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Review

Food safety risk assessment in Vietnam - Current situation and way forward

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Abstract

Risk assessment is an important scientific step in risk-based food safety (FS) management that has been applied in many countries. In Vietnam, despite being regulated by law, risk assessment activities have not been widely implemented due to inadequate attention and limited resources, which reduces its roles in FS management. Several challenges of FS risk assessment in Vietnam are related to institutional organizations, data management, human resources, and the characteristics of the food supply chain. This article aims to review the progress of risk assessment activities in Vietnam. Different risk assessments have been conducted for various chemical hazards such as pesticides, mycotoxins, preservatives, heavy metals, and environmental residuals, whereas fewer risk assessments have been implemented for microbial hazards, which were mainly focused on common food poisoning pathogens, like *Salmonella*, *Staphylococcus aureus*, and *E. coli*. This article also analyzes risk assessment models from countries and regions such as China, Japan, the United States, Europe, and ASEAN in order to identify the issues and challenges in Vietnam. Based on the review and analysis, we recommend that Vietnam take action to implement risk assessment activities as a tool for effective FS management.

***Keywords**: risk assessment, food safety, Vietnam, chemical hazard, microbial hazard, VFSA*

1. INTRODUCTION

Food safety (FS) remains a primary concern for both the Vietnamese government and the public community. Since the enactment of the Vietnamese Food Safety Law in 2010, numerous policies and solutions have been developed and applied to enhance FS [1]. While some progress has been made, many challenges still persist. Reports indicate that FS management in the country has not fully adopted a "risk-based" approach as stipulated by the Food Safety Law [2-4].

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According to the Codex Alimentarius Commission (CAC), the risk analysis framework consists of three distinct but closely linked components: (1) risk assessment, (2) risk management, and (3) risk communication (Figure 1), of which risk assessment is the "scientific component" [5-7]. The World Health Organization (WHO) advocates for risk-based FS management derived from risk assessment outputs. The model has been employed by many countries, including Vietnam. This approach necessitates a systematic connection among data on food hazards, foodborne diseases, food consumption, and other relevant information throughout the food chain, from farm to fork. It also requires the involvement of the entire food management authorities and research institutions rather than isolating responsibilities within specific segments of the chain [5, 8].

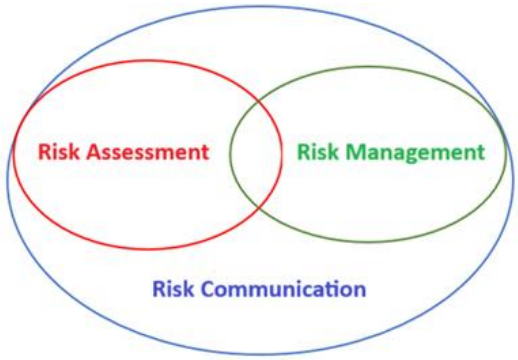

Figure 1. *Risk analysis framework according to CAC*

Risk assessment is a scientific evaluation process including four key steps: hazard identification, hazard characterization, exposure assessment, and risk characterization. Hazard identification involves detecting biological, chemical, and other agents that have the potential to cause adverse health effects in a particular food or food group. Hazard characterization provides qualitative or quantitative assessments of the health effects associated with the identified agents. Exposure assessment then addresses the quantity, intensity, and duration of exposure within the community, as well as the various routes of exposure (inhalation, ingestion, dermal contact, or ingestion/drinking). Risk characterization offers a qualitative and/or quantitative estimate of the likelihood and severity of known or potential adverse health effects in a population, incorporating the uncertainties from the previous steps [7].

In Vietnam, the National Institute for Food Control (NIFC), a technical agency under the Ministry of Health (MOH), is responsible for conducting FS risk assessments. On July 8, 2024, the MOH issued the decision (No. 1936/QD-BYT) to establish the Vietnam Center for Food Safety Risk Assessment (VFSA) under the NIFC. This decision marks a significant step forward providing scientific evidence for risk-based FS management in the country.

This article aims to review the regulations and implementation of risk assessment in Vietnam over the past decade since the enactment of the Food Safety Law (2010). It will also synthesize the FS risk assessment models of different countries, thereby identifying the strategies and solutions applicable to Vietnam.

2. FOOD SAFETY RISK ASSESSMENT ACTIVITIES IN VIETNAM

2.1. Legal documents and policy implementation on food safety risk assessment in Vietnam

Vietnam's Food Safety Law stipulates risk analysis for the following cases: (1) Food with a high poisoning rate; (2) Food with monitoring results showing a high rate of violation; (3) Environment, food production, and trading establishments suspected of causing pollution; and (4) Food, food production, and trading establishments are analyzed for risk according to management requirements. This Law also clearly defines FS risk assessment as the investigation and testing to identify hazards from biological, chemical, and physical agents while evaluating the risks these hazards pose to public health [1].

On March 27, 2013, the Prime Minister issued Decision No. 518/QD-TTg approving the Project to develop a rapid alert system and a FS risk analysis system in Vietnam. However, to date, Project 518/QD-TTg has not achieved its goals, and Vietnam has yet to develop a risk-based FS management system. The implementation of risk analysis tasks was hampered because project activities were integrated into the National Target Program on Population Health, which ended in 2020, leaving no independent funding source. Consequently, only limited progress has been made, and the establishment of a risk analysis framework has not progressed due to insufficient resources [9].

In 2013, the University of Public Health initiated the formation of a Task Force for Food Safety Risk Assessment in Vietnam, which included managers and scientists from the Ministry of Health, the Ministry of Agriculture and Rural Development, universities, research institutes, and international partners in Vietnam. The Task Force has conducted different research, training, and workshop activities. It has also issued two guidelines on chemical and microbiological risk assessment in FS as well as case studies. However, due to the lack of strong commitment from FS management agencies, the risk assessment results have not been effectively used and have yet to serve as a scientific basis for risk-based FS management [10].

The Ministry of Agriculture and Rural Development (MARD) issued Circular No. 02/2013/TT-BNNPTNT, assigning the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), now called NAFIQPM, as the focal point for FS risk analysis. This Circular stipulates the FS risk analysis process, including the establishment of a Food Safety Risk Assessment Expert Council [11]. However, to date, the risk profile and risk assessment report mandated by this Circular have not been implemented and published.

In response to the need for a structured approach to FS risk assessment, the Ministry of Health (MOH) assigned the National Institute for Food Control (NIFC) to carry out these assessments by Decision No. 6065/QD-BYT dated December 30, 2019 [12]. Based on a proposal by the NIFC and the Vietnam Food Administration (VFA), the MOH issued Decision No. 1973/QD-BYT to establish a Technical Group for Food Safety Risk

Assessment on April 27, 2023. This Group comprises experts from various departments, divisions, institutes, universities, and academies under the MOH, MARD, and the Ministry of Industry and Trade (MOIT). To date, the Group has explored global risk assessment models and the current situation in Vietnam while advising on the establishment of a national center for FS risk assessment. On July 8, 2024, the MOH issued Decision No. 1936/QD-BYT to establish the Vietnam Center for Food Safety Risk Assessment (VFSA) under the NIFC. This decision represents a significant legal basis for assessing FS risks and pushing the initial start of the transition to a risk-based FS management approach in Vietnam.

2.2. Food safety risk assessment studies in Vietnam

In recent years, many studies have been conducted in Vietnam to determine and evaluate food hazards. While most studies have focused on determining the presence or content of hazards, there has been insufficient emphasis on assessing the risks these hazards pose to human health through diet. However, in recent years, a number of studies have been systematically conducted following the 4-step risk assessment for identifying the risks of chemical and microbial agents in food, in accordance with Codex's guidelines.

2.2.1. Risk assessment of chemicals in food

Several studies assessing chemical risks have been conducted in Vietnam, ranging from pesticide residues, mycotoxins, heavy metals, environmental contaminants, food additives, and other related compounds. Table 1 summarizes some health risk assessment studies of chemicals in food in Vietnam that have been published in recent years.

Pesticide residues have always been a persistent hazard in agricultural products, especially vegetables. In Vietnam, although maximum residue limits (MRLs) have been established for certain pesticides on different agricultural products, the misuse of pesticides may cause unknown health effects on consumers. However, to date, only two published studies assessing the risk of pesticides have been conducted in Vietnam. D. T. V. Huong *et al*. (2018) conducted a risk assessment of four pyrethroids including λ- cyhalothrin, permethrin, cypermethrin, and deltamethrin in four types of vegetables in Ha Nam province, and found that the non-cancer risks and carcinogenic risks of these substances were negligible [13]. Another study by Nguyen Dang Giang Chau *et al*. conducted in Thua Thien Hue and Quang Binh from November 2018 to June 2019 identified a health risk associated with fipronil residues in vegetables, with a health hazard index value of 2.32, significantly exceeding the reference value of 1 and indicating a potential risk [14]. These studies have only evaluated the effects of some pesticides on certain vegetables and have not comprehensively looked at the cumulative effects of many compounds when they are present simultaneously. Furthermore, food consumption patterns and the combined effects of various products have not been thoroughly investigated.

Table 1. *Chemical risk assessment studies in Vietnam*

Author, time, ref.	Hazards	Food	Location, time	Method	Results
D. T. V. Huong, 2020 [13]	Pesticides (Pyrethroids: λ-cyhalothrin, permethrin, cypermethrin, deltamethrin)	Vegetables (Head mustard, Leaf mustard, Choy sum, Bok choy)	Ha Nam, April 2018 off-season and October 2018 main-season	Non-cancer risks: The chronic hazard index (HI). Carcinogenic risks: Incremental lifetime cancer risk (ILCR)	HI, less than 1, meaning no significant non-cancer risk. The sum ILCR values for all four vegetables are 4.21×10^{-6} and 4.68×10^{-6} for adults and kids, meaning there is an acceptable carcinogenic risk.
Nguyen Dang Giang Chau, 2022 [14]	Pesticides (3 herbicides, 3 insecticides, 4 fungicides)	Vegetables (Mustard greens, lettuce, green onions, pennywort)	Thua Thien Hue and Quang Binh, November 2018 to June 2019	The health hazard index (HHI) was calculated by dividing estimated daily intake (EDI) by acceptable daily intake (ADI).	EDI values ranged from 8.10^{-5} to 462.10^{-5} mg/kg bw/day. The health risk was related to the residues of fipronil in vegetables collected in Thua Thien Hue province (EDI was 46.10−5 mg/kg bw/day) with HHI values of 2.32.
Bui Thi Mai Huong, 2016 [15]	Mycotoxins: Aflatoxins (AFs) and fumonisins (FBs)	Rice and maize	Lao Cai, October 2009	Cancer risk of AFB1 exposure using average potency. Non-cancer risk of FBs using its tolerable daily intake (TDI).	Liver cancer risk associated with AFB1 was 1.5 per 100,000 adults and 2.3 per 100,000 children per year. The average intake of FB is lower than the TDI.
Bui Thi Mai Huong, 2016 [16]	Mycotoxins (aflatoxin B1, ochratoxin A, and fumonisins)	Composite food	Lao Cai, nine sub-regions, time not stated	Population cancer risk of AFB1 exposure using average potency. MOE approach using BMDL10.	The liver cancer risk associated with AFB1 was 2.7 cases/100,000 person/year. The margin of exposure (MOE) linked to OTA and FBs were 1124 and 1954 indicating risk levels of public health concern.
Bui Thi Mai Huong, 2019 [17]	Mycotoxins: aflatoxin B1 (AFB1), ochratoxin A (OTA), and fumonisins	Composite food	Lao Cai	For AFB1: HCC was applied for AFB1. For OTA, MOE using BMDL10 (21 µg/kg bw/day). For BF1: MOE using BMDL10 (150 µg/kg bw/day).	Liver cancer risk related to AFB1 was 12.1 cases in 100,000 persons/year. MOE associated with OTA was 127, and MOE associated with FBs was 542 indicating health risks.

Author, time, ref.	Hazards	Food	Location, time	Method	Results
Do Huu Tuan, 2020 [18]	Mycotoxins: aflatoxin B1 (AFB1), ochratoxin A (OTA), fumonisin B1 (FB1), and zearalenone (ZEA)	Maize, rice, peanut, and sesame	Hanoi, Thanh Hoa, and Ha Giang, October 2016 to September 2017	OTA, ZEA, and FB1: comparison of exposure dose with their PMTDI or PMTWI. AFB1: Calculation of average potency of liver cancer risk and margin of exposure (MOE) approach.	The mean exposures to OTA in Ha Giang were about 2.4–3.6 times higher than its PMTWI. There was no risk of FB1 and OTA in Hanoi and Thanh Hoa. Exposure to AFB1 could lead to 0.23, 0.65, and 21.0 cases of liver cancer per 100,000 people in Hanoi, Thanh Hoa, and Ha Giang. Unsafe exposure to OTA and FB1 in the highland region.
Phan Thi Kim Lien, 2023 [19]	Mycotoxins (aflatoxin and fumonisin)	Rice	Can Tho, Dong Thap and An Giang, July 2019	Margin of exposure (MoE) and the average potency of cancer risk	MoE related to FBs was higher than 100, ranging from 105 to 575 for all groups, and FBs exposure was lower than PMTDI. MoE associated with AFs exposure is lower than 10,000. The mean HCC risk ranged from 0.05 to 0.13 cases/year/100,000 individuals for children, adolescents, adults, and elderly.
Nguyen Hung Long, 2019 [20]	Food additives: benzoates, sorbates, cyclamate, saccharin, tartrazine, and sunset yellow	Vietnamese diets	6 provinces (Ha Noi, Ho Chi Minh, Thua Thien Hue, Nam Dinh, Tay Ninh and, Quang Tri), 2017	Comparison of total intake to ADI of food additives	The total intake of sorbate and benzoate in the group of children under 5 years old had the highest value, 38% of ADI. With the assumption that people used all types of food, 0.8% of the population had an intake of benzoate that exceeded its ADI.
Tran-Lam Thanh-Thien, 2023 [21]	Food additives (seven parabens and their four metabolites)	Fish from five species (Indian halibut, silver pomfret, large head hairtail, Indian mackerel, yellow stripe scad)	Along the coastline of Vietnam, August 2022	The estimated daily intake (EDI) of PBs and m-PBs in a fish sample. The hazard quotient (HQ) was based on the reference dose using NOAEL. The Hazard Index (HI, %) was the cumulative exposure of the analyzed compound.	The HI values exhibited percentages below 100%. Hence, the risk of seafood consumption to human health is low.

Author, time, ref.	Hazards	Food	Location, time	Method	Results
Tran-Lam Thanh-Thien, 2024 [22]	44 endocrine-disrupting chemicals: organic UV compounds, pharmaceutically active compounds, hormones, and phthalate esters	Fish from five species (Indian halibut, silver pomfret, largehead hairtail, Indian mackerel, yellowstripe scad)	Along the coastline of Vietnam, August 2022	Calculation of the average daily intake (ADI), hazard quotient (HQ), and hazard index (HI)	As a result, a notable disparity in the composition of organic ultraviolet compounds has been observed among the three regions of North, Central, and South Vietnam (Mann-Whitney U test, $p < 0.05$). Despite these findings, EDC-contaminated fish did not pose any health risks to Vietnam's coastal population.
Tran Cao Son, 2020 [23]	N-Nitrosamine: N-Nitroso-dimethylamine (NDMA)	The diet of children from 6 to 36 months: rice porridge, cereal-based foods, canned purees, sausages, and processed meats	Hanoi, 2018	Non-carcinogen effect assessment using TDI of 4.0 to 9.3 ng/kg bw/day. Liver cancer risk based on a slope factor of 51 per mg/kg bw/day	The exposure doses of NDMA were as high as 8.55 ng/kg bw/day and did not exceed the TDI. The cancer risk when consuming sausages and processed meats was higher than the reference value means that the consumption of sausages and processed meats for a long time (30 years) can be a reason for liver cancer risk.
Tran Cao Son, 2023 [24]	3-MCPD esters and glycidyl esters	Infant formulas and follow-on formulas for children under 36 months of age	Hanoi, Ho Chi Minh City, Bac Ninh, Hai Duong, Ha Nam, Binh Duong, and Dong Nai, 2021	The exposure dose of 3-MCPDE was compared with its PMTDI of 4 mg/kg bw/day	Neither mean values nor the percentile 95% values of 3-MCPDE exposure doses exceed the PMTDI.
Phan Thi Lan-Anh, 2020 [25]	Total PAHs, PAHs4 (benz[a] anthracene, chrysene, benzo[b]fluoranthene, and benzo[a] pyrene)	Tea (green tea, oolong tea, black tea, herbal tea)	Markets (Vietnamese and imported teas), time not stated	MOEs were calculated using the BMDL10 for BaP (0.07 mg/kg bw/day) and PPAH4 (0.34 mg/kg bw/day).	MOE values were 1,000,000 to 2,500,000 for BaP and 1,200,000 to 2,400,000 for PAH4 => no risk of exposure to PAHs obtained from teas.

Author, time, ref.	Hazards	Food	Location, time	Method	Results
Nguyen Thi Quynh Hoa, 2022 [26]	17 perfluoroalkyl substances (PFAS) including 13 perfluoro carboxylic acids (PFA) and 4 perfluoro-alkyl sulfonates (PFS)	Freshwater fish	West Lake and Yen So Lake, Hanoi	Comparison of intake levels to reference doses and tolerable weekly intake	Daily intake doses of PFOS and PFOA were markedly lower than the US EPA reference dose of 20 ng/kg/day. Weekly intakes of the sum of PFHxS, PFOS, PFOA, and PFNA were lower than the EFSA tolerable weekly intake of 4.4 ng/kg/week.
Tran Thi Tuyet-Hanh, 2015 [27]	Dioxin/furans	Local high-risk food: chicken meat & eggs, duck meat & eggs, fish and snails, beef and pumpkin	Bien Hoa and Da Nang	Estimated daily intake from each type of food (pg/day) = dioxin concentration in food (TEQ pg/g) x daily food consumption level (g/day).	Consumption of local high-risk foods resulted in extremely high dioxin daily intakes (60.4-102.8 pg TEQ/kg bw/day in Bien Hoa; 27.0-148.0 pg TEQ/kg bw/day in Da Nang), far above the WHO recommended TDI (1–4 pg TEQ/kg bw/day).
Nguyen Van Anh, 2009 [28]	Heavy metals (arsenic)	Groundwater	Ha Nam, dry season (February 2006) and rainy season (September 2006)	The average arsenic daily dose (ADD) through the drinking water pathway. Hazard Quotient (HQ): the ratio between ADD and the reference dose (RfD)	The ADD for treated groundwater ranged from < 0.1–1.1 µg/kg day. The ADD for raw groundwater was from 1.1–4.3 µg/kg per day. The potential carcinogenic rate of 5 in 1000 people is significant for people using untreated groundwater.
Nguyen Thuan Anh, 2014 [29]	Heavy metals (lead, cadmium, and mercury)	Shellfish	Nha Trang, May 2008 to January 2009	Comparison of the intakes with PTWI	The dietary intakes of lead, cadmium, and mercury were below the provisional tolerable weekly intakes.
Nguyen Kien Thanh, 2019 [30]	Heavy metals (arsenic)	River water	Nhue River (Hanoi), during 2010–2017	Human health risks of PTEs were evaluated by estimating hazard index (HI) and cancer risk through ingestion and dermal contact for adults and children.	The non-carcinogenic risks of As were higher than 1.0 at all sites for both adults (HI = 1.83–7.4) and children (HI = 2.6–10.5), while As posed significant carcinogenic risks for adults (1×10^{-4}–4.96×10^{-4}).

A number of studies have been conducted and published on mycotoxins in Vietnam. The studies were conducted quite systematically and assessed both acute risks through comparison with tolerable daily intake (TDI) and margin of exposure (MOE) or cancer risks through average potency of liver cancer risk. Bui Thi Mai Huong *et al*. conducted a study in Lao Cai, when consuming maize and rice, liver cancer risk associated with aflatoxin B1 (AFB1) was 1.5 per 100,000 adults and 2.3 per 100,000 children per year [15] and the corresponding value when consuming composite foods was 2.7 cases/100,000 person/year [16]. Another study in Lao Cai reported a higher liver cancer risk of 12.1 cases per 100,000 individuals per year linked to AFB1 [17]. The National Institute for Food Control's study on aflatoxin B1, ochratoxin A, fumonisin B1, and zearalenone in several higher-risk foods including maize, rice, peanuts, and sesame in Hanoi, Thanh Hoa, and Ha Giang conducted in 2019 showed that the exposure to AFB1 could lead to 0.23, 0.65, and 21.0 cases of liver cancer per 100,000 adult people per year in Hanoi, Thanh Hoa, and Ha Giang, respectively. The risk of AFB1 is particularly high in the highlands of Ha Giang due to the maize-based diet and improper maize storage methods [18]. In 2023, Phan Thi Kim Lien's research team published a paper on aflatoxin and fumonisin in rice in Can Tho, Dong Thap, and An Giang showing the risk of AFB1 exposure with MOE lower than 10,000. According to this study, the mean hepatocellular carcinoma (HCC) risk ranged from 0.05 to 0.13 cases/year/100,000 individuals for children, adolescents, adults, and elderly [19]. While these studies consistently found low risks from other mycotoxins, such as ochratoxin A, fumonisins, zearalenone, and deoxynivalenol, the high risk associated with aflatoxin-contaminated food consumption calls for special attention to the health risks of mycotoxins in the diet.

Additives and metabolites are other subjects of risk assessment studies. The method of assessing the risk of these compounds is mainly based on comparing the exposure dose with the TDI or reference dose to evaluate the hazard quotient (HQ) and hazard index (HI). According to Nguyen Hung Long *et al.*, the risk of six food additives, including benzoates, sorbates, cyclamate, saccharin, tartrazine, and sunset yellow, was low, with the exposure dose lower than their TDIs. With the assumption that people used all types of studied food, 0.8% of the population had an intake of benzoate exceeding its ADI [20]. Tran-Lam Thanh-Thien *et al.* found that the HI values for fish consumption in various coastal provinces were below 100%, indicating that the health risks associated with seafood consumption were relatively low [21]. Similar results were obtained in another study involving forty-four endocrine-disrupting chemicals including organic ultraviolet compounds, pharmaceutically active compounds, hormones, and phthalate esters [22]. In summary, the acute toxicity risk of these compounds in the Vietnamese diet is relatively low.

Risk assessment studies of processing contaminants in food matrices have also been published recently. Tran Cao Son *et al.* conducted a study in 2018 on the risk of N-Nitrosodimethylamine (NDMA) in the diets of children aged 6 to 36 months. The study, which included foods such as rice porridge, cereal-based products, canned purees, sausages, and processed meats in Hanoi, found that while NDMA exposure did not exceed the TDI, prolonged consumption of sausages and processed meats (over 30 years) could potentially contribute to liver cancer risk [23]. Recently, another publication by this research group showed a low risk of 3-MCPD esters and glycidyl esters in infant formulas and follow-on formulas for young children [24]. Lan-Anh Phan Thi *et al.* studied total polyaromatic hydrocarbons (PAHs), PAHs4 (benz[a]anthracene, chrysene, benzo[b] fluoranthene, and benzo[a]pyrene) in teas (green tea, oolong tea, black tea, herbal tea) purchased on the market including domestically produced and imported teas, MOEs values for Bisphenol A (BaP) and PAH4 were all higher than the reference level of 10,000 that indicating a low risk of PAHs obtained from teas [25].

Environmental chemical contamination is also a source of hazard that can have adverse effects on health. Several risk assessment studies have been conducted on these contaminants in drinking water or foods at high risk of exposure. Another study by Nguyen Thi Quynh Hoa *et al*. on the risk of 17 perfluoroalkyl substances (PFAS) including 13 perfluoro carboxylic acids (PFA) and 4 perfluoroalkyl sulfonates (PFS) in Freshwater fish at West Lake and Yen So Lake, Hanoi found that daily intake doses of PFOS and PFOA were significantly lower than the reference dose of 20 ng/kg/day. And weekly intakes of the sum of PFHxS, PFOS, PFOA, and PFNA were lower than the European Food Safety Authority (EFSA) tolerable weekly intake of 4.4 ng/kg/week [26]. The risk of dioxin/furans has also been studied by Tran Thi Tuyet-Hanh and colleagues on local foods in the two most severe dioxin hot spots, Bien Hoa and Da Nang. Accordingly, high-risk foods in these areas resulted in extremely elevated dioxin intake levels, ranging from 60.4–102.8 pg TEQ/kg bw/day in Bien Hoa and 27.0–148.0 pg TEQ/kg bw/day in Da Nang, far exceeding the World Health Organization’s recommended tolerable daily intake (TDI) of 1–4 pg TEQ/kg bw/day [27].

Some authors have also studied the risk of heavy metal pollution using the method of determining the average arsenic daily dose (ADD) and then assessing the hazard quotient (HQ) by comparing it with the reference dose (RfD). Nguyen Van Anh *et al*. assessed the risk of arsenic in groundwater in Ha Nam in 2 dry seasons and rainy seasons, showing that when people used untreated groundwater, the ADD was 1.1–4.3 µg/kg per day, increasing the risk by more than 4 times compared to treated water. More than 40% of the people consuming treated groundwater may be at chronic risk for arsenic exposure [28]. Another study by Nguyen Thuan Anh *et al.* assessed the risk of 3 heavy metals lead, cadmium, and mercury in mollusks in Nha Trang, showing a low risk of these compounds [29]. For river water, the study by Kien Thanh Nguyen *et al.* showed that the non-carcinogenic risks of Arsenic were higher than 1.0 posing significant carcinogenic risks for adults [30].

It can be seen that there have been quite several studies conducted in Vietnam recently assessing the risks of a variety of hazards on many different food products to human health. However, most of these studies have only evaluated one or some sources of exposure. There are still many other sources of exposure that have not been comprehensively considered which may lead to underestimation of the risk. Most of studies only provide risk levels but have not performed modeling towards solutions to reduce risks. Some studies have small sample sizes and only represent a small group of residents in a local area. Although many studies have made recommendations to reduce risks (if any), due to various reasons that these studies' results were not strongly convincing for policy changes to effective FS management in our country.

2.2.2. Risk assessment of microbial in food

Coexisting with chemical hazards in food is the presence of pathogenic microorganisms (viruses, bacteria, parasites, protozoa) or toxins (staphylococcal enterotoxin, aflatoxin, etc.) that can harm human health when ingested. Therefore, microbial risk assessment, a category within FS risk assessment, plays a crucial role in protecting public health and ensuring human safety. However, this task remains a major challenge in many countries, especially developing countries like Vietnam, with its multi-model economy, complex food production and processing, and unique business models compared to other countries.

In recent years, numerous studies have been conducted to identify the exposure rate and characteristics of antibiotic resistance and virulence factors of pathogenic microorganisms in food, such as *Salmonella* [31-34], *E. coli* [35-37], *Staphylococcus aureus* [38-40], *Bacillus cereus* [39, 41], *Clostridium perfringens* [42-44]. However, the number of research conducted to assess the risk of these pathogenic microorganisms in Vietnam remains limited and only focuses on large-scale food poisoning agents as presented in Table 2.

***Table 2.** Microbial risk assessment studies in Vietnam*

Author, year, ref.	**Hazards**	**Food**	**Location, time**	**Method**	**Results**
Luu Quoc Toan, 2013 [45]	*Salmonella*	Pork	Hanoi, November 2010 to March 2011	Quantitative Microbial Risk Assessment [46]	The infection risk of *Salmonella* was from 2.1×10^{-4} to 4.9×10^{-4} by single exposure (per consumption). The annual risk was 4.3×10^{-2} to 9.5×10^{-2}.
Kieu Thanh Truc, 2014 [47]	*E. coli O157:H7*, *Giardia lamblia*, and *Cryptosporidium parvum*	Raw water spinach	Hanam, 2014	Quantitative Microbial Risk Assessment [46]	The diarrhea risk associated with *E. coli* O157:H7, *C. parvum*, and *G. lamblia* when consuming raw water spinach washed three times was 0.25, 0.23, and 0.
Dang Xuan Sinh, 2016 [49]	*Salmonella*	Boiled pork	Hung Yen, April 2014 to March 2015	Codex Alimentarius Commission quantitative microbial risk assessment [48]	The annual incidence rate of salmonellosis in humans was estimated to be 17.7% (90% CI 0.89–45.96).
Nguyen Thi Giang, 2018 [50]	*S. aureus*	Pork and poultry eggs	Hanoi, April 2015 to December 2015	Quantitative Microbial Risk Assessment [46]	Pork consumption: the average risk of poisoning is 3.4×10^{-4} (90% CI 0.15×10^{-4} – 10.38×10^{-4}). Poultry egg consumption: the average risk of poisoning is 1.4×10^{-4} (90% CI 0.06×10^{-4} – 4.24×10^{-4}). Both: the average risk of poisoning is 4.85×10^{-4} (90% CI 0.078×10^{-4} – 12.08×10^{-4}).

The study by Toan *et al*. is one of the first to apply the quantitative microbial risk assessment (QMRA) framework. The authors conducted an analysis of pork collected from four markets in Long Bien District, Hanoi. Combined with data on consumption levels and common processing methods, the study estimated the risk of *Salmonella* infection in humans from pork consumption. According to the authors, 25% of pork samples sold in the markets in Long Bien District were positive for *Salmonella*, with specific contamination levels ranging from 100 to 27,500 bacteria/25g of meat. The average pork consumption is 86.1 g/person/day, with an average consumption frequency of 219 days/person/year. Therefore, the average risk of *Salmonella* infection from consuming pork meal ranges from 2.1×10^{-4} to 4.9×10^{-4}. Additionally, the average risk of *Salmonella* infection for the population from eating pork in one year ranges from 4.3×10^{-2} to 9.5×10^{-2} [45].

The study conducted by Truc *et al.* is the first risk assessment focused on the category of fresh vegetables, specifically water spinach, in Hanam, Vietnam. This research evaluated the potential for diarrhea risk associated with the presence of *E. coli* O157:H7, *G. lamblia*, and *C. parvum* in water spinach that was washed once, twice, and three times by soaking in tap water. The results indicated that the bacterial load in unwashed water spinach was significantly reduced from 3.23 ± 1.64 CFU/g to 1.42 ± 1.77 CFU/g after one, two, and three washes. The average consumption of raw water spinach was estimated at 40.22g/person/meal, with a mean frequency of 1.39 meals/person/year. Consequently, the diarrhea risks associated with consuming raw water spinach washed three times were calculated to be 0.25 for *E. coli* O157:H7, 0.23 for *C. parvum*, and 0 for *G. lamblia*. This study highlights the high levels of microbial contamination in raw water spinach cultivated along the Nhue River. It is recommended that appropriate practices for preparing and consuming raw water spinach be adopted at the household level to reduce or prevent the risk of infection and diarrhea caused by microbial contamination.

In 2016, Sing *et al*. conducted a risk assessment of salmonellosis infection from consuming boiled pork in Hung Yen Province, Vietnam. The annual incidence rate of salmonellosis caused by *Salmonella* bacteria is estimated to be 17.7% (90% CI 0.89–45.96). The most significant risk factors stemmed from the practices of pork handling in households and the prevalence of *Salmonella* in pork sold in the market. The research results show that the authors successfully established a risk assessment model based on the Codex Alimentarius Commission quantitative microbial risk assessment [48]. The probability of salmonellosis infection was determined based on the prevalence of *Salmonella* in the pork value chain (38.9% in offal, 41.7% in carcasses, and 44.4% in cut pork) along with predictions of cross-contamination potential, the reduction of microbial concentration after cooking, and consumption data collected from 30 households. This study is evidence of the high risk of *Salmonella* exposure in consumers who ingested boiled pork, highlighting the urgency of control measures to improve FS in the area [49].

Besides *Salmonella*, *S. aureus* is a common cause of food poisoning in Vietnam. A research group of Giang *et al.* conducted a risk assessment of food poisoning due to the consumption of infected pork and poultry eggs in Hanoi primary schools. The assessment results were calculated based on a cross-sectional survey of cooked food for analysis. The contamination levels of *S. aureus* in pork and poultry eggs were 390 CFU/g and 320 CFU/g, respectively; corresponding to consumption levels of 95.7 g/pupil/day and 15.9 g/pupil/day for the two food types. Applying the quantitative microbial risk assessment framework for food according to FAO/WHO guidelines, the risk of pupils suffering food poisoning when consuming pork was 3.4×10^{-4}, and when consuming poultry eggs was 1.4×10^{-4}. When a student eats both eggs and pork contaminated with *S. aureus*, the risk of food poisoning for primary school pupils is 4.85×10^{-4} [50].

Although the results of the three studies have initially provided detailed descriptions of FS risks related to microbial hazards such as *Salmonella* and *S. aureus*, these studies still have limitations. First, due to the nature of risk assessment, which uses mostly mathematical models to represent the distribution function of specific variables, the data it provides always has a certain degree of uncertainty. Additionally, in Vietnam, the data used for exposure assessment is often inherited from research designs in the world, including α, and β coefficients or cross-contamination rates from raw food to cooked food during processing. Moreover, most current studies assess cross-contamination during processing, not including contamination from other factors or at different stages in the food chain from farm to fork. Risk assessment models are not specific to different sensitive populations (e.g., elderly and children) or different bacterial strains (e.g., *Salmonella* serotypes). Notably, studies to date have not conducted sampling in households due to ethical issues, hence, the research results do not truly represent the risk of *Salmonella* infection in reality.

There is a need to improving microbial risk assessment in Vietnam that requires a comprehensive approach. This includes enhancing data collection and management through the establishment of a national database and standardized reporting systems. The data collected must accurately reflect food consumption patterns in Vietnam, as well as potential cross-contamination rates that may occur throughout the food supply chain from farm to table. To ensure accuracy, real-world sampling in households is essential for assessing the effectiveness of microbial reduction achieved through food processing methods. Additionally, advancements in science and technology, such as whole-genome sequencing platforms and metagenomics analysis, provide valuable tools for risk assessment. These technologies enable precise discrimination of bacterial strains involved in foodborne illnesses and assist in identifying their sources. Moreover, in order to enhance hazard identification, thereby facilitating more targeted risk assessment and management strategies.

3. FOOD SAFETY RISK ASSESSMENT MODELS AROUND THE WORLD

Most developed countries assign one or more units to be responsible for carrying out risk assessment activities. In this section, the risk assessment agencies of some countries and regions will be analyzed.

3.1. China

According to the Food Safety Law of the People's Republic of China 2009, the National Health Commission is responsible for FS risk assessment at the national level, and the National Expert Committee on Food Safety Risk Assessment (NECFSRA), consisting of 42 scientists is responsible for organizing and conducting the risk assessment projects. The China National Center for Food Safety Risk Assessment (CFSA) was established in October 2011 and serves as the secretariat for all the NECFSRA activities. Other FS-related government agencies are invited to make proposals on risk assessment and contribute scientific data and information when requested. CFSA has organized and completed nearly 100 risk assessment projects and emergency risk assessment tasks since 2011. It has published 13 risk assessment guidance documents, including technical guidance for conducting FS risk assessment and data collection requirements for risk assessment, as well as other documents. All the data including the consumption, toxicity, and contaminant databases, controlled by CFSA, have played an important role in risk assessment in China [51].

3.2. Japan

In Japan, the Food Safety Commission of Japan (FSCJ) belongs to the Cabinet Office, is a risk assessment organization that operates independently of risk management ministries. FSCJ is also responsible for “risk communication” so that information on risk assessment is provided accurately and intelligibly. FSCJ is composed of 16 specialized committees and conducts risk assessments of human health caused by microorganisms, chemicals, and other substances in food, based on scientific evidence. FSCJ assessments are mainly conducted in response to requests from risk managers. In addition, FSCJ also conducts risk assessments on its own when deemed necessary. FSCJ conducts 7-8 FS risk assessment research programs with a research period of approximately 2 years and 4-6 FS monitoring programs every year to collect, organize and analyze data, and information necessary for risk assessment. Moreover, it also publishes risk assessment guidelines and reports [52].

3.3. The United States of America

The U.S. FS system at the federal level includes the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS), the U.S. Environmental Protection Agency (EPA), and the National Marine Fisheries Service (NMFS). The FDA's Center for Food Safety and Applied Nutrition (CFSAN) regulates the safety, nutritional value, sanitation, and labeling of food products. Since 2002, CFSAN has developed a practical risk analysis framework for conducting risk assessment and management, including a risk management team responsible for developing risk assessment questions to be addressed, making assumptions, monitoring the assessment, and developing action plans. The risk assessment team is responsible for conducting assessments and refining the assumptions made by the risk management team, explaining the uncertainty of the results, and the impact of the assumptions on the results. The risk communication team is responsible for providing input to the risk assessment and risk management teams based on identifying stakeholder concerns, information needs, and perceptions; and developing public health messages based on assessment results and management plans. CFSAN also coordinates with agencies within FSIS and EPA to assess risks to products regulated by those agencies [53-54].

3.4. Europe

In 2002, the European Union set up the European Food Safety Authority (EFSA) to serve as an impartial source of scientific advice to risk managers and to communicate risks associated with the food chain. EFSA collects and analyses existing research and data, and provides scientific evidence to support the decision-making of risk managers. EFSA works closely with the risk assessment bodies of Member States through its Advisory Forum, National Focal Points, and Scientific Networks. EFSA receives requests for scientific advice mainly from the European Commission, the European Parliament, or the Member States. There are 10 scientific expert panels, each focusing on a different area of the food chain. Working groups usually consist of panel members together with additional scientists from their areas of expertise. EFSA has a system of data collection networks or calls for data from Member States. The results of the risk assessment are published on the EFSA website and the EFSA Journal. In each European country, risk assessment bodies are assigned technical units and play a role in carrying out risk assessments in their country. Some of the well-known risk assessment centre include BfR in Germany, ANSES in France, RIVM in the Netherlands, and DTU in Denmark. They are also linked to EFSA to carry out studies on issues of common interest to the whole of Europe [55].

3.5. ASEAN

The ASEAN Risk Assessment Centre for Food Safety (ARAC) was established in 2014 under the guidance of the ASEAN Health Ministers Meeting and the Senior Officials Meeting for Health Development. ARAC is an independent scientific body with the function of integrating the risk assessment mechanism in ASEAN countries in monitoring the implementation and evaluating the effectiveness of risk assessment activities in the region. ARAC consists of three components: the Secretariat, the Scientific Committee (SC), and the Scientific Panel (SP). Malaysia serves as the secretariat of ARAC. The FS risk assessment centers in each ASEAN country send scientists to participate in the SC and SP of ARAC. To date, ARAC has only completed one risk assessment study on aflatoxins and issued a number of standard operating procedures (SOPs) for risk assessment [56]. ARAC was established following the EFSA model, however, due to many regionalspecific reasons, it still needs to improve a lot to contribute more to FS management in ASEAN.

It can be concluded that risk-based FS management is a global trend. Risk assessment agencies have been established in each country and at the regional level. Most of these agencies have been established and operating for more than 10 years, providing scientific evidence and recommendations for risk management and risk communication. In terms of organizational structure, the risk assessment agency is independent of the risk management agency, with the task of providing independent and transparent scientific advice based on scientific evidence to policymakers, through cooperation with partners and open dialogue with society. These centers establish scientific panels or expert committees for different areas of expertise and use the Codex's four-step methodology. Some centers have laboratories and risk communication divisions, but most do not and only focus on data collection and analysis. Data management is extremely important for the operation of these centers. The model of China's CFSA according to WHO standards has been a very successful model and can be referenced for implementation in Vietnam in the context of similar FS management and culture between the two countries.

4. CHALLENGES AND FUTURE DIRECTIONS FOR THE DEVELOPMENT OF FOOD SAFETY RISK ASSESSMENT IN VIETNAM

4.1. Challenges

After 15 years of implementation, Vietnam's Food Safety Law has brought about fundamental and more effective changes in FS management. However, a risk-based FS management system has not yet been truly operationalized in Vietnam. In the context of the rapid development of the food, chemical, and material industries and the expansion of Vietnam's trade with the world, risk assessment has not yet demonstrated its role as a scientific foundation, providing evidence for risk management and risk communication. FS risk assessment in Vietnam is still in its first steps with many difficulties and challenges, specifically as follows:

(1) Risk-based "thinking" has not yet permeated and become a "culture" in the guidelines of FS management organizations. Risk question, the starting point of any risk assessment study, is not properly asked by FS risk managers. Much of FS management is still based on spreading across many different product groups, and many different hazards and is not preventive but only tried to solve when a food incident or food poisoning occurs or worse, it may cause a fault in communication.

(2) FS monitoring data at the national level has not been compiled and analyzed. In fact, due to the organizational structure of the management, which assigns responsibility to each product group, data is currently scattered among many different agencies and organizations. Monitoring data at the national level (MOH, MARD, MOIT) and at the local level have not been connected and there is no permanent agency to collect, manage, and analyze these data sources. Moreover, the FS monitoring program at the national level is inadequate due to a lack of resources and has not focused on high-risk food products so that appropriate management measures can be taken.

(3) Current food consumption data mainly focuses on a few main product groups and has not been updated since 2010. In Vietnam, the National Institute of Nutrition is the focal point for conducting food consumption surveys and is also the representative of food consumption in ARAC. However, most risk assessment studies have to conduct surveys to obtain their own consumption data with unified and synchronized methods.

(4) There is no mechanism for cooperation in exchanging data and information between agencies in FS. The truth is that with the current FS management organization in Vietnam, a risk assessment study involves different areas under the management of different agencies. Coordination in research, exchange, and provision of information between FS management agencies under different ministries needs to be coordinated, especially in risk assessment activities.

(5) Resources for risk assessment activities are still very limited, including financial and human resources. In fact, there have been positive changes when some organizations have begun to shift their investment to risk assessment research as well as training human resources to conduct risk assessment. However, it is clear that these investments are still very modest compared to the resources actually needed to conduct a systematic risk assessment.

(6) Nearly half of food poisoning cases in Vietnam are caused by microbial agents. However, microbial risk assessment studies are still very limited. Given the climate conditions and food processing methods in Vietnam, the risk of food poisoning cases caused by microbial agents is always present and needs to be systematically assessed to propose solutions for risk management.

(7) Due to its infancy, the participation of Vietnamese risk assessment agencies in international and regional risk assessment forums is still limited. Vietnamese representatives have not contributed much to the activities of specialized risk assessment working groups such as Codex committees and technical groups (JECFA, JMPR, CCFH ...), JEMRA, and ARAC. International risk assessment projects in Vietnam have potential and opportunities for implementation but have not been developed as expected.

(8) FS risk assessment in Vietnam may differ from the developed countries when it comes to assessing the food chain. Food is supplied not only by official sources but also by many informal sources. Many food suppliers are small-scale farmers, and producers, spontaneous and unregulated. Therefore, risk assessment activities need to be locally practical to be able to contribute to risk-based FS management.

4.2. Recommendations

In order to overcome the above challenges, the changes are needed not only in risk assessment but also in risk management and risk communication. The successful lesson of the China National Center for Food Safety Risk Assessment (CFSA) can be replicated in Vietnam in the context of the similarity in FS management system, people customs, and culture between the two countries. In the framework of this article, some specific solutions to improve the FS risk assessment in Vietnam are proposed as follows:

(1) Develop a focal unit for FS risk assessment. The Vietnam Center for Food Safety Risk Assessment (VFSA) under the NIFC established by the MOH is the first important step. This Center needs to be facilitated in terms of mechanisms and resources to become a focal point in FS risk assessment activities. Figure 2 shows the proposed model of relationships of VFSA to carry out the task of FS risk assessment. It is important that the risk assessors and the risk manager should have mutual understanding each other to make able to answer the risk questions while in hand with a limited resources.

Figure 2. *Proposed model of VFSA position and its relationships*

(2) Improve the capacity of risk assessment of VFSA and other national research institutes, key universities, and key laboratories through cooperation, training, and research programs on risk assessment. In parallel with risk assessors, it is necessary to organize training programs on risk analysis including risk management and risk communication for risk managers at the central and local levels. The participation of international experts through projects of governments and international organizations in Vietnam such as WHO, FAO, WB, etc. play an important role in capacity-building activities.

(3) Establish a data management system for FS risk assessment, including monitoring data, food consumption data, and other related data, as well as a mechanism for data sharing between agencies and organizations. The national surveillance annual programs should be revised so that they can incorporate risk assessment data collection. Good data management will help risk assessment agencies save resources when conducting risk assessments and quickly answer questions from regulatory agencies.

(4) The VFSA needs to participate, sharing experiences and contribute more to international and regional forums on risk assessment such as JECFA, JMPR, JEMRA, EFSA, and ARAC... Through these forums, in parallel with updating knowledge, methods, and information on risk assessment for each specialized field, connecting and establishing cooperation projects, workshops, training, and staff exchanges will become very useful for each field.

(5) Resources should be allocated to conduct risk assessment studies in accordance with WHO/FAO guidelines, emphasizing the evaluation of microbiological hazards in addition to chemical hazards. Furthermore, a comprehensive total diet study is necessary to gain a holistic understanding of the risks associated with various food groups in Vietnam. It is essential to update and incorporate information on the burden of foodborne diseases into risk assessments. Additionally, modern methodologies such as whole genome sequencing and metagenomics should be utilized to investigate and assess the risks posed by foodborne microorganisms.

5. CONCLUSION

Risk assessment activities in Vietnam have been reviewed in terms of both organizational aspects and research conducted in the two fields of chemistry and microbiology. Difficulties and challenges come from the organizational structure of activities, the management and sharing of monitoring data and food consumption data, limited participation in international and regional risk assessment forums as well as the capacity to conduct risk assessment research and the specific characteristics of the food chain in Vietnam. Based on the study of the organizational model and functions of risk assessment centers in some countries and regions together with the practice in Vietnam, the Vietnam Center for Food Safety Risk Assessment (VFSA) has been established and needs to be facilitated to develop in order to overcome the challenges pointed out and support FS management towards risk-based according to WHO/FAO guidelines.

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