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Article

Comparison of Risk Assessment Schemes in GHPs and HACCP, FSMA Preventive Controls for Human Food, ISO 22000, and GFSI Recognized Standards with Risk Scoring Guidance in General Use with Fresh Produce

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Abstract: The intention of this qualitative research study was to provide a basic risk concept by comparing food risk assessment schemes and preparing general food risk scoring guidance for developing a simple and reliable practical fruit and vegetable qualitative food safety risk matrices for fresh produce entrepreneurs. These practical food safety risk matrices were verified using FDA fruit and vegetable food safety risk data. The FDA data were converted to a qualitative risk matrix referring to the fruit and vegetable 3 × 3 qualitative food safety risk matrix reference model. Other common qualitative risk matrix models, namely 3 × 3, 4 × 3, and 5 × 5, were constructed based on probability and severity scores for each hazard, as given in the FDA data. These were designated as practical fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models. The results of these models were compared with the fruit and vegetable 3 × 3 reference model. The two best compatible models are the 5 × 5 and 3 × 3 qualitative food safety risk matrix models. A preference test from focus group containing 12 participants showed good satisfaction overall, indicating that the practical fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models are useful for entrepreneurs. Understanding of basic risk concepts and verified scientific referencing of food safety risk matrices can improve entrepreneur's risk assessment. This can be performed by using practical–scientific food safety risk matrices.

Keywords: food risk assessment scheme comparison; fruit and vegetable; fresh produce; qualitative food safety risk matrix model; food safety risk map plotting matrix

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1. Introduction

Risk assessment is a common tool to be used before conducting risk management. The FAO has categorized risk into two components: probability, and severity. There are two common risk assessment tools: qualitative and quantitative risk assessment. Qualitative risk assessment can be based on yes–no questions, a decision tree, or by rating risks as high, medium, or low. Quantitative risk assessment focuses on numeric expression. However, semi-quantitative risk assessment can also be used, in which qualitative and quantitative risk assessments are combined. An example of semi-quantitative risk assessment is risk ranger [1].

Since risk assessment tools are so varied, it can be problematic for some entrepreneurs to selecting the correct one. As a result, the following problems have been encountered during site visits:

1. Using improper risk assessment tools for food safety risk assessment. For example, using incident management risk assessment tools for food safety risk assessment. Moreover, it was found that some risk ratings from scientific references did not match the incident management risk definition;
2. Using a scientific reference unrelated to intended score to avoid significant risk e.g., giving a low severity score for Salmonella spp., whereas the scientific reference gives a medium level risk;
3. Confusing risk categories and being unable to design a proper risk management e.g., mixing food quality or undesirable qualities into a food safety or food hazard risk assessment;
4. Some standards have their own requirements in some risk assessments, and this may cause confusion to entrepreneurs e.g., input materials risk assessments have differed from hazard analysis for some issues such as issues concerning detection of food quality fraud;
5. Being unaware of the specific risk profiles available;
6. Being unable to interpret scientific data to score risk e.g., lacking the knowledge that primary and transmitted sources can be linked to the risk occurrence score, or being unable to convert pathogenic data on severe or injury or illness into severity score.

Risk assessment was practiced 2400 years ago by the Athenians for decision making [2]. However, the first food safety risk assessment was conducted by Pillsbury for the National Aeronautics and Space Administration (NASA) during the 1960s. It was continued to be developed by many well-known organizations, for example the Food and Agriculture Organization (FAO), the Canadian Food Inspection Agency (CFIA), the Food Safety Preventive Controls Alliance (FSPCA), Preventive Control for Animal Food, and the Global Food Standard Initiative (GFSI) [3]. Food safety risk assessments have commonly considered probability and severity levels in making final decisions on the levels of each hazard [4]. There are many risk rankings models. A risk matrix is a type of risk ranking in which there are two common types: qualitative and semi-qualitative risk matrices [5]. The qualitative risk matrix is the easiest to use, as it has a low cost and saves time for entrepreneurs [5]. There are many qualitative risk matrix models, e.g., 3 × 3, 4 × 4, 5 × 5 or 4 × 6 [1,5–11]. Additionally, there are many fruits and vegetable risk profiles which can be used as reference, for example from the FAO (1998), the United Nations (2007), McIntyre et al. (2008), Bassett and McClure (2008), the FDA (2012), the Food Safety Preventive Controls Alliance (2016), and the European Scientific Committee on Food (2002) [12–19]. However, many fresh produce entrepreneurs are still confused over scientific data as applied to their own qualitative risk matrix models, especially on score selection or matching scientific data with each scored definition [20].

Field application of the farm food safety risk assessment (FRAMp) is a tool for small and medium fresh produce farms in the United Kingdom [21,22]. This is an example of a risk assessment tool which supports local fresh produce entrepreneurs. However, this approach focused on only one designed risk assessment model using Microsoft Excel as a platform for small and medium fresh produce farmers to use. Alternatively, the US FDA has also established a summary of simplifying scientific data, as shown in Tables 16 and 17 of the "Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" [23]. However, this guidance is still complicated for local fresh produce entrepreneurs to use, as it requires the conversion of exposure data, hospital, and death data, together with significant data of probability and severity scores for each qualitative risk matrix model.

Hence, this research is aimed at resolving the above problems by starting from a comparison of risk assessment schemes in GHPs and HACCP, FSMA Preventive Controls for Human Food and Animal Food Final Rules, ISO 22000, and GFSI Recognized Standards, with guidance for risk scoring in general use and in the specific application of fresh produce. A basic food risk summary is prepared, as well as more practical fruit and vegetable qualitative food safety risk matrix models for entrepreneurs, using Tables 16 and 17 of the

FDA (2015) [23] as a fruit and vegetable risk profile reference. The Center for Food Safety and Applied Nutrition, Food and Drug Administration, of the U.S. Department of Health and Human Services launched the Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223) in August 2020 [24]. The FDA Risk-Ranking Model used a 3 × 3 qualitative risk matrix. Probability, severity, and significant levels for each hazard were created by using the 3 × 3 qualitative risk matrix model to fit with the data in Tables 16 and 17 of the FDA document (2015) [23]. This is a donated reference fruit and vegetable 3 × 3 qualitative food safety risk matrix model. The scientific data from Tables 16 and 17 [23] were used to construct other common qualitative risk matrix models e.g., 3 × 3, 4 × 3, and 5 × 5, to be compared with the fruit and vegetable 3 × 3 reference qualitative food safety risk matrix model. Moreover, a preference test with focus group consisting of 12 participants was conducted to confirm the ease of use of these qualitative food safety risk matrix models by local fresh produce entrepreneur groups.

2. Materials and Methods

2.1. Comparison of Food Risk Assessment Scheme in GHPs and HACCP, FSMA Preventive Controls for Human Food and Animal Food, ISO 22000, and GFSI Recognized Standards

The risk assessment schemes given in the General Principles of Food Hygiene or Good Hygiene Practices (GHPs) and Hazard Analysis and Critical Control Point, (HACCP), Food Safety Modernization Act (FSMA) Preventive Controls for Human Food and Animal Food Final Rules, ISO 22000, and GFSI Recognized Standards e.g., FSSC 22000, IFS Food, SQF, and BRCGS Food, were studied and compared.

2.2. Preparing Summary of Basic Food Risk

Food risk can be classified into two main groups: food safety and food quality, which can be linked to food integrity as defined by Codex Alimentarius 2018 [25]. Food integrity can be categorized into three main parts: food safety, food quality, and food authenticity (non-food fraud). The summary of basic food risk can help entrepreneurs to classify which risks are food safety hazards for identification and evaluation in food safety risk assessment.

2.3. Preparing General Food Risk Scoring Guidance

Food risk scoring guidance for both food safety, food quality, and food authenticity was prepared with generic food scientific references e.g., FSPCA Preventive Controls for Human Food.

2.4. Preparing Specific Fresh Produce Risk Scoring Guidance

The specific fresh produce risk scoring guidance was prepared as example with the following activities.

2.4.1. Determining the Likelihood of Probability and Severity in Each Qualitative Risk Matrix Models

The 3 × 3, 4 × 3, and 5 × 5 qualitative risk matrix models were determined from a definition of probability and severity using a 4 × 4 Rubric Score Definition from the FSPCA Preventive Control for Animal Food as a reference. This document is the most recent and most comprehensive [1,13,26].

2.4.2. Selecting Related Simplify Justification Scientific Data for Fresh Produce Entrepreneur Group and Creating 3 × 3 Qualitative Food Safety Risk Matrix Model for Tables 16 and 17

The United States Food and Drug Administration (US FDA) document "Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" in August 2015 [23] was used as a fruit and vegetable risk profile reference, based on the hazards summarized in Tables 16 and 17 of the document. Low, medium, and high levels were defined compatible with a 3 × 3 qualitative risk matrix model.

2.4.3. Scoring Tables 16 and 17 into Other Common 3 × 3, 4 × 3, and 5 × 5 Qualitative Risk Matrix Models

The data summarized in Tables 16 and 17 [23] were scored into 3 × 3, 4 × 3, and 5 × 5 qualitative risk matrix models. Moreover, 4 × 3 FAO and 5 × 5 GFSI recommended risk matrix model were used in many local entrepreneurs in Thailand. Further comparisons were made with a fruit and vegetable 3 × 3 reference qualitative food safety risk matrix model.

2.4.4. Comparing Significant Hazards from all Fruit and Vegetable Qualitative Food Safety Risk Matrix Models with Tables 16 and 17

Significant hazards from all fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models were compared with Tables 16 and 17 [23].

2.5. Preference Test for Fruit and Vegetable 3 × 3 Reference Qualitative Risk Matrix Model and Practical Fruit and Vegetable 3 × 3, 4 × 3, and 5 × 5 Qualitative Risk Matrix Models

All practical fruit and vegetable qualitative food safety risk matrix models, together with the reference qualitative food safety risk matrix model, were tested on a focus group consisting of 12 participants according to the method outlined by Onwuegbuzie and Collins (2007) [27]. Concerned open questions according to Rowley (2012) [28] were created for the study. Science knowledge, hazard analysis knowledge, hazard analysis experience, fruit and vegetable risk assessment model preference, and ease of fruit and vegetable risk assessment model use were questioned.

Each factor for the preference test was determined as score for ease of statistic at summary as detailed below.

Bioscience knowledge (0 = No bioscience knowledge, 1 = Bioscience knowledge);

Hazard analysis knowledge (0 = None, 1 = Basic, 2 = In Depth);

Hazard analysis experience (0 = None, 1 = Basic, 2 = Expert);

Fruit and vegetable 3 × 3 reference qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable),

Practical fruit and vegetable 3 × 3 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable);

Practical fruit and vegetable 4 × 3 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable);

Practical fruit and vegetable 4 × 4 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable);

Practical fruit and vegetable 5 × 5 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable);

Ease of qualitative food safety risk matrix model use after training (0 = Inability, 1 = Need Coaching, 2 = Well Performing); and

Segregation of food safety risk matrix for biological, chemical and physical hazards (0 = Non-preferable, 1 = Preferable).

Participants were requested to evaluate hazard by themselves with all practical fruit and vegetable qualitative food safety risk matrix models, including answering the open questions on their preference for all practical fruit and vegetable qualitative food safety risk matrix models.

2.6. Checking with Local Entrepreneur Test Results as per Thailand Fruit and Vegetable Testing Law

Microbiological, chemical, and physical test results before and after rinsing, as per Thailand's fruit and vegetable testing law, were performed by accredited laboratories in Thailand, with random testing by local entrepreneurs.

3. Results and Discussions

3.1. Comparison of Food Risk Assessment Scheme in GHPs and HACCP, FSMA Preventive Controls for Human Food and Animal Food, ISO 22000, and GFSI Recognized Standards

Table 1 shows a comparison of food risk assessment schemes in the General Principles of Food Hygiene or Good Hygiene Practices (GHPs) and Hazard Analysis and Critical Control Point, (HACCP), Food Safety Modernization Act (FSMA) Preventive Controls for Human Food and Animal Food Final Rules, ISO 22000, and GFSI Recognized Standards e.g., FSSC 22000, IFS Food, SQF, and BRCGS Food.

The issues in the first column show common concepts. The issue of food contaminants covers both food safety and food quality. Basic prerequisites program such as cleaning and sanitizing are highlighted. These may require increased control in hazard mitigation plans for some ready-to-eat product categories. There are comparisons of food safety, or food hazards assessment, and the control points are noted from each reference. It should be noted that the FSPCA Preventive Controls for Human Food has classified preventive controls into four types: process, allergen, sanitation, and supply chain program, with links to recall classification. The others used a generic term, and the recall procedure was separated in a prerequisites program or a general management system.

Most control measures have monitoring requirements. A supply chain program was used for verification only, but can be written in a monitoring format as well. Correction refers to immediate action, and corrective action is focused on root cause analysis to prevent affected product from reaching the hands of consumers.

Validation was especially enforced for control measures related to process preventive controls. Other preventive controls, such as allergen and sanitation preventive controls, are also option for validation. Validation is not required for supply chain programs due to the fact that supply chain program activity is based on verification rather than monitoring.

Only the BRCGS Food Safety Standard strongly mentions input materials risk. This is by covering food safety, food quality, and food authenticity, through linking to food fraud detection for both food safety fraud and food quality fraud. This aspect is different from hazard assessments, hazard analysis and critical control points, which focus only on food safety issues.

Food fraud detection was of strict concerned in the Global Food Safety Initiative (GFSI) recognized standards e.g., BRCGS Food Safety, IFS Food, SQF for Manufacturing, and FSSC 22000.

Food quality was controlled with a prerequisites program. The FSMA Preventive Controls for Human Food also mentions defect action levels for food quality issues.

Threat assessment was combined in the Global Food Safety Initiative (GFSI) recognized standards e.g., BRCGS Food Safety, IFS Food, SQF for Manufacturing, and FSSC 22000, while FSMA was placed into the Intentional Adulteration Final Rule as a separate regulation.

Incident management was acknowledged in the Global Food Safety Initiative (GFSI) recognized standards e.g., BRCGS Food Safety, IFS Food, SQF for Manufacturing, and FSSC 22000, and linked to recall procedure.

3.2. Summary of Basic Food Risk

The summary of basic food risks is shown in Table 2, which presents food risk sources, food risk forms, food risk groups, and food integrity group. This provides an overall food risk figure before moving to food safety risk assessment on the next step.

Food risks can be classified into two main sources: unintentional and intentional. The intentional sources can be separated into two parts: food fraud, and malicious tampering of food.

Food risks can be divided into three common forms: physical, chemical, and biological.

Table 1. Comparison of food risk assessment scheme in GHPs and HACCP, FSMA Preventive Controls for Human Food and Animal Food, ISO 22000, and GFSI Recognized Standards.

Issues	GPFH (GHPs HACCP) Rev. 5	PCHF	PCAF	BRCGS Food	IFS Food	SQF MFG	ISO 22000	FSSC 22000
Contaminants	Food Safety and Food Suitability in GHPs	Food Safety and Defect Action Level or Quality Undesirable in CGMPs	Food Safety and Defect Action Level or Quality Undesirable in CGMPs	Food Safety and Food Quality in PRPs	Food Safety and Food Quality in PRPs	Food Safety and Food Quality in PRPs	Food Safety and Food Quality in ISO 22002-X	Food Safety and Food Quality in ISO 22002-X
Cleaning and Sanitizing	GHPs and Greater Attention GHPs	CGMPs	CGMPs	PRPs	PRPs	PRPs	ISO 22002-X	ISO 22002-X
Product Description	GHPs	Food Safety Plan	Food Safety Plan	HACCP	HACCP	HACCP	Hazard Control Plan	Hazard Control Plan
Flow Diagram	GHPs	Food Safety Plan	Food Safety Plan	HACCP	HACCP	HACCP	Hazard Control Plan	Hazard Control Plan
Process Description	GHPs	Food Safety Plan	Food Safety Plan	HACCP	HACCP	HACCP	Hazard Control Plan	Hazard Control Plan
Operational Control	GHPs	CGMPs	CGMPs	PRPs	PRPs	PRPs	ISO 22002-X	ISO 22002-X
Monitoring	GHPs	CGMPs	CGMPs	PRPs	PRPs	PRPs	ISO 22002-X	ISO 22002-X
Corrective Action	GHPs	CGMPs	CGMPs	PRPs	PRPs	PRPs	ISO 22002-X	ISO 22002-X
Validation	GHPs; Cleaning	CGMPs; Basic Sanitation	CGMPs; Basic Sanitation	PRPs; Cleaning	PRPs; Cleaning	PRPs; Cleaning	ISO 22002-X; Cleaning	ISO 22002-X; Cleaning
Verification	GHPs	CGMPs	CGMPs	PRPs	PRPs	PRPs	ISO 22002-X	ISO 22002-X
Record	GHPs	CGMPs	CGMPs	PRPs	PRPs	PRPs	ISO 22002-X	ISO 22002-X
Hazards	• Biological • Chemical (including Allergen, Radioactive, and Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Economically motivated hazard, or Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Economically motivated hazard, or Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Product Safety Fraud) • Physical	• Biological • Chemical (including Allergen, Radioactive, and Product Safety Fraud) • Physical
Hazard Sources	• Unintentional	• Unintentional • Intentional for Economically motivated hazard, or Product Safety Fraud	• Unintentional • Intentional for Economically motivated hazard, or Product Safety Fraud	• Unintentional • Intentional ○ Economically motivated hazard, or Product Safety Fraud ○ Malicious (can be 3 hazard forms as above referred (Biological, Chemical (including Allergen and Radioactive) and Physical	• Unintentional • Intentional for Economically motivated hazard, or Product Safety Fraud	• Unintentional • Intentional for Economically motivated hazard, or Product Safety Fraud	• Unintentional • Intentional for Economically motivated hazard, or Product Safety Fraud	• Unintentional • Intentional for Economically motivated hazard, or Product Safety Fraud
Occurrence in absence control	Hazard Analysis	Simplest Qualitative Hazard Analysis with Justification Example	Rubric Score Hazard Analysis with Justification Example	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as ISO 22000 Questions	Hazard Analysis as ISO 22000 Questions
Severity in absence control	Hazard Analysis	Simplest Qualitative Hazard Analysis with Justification Example	Rubric Score Hazard Analysis with Justification Example	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as ISO 22000 Questions	Hazard Analysis as ISO 22000 Questions

Table 1. *Cont.*

Issues	GPFH (GHPs HACCP) Rev. 5	PCHF	PCAF	BRCGS Food	IFS Food	SQF MFG	ISO 22000	FSSC 22000
Significant hazard	Hazard Analysis	Simplest Qualitative Hazard Analysis with Justification Example	Rubric Score Hazard Analysis with Justification Example	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as HACCP Codex Alimentarius	Hazard Analysis as ISO 22000 Questions	Hazard Analysis as ISO 22000 Questions
Control measure	Critical Control Point	Preventive Controls. • Process • Allergen • Sanitation • Supply Chain	Preventive Controls. • Process • Sanitation • Supply Chain	• Control Point • Critical Control Point	• Control Point • Critical Control Point	• Control Point • Critical Control Point	• Operational Prerequisites Program • Critical Control Point	• Operational Prerequisites Program • Critical Control Point
Control Limit	• Observable • Measurable	• Observable • Measurable	• Observable • Measurable	• Observable • Measurable	• Observable • Measurable	• Observable • Measurable	• Observable for OPRP • Measurable for OPRP or CCP	• Observable for OPRP • Measurable for OPRP or CCP
Limit Control Name	Critical Limit	• Parameters and Values • Criterion	• Parameters and Values • Criterion	Critical Limit	Critical Limit	Critical Limit	• Action Criterion • Critical Limit	• Action Criterion • Critical Limit
Monitoring	Critical Control Point	Preventive Controls • Process • Allergen • Sanitation	Preventive Controls • Process • Sanitation	Critical Limit	Critical Limit	Critical Limit	• Action Criterion • Critical Limit	• Action Criterion • Critical Limit
Correction		During Production Preventive Controls • Process • Allergen • Sanitation	During Production Preventive Controls • Process • Sanitation	Immediately action	Immediately action	Immediately action	Timely action for critical control point	Timely action for critical control point
Corrective Action	Critical Control Point	Root cause analysis, prevent recurrence and prevent affected product entering to commerce Production Preventive Controls • Process • (Allergen) • (Sanitation) • Supply Chain	Root cause analysis, prevent recurrence and prevent affected product entering to commerce Production Preventive Controls • Process • (Sanitation) • Supply Chain	Root cause analysis and prevent recurrence	Root cause analysis and prevent recurrence	Root cause analysis and prevent recurrence	Root cause analysis and prevent recurrence	Root cause analysis and prevent recurrence

Table 1. *Cont.*

Issues	GPFH (GHPs HACCP) Rev. 5	PCHF	PCAF	BRCGS Food	IFS Food	SQF MFG	ISO 22000	FSSC 22000
Validation	Critical Control Point	Preventive Controls. • Process • (Allergen) • (Sanitation)	Preventive Controls. • Process • (Sanitation)	Critical Control Point	Critical Control Point	Critical Control Point	• Operational Prerequisites Program • Critical Control Point	• Operational Prerequisites Program • Critical Control Point
Verification	• Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Supply Chain Program • Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Supply Chain Program • Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action	• Calibration • Raw materials, Packaging materials, in-process products, finished products testing • Environmental testing • Monitoring • Corrective Action
Reanalysis	• Appropriate period • When change	• Every 3 years • When change • Unanticipated problems	• Every 3 years • When change • Unanticipated problems	• Annually • When change	• Annually • When change	• Annually • When change	• Annually • When change	• Annually • When change
Records	Appropriate period	At least 2 years Linked to preventive controls Recall	At least 2 years Linked to preventive controls Recall	Shelf life plus 1 year	Shelf life plus 1 year	Shelf life plus 1 year	Shelf life plus 1 year	Shelf life plus 1 year
Recall	GHPs	• Class 1 SAHCODHA • Class 2 Injury/Illness • Class 3 no health impact	• Class 1 SAHCODHA • Class 2 Injury/Illness • Class 3 no health impact	Linked to incident management	In management system part	In management system part	In management system part	In management system part
Input Materials Risk Assessment	Hazard Analysis at receiving step	Hazard Analysis at receiving step	Hazard Analysis at receiving step	• Hazards • Product Fraud Detection for either product safety fraud or quality fraud	Hazard Analysis at receiving step	Hazard Analysis at receiving step	Hazard Analysis at receiving step	Hazard Analysis at receiving step

Table 1. *Cont.*

Issues	GPFH (GHPs HACCP) Rev. 5	PCHF	PCAF	BRCGS Food	IFS Food	SQF MFG	ISO 22000	FSSC 22000
Fraud Assessment				• Fraud Occurrence ○ History ○ Economic gain ○ Access to supply chain ○ Nature of product • Fraud Detection	• Fraud Occurrence • Fraud Detection	• Fraud Occurrence • Fraud Detection		• Fraud Occurrence • Fraud Detection
Supplier Control	GHPs or HACCP	Supplier chain program for raw materials risk handled by supplier • Onsite Audit for SAHCODHA raw materials risk • Exemption for FSVP, and Qualified Facility	Supplier chain program for raw materials risk handled by supplier • Onsite Audit for SAHCODHA raw materials risk • Exemption for FSVP, and Qualified Facility	Overall input materials risk rating as • Low risk materials required supplier questionnaire and traceability at first and every 3 years • Non-low risk materials required GFSI Certificate or Supplier Audit by competence auditor	Supplier selection and evaluation or HACCP	Supplier selection and evaluation or HACCP	Supplier selection and evaluation or HACCP	Supplier selection and evaluation or HACCP
Incoming Inspection	GHPs or HACCP	Supplier chain program for raw materials risk handled by supplier • CoA • Test Report	Supplier chain program for raw materials risk handled by supplier • CoA • Test Report	Each risk of input materials linked to testing requirement • Visual • CoA • Test Report • Full Analysis	Incoming inspection	Incoming inspection	Incoming inspection	Incoming inspection
Quality Control	GHPs	CGMPs • Defect Action Level	CGMPs	• PRPs • Product Safety and Quality Operational Control Plan	• PRPs • Product Safety and Quality Operational Control Plan	Critical Quality Point	PRPs ISO 22002-X	As ISO 9001
Threat Assessment	Not mention	Not in Preventive Controls Final Rule, but put in Intentional Adulteration Final Rule for Human Food Simple tool is key activity types in area and processing step and vulnerable assessment or CARVER + shock	No requirement for Animal Food	Focus on area assessment for probability and impact when success is focused on production stop, property loss and consumer health impact. For malicious in processing step were mentioned in HACCP part as combining from hazard analysis and intentional adulteration vulnerable assessment in each processing step.	Focus on area assessment and impact when success; production stop, property loss and consumer health impact.	Focus on area assessment and impact when success; production stop, property loss and consumer health impact.	Focus on area assessment and impact when success; production stop, property loss and consumer health impact.	Focus on area assessment and impact when success; production stop, property loss and consumer health impact.
Incident management	Not mention	Not mention	Not mention	Focus on disruption, event, sabotage, and cyber-attack then link to recall procedure.	Similarly, to BRCGS Food.	Similarly, to BRCGS Food.	Referred in emergency preparedness and response requirement.	As ISO 22000.

Table 2. Basic food risk summary.

Food Risk Sources	**Food Risk Forms Example**			**Food Risk Group**		**Food Integrity**		
	Physical	**Chemical**	**Biological**	**Food Safety**	**Food Quality**	**Food Safety**	**Food Quality**	**Food Authenticity**
Unintentional	Metal, Glass, Plastic, Wood	Natural occurring; Mycotoxins, Formulating, Accident; Dioxin	Pathogenic group	✓		✓		
	Hairs, Insects	Sensory	Microbial indicators group; TPC, Coliforms, Yeast, Molds, *E. coli*		✓		✓	
Intentional—Food fraud		Melamine, Sudan Red		✓		✓		
		Organic, Non-GMO, Global GAP			✓			✓
Intentional—Food malicious	Needles	Arsenic	*Clostridium botulinum* toxin	✓				✓

Food risk can be categorized into two main groups: food safety and food quality contaminants [29].

Food integrity was defined to three groups: food safety, food quality, and food authenticity (no food fraud) by Codex Alimentarius 2018 [25].

In Table 2, the basic food risk summary shows the relationship of the above items for ease of understanding, before focusing on food safety risk assessment.

3.3. General Food Risk Scoring Guidance

Table 3 shows general potential food risk scoring guidance for both food quality and food safety with generic food scientific reference.

Food risk was identified as covering food safety, food quality, and food fraud with potential scores for occurrence and severity for food safety, including food safety fraud and malicious actions. Potential scores for food quality are given for occurrence and quality impact. Fraud occurrence and fraud detection are given for both food safety fraud and food quality fraud. Moreover, potential score recommendations are shown general scientific references.

Occurrence scores can be given to sources, facility, and environment, while severity score can be applied as intended targets or vulnerable groups.

3.4. Specific Fresh Produce Risk Scoring Guidance

Determination of probability and severity for each qualitative food safety risk matrix model:

The 4×4 Rubric Score as given in the FSPCA Preventive Control for Animal Food [26] was selected as reference for determining probability and severity in the 3×3, 4×3, and 5×5 qualitative food safety risk matrix models. The determination of score definitions in going from a 4-ranking model (high, medium, low, and very low) to a 3-ranking model (high, medium, and low) was performed by merging the definitions of very low and low, whereas in going from a 4-ranking model (high, medium, low, and very low) to a 5-ranking model (very high, high, medium, low, and very low), the definitions of very high, high, medium, low, and very low or never, and no impact were used. The results are shown as in Tables 4 and 5.

Table 3. General food risk scoring guidance.

Risk Forms • **Biological**	**Risk Sources**				**Hazard Assessment**		**Justification for Hazard Assessment**		**Fraud Assessment**		**Justification for Fraud Assessment**	
• Chemical including Allergen, Radiological, Product Safety Fraud and Quality Fraud • Physical	Unintentional	Intentional Malicious	Product Safety Fraud	Quality/ Technical Fraud	Occurrence	Severity	Occurrence	Severity	Fraud Occurrence	Fraud Detection	Fraud Occurrence	Fraud Detection
B Pathogenic Bacteria in High Severity Group; Clostridium botulinum, Pathogenic E. coli, Listeria monocytogenes	✓				Depend on source/facility/process	H	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4				
B Pathogenic Bacteria in Moderate Severity Group; Salmonella spp.	✓				Depend on source/facility/process	M	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4				
B Pathogenic Bacteria in Low Severity Group; Staphyloccocus aureus	✓				Depend on source/facility/process	L	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4				
B Adding Pathogenic Bacteria in High Severity Group; Clostridium botulinum		✓			Depend on source/facility/process	H	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4	FSPCA Preventive Controls for Human Food Chapter 4 and A4-4				
B Quality Undesirable or Indicator Microbials; TPC, Yeast, Molds, Enterobacteriaceae, Coliforms, E. coli	✓				Depend on source/facility/process	No score in hazard term for quality fraud, but it can be score as quality impact at M or it can impact as rejection by customers.	FSPCA Preventive Controls for Human Food Chapter 4	FSPCA Preventive Controls for Human Food Chapter 4				
C Natural Occurring; Mycotoxins	✓				Depend on source/facility/process	L or M depend on type	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Natural Occurring; Heavy metals	✓				Depend on source/facility/process	L or M depend on type	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Formulating: antibiotics, pesticides, preservatives	✓				Depend on source/facility/process	L or M depend on type	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Incident; Cleaning agent residues; NaOH	✓				Depend on source/facility/process	H	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				

Table 3. *Cont.*

Risk Forms • **Biological**	**Risk Sources**			**Hazard Assessment**		**Justification for Hazard Assessment**		**Fraud Assessment**		**Justification for Fraud Assessment**	
C Industrial Contamination; PCBs, Dioxin	✓			Depend on source/facility/process	L or M depend on type	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Adding Toxic Substances		✓		Depend on Food Defense Measures	M or H depend on chemical substance type	Potential Malicious Data	EPA				
C Allergen Itself Anaphylaxis Group; Peanut, Tree nuts, Crustaceans	✓			H	H	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Allergen Itself Non-Anaphylaxis Group	✓			H	M	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Allergen Cross-contact Anaphylaxis Group; Peanut, Tree nuts, Crustaceans	✓			Depend on source/facility/process/human	H	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Allergen Cross-contact Non-Anaphylaxis Group	✓			Depend on source/facility/process/human	M	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Adding Allergen Itself Anaphylaxis Group; Peanut, Tree nuts, Crustaceans		✓		Depend on Food Defense Measures	H	Potential Malicious Data	FSPCA Preventive Controls for Human Food Chapter 5				
C Radioactive	✓			Depend on sources/process	M or H depend on type	FSPCA Preventive Controls for Human Food Chapter 5 and EPA	FSPCA Preventive Controls for Human Food Chapter 5 and EPA				
C Adding Radioactive		✓		Depend on Food Defense Measures	M or H depend on type	Potential Malicious Data	FSPCA Preventive Controls for Human Food Chapter 5 and EPA				
C Food Safety Fraud			✓	Depend on sources/process	L, M, or H depend on chemical substance replacement	FSPCA Preventive Controls for Human Food Chapter 5 and Food Fraud Database	FSPCA Preventive Controls for Human Food Chapter 5 and Food Fraud Database				
C Food Safety Fraud			✓					Depend on sources/process	L, M, or H depend on sophisticated detection	Food Fraud Database	Food Fraud Database

Table 3. *Cont.*

Risk Forms • **Biological**	**Risk Sources**			**Hazard Assessment**		**Justification for Hazard Assessment**		**Fraud Assessment**		**Justification for Fraud Assessment**	
C Quality undesirable; Off-odour, off-taste	✓			Depend on source/facility/process	No score in hazard term for quality fraud, but it can be score as quality impact at M or it can impact as rejection by customers.	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
C Quality Fraud; Non-toxic species switching, Organics, Non-GMO, Halal, Kosher, Global GAP			✓	Depend on sources/process/history/nature	No score in hazard term for quality fraud, but it can be score as quality impact at H or it can impact as recall class 3 level defined by FDA.	Food Fraud Database	Food Fraud Database				
C Quality Fraud; Non-toxic species switching, Organics, Non-GMO, Halal, Kosher, Global GAP			✓					Depend on sources/process	L, M, or H depend on sophis-ticated detection	Food Fraud Database	Food Fraud Database
P Glass, Plastic, Bone, Wood, Metal	✓			Depend on source/facility/process/human	M or H depend on target group	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				
P Adding Bones, Glasses, Plastics, Metals		✓		Depend on Food Defense Measures	M or H depend on target group	Potential Malicious Data	FSPCA Preventive Controls for Human Food Chapter 5				
P Quality Undesirable; Hair, Insect	✓			Depend on source/facility/process	No score in hazard term for quality fraud, but it can be score as quality impact at M or it can impact as rejection by customers.	FSPCA Preventive Controls for Human Food Chapter 5	FSPCA Preventive Controls for Human Food Chapter 5				

Table 4. All qualitative food safety risk matrix models' occurrence or probability scores summary.

Occurrence **5 × 5** ***Modified from Adverb of Frequency Scales***	**Occurrence** **4 × 4** **Reference from 4 × 4 Rubric Score Definition in FSPCA Preventive Control for Animal Food**	**Occurrence** **3 × 3** **Modified from 4 × 4 Rubric Score Definition in FSPCA Preventive Control for Animal Food**	**Occurrence** **4 × 3** **Reference from FAO HACCP System and Modified from 4 × 4 Rubric Score Definition in FSPCA Preventive Control for Animal Food**
Very High—5 Always, Constantly	High—4 Immediate danger that hazard will occur	High—3 Immediate danger that hazard will occur	High—4 Immediate danger that hazard will occur
High—4 Usually, Normally, Regularly, Often	Medium—3 Probably to occur in time if not corrected	Medium—2 Probably or possible to occur in time if not corrected	Medium—3 Probably to occur in time if not corrected
Medium—3 Sometimes, Occasionally	Low—2 Possible to occur in time if not corrected	Medium—2 Probably or possible to occur in time if not corrected	Low—2 Possible to occur in time if not corrected
Low—2 Rarely, Seldom	Very Low—1 Unlikely to occur; may assume hazards will not occur	Low—1 Unlikely to occur; may assume hazards will not occur	Very Low/Negligible—1 Unlikely to occur; may assume hazards will not occur
Very Low—1 Hard ever, Never	Very Low—1 Unlikely to occur; may assume hazards will not occur	Low—1 Unlikely to occur; may assume hazards will not occur	Very Low/Negligible—1 Unlikely to occur; may assume hazards will not occur

Table 5. All qualitative food safety risk matrix models' severity scores summary.

Severity 5 × 5 Modified from 4 × 4 Rubric Score Definition in FSPCA Preventive Control for Animal Food	**Severity 4 × 4 Reference from 4 × 4 Rubric Score Definition in FSPCA Preventive Control for Animal Food**	**Severity 3 × 3 Modified from 4 × 4 Rubric Score Definition in FSPCA Preventive Control for Animal Food**	**Severity 4 × 3 Reference from FAO HACCP System**	**Example Severity Score from FAO HACCP System**
Very high—An imminent and immediate danger of death or severe illness	High—An imminent and immediate danger of death or severe illness	High—An imminent andimmediate danger of death or severe illness	High—A life threatening	*Clostridium botulinum, Salmonella typhi, Listeria monocytogenes, Escherichia coli* O157:H7, *Vibrio cholerae, Vibrio vulnificus*, Paralytic shellfish poisoning, Amnesic shellfish poisoning
High—B Danger or illness may be severe, but it is not imminent or immediate	Medium—B Danger or illness may be severe, but it is not imminent or immediate	Medium—B Danger or illness may be severe, but it is not imminent or immediate	Medium—B Severe or chronic	*Brucella* spp., *Campylobacter* spp., *Salmonella* spp., *Streptococcus* type A, *Yersinia enterocolitica*, Hepatitis A virus, Mycotoxins, Ciguatera toxin
Medium—C Illness or injury may occur, but impact is reversible	Low—C Illness or injury may occur, but impact is reversible	Low—C Illness or injury may occur, but impact is reversible, or illness or injury is minor	Low—C Moderate or mild	*Bacillus* spp., *Clostridium perfringens*, *Staphylococcus aureus*, Norwalk virus, most parasites, Histamine-like substances, and most heavy metals that cause mild acute illness.
Low—D Illness or injury is minor	Very Low—D Illness or injury is minor	Low—C Illness or injury may occur, but impact is reversible, or illness or injury is minor	Low—C Moderate or mild	*Bacillus* spp., *Clostridium perfringens, Staphylococcus aureus*, Norwalk virus, most parasites, Histamine-like substances, and most heavy metals that cause mild acute illness.
Very low—E No impact	Very low—D Illness or injury is minor	Low—C Illness or injury may occur, but impact is reversible, or illness or injury is minor	Low—C Moderate or mild	*Bacillus* spp., *Clostridium perfringens, Staphylococcus aureus*, Norwalk virus, most parasites, Histamine-like substances, and most heavy metals that cause mild acute illness.

3.5. Creating Practical Fruit and Vegetable 3 × 3 Reference Qualitative Food Safety Risk Matrix Model as Tables 16 and 17 of FDA 2015

Data on exposure and impact to health via hospital and death details in the Serious Adverse Health Consequences or Death to Human or Animal (SAHCODHA) and on significant hazard, as defined in Tables 16 and 17 [23] were converted into the fruit and vegetable 3 × 3 reference qualitative food safety risk matrix model, as shown in Figure 1.

Immediate danger that hazard will occur.	High 3	3-C NOT SAHCODHA E.g. Norovirus	3-B SAHCODHA E.g. *Salmonella* spp.	3-A SAHCODHA E.g. Food Allergen, Sulfites, *L. monocytogenes*
Probably or Possible will occur in time if not corrected.	Medium 2	2-C NOT SAHCODHA E.g. *B. cereus*	2-B SAHCODHA E.g. *E. coli* O157:H7, *Cryptosporidium*	2-A SAHCODHA
Unlikely to occur; may assume hazard will not occur.	Low 1	1-C NOT SAHCODHA E.g. *S. aureus*	1-B NOT SAHCODHA E.g. Foreign objects, Mycotoxin	1-A SAHCODHA E.g. *Clostridium botulinum*, Hepatitis A virus
Probability		Low C	Medium B	High A
	Severity	Illness or injury may occur, but impact is reversible, or Illness or injury is minor.	Danger and illness may be severe, but it is not imminent or immediate	Imminent & Immediate Danger of Death or Severe illness

Figure 1. Fruit and vegetable 3 × 3 reference food safety risk matrix model.

Exposure data can be interpreted as probability [23], while hospital and death data are used for the severity score. Each hazard's significance level was used for final decision checking.

However, it was found that there are no details of some of the hazards mentioned in Table 17 of the FDA 2015 e.g., pesticides, heavy metals, and radioactive materials. This may limit the use of the model in regions containing these hazards.

3.6. Scoring Tables 16 and 17 of FDA 2015 into Other Common 3 × 3, 4 × 3, and 5 × 5 Qualitative Food Safety Risk Matrix Models

Exposure, hospital, and death data, including significance levels of each hazard as identified in Tables 16 and 17 [23], were also used for the construction of other common 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models, with the same concept of interpretation as given above. These models described the practical fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models, as shown in Figures 2–4.

3.7. Comparing Fruit and Vegetable 3 × 3 Reference Qualitative Food Safety Risk Matrix Model to Other Practical Fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 Qualitative Food Safety Risk Matrix Models

As referred to above, the fruit and vegetable 3 × 3 reference qualitative food safety risk matrix model was created for comparison to other practical fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models commonly used by many entrepreneurs [5,11]. As shown in Figures 2–4, some hazards dropped significantly in rank when changing qualitative risk matrix models. This issue will be discussed in next clause number as bellowed.

3.8. Comparing Significant Hazards from all Fruit and Vegetable Qualitative Food Safety Risk Matrix Models with Tables 16 and 17 of FDA 2015

All hazards, either significant or non-significant, from all practical fruit and vegetable 3 × 3, 4 × 3, and 5 × 5 qualitative food safety risk matrix models, were compared with Tables 16 and 17 [23], as shown in Table 6 of this paper.

Immediate danger that hazard will occur.	High 3	3-C Minor E.g. *S. aureus*	3-B Major E.g. Non-Anaphylaxis Allergen, *Salmonella* spp.	3-A Major E.g. Anaphylaxis Allergen
Probably or Possible will occur in time if not corrected.	Medium 2	2-C Satisfactory E.g. *B. cereus*, Pesticides, Mycotoxins, Heavy metals	2-B Minor E.g. Foreign objects, *Cryptosporidium*, Hepatitis A virus, Norovirus	2-A Major E.g. *Clostridium botulinum, E. coli* O157:H7, *L. monocytogenes*
Unlikely to occur; may assume hazard will not occur.	Low 1	1-C Satisfactory E.g. Radioactive	1-B Satisfactory	1-A Minor
Probability		Low C	Medium B	High A
	Severity	Illness or injury may occur, but impact is reversible, or Illness or injury is minor.	Danger and illness may be severe, but it is not imminent or immediate	Imminent & Immediate Danger of Death or Severe illness

Figure 2. Practical fruit and vegetable 3 × 3 food safety risk matrix model.

Immediate danger that hazard will occur.	High 4	4-C Minor E.g. *S. aureus*	4-B Major E.g. Non-Anaphylaxis, *Salmonella* spp.	4-A Critical E.g. Anaphylaxis Allergen
Probably will occur in time if not corrected.	Medium 3	3-C Minor	3-B Major	3-A Major E.g. *E. coli* O157:H7
Possible to occur in time if not corrected.	Low 2	2-C Minor E.g. Pesticides, Mycotoxins, Heavy metals, *B. cereus*	2-B Minor E.g. Foreign objects, *Cryptosporidium*, Hepatitis A, Norovirus	2-A Minor E.g. *L. monocytogenes*, *Clostridium botulinum*
Unlikely to occur; may assume hazard will not occur.	Very Low 1	1-C Satisfactory E.g. Radioactive	1-B Satisfactory	1-A Satisfactory
Probability		Low C	Medium B	High A
	Severity	Moderate or Mild Illness or injury may occur, but impact is reversible, or Illness or injury is minor.	Severe or Chronic Danger and illness may be severe, but it is not imminent or immediate	Life-Threatening Imminent & Immediate Danger of Death or Severe illness

Figure 3. Practical fruit and vegetable 4 × 3 food safety matrix model.

Always, Constantly	Very High 5	5-E Minor	5-D Major	5-C Major	5-B Major E.g. Non-Anaphylaxis,	5-A Major E.g. Anaphylaxis Allergen
Usually, Normally, Regularly, Often	High 4	4-E Minor	4-D Minor	4-C Major E.g. *S. aureus*	4-B Major E.g. *Salmonella* spp., *E. coli* O157:H7	4-A Major
Sometimes, Occasionally	Medium 3	3-E Satisfactory	3-D Minor	3-C Minor E.g. *B. cereus*, Pesticides, Mycotoxins, Heavy metals,	3-B Major E.g. Foreign objects, Hepatitis A, Norovirus, *Cryptosporidium*	3-A Major E.g. *Clostridium botulinum*, *L. monocytogenes*
Rarely, Seldom	Low 2	2-E Satisfactory	2-D Satisfactory	2-C Minor E.g. Radioactive	2-B Minor	2-A Major
Hard Ever or Never	Very Low 1	1-E Satisfactory	1-D Satisfactory	1-C Satisfactory	1-B Minor	1-A Minor
Probability		Very Low E	Low D	Medium C	High B	Very High A
	Severity	No impact	Illness or injury is minor.	Illness or injury may occur, but impact is reversible	Danger and illness may be severe, but it is not imminent or immediate	Imminent & Immediate Danger of Death or Severe illness

Figure 4. Practical fruit and vegetable 5 × 5 food safety matrix model.

Table 6. Comparison of all significant hazards in each practical fruit and vegetable qualitative food safety risk matrix models with Tables 16 and 17 (FDA, 2015).

Hazards	SAHCODHA List as FDA Aug 2015	4 × 3 Food Safety Risk Matrix Model Significant	3 × 3 Food Safety Risk Matrix Model Significant	5 × 5 Food Safety Risk Matrix Model Significant
Food allergens	Yes	Yes	Yes	Yes
Salmonella spp.	Yes	Yes	Yes	Yes
L. monocytogenes	Yes	No	Yes	Yes
E. coli O157:H7	Yes	Yes	Yes	Yes
Clostridium botulinum	Yes	No	Yes	Yes
Hepatitis A	Yes	No	No	Yes
Cryptosporidium	Yes	No	No	Yes
Norovirus	No	No	No	Yes
Bacillus cereus	No	No	No	No
Staphylococcus aureus	No	No	No	Yes
Mycotoxins	No	No	No	No
Foreign objects	No	No	No	Yes
Pesticides	Not mention	No	No	No
Heavy metals	Not mention	No	No	No
Radioactive	Not mention	No	No	No

From the serious adverse health consequences or death mentioned in Tables 16 and 17 [23] are the following causes: food allergens, *Salmonella spp.*, *Listeria monocytogenes*, *E. coli* O157:H7, *Clostridium botulinum*, *Hepatitis A* virus, and *Cryptosporidium*, while *Bacillus cereus*, *Norovirus*, *Staphylococcus aureus*, mycotoxins, and foreign objects are considered to be non-significant hazards. However, there is no mention, of pesticides, heavy metals, or radioactive materials in these tables.

From the practical fruit and vegetable 3 × 3 qualitative food safety risk matrix model that was used to evaluate to the same hazards as given in Tables 16 and 17 [23], it was found that *Hepatitis A* and *Cryptosporidium* are non-significant hazards, which differs from the FDA result, while the rest of the significant and non-significant hazards are the same as the FDA result.

When the practical fruit and vegetable 4 × 3 qualitative food safety risk matrix model was used to evaluate the same hazards given in Tables 16 and 17 [23], it was found that *Listeria monocytogenes*, *Clostridium botulinum*, *Hepatitis A* virus, and *Cryptosporidium* were non-significant hazards, which differs from the FDA result. The other significant and non-significant hazards gave the same result as the reference model.

The practical fruit and vegetable 5 × 5 qualitative food safety risk matrix model, when used for evaluation of the hazards in Tables 16 and 17 [23], gave the same result for all significant hazards. However, three of five of the non-significant hazards listed in Tables 16 and 17, namely *Norovirus*, *Staphylococcus aureus* and foreign objects, become significant hazards when using this qualitative risk matrix model.

The fruit and vegetable 4 × 3 qualitative food safety risk matrix model provided different significance levels to the other matrices. It can be noted that the 4 × 3 matrix is not diagonally symmetrical.

Each practical fruit and vegetable qualitative food safety risk matrix model gave different scores and significance on some hazards. Serious adverse health consequences or death, as mentioned in Tables 16 and 17 [23], may not fit the hazard probability for fresh cut facilities in Thailand. For instance, *Norovirus* and *Cryptosporidium* were identified as having a high probability. However, there are few such hazards in fresh cut facilities in Thailand. However, fresh cut facilities in regions such as Thailand could have some issues related to pesticides, heavy metals, and radioactive materials in some areas. However, these factors are not mentioned in Tables 16 and 17 [23].

The practical fruit and vegetable 5 × 5 qualitative food safety risk matrix model gave the highest compatibility with Tables 16 and 17 [23]. The 3 × 3 qualitative food safety risk matrix model gave compatible results for five of the seven significant hazards, and all of the non-significant hazards in Tables 16 and 17 [23]. In contrast, in the 4 × 3 qualitative food safety risk matrix model, only three of the seven significant hazards were compatible with Tables 16 and 17 [23].

In addition, the practice fruit and vegetable 5 × 5 qualitative food safety risk matrix model is also similar to the Corporate Risk Map Plotting Food Fraud Initial Screening Risk Assessments, which was created by Spink J., Moyer D.C. and Speier-Pero C. (2016) [30]. This presents that the practical fruit and vegetable risk map plotting matrices can be applied for local small enterprises.

3.9. All Practical Fruit and Vegetable Food Safety Risk Matrix Models Preference Test

All practical fruit and vegetable qualitative food safety risk matrix models were tested for preference by 12 participants of a focus group [27,31] after training them in the use of these models. Overall, six persons of non-bioscience knowledge and another six persons of bioscience knowledge from five fruit and vegetable business organizations were trained in using the models. The results are shown in Table 7 and Figure 5.

In total, four of the six people with bioscience knowledge and three of the six people with non-bioscience knowledge performed well when using the qualitative food safety risk matrix models. The remaining persons required some coaching during the risk assessment testing. In total, four of the twelve participants preferred the 3 × 3 reference qualitative food safety risk matrix model. Another four out of the remaining eight preferred the practical fruit and vegetable 3 × 3 qualitative food safety risk matrix model, and the remaining people preferred the practical fruit and vegetable 4 × 4 qualitative food safety risk matrix model, as shown in Surareungchai S., et al. (2021) Simplify product safety and quality risk analysis of raw materials for conventional, soilless culture, and organic salads for the reasons of simplicity and ease of understanding [32].

Table 7. All practical fruit and vegetable qualitative food safety risk matrix models' preference test.

Factors	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6	Participant 7	Participant 8	Participant 9	Participant 10	Participant 11	Participant 12
Bioscience knowledge (0 = Non-bioscience knowledge, 1 = Bioscience knowledge)	0	0	1	1	1	0	1	0	1	1	0	0
Hazard analysis knowledge (0 = None, 1 = Basic, 2 = In Depth)	1	1	1	1	1	0	1	1	1	1	1	0
Hazard analysis experience (0 = None, 1 = Basic, 2 = In Depth)	0	1	0	0	0	0	1	0	1	1	1	0
Practical fruit and vegetable 3 × 3 reference qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable)	2	1	2	2	1	2	1	1	1	1	1	1
Practical fruit and vegetable 3 × 3 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable)	1	2	1	1	1	1	1	2	1	1	2	2
Practical fruit and vegetable 4 × 3 qualitative food safety risk matrix model reference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable)	1	1	1	1	1	1	1	1	1	1	1	1
Practical fruit and vegetable 4 × 4 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable)	1	1	1	1	2	1	2	1	2	2	1	1
Practical fruit and vegetable 5 × 5 qualitative food safety risk matrix model preference (0 = Non-preferable, 1 = Acceptable, 2 = Preferable)	1	1	1	1	1	1	1	1	1	1	1	1
Ease of qualitative food safety risk matrix model use after training (0 = Inability, 1 = Need coaching, 2 = Well performing)	1	1	2	1	2	1	2	2	2	1	2	2
Segregation of food safety risk matrix for biological, chemical and physical Hazards (0 = Non-preferable, 1 = Preferable)	1	0	1	1	1	1	1	1	1	0	0	0

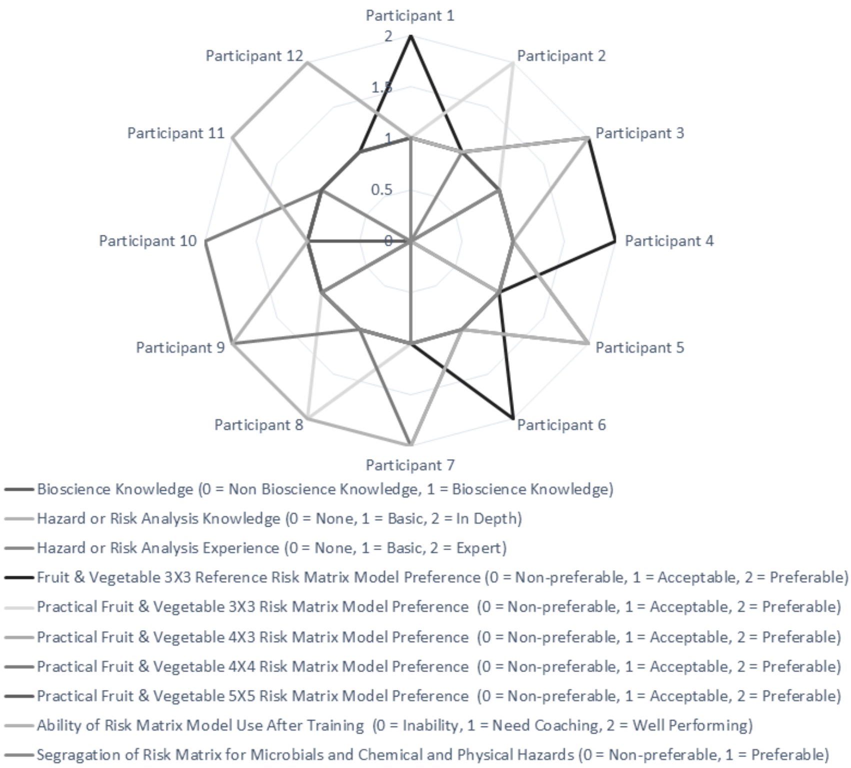

Figure 5. Fruit and vegetable food safety risk map plotting matrices' preference test.

3.10. Checking with Local Entrepreneur Test Results as per Thailand Fruit and Vegetable Testing Law

Microbiological, chemical, and physical test results before and after rinsing, as per Thailand's fruit and vegetable testing laws, are shown in Table 8—conventional ready-to-eat mix salads test results are summarized.

The test results were produced by accredited laboratories in Thailand during the research period as preliminary random checking.

Microbiological test results were compared with microbiological criteria for food and food contact materials no. 3 B. E. 2560 by the Department of Medical Science, Thailand. Before rinsing in water containing chlorine at 150 ppm, samples produced a total plate count that was above the criteria (1×10^6 cfu/g). Microbiological tests after rinsing in water with chlorine (150 ppm) showed the criteria plate counts to be below this, whereas other microbiological tests (E. coli, Salmonella spp., Listeria monocytogenes and Staphylococcus aureus) showed criteria cell counts below this both before and after rinsing in water with 150 ppm chlorine.

Tests for the four pesticides groups given in the Notification of Ministry of Public Health, Thailand no. 387 B. E. 2560, did not reveal any pesticide presence either before or after rinsing in water with 150 ppm chlorine.

Physical contaminants, using the entrepreneurs' inspection report and criteria (e.g., metal, plastic, glass, wood, and other undesirable quality issues), were not evident either before or after rinsing in water with 150 ppm chlorine.

All tests showed a low occurrence of the main fruit and vegetable risks in Thailand. However, occurrence scoring consideration should not only focus on internal data (FSPCA, 2016 and 2017). Hence, significant hazards mentioned in the Tables 16 and 17 of the FDA document (2015) should be used during risk assessment by facilities.

Table 8. Conventional ready-to-eat mix salads test results summary.

Items	References	Criteria	Before Rinsing in Water with 150 ppm Chlorine Residue			After Rinsing in Water with 150 ppm Chlorine Residue		
			Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3
TPC	Microbiological criteria in food and food contact materials no. 3 B. E. 2560 by Department of Medical Science, Thailand	<1 × 10^6 cfu/g	3.3 × 10^6	1.8 × 10^6	9.8 × 10^6	3.7 × 10^5	6.4 × 10^4	5.8 × 10^4
E. coli		<100 cfu/g	<3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Salmonella spp.		Not detected in 25 g	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
Listeria monocytogenes		Not detected in 25 g	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
Staphylococcus aureus		<100 cfu/g	<10	<10	<10	<10	<10	<10
4 Groups Pesticide	The Notification of Ministry of Public Health, Thailand no. 387 B. E. 2560	Not over maximum residues level	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
Physical	Entrepreneur's criteria	No filth	None	None	None	None	None	None

4. Conclusions

A comparison of the food risk assessment schemes in GHPs and HACCP, FSMA Preventive Controls for Human Food and Animal Food, ISO 22000, and GFSI Recognized Standards was performed. Basic food risks and general food risk scoring guidance, including specific fresh produce risk scoring guidance were summarized. Practical fruit and vegetable qualitative food safety risk matrix models developed within this research can be useful tools for entrepreneurs, particularly those involved in fresh produce in Thailand for either domestic or export purposes. The interpretation was derived and verified using accepted scientific data Tables 16 and 17 in the FDA document (2015), and transformed into various simple, well-known qualitative risk matrix models. The 5 × 5 and 3 × 3 risk matrices models are the first two best compatible with 5 × 5. Understanding of food risk assessment and scientific justification is crucial issue for positive food safety culture throughout the organization in a new era of food safety implementation scheme either by laws or voluntary standards. However, these verified food safety risk matrix models are only for identification of individual hazards in fresh produce materials. They do not describe the hazards associated with processing. The next phase of the research will be running pilot scale verification within a pilot facility.

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