture, with both agencies receiving assistance from regulatory bureaus such as the Bureau of Animal Industry (BAI), National Meat Inspection Service (NMIS), Bureau of Fisheries and Aquatic Resources (BFAR), and the Bureau of Plant Industry (BPI).[68] On top of the existing regulatory systems implemented by these agencies as mandated by the FSA 2013, the Philippines has been jointly working with the European Union (EU) on the EU-Philippine Trade Related Technical Assistance (TRTA) project. This collaboration has brought about the establishment of the Philippine Rapid Alert System for Food and Feed, otherwise known as the PHILRASFF with the aim to improve risk communication in the country.[69]

The PHILRASFF is an advanced web-based alert system that allows food authorities to promptly disseminate information regarding the necessary food safety intervention in response to incidents and risks related to food and feed.[69,70] The PHILRASFF also aids the regulatory agencies involved in the chain of food and feeds in making an immediate and coordinated response to health threats posed

by detected risks in food or feeds.[70] Such responses may include the conduct of food detention and the issuance of food recalls.[71]

Food recalls are issued as a corrective action against an already distributed food product deemed to be contaminated, adulterated, mislabeled, or generally unsafe for human consumption.[72] Guidelines on Product Recall are provided to all licensed manufacturers, traders, distributors including importers, exporters, wholesalers, and retailers of health products through the FDA Bureau Circular No. 12.[63] As stated in Section 5(k) of Republic Act No. 9711 (FDA Act of 2009), the FDA has "the power to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive," after due process.[67]

Between 2008 and 2018, there had been a total of eight (8) product recalls issued by the Philippine Food and Drug Administration[73] for food categories such as meat, poultry, fruits and vegetables, cheese, and fish and fish products, including mollusks, crustaceans, and echinoderms (Table 6). Based on the summarized records, the most common reason for food product recall was due to microbiological contamination such as *Listeria monocytogenes and Escherichia coli.*

Table 6: Summary of food recall records on local, imported, and exported Philippine food commodities from 2008 to 2018.[73]

Date	Food Category	Commodity	Origin of Commodity	Reason for Recall
31-Mar-17	08.1 Fresh meat, poultry, and game	Raw beef	Local	Adulteration with rotten raw meat
31-Aug-17	08.1 Fresh meat, poultry, and game	Poultry meat and by-products	Local	MC with Avian influenza
11-Jul-18	04.2.2.1 Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds and nuts and seeds	Frozen corn and other vegetables	Imported	MC with *L. monocytogenes*
		Frozen peas	Imported	MC with *L monocytogenes*
		Frozen corn	Imported	MC with *L monocytogenes*
01-May-19	01.6 Cheese and analogues	Cheese	Imported	*MC with E. coli*
		Cheese	Imported	*MC with E. coli*
15-Aug-16	09.1.2 Fresh molluscs, crustaceans, and echinoderms	Scallops (wild harvest, raw, frozen)	Exported	MC with Hepatitis A

MC – microbiological contamination
**including mollusks, crustaceans, and echinoderm*

Food Safety in Street Foods

According to Article V Section 15 of the FSA of 2013, the implementation of food safety requirements of food business including the street food industry or ambulant vending is under the jurisdiction of the Local Government Units (LGUs).[9] The identified gap in the concept of food safety in the street food industry and ambulant vendors in the country was generally influenced by the practice of a vendor to compromise food safety for business profits.[74,75] This was supported by the findings from the study of Rustia *et al*.[76] entitled "Food Safety Knowledge Assessment Model for Pre-trained Food Handlers" where a Training Needs Assessment (TNA) model was developed to evaluate the knowledge of street food vendors to food safety relevant to the Code

on Sanitation of the Philippines (PD 856 of 23 December 1975). Based on the results of the study, two important factors were proposed that can bridge the gap in terms of the food safety of the street food industry in the country particularly regular training and provision of support resources for facilities.[76] Vendor-employees showed a high percentage of knowledge translation to practice due to the constant exposure in their daily tasks.[76] However, other food safety practices based on PD 856 such as display of sanitary permits, health certificate IDs, washing of raw fruits with potable water, washing hands thoroughly with soap and water, and use of chlorine solutions for utensils, were not properly demonstrated by the street food vendors.[76]

Inadequacies in Governance

The heterogeneous structure of food sectors in developing countries such as the Philippines impedes the function of the government in implementing a unified food safety regulatory system in the country.[77] According to the World Bank Development Report[78] in the Philippines, the services sector in the country are mainly informal with three-fourths of the sector engaged in small retail trade such as street food-vending and backyard slaughter, and public transportation. The micro, small, and medium enterprises (MSMEs) in the Philippines had reached 99.56% of the distribution of business enterprises and 13.22% of which falls under accommodation and food service activities.[79] The combination of these food sectors with the large-scale food industries makes it difficult for the government to develop substantial food safety policies and regulations that would fit the needs and demands of all markets.[80]

Varying food sectors also complicates the generation of food safety programs as the demands and needs of the different sectors are greatly diverse.[81] Based on the 2018 Survey of Entrepreneurs and MSMEs in the Philippines,[82] there was identified low awareness on the different policies for MSMEs - *Magna Carta* for Micro, Small, and Medium Enterprises (48% awareness), *Go Negosyo Act* (40%) which encases the building of infrastructure in support to MSMEs, and the Barangay Micro Business Enterprises Act (29%) which aids micro-enterprises in company registration through the provision of financial incentives. The findings showed that the policies legislated by the government fail to reach the end-users (referring to the producers, manufacturers, retailers, etc.) who were found to be unaware of the policies.

Furthermore, the certification of Hazard Analysis Critical Control Points (HACCP), described as the global language of food safety, varies between countries and is affected by customer demands and trade.[81] Several gaps were identified that hinders food establishments in the Philippines particularly the MSMEs and the informal food sectors, to be HACCP certified.[83,84] It was observed that there was insufficient funding for the construction and improvement of facilities and infrastructures needed for monitoring critical control points (i.e. metal detectors) and maintenance of HACCP implementation, and lack of awareness, knowledge, and expertise to HACCP.[83,84] Similar gaps were also identified with the MSMEs compliance to food safety regulations.[85] Yapp and Fairman[85] reported that lack of knowledge on the food safety principles and requirements, lack of motivation in complying with legislation due to underestimation of its importance, and lack of trust with the legislators that are not perceived as trustworthy prevent the small and medium-sized enterprises to comply with food safety regulations. Considering MSMEs and the informal food services sector of the country with low customer demand and pressure in the food industry, the extent of ensuring food safety is diminished.[86]

To help address the gaps on in inadequacy of governance among MSMEs, the Philippine Department of Science and Technology (DOST) initiated a program called Small Enterprise Technology Upgrading Program (SETUP) to empower MSMEs through technical assistance, training, and provision of funds and equipment that have proven to be effective given the success stories from the local MSMEs.[87]

Response to Food Safety Issues

Relevant to local MSMEs, the Philippine FDA[88] recently released a public advisory (FDA Advisory No. 2019-120) on the ban of Philippine coconut wine ("*lambanog*") in the first quarter of 2019 following the issues on *lambanog* poisoning cases in 2018[89] and 2019.[90]

Moreover, another incidence in 2019 has led the FDA[91] to announce, through the FDA Advisory No. 2019-144, that five (5) vinegar brands out of

the 39 vinegar samples (available in the market) the agency collected and tested for authenticity were determined to contain synthetic acetic acid. The identified vinegar brands were stated to have violated the Department of Health Administrative Order 134 s. 1970 dictating the Standard of Identity and Quality of Vinegar.[92] Taking into account the actions undertaken by the FDA, the Philippine Department of Trade and Industry (DTI), initiating its mandate in ensuring consumer access to safe and quality goods and services,[92] issued a public advisory discouraging consumers from buying the five (5) identified vinegar brands.[93]

Prior to reports on the confirmed cases of African Swine Fever (ASF) in the country,[94] the Philippine Department of Agriculture National Meat Inspection Service (DA-NMIS) had released a public advisory and Memorandum Order No. 2019-01-0017 to concerned officials and meat inspector officers to raise awareness and provide precautionary measures on controlling ASF.[95] As of this September 2019, there had been 11 areas in the Philippines with confirmed ASF, incidences and the Philippine Department of Agriculture (DA) conducted immediate mass culling of pigs (estimated total of 15,000 pigs).[94] Concerning the pork processing industries, the Philippine FDA released an advisory ordering only the use of carcass or meat from NMIS-accredited slaughterhouses or abattoirs.[96]

Strengthening the Current Food Safety Control System

Given the food safety issues and challenges mentioned above, it is safe to say that there is a need to strengthen the current food safety control system in the Philippines.

The FAO Strategies for a food chain approach to food safety and quality, also known as the farm-to-fork approach, is a holistic, preventive, and risk-based approach which recognizes food safety as a shared responsibility between the government and all the participants in the food chain including producers, processors, and traders.[97,98] It looks into the importance of hazard control at every point of the food chain and directs these controls to prevent food hazards from entering the food chain through the use of existing preventive codes of practice such as Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), and the Hazard Analysis and Critical Control Point (HACCP) system. The approach also utilizes risk analysis for sound scientific basis and to eliminate unnecessary controls for a more efficient system that reiterates the importance of risk profiling in providing a solid foundation for an improved national food safety program.[97,98, 111]

As risk analysis is part of the Codex framework that the World Trade Organization recognizes and recommends to its member countries through the SPS agreement,[14,15,17] a lot of countries, if not already, are working towards a risk-based food safety system. Some of the countries with established food safety systems that utilize risk analysis include the European Communities, the United States of America (USA), Australia and New Zealand, and Hong Kong among others.

The European Union (EU), also referring to the European Communities, established the food safety system of the EU, European Food Safety Authority (EFSA) as the risk assessor, and the Rapid Alert System for Food and Feed (RASFF) for immediate detection of public health risk in the food chain which is continuously improved for food incident preparedness and response.[112] The EFSA, through risk assessment, has been able to provide scientific opinion and advice on melamine in composite foods from China (2008), to determine the source of *E. Coli* O104:H4 outbreaks in Germany and France and afterward, provided recommendations for consumer protection, and to record food recalls and detentions due to quality and safety issues through the RASFF.[112]

Meanwhile, various US government agencies and organizations, such as the US Food and Drug Administration - Center for Food Safety and Applied Nutrition (US FDA-CFSAN),[113] the US Department of Agriculture - Food Safety Inspection System (USDA-FSIS),[114] and the US Protection Agency (US EPA)[115] among others, utilize risk analysis in initiatives, activities, and responses relevant to food safety. It is believed that the USA is already equipped with attributes of an effective food safety system with key points on monitoring, surveillance, inspection, enforcement, outbreak management, research, and education.[116]

For Australia and New Zealand, ministers responsible for food regulation from both countries worked hand-in-hand to establish Food Standards Australia New Zealand (FSANZ) which purpose is to develop and administer food standards code.[117] FSANZ is also supported by New Zealand Food Safety (NZFS)[118] and the Australian Department of Agriculture.[119] FSANZ is one of the science and risk-based organizations that has completely integrated the risk analysis principles in the development of food safety policies and legislations, and to respond to emerging and emergency food safety issues.[117] Australia and New Zealand have effective and transparent food safety systems in which policies, initiatives, and activities are comprehensible and actively communicated to the general public.[117,118] The strong foundation of risk analysis in the FSANZ system has helped to establish an efficient and cost-effective food safety system and educate stakeholders relevant to food safety which ultimately facilitates food trade and increase consumer confidence.[117] Risk profiles are not only developed to assist risk managers and regulators in decision-making for food safety control measures but also for other stakeholders along the food supply chain to understand food safety hazards and corresponding public health risks.[118]

In Asia, Hong Kong established a risk-based approach to food safety control through the establishment of its Centre for Food Safety (CFS) in 2006 which is regularly audited for improvement.[120] The food safety system of Hong Kong includes periodical food safety risk assessments, an established food incidents surveillance system, and an effective risk communication strategy.[120] The CFS publishes easy-to-read and laymanized "Risk-in-brief" documents to share information on food safety topics and issues to the general public.[121]

These countries laid the groundwork for an effective risk-based food safety system that has an efficient and proactive approach in dealing with arising food safety issues by utilizing risk analysis and improving its framework to adapt to the national food safety needs of each country.

The ASEAN also recognizes the importance of risk assessment, a component of risk analysis, in providing a scientific basis for the development of food safety measures. As such, the ASEAN Risk Assessment Center (ARAC) has been launched through the initiative of the ASEAN Expert Group on Food Safety with its commitment to "strengthen national food control systems and work together to contribute towards safe and quality food in the ASEAN Community."[122]

As the Philippines is still in its early stage of improving its food safety system, it would be better to have an overview of the current system and to establish the localized risk analysis process first. Following the recommended generic risk management process, risk profiling will be able to jumpstart the improvement that the country needs. Other concepts that can aid in employing risk analysis, such as the disability-adjusted life year (DALY), the appropriate level of protection (ALOP), and the food safety objective (FSO), may be used to further improve the utilization of the framework for a strengthened food safety system.

The Concept of Disability-Adjusted Life Year

The DALY is a unit used for measuring the burden of disease.[101] It is defined as the total number of potential years of life lost due to early mortality and the years of productive life lost due to disability.[102] The DALY is a useful tool in determining which diseases are of priority as this leads to better planning and allocation in terms of the health resources of a population.[101] Moreover, it will be easier to address the risks and hazards associated with the diseases through risk assessment since the priority diseases will already be targeted.[103]

Wong *et al*.[104] generated a priority list of health conditions that need to be addressed in the Philippines and used the burden of disease data from 2013 to project the rest of the disease burden for 2015 to 2035. Although the study focused on diseases in general, future studies may be done using the same principle to specifically account for foodborne diseases. This way, the data that will be obtained may be utilized in strengthening food safety in the country.

The Appropriate Level of Protection

In protecting the public health of its population, the WTO, under the SPS Agreement, established a concept of the Appropriate Level Of Protection (ALOP), defined as "the level of protection deemed appropriate by the Member establishing a sanitary

or phytosanitary measure to protect human, animal or plant life or health within its territory".[105] This is to recognize the right of a WTO member country to come up with its ALOP that is appropriate to protect the life of its population.[105] ALOP can be expressed either qualitatively such as public health goals or quantitatively such as the probability of a given population to getting sick when contaminated with a specific amount of food hazard.[106] However, since ALOPs are set at a population level, this measure would not be of much help for food safety management in practice.[106,107] In response to this, the development of a specific guidelines to comply with, such as the food safety objective (FSO), is necessary.

The Food Safety Objective

The FSO is defined by the Codex Alimentarius Commission[108] as: "the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection (ALOP)." In principle, FSO could also apply to other types of hazards.[106] Following the risk analysis framework, the development of FSO adheres to provide a more effective implementation of food safety policies as it directly connects the food safety control system set by the government at a national level.[106,107] Together with the food safety management system, which is composed of different food supply chains at an operational level, FSO can achieve a common goal of securing consumer welfare.[106,107]

The setting of an FSO involves the government assisting the public and private food sectors involved in the food safety management system (i.e. primary producers, manufacturers, processors, food caterers, traders and distributors, and food retailers) on how a particular acceptable level of a specific food hazard may be attained and maintained in order to control the risk of contamination.[106] This is done through the establishment of a set of guidelines specific to a food product that consists of the food hazard, the limit or ranged to be attained, and the particular process step where the level must be achieved.[107] Such control level can only be established through risk analysis, specifically risk profiling.[106,107] As numerous factors are affecting a specific food hazard, the establishment of a risk profile provides an in-depth examination of the hazard in a particular food commodity to come up with a risk estimate that is needed for the development of an FSO and ALOP.[106,107]

A harmonious relationship between the three interrelated aspects of food safety risk analysis would produce findings which could predict food safety breaches and therefore, serve as bases for the development of preemptive policies that would prevent food safety-related issues in the public. A strong food production system that is protected by such policies, regulations, and measures is essential to society, not only because it protects the general public health, but also the other key social aspects especially commerce and trade. A balance between protecting the public from health adversity and the promotion of smooth, free, and fair trade must be achieved through the correct execution of a food safety risk analysis.[106,107]

Conclusion

The Philippines has already taken the first step in strengthening the national food safety control system through establishing the Food Safety Act of 2013 stipulating the use of risk analysis as a scientific basis in developing policies and programs for food safety. However, the country is still in the process of knowing what needs to be prioritized. A clear view of the definition of risk can potentially instigate a more effective system. Risk profiling, a preliminary risk management activity, will be able to identify the gaps that should be addressed to be able to better respond to food safety issues. Moreover, capacitating the manpower in the risk analysis framework with the risk profiling mechanism and building databases to aid in completing the risk profiles will be beneficial to and will provide better opportunities for the country.

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Conflict of Interest

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