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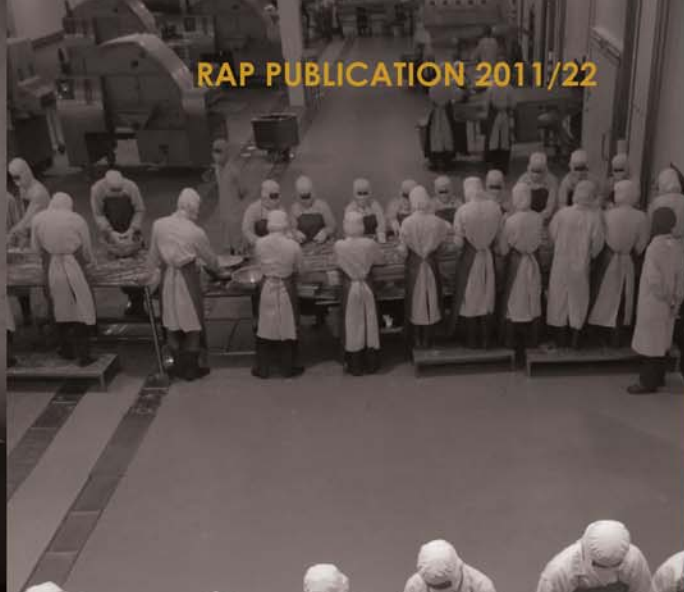
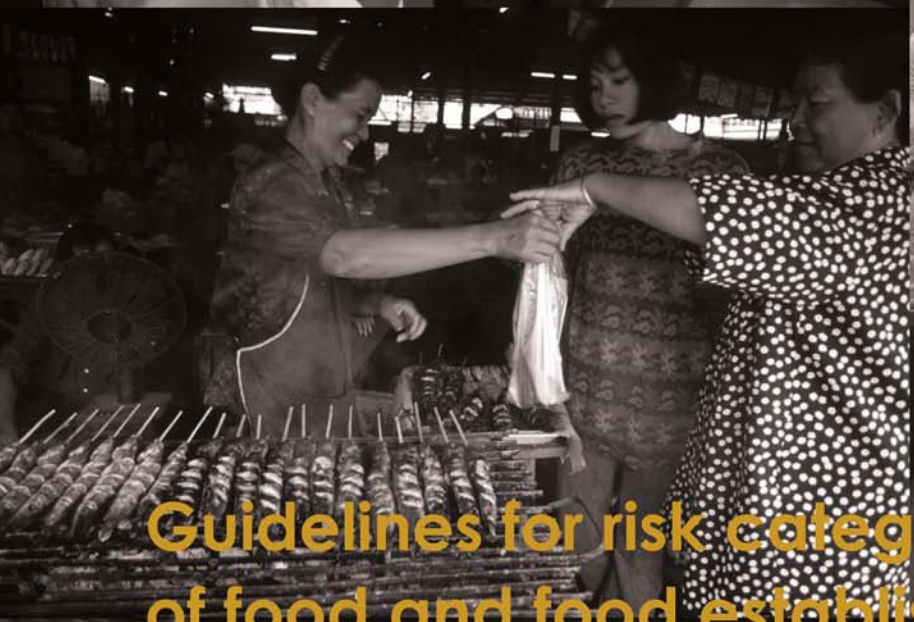
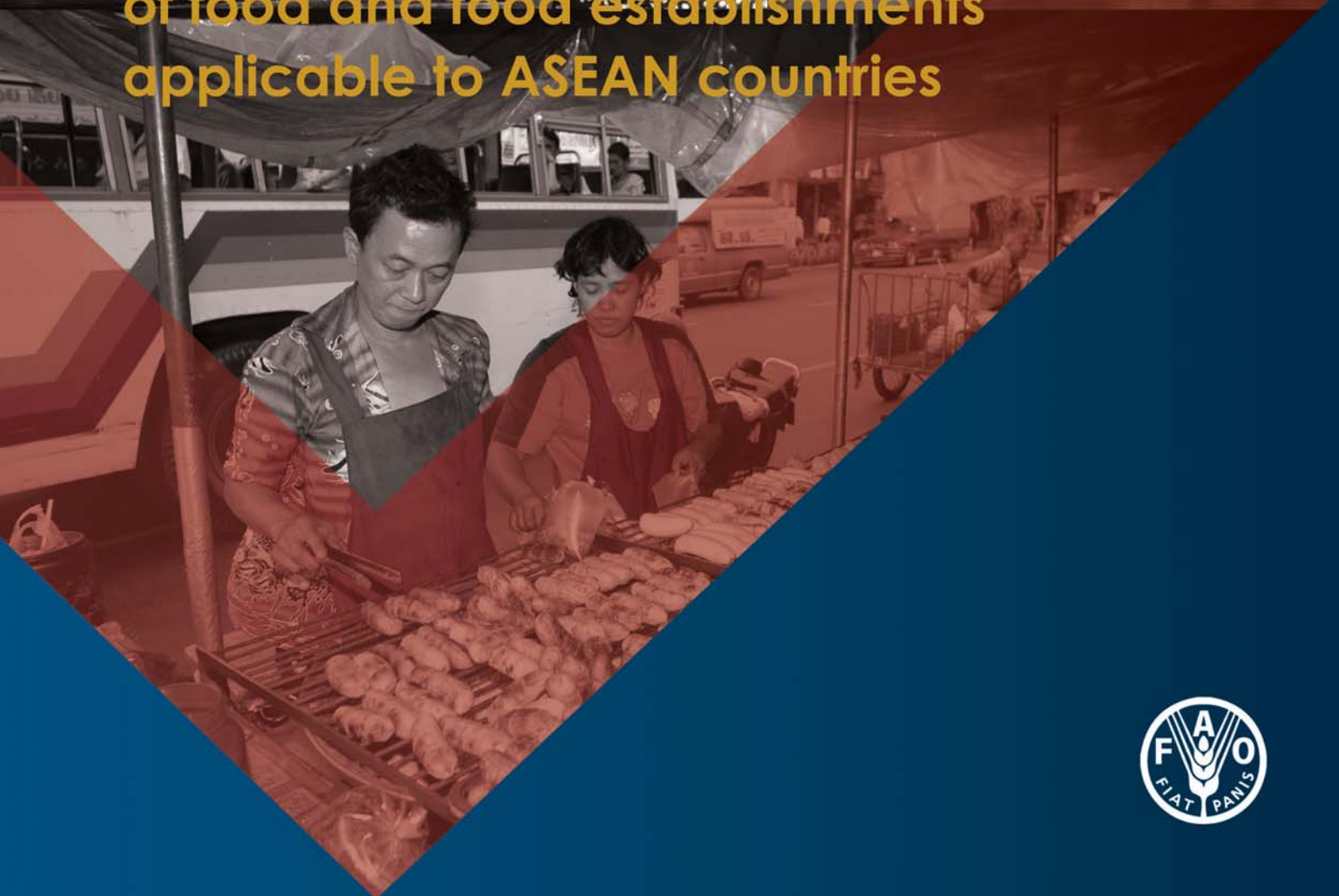




Guidelines for risk categorization of food and food establishments applicable to ASEAN countries



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Guidelines for risk categorization of food and food establishments applicable to ASEAN countries

Prepared by

Dedi Fardiaz, Department of Food Science and Technology,
Bogor Agricultural University, Indonesia

With support from

Ramesh Bhat, Project Consultant with FAO

Under the technical guidance of Shashi Sareen,
Senior Food Safety and Nutrition Officer, FAO, Bangkok

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC
Bangkok, 2011

This publication is a product of

The FAO regional project
"Enhancing food safety by strengthening
food inspection systems in ASEAN countries"
(GCP/RAS/222/JPN)

ISBN 978-92-5-107056-7

Foreword

Food safety is of considerable significance from both the health and economic perspectives. Safe food protects the health of consumers by preventing both acute and chronic food borne diseases. With globalization and a greater movement of food across borders, quality and safety have become especially critical. Consumers are showing a preference for high quality and safe food while at the same time governments are laying down stringent requirements relating to pesticide residues, contaminants, microbiological parameters, pests and diseases, as well as various aspects of hygiene controls so as to protect the health and safety of their populations.

Problems related to ensuring the quality and safety of foods are complex and systemic, often extending from the production environment to the end consumer involving the entire food chain. Recently there has been a shift from end product inspection and testing to a preventative systems approach based on risk. This necessitates not only implementing standards for the end product but also standards on good practices to include Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP) systems at various stages of the food chain consisting of the primary production sector, the processing sector, distribution, retail and food service (including street foods) outlets and the consumer sector. The role of food control, which is of paramount importance to assure food safety and quality, has also shifted from end product inspection and testing with corrective actions towards food safety concerns to preventive checks on the controls put in place in operations to address food borne risk factors all across the food chain. This approach necessitates not only a change in the mindset of inspectors – from regulators to food safety professionals – but also a need for additional and varied skills for the purpose.

In order to address the various issues connected with this important activity of food control, under the regional project "Enhancing Food Safety by Strengthening Food Inspection Systems in ASEAN Countries", funded by the Government of Japan, a number of capacity development activities for the ASEAN countries were implemented as part of the project such as workshops and training courses and preparation of case studies, all covering various aspects of food inspection. As part of the activities, this guideline document on "Risk categorization of food and food establishments applicable to ASEAN countries" was developed. The purpose of the document is to provide a framework for categorizing establishments based on risk so as to allow regulatory agencies responsible for food inspection to prioritize inspections of food businesses on the basis of the degree of risk they pose to the population so that high-risk food businesses may be inspected more frequently than lower risk food businesses.

I take this opportunity to convey FAO's appreciation and gratitude to the Government of Japan for its liberal contribution towards this project. It is hoped that this document will provide useful guidance to the governments of countries of the ASEAN region as well as to other developing countries.

Hiroyuki Konuma
Assistant Director-General and
Regional Representative for Asia and the Pacific
Food and Agriculture Organization of the United Nations

Contents

Abbreviations and acronyms

a_w	water activity
ANZFA	Food Standards Australia and New Zealand
ASEAN	Association of Southeast Asian Nations
CDC	Centers for Disease Control (United States)
FAO	Food and Agriculture Organization of the United Nations
FAORAP	Food and Agriculture Organization of the United Nations Regional Office for Asia and the Pacific
FDA	Food and Drug Administration
FPTCFSP	Federal Provincial Territorial Commission on Food Safety Policy
FSAI	Food Safety Authority of Ireland
FSAME	Food Safety Australia Minter and Ellison
GAP	Good Agriculture Practices
GMP	Good Manufacturing Practices
RCM	risk categorization model
SME	small and medium enterprise
WHO	World Health Organization

Preamble

Maintaining a safe and nutritious food supply is an essential prerequisite to achieving food security, good nutrition and safeguarding the general health of populations. Food inspection plays an important role in this by making sure food meets the required standard and by preventing the adulteration of food and commercial fraud with respect to the sale of food, especially in terms of the mislabelling of food products. The improvement of national food control systems in general and food inspection in particular, including harmonization of total inspection systems, have become priorities in ASEAN countries because of the need to enhance the overall food safety situation of the region.

The project "Enhancing food safety by strengthening food inspection systems in ASEAN countries" (GCP/RAS/222/JPN) was funded by the Japanese government and was started in 2007. The objective of this project was to enhance food safety by strengthening food inspection systems in ASEAN countries covering domestically produced food, food import control and food export control. As part of the project, a number of capacity-building activities such as regional workshops and regional and national training courses in various aspects of food inspection were organized. Moreover, case studies and guidelines related to food inspection were prepared.

The project has contributed primarily to strengthening food inspection systems, including risk-based inspection and to facilitating recognition of and compliance with international food safety standards and guidelines with special reference to food inspection and certification. This should lead to improved food safety conditions in ASEAN countries, enhanced public health protection from food-borne diseases and should facilitate food trade by increasing competitiveness in the international market.

The idea of preparing guidance documents under the FAO regional project "Enhancing food safety by strengthening food inspection systems in ASEAN countries" (GCP/RAS/222/JPN) was placed before the 7th meeting of the ASEAN Expert Group on Food Safety (AEGFS) held in Singapore during 13–15 October 2009, by the FAORAP. During the meeting it was considered that priority should be given to the preparation of this guidance document *for risk categorization of food and food establishments applicable to ASEAN countries*.

The significance of preparing a guidance document to provide a framework for risk categorization in ASEAN countries based on the experiences gained in the region was introduced to the participants of the fourth regional workshop "SPS measures and their impact on food inspection and certification including managerial aspects" of the FAO held in Bangkok, Thailand on 25 and 26 August 2010. The participants were urged to identify the foods of importance and offer their suggestions on categorizing foods on the basis of the risks they posed. The principles and examples of risk categorization and their implications for the ASEAN countries were explained. Participants from the various countries represented provided feedback, especially in relation to: i) how their countries have been working on drafting a risk categorization document; ii) how their countries have categorized the foods and the risks they pose; iii) how it is mandatory for sellers to receive certification if they deal in high risk foods; and iv) the types of high risk foods containing specifically chemical contaminants.

The subject was further elaborated and discussed during the final strategy workshop of the FAO held in Hanoi, Viet Nam on 25 and 26 May 2011. Different approaches to categorizing food

businesses were dicussed. The Bangladesh risk categorization model (now under development) was presented as an example of a model that might be emulated. A group discussion was organized after the presentations and the decision tree model used to categorize food businesses based on risk applicable to ASEAN countries was selected as the best approach in ASEAN countries.

Furthermore, during the FAO/WHO regional workshop on "The use of science throughout the food chain for safe foods" held in Bali, Indonesia during 18–20 November 2010 a round table discussion to identify ways to implement risk-based inspections and inspection frequencies in Asia was held. The participants provided examples of high risk foods and risk factors important for those foods.

This document has been prepared on the basis of inputs received in various workshops referred to above. We are very grateful for the contribution of participants of all three workshops.

Helpful suggestions were also received from Jean-Michel Poirson and Patrick Otto, the staff of the FAO headquarters in Rome and a special note of thanks is due to them as also Mr Mitsuo Nakamura, Project Coordinator and to the government of Japan whose generous financial contribution to the project made these guidelines possible.

Guidelines for risk categorization of food and food establishments applicable to ASEAN countries

1. Introduction

In the World Food Summit (FAO, 1996) "the right of everyone to have access to safe and nutritious food" was reaffirmed. This declaration indicates that food safety and quality are basic human rights and therefore efforts have to be made in each country to establish and implement appropriate food safety and quality control systems. It is the responsibility of the national government to protect the health of the population as well as to ensure a sufficient and safe food supply. In order to fulfill this responsibility, the national government should establish a national food control system addressing safety issues throughout the food chain – from the farm to the table – that includes food production, handling, storage, processing and distribution as well as protecting consumers' health and protecting against food fraud. The national food control system once established should include not only a mechanism for hazard prevention but also a mechanism for law enforcement. Any developments in food safety regulations should be based on a consideration of risk and be harmonized with Codex Alimentarius and other relevant international standards.

The *Guidelines for strengthening national food control systems* was published by FAO/WHO in 2003 to help member countries to develop an integrated regulatory system for food control founded on a transparent, risk-based approach with the involvement of all the concerned stakeholders in the food chain. A proper food control infrastructure and regulatory framework with all the essential components should be in place to ensure the effective operation of the food control system. These components include: i) food legislation; ii) food control management; iii) inspection activities; iv) laboratory services; and v) information, education, communication and training. For the effective planning and implementation of food control programmes, the provision of scientific advice is essential (FAO/WHO, 2007).

The development of relevant and enforceable food laws and regulations is an essential component of a food control system. Therefore, food legislation should ensure a high level of health protection and provide a mechanism for food recall in cases of non-compliance. Effective food control systems require policy and operational coordination at the national level. Therefore, in developing food control management it is necessary to establish a clear policy that mandates a responsible authority or a well-defined coordination mechanism. Furthermore, inspection activities are required for the implementation of food laws and regulations.

1.1 Risk-based inspection

Traditionally, regulatory inspection activity is carried out with emphasis on assessing compliance with all applicable regulations. This kind of inspection is done to improve basic sanitation and to upgrade food establishments. However, with traditional inspection the regulator only tries to find existing food hazards and to ensure their correction. This approach emphasizes reactive rather than preventive measures and it is not focused on preventing future violations from occurring. Developing a risk profile is one of the risk management activities and prioritization of risk would assist in designing and implementing regulatory control measures. A risk-based approach has

been suggested as a way of improving the effectiveness of inspection (FAO, 2008). In this modern risk-based approach, the focus of inspection changes from simple compliance verification of a product or food establishment to assessment of the controls put in place in the operation to address food-borne disease risk factors that could put the processor's products at risk. The concept of high-risk category foods found in the recent Law on Food Safety promulgated in 2010 in Viet Nam is in tune with modern risk-based food inspection.

In conducting risk-based inspections, a food inspector should understand the meaning of food-borne disease risk factors that may cause food-borne diseases in consumers if left uncontrolled. In other words, risk factors are the poor conditions, procedures, or practices that result in out-of-control biological, chemical or physical food safety hazards. It is on these factors that the inspector must concentrate during inspections to have a meaningful impact on food safety. Various important food-borne disease risk factors have been identified in many countries. The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993–1997, *Surveillance for food-borne disease outbreaks – United States* (CDC, 2000) identifies the most significant contributing factors to food-borne illnesses. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the Food and Drug Administration (FDA) as "food-borne illness risk factors." (FDA, 2006) The food-borne illness risk factors are:

- food from unsafe sources;
- inadequate cooking;
- improper holding temperatures;
- contaminated equipment; and
- poor personal hygiene.

Other examples of widely identified risk factors for food-borne disease are:

- cross contamination (e.g. from a raw to a ready-to-eat product);
- food handlers' health status;
- water quality; and
- the presence of pests.

By focusing inspections on the occurrence of risk factors that may cause food-borne diseases, the inspector will be able to determine whether the quality and safety management system of the food establishment is adequate. Hence, the inspections are based on risk and will thus fulfill the ultimate purpose of protecting the consumers' health. With this risk-based approach, the inspector will also reduce sampling problems, because product sampling and analysis is done for verification purposes only and no longer as a means to ensure product safety.

1.2 The need for categorizing food businesses on the basis of risk

The types of food that are handled or the processing procedures that are used by food businesses generally vary from one business to another. Therefore, one food business may have different food-borne disease risk factors from the others. For example, a processing plant producing foods that require cooking prior to consumption such as raw chicken or fish will have different risk factors compared to others that produce ready-to-eat products that do not require cooking prior to consumption. Products such as raw chicken or fish are high-risk foods because they naturally carry a high load of pathogenic bacteria. Therefore, if such products are handled, preparation procedures or practices related to cross-contamination and cooking should be a priority during

the inspection. If there are foods that go one or several times through the temperature "danger zone" (4.4–60ºC) at which pathogenic micro-organisms are most likely to proliferate, cooling and holding practices must be reviewed (FAO, 2006).

By identifying whether the foods handled or food preparation procedures used are high-risk, the inspector can focus on those foods or procedures that are most likely to cause food-borne diseases if uncontrolled. In addition, the number of expected consumers is another related risk to be considered because a product having a wide distribution and a large number of consumers is more likely to cause extensive outbreaks of food-borne diseases than one with a reduced market reach. Other risk factors include the structure, layout and condition of the premises, type of consumers such as vulnerable segments of the society, e.g. infants/young children, storage, compliance history of the food business and issues such as implementation of food safety management systems, including control systems in place.

1.3 Purpose of categorizing food businesses on the basis of risk

It is generally not possible for food authorities to inspect all establishments frequently because of factors such as time, cost, lack of human resources; nor is it desirable to inspect all establishments with the same frequency. The purpose of classifying food businesses according to risk category is to allow the regulatory agency responsible for food inspection to prioritize inspections of food businesses on the basis of the degree of risk they pose to the population so that high-risk food businesses may be inspected more frequently than lower risk food businesses.

1.4 The need for and scope of these guidelines

These guidelines have been prepared to provide a framework for risk categorization in ASEAN countries. It is expected that the guidelines will assist the regulatory agencies responsible for food inspection, in ASEAN countries in particular, to prioritize their food inspection activities on the basis of risk.

The guidelines cover: i) general introduction to the determination of food business risk categories; ii) various approaches to categorizing food businesses on the basis of risk; iii) the introduction of a decision tree model for risk categorization that includes high-risk, medium-risk, and low-risk food businesses applicable to ASEAN countries; and iv) the application of the model in risk categorization of businesses dealing with primary and secondary foods. This document does not cover in detail the food risk scenario of individual countries. As the types and conditions of food businesses differ from one country to another, it is suggested that national authorities review the model and examples of categorizing food businesses on the basis of risk shown in this document. A more comphrehensive approach, which is also discussed in this document, can be followed depending on the needs of each country.

These guidelines were prepared for use by national authorities involved in food inspection in ASEAN countries in particular but may be used by other countries also. Food control authorities may use these guidelines for training food inspectors to focus their work using a risk-based approach. This may be used in conjunction with the FAO risk-based food inspection manual.

2. Definitions used in these guidelines

Various definitions in relation to risk-based inspection and food business risk categorization have been developed by regulatory agencies in several countries. These definitions have been used to develop definitions in these guidelines. Annex 1 shows the comparison of existing definitions of risk-food categories from various regulatory agencies. In all definitions, the possibility of pathogenic micro-organisms to grow in foods is the basis for the development of risk-food categories. Furthermore, food-borne disease risk factors were used as the basis for classification of food businesses according to risk category. Pathogenic bacteria, viruses, and parasites are the major causes of food-borne diseases. Examples of pathogenic bacteria associated with food-borne diseases are *Salmonella enteritidis*, *Campylobacter*, *Escherichia coli* O157:H7, *Listeria monocytogenes, Vibrio parahaemolyticus* and *Yersinia enterocolitica*. Noroviruses and Hepatitis A virus as well as *Cryptosporidium parvum, Cyclospora cayetanensis* and *Giardia lamblia* parasites are other micro-organisms associated with food-borne diseases (WHO, 2003).

Food-borne diseases may also be caused by harmful chemicals such as pesticide residues, polycyclic aromatic hydrocarbons (PAH), veterinary drug residues, toxins and heavy metals. Unlike food-borne diseases caused by micro-organisms, the period of time between exposure to chemicals and their effects is usually long. These effects may include cancer, birth defects and damage to the nervous system, the reproductive system and the immune system (WHO, 2003). The presence of chemicals in food is sometimes a result of prohibited chemical additives that are misused by the food businesses, small enterprises in particular, for special purposes such as preserving or colouring. The misuse of prohibited chemical additives in the preparation of food by small-scale enterprises is sometimes found in ASEAN countries. Examples are formalin for preserving meat or fish balls, tofu and wet noodles; borax for firming the texture of chips; rhodamin B for colouring fish paste, red chips and other red coloured foods; and metanil yellow for colouring fresh chicken or other yellow coloured foods such as chickpeas. The recent incidence of deliberate adulteration of milk with melamine in China and its health hazards for children has shown the need to keep a constant vigil against the introduction of newer chemicals in the food chain.

The following definitions are used for the purpose of these guidelines:

Hazard: A biological, chemical or physical agent in food, or a condition of food, with the potential to cause an adverse health effect.

High-risk foods: foods that may contain pathogenic micro-organisms and will support the formation of toxins or the growth of pathogenic micro-organisms and foods that may contain harmful chemicals. Raw meat, fish, oysters, poultry and milk are examples of high-risk foods. Other examples include tofu, meat pies and salami. These foods pose a particularly high risk if they are not processed or cooked adequately.

Medium-risk foods: foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic micro-organisms. Examples are some fruits and vegetables, juices, canned meats, pasteurised milk, dairy products, ice cream, peanut butter, cooked rice and lasagne and milk-based confectionery.

Low-risk foods: foods that are unlikely to contain pathogenic micro-organisms and will not normally support their growth because of food characteristics and foods that are

unlikely to contain harmful chemicals. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionery, alcohol and fats and oils.

Food businesses: undertakings, whether for profit or not, and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of foods.

High-risk food businesses: food businesses dealing with high-risk foods or high-risk production methods where the potential exists to put vulnerable groups (e.g. infants, the elderly, pregnant women and the sick) or large numbers of consumers at serious risk.

Note: In the ASEAN context food businesses that have a history of misusing prohibited chemical additives or adding excessive amounts of food additives in the preparation of food are also categorized as high-risk food businesses.

Medium-risk food businesses: food businesses involving operations with the potential to pose a significant risk to consumers. These establishments are those where high-risk ready-to-eat foods are not prepared but the scale of the business is large. Such foods include: shellfish/fish (cooked and raw), raw meat, cooked meat/poultry and meat/poultry products, milk and milk products, egg and egg products.

Low-risk food businesses: food businesses involving operations where the potential to cause harm to consumers is low.

3. Determination of risk category

3.1 Common flow of food from farm to table in ASEAN countries

Everyone participating in the food chain from the farm to the table has an important role and some responsibility to keep the food safe and ensure its high quality. Depending on the type of food and food business, the chain can be very simple or very complex. An example of a complex food chain is the flow of food from farmers or fishermen to food collectors or consolidators and other intermediaries, distributors, processors, manufacturers, retailers, and finally to consumers. Figure 1 below shows that the common flow of food originates from primary production as primary products or from processors/manufacturers as manufactured products to consumers through alternative links such as distributors, transporters, and wholesalers, retailers and other service sectors such as hospitals, school canteens, hotels and restaurants or even street hawkers. The way the food is handled and the hygienic conditions surrounding the food in the entire chain will greatly influence the safety and quality of the food. Therefore, risk-based inspection should be applied throughout the entire food chain and categorizing food businesses on the basis of risk will help the inspector set priorities for inspection.

One alternative link commonly found in the food flow from the farm to the table in ASEAN countries is the presence of the market as a place for the transaction of both primary and secondary products. Food markets, in particular traditional food markets, are the places where food manufacturers, particularly small and medium enterprises (SMEs) come to purchase their raw materials and to sell their products. A number of food-borne disease outbreaks have been transmitted through food and live animals in markets (WHO, 2006). A common feature of most food markets is the availability of a wide array of foodstuffs including fruits and vegetables, grains and tubers, and foods of animal origin such as meats, poultry, fish, eggs and dairy products, as well as processed and semi-processed foods. These foods are often sold fresh by

local producers at reasonable prices. In addition, many markets offer live animals, such as chickens and ducks, which are often slaughtered and dressed in the market. Food markets also offer an array of street-vended foods, which are an important source of ready-to-eat foods that are accessible and affordable for even the lowest income members of the community. Because food markets link very closely with small- and medium-size food businesses, the hygiene and sanitation conditions of food markets will determine the safety of raw materials and ingredients used by the food manufacturers.

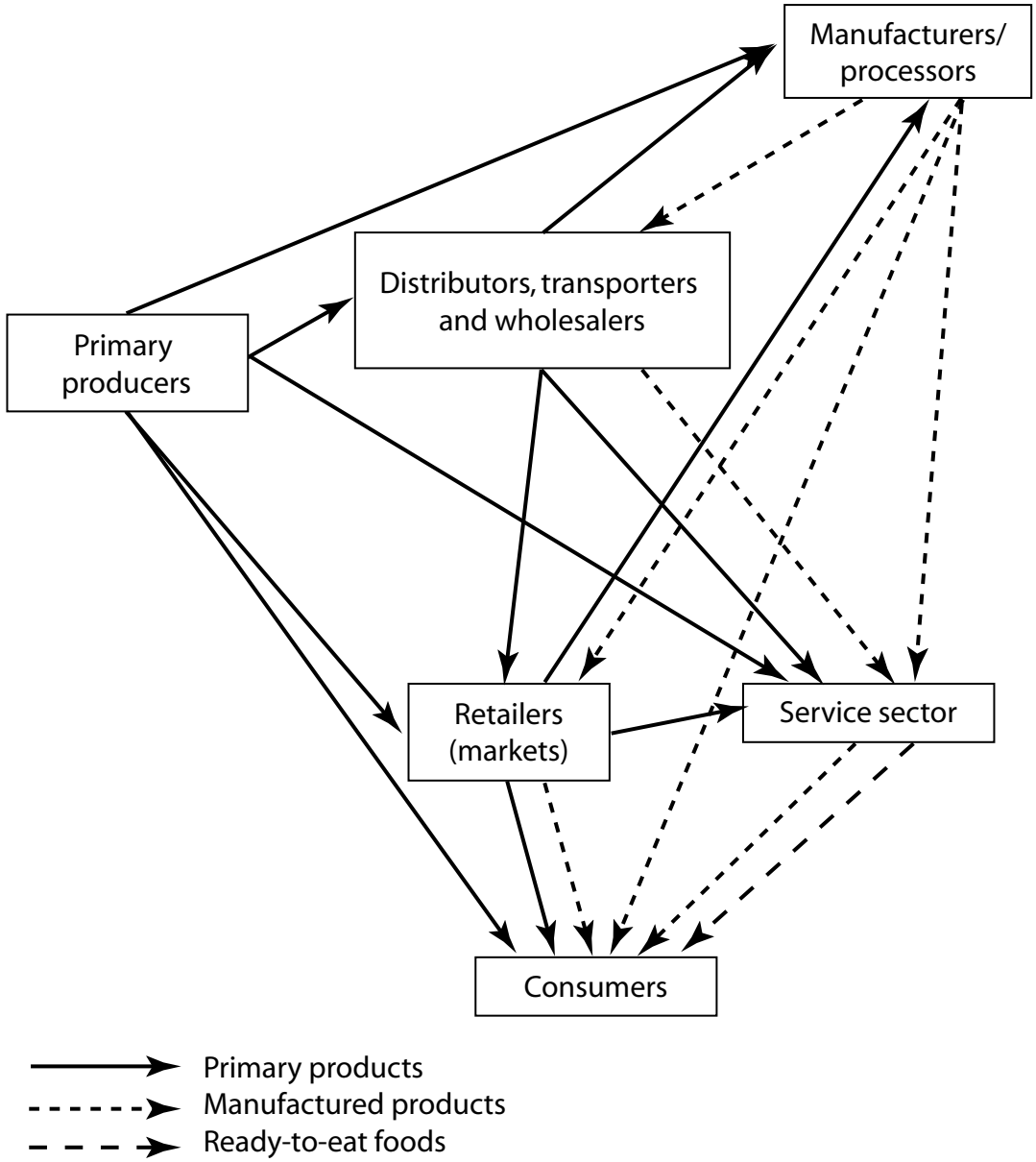


Figure 1. Common flow of food from the primary production site to consumers

3.2 Types of food businesses

As seen in figure 1, food businesses in general may be divided into broad categories as follows (also see box 1 for examples of type of food businesses in ASEAN countries):

- primary producers;
- manufacturers;
- distributors, transporters and wholesalers;
- retailers (markets);
- service sector; and
- manufacturers selling directly to the final consumer.

Primary producers are food businesses at the primary production stage producing raw food for human consumption such as rice farms, fish farms, fruit and vegetable farms, poultry farms, dairy and beef cattle farms and bee-keepers.

Manufacturers/processors are food businesses at the secondary production stage participating in food manufacturing/processing and/or food packaging such as the milk industry, canning industry, bakery industry, jam and jelly manufacturers. Food processors that convert the primary foods to flour, for example, will also be included in this category.

Distributors include pre-retail distribution activities (particularly importation, wholesaling, wholesale storage and multipurpose wholesalers who distribute not only to retailers but also to restaurant owners or consumers).

Retailers are food businesses participating in food retail activity that sell the food to the final consumer such as supermarkets and market stalls commonly found in traditional markets.

Service sector includes all forms of catering, including take-away food stalls and catering facilities in firms, school canteens, restaurants and public institutions.

Manufacturers selling directly to the final consumer include bakers, ice cream manufacturers and on-farm manufacturers such as brown sugar processors.

Box 1. Examples of types of food businesses in ASEAN countries

Primary producers may be medium or large farms, and in the case of ASEAN the primary producers may be small, family-owned farms. Depending on the size of its business, the primary products may be sold and delivered directly or through distributors/wholesalers to food manufacturers, retailers, or restaurants and caterers. In case of small farms, the primary products may be sold to consumers through retailers in traditional markets.

Food manufacturers may be large, medium or small and some even tiny which commonly operate from home.

Retailers selling their products, whether primary or manufactured products, in traditional markets is very common in ASEAN countries. Foods from retailers at traditional markets are commonly sold to SMEs as raw materials for their food businesses.

Small size restaurants and street food vendors that are part of the **service sector** are commonly found in ASEAN countries. They sell foods and beverages prepared and/or sold in streets and other public places for immediate consumption or consumption at a later time without further processing or preparation.

3.3 Risk factors related to food

Food-borne diseases/illnesses occur most frequently because of consumption of food contaminated by microbiological or chemical hazards. Some types of food are more likely to be contaminated with microbial organisms and support their growth. Depending on pH and water activity (a_w) of the food, microbial organisms that grow on it can be pathogenic. Raw perishable foods of animal origin such as meat, fish, milk, poultry and eggs with pH of more than 4.5 and a_w of more than 0.90 are foods that easily become contaminated with pathogenic bacteria and cause food-borne diseases. Therefore, these perishable foods can be categorized as high-risk foods and will remain like this if there is no treatment or process applied to reduce the a_w and pH and to keep the temperature of the food low enough to prevent microbial growth. High-risk foods associated with microbiological hazards can receive heat treatment or undergo other methods of processing to reduce microbial pathogens and thus become products with a reduced risk.

In addition to microbiological contaminants, which are generally known to be a high risk factor in causing acute food-borne diseases all over the world, food-borne trematodes as well as chemical contaminants common in ASEAN countries can also cause acute and chronic diseases. Chemical hazards present in food may arise from a diversity of sources, including industrial pollution of the environment (e.g. lead, mercury, cadmium, arsenic, polychlorinated biphenyls and radionuclides), improper use of agrochemicals (e.g. pesticides, fertilizers and drugs used in animal husbandry), and natural biological sources (e.g. plant toxins, marine and shellfish toxins and mycotoxins). Chemical hazards may also be present in food because of misuse of prohibited chemical additives during the preparation of food or even wilful adulteration.Therefore, foods that are likely to contain harmful chemicals, including prohibited chemical additives, are categorized as high-risk foods.

Based on the possibility of the presence of microbiological and chemical hazards in food, these guidelines divide foods into three categories on the basis of risk factors related to food, namely, high-risk foods, medium-risk foods, and low-risk foods as described previously.

Categorizing food on the basis of risk sometime requires a complex approach because of the diversity of products and the treatment given to the products. An example is the determination of the level of risk in fish and fishery products adapted from Huss *et al*. (2003) as shown in annex 2. The risk level of fish and fishery products is determined on the basis of characteristics that increase risk (no terminal heat application, bad safety record, and no critical control point identified for a hazard) and events that reasonably are likely to occur and that will increase risk (harmful contamination or recontamination, abuse of handling-time-temperature and growth or accumulation of hazards). Based on these criteria, molluscan shellfish which are live and eaten raw are categorized as a high-risk food. Frozen freshwater finfish can be categorized as a low-risk food because it has only a minimal potential to harm consumers. Fermented fish with salt content of less than 8 percent is categorized as a high-risk food, whereas semipreserved fish with salt content of more than 6 percent, pH below 5 and with added preservatives such as benzoate and sorbate can be categorized as a medium-risk food (FAO, 2009).

3.4 Risk factors related to food businesses

Food-borne disease risk factors associated with food businesses are also important and should be considered before categorizing food businesses on the basis of risk. These are mostly related to

handling or processing practices commonly applied in primary or secondary food operations. Attention should be given to those practices that may result in food-borne diseases in consumers if left uncontrolled. Establishments handling uncooked and unpackaged foods, for example, have a greater potential for contaminating these foods than if the foods are prepackaged. Compliance with handling and processing requirements is a very important factor that will influence food business risk categorization. Annex 3 shows how compliance and product characteristics will determine the priority of establishments for categorization and inspection. For example, if compliance in fish handling is high and fresh fish is used for processing and direct consumption after cooking then the priority for inspection is low and this type of fish handling can be categorized as a low-risk food business. On the other hand, if compliance in a retail fish market is low and this market sells a variety of fresh and processed products some of which are consumed without further processing then this type of market can be categorized as a high-risk food business (FAO, 2009).

The following are examples of some relevant food-borne disease risk factors associated with the relatively simple primary food operations of a typical fruit packing station (FAO, 2008):

- incoming fruit contaminated with pesticide residues and/or enteric pathogens;
- contaminated wash water;
- poor design of facilities: toilets open into packing area, packing station open to dust, poor drainage of floors, floors and/or walls are cracked or absorb water;
- presence of pests or other animals;
- sick employees or staff;
- lack of personal hygiene (e.g. dirty clothes, shoes), failure to wash hands or improper washing;
- dirty boxes/crates; and
- recontamination during transportation to market.

Food-borne disease risk factors associated with types of foods or food processing operations may be common to many countries or unique to a particular country. Various important food-borne disease risk factors have been identified in many countries and thus can be considered “universal”. Some examples of widely identified risk factors for food-borne disease (FAO, 2008) are:

- cross contamination (e.g. from a raw to a ready-to-eat product);
- food from unsafe sources;
- inadequate cooking;
- improper holding temperatures;
- contaminated equipment;
- poor personal hygiene;
- food handlers’ health status;
- water quality; and
- presence of pests.

The origin, nature or traditional processing and handling methods of specific food products in one country may differ from those in another country. This will determine the level of associated food-borne disease risk factors in that country. Therefore, it is important that national food control authorities conduct epidemiological surveillance to determine food-borne disease risk factors by linking the incidence of food-borne diseases with their origin through investigation of outbreaks. For example, it has been recognized recently that fish-borne zoonotic trematodes (FZTs) can cause liver and intestinal infections. Chronic infections can cause cancer of the bile

duct and serious pathological changes in the heart, brain and spinal cord. The most important species, with respect to the number of people infected, belong to the genera *Clonorchis* and *Ophisthorchis* (liver flukes), *Paragonimus* (lung flukes), and to a lesser extent *Heterophyes* and *Echinochasmus* (intestinal flukes) (FAO, 2009). Fish contaminated by these trematodes will indeed pose a health risk to people that commonly consume raw, inadequately cooked, or pickled fish. A public health problem associated with consumption of fish contaminated by FZT is frequently found in ASEAN countries such as Viet Nam, Lao PDR, Thailand, Cambodia. FZTs have been detected recently in freshwater fish in Lao PDR (Rim *et al*., 2008), Cambodia (Touch *et al*., 2009), and Viet Nam (Phan *et al*., 2010)

4. Food business risk categorization

4.1 Approaches to categorizing food businesses on the basis of risk

Risk categorization is a complex process that may be influenced by a number of factors. Therefore, different approaches have been used in classifying food businesses on the basis of risk category. In developing a risk categorization model for these guidelines, three approaches, namely: (i) use of risk categorization model (RCM) questionnaires (FPTCFSP, Canada, 2007); (ii) use of a scoring system (ANZFA, 2000); and (iii) use of a decision tree model (DHA, Australia, 2007) were compared. Details of these approaches and a summary of the results of the comparison are provided in annex 4. After comparing these three approaches the approach using a decision tree model was selected since it is simple and may be applicable for ASEAN countries. A decision tree is a decision support tool for helping to choose between different courses of action. It is a set of questions for determining the options and arriving at a decision.

4.2 Approach using a decision tree model

In this approach there are three key questions that have to be answered sequentially leading to a decision on food business risk categorization. Four food business risk categories, namely, Priority 1, 2, 3, and 4, will be determined, and according to the definitions, Priority 1 and 2 can be classified as high-risk food businesses, Priority 3 as medium-risk food businesses, and Priority 4 as low-risk food businesses. Although it looks simple, there are many factors that need to be considered in order to use this decision tree model correctly, and more questions may also be needed in addition to the three key questions referred to above.

It is necessary to assess or inspect the food establishments before its risk category can be determined. In some countries these practices may be difficult to implement because of various factors such as time, cost, and inadequacy of human resources. Therefore, there is a need to develop guidelines for food business risk categorization that are simple and can be applied easily without too many resources. Once food businesses have been classified according to risk category, the authority in a country can prioritize inspections of food businesses on the basis of the level of risk. Higher-risk food businesses should be inspected more often than lower-risk food businesses.

The decision tree model used to categorize food businesses on the basis of risk applicable to ASEAN countries was introduced along with other different approaches in categorizing food businesses on the basis of risk at the FAO workshop "Final strategy workshop" held in Hanoi, Viet Nam on 25 and 26 May 2011 under the project "Enhancing food safety by strengthening food inspection systems in ASEAN countries (GCP/RAS/222/JPN)." The recommendations taken from the group discussions are as follows:

- to categorize food and food businesses that are of importance to this region such as meat and meat products, fish and fishery products, milk and milk products, and fresh fruit and vegetables eaten raw;
- to categorize food businesses such as street food vendors, catering establishments and restaurants, large, small and medium food processing enterprises; and
- to develop risk categorization using the decision tree model.

4.3 Application of a decision tree model – the sequence of questions

In applying this model the following simple questions have been prepared and in determining food business risk category these questions should be answered sequentially. See figures 2 to 4 for a detailed application of the decision tree model in these guidelines.

4.3.1 Questions used in the decision tree model – primary foods (figure 2)

Question 1 (QP1):
Could a food safety hazard realistically be present in the primary product that could be transferred to a product derived from the primary product?

Question 2 (QP2):
Is there a practical hazard control action, demonstrated to be effective, that can be implemented on the farm?

Question 3 (QP3):
Is an action on the farm critical to the safety of the product at the time of consumption?

Question 4 (QP4) (additional question):
Is it possible that prohibited chemical additives such as formalin or borax have been added to the primary products?

Note:
This additional question is raised because food businesses, small-scale or household entreprises in particular, sometimes misuse prohibited chemical additives such as formalin or borax as preservatives in order to prolong the freshness of the primary product. The food businesses which are assumed to misuse these chemicals in the primary product are categorized as high-risk food businesses. Some examples of foods frequently found to be treated with prohibited chemical additives in ASEAN countries are presented in box 2.

Box 2. Examples of high-risk foods and risk factors important for those foods in ASEAN countries*

Cambodia: Meat and meat products including fish – borax; raw vegetables – *Salmonella*, *E coli*; noodles – food additives; chili sauce – colour (Sudan red).

Indonesia: Street foods – non-permitted colours; tofu and noodles – prohibited chemical additives such as formalin; nutmeg – aflatoxins.

Lao PDR: Seafoods, milk products vegetables and fruits – pesticide residues, non-permitted food additives.

Malaysia: Vegetables – pesticide residues; seafood – microbial contaminants; peanuts – aflatoxins; noodles – borax, colours.

Philippines: Prawn and meat – drug residues.

Thailand: Fishery products – antibiotic/veterinary drug residues; fruits and vegetables – pesticide residues, microbial contaminants.

Viet Nam: Meat products and mineral water – microbial contaminants; fruits and vegetables – pesticide residues.

* Identified by participants of some of the ASEAN countries during the FAO/WHO regional workshop on the use of science throughout the food chain for safe foods held in Bali, Indonesia, 18–20 November 2010.

4.3.2 Questions used in the decision tree model – secondary foods (figures 3 and 4)

Question 1 (QS1):
Could the business sector introduce a hazard to the food, or fail to control the level of a hazard that could be present?

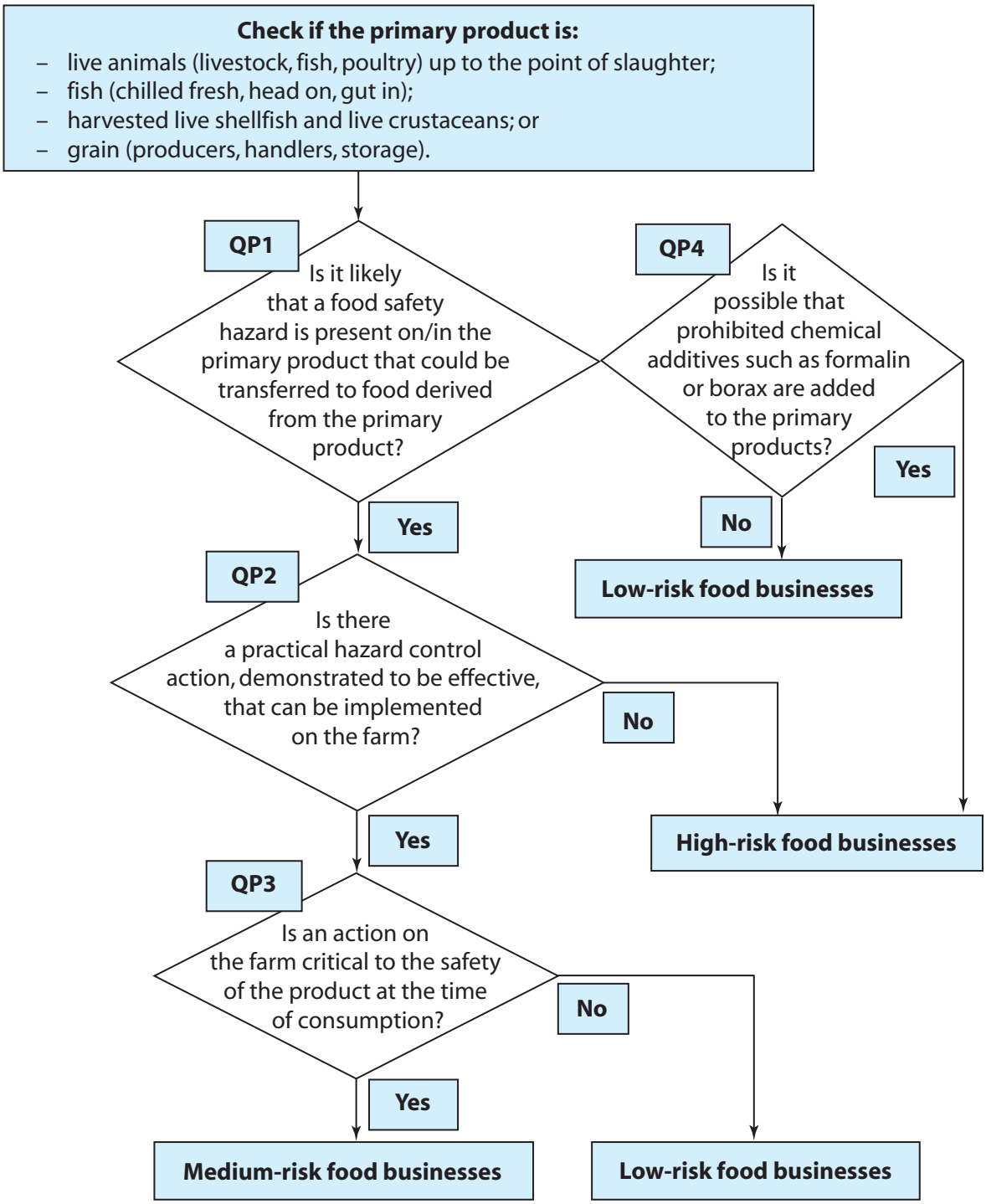
Note:
Hazards that may be introduced to the food, for example, as prohibited chemical additives such as formalin, borax, rhodamin B and metanil yellow. Excessive amounts of food additives added to food are considered as hazards too. Box 2 shows foods in ASEAN countries that may contain prohibited chemical additives or excessive amounts of food additives.

Question 2 (QS2):
Does the business sector need to take action(s) to eliminate, reduce or control a hazard critical to the safety of product when it is consumed?

Question 3 (QS3):
Will/could the presence of the hazard lead to severe public health consequences?

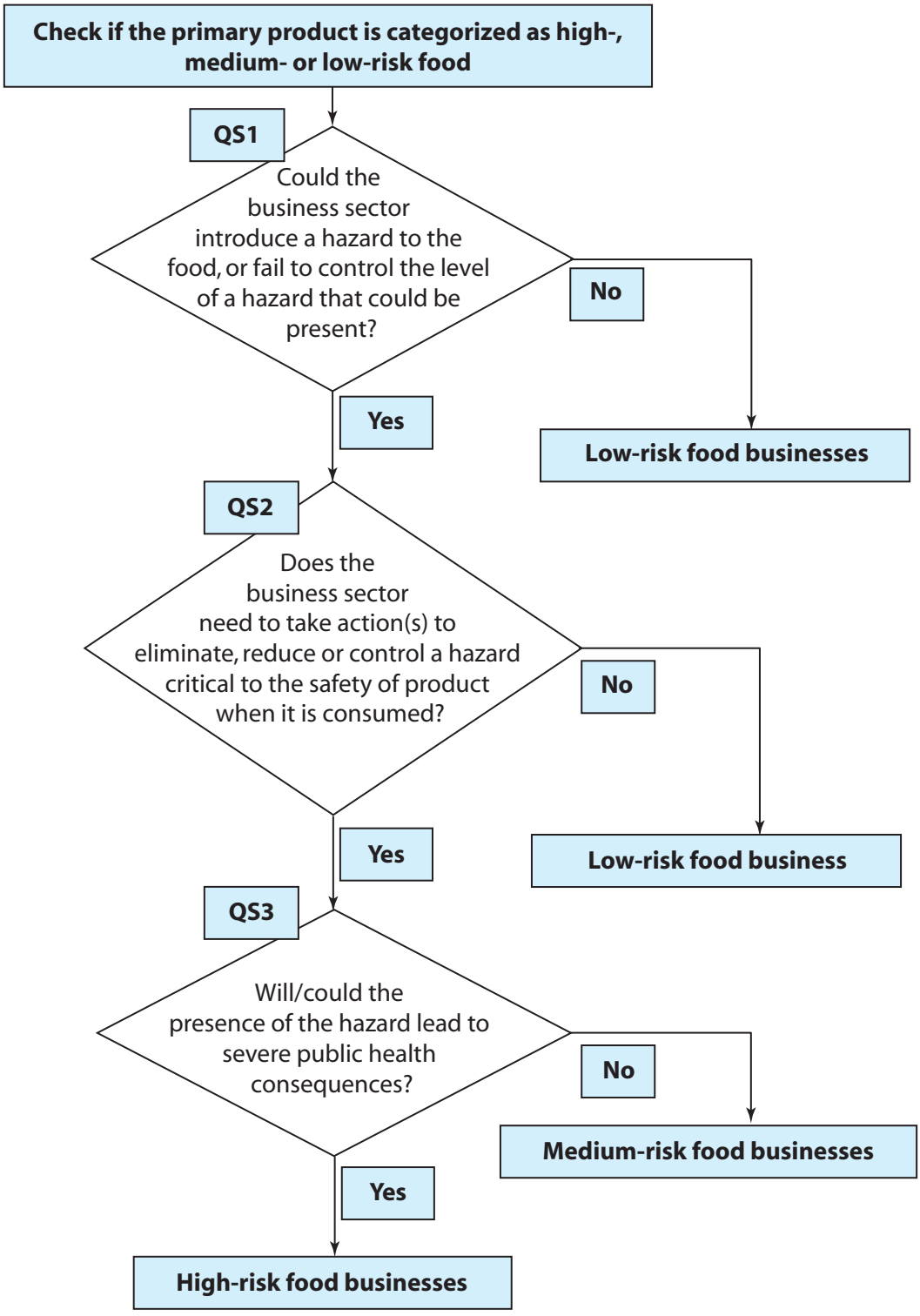
4.4 Application of the decision tree model – tabulating the results

This decision tree model has been applied in risk categorization of businesses dealing with primary and secondary foods as explained below. In applying the decision tree model, first, a table with the following columns is prepared: businesses dealing with primary and secondary foods; main activity (of the food business); decision tree questions (four questions QP1, QP2, QP3, and QP4 in the case of businesses dealing with primary foods and three questions QP1, QP2, and QP3, in the case of businesses dealing with secondary foods, and risk category (high, medium, and low). Second, questions in figures 2 to 4 should be answered sequentially according



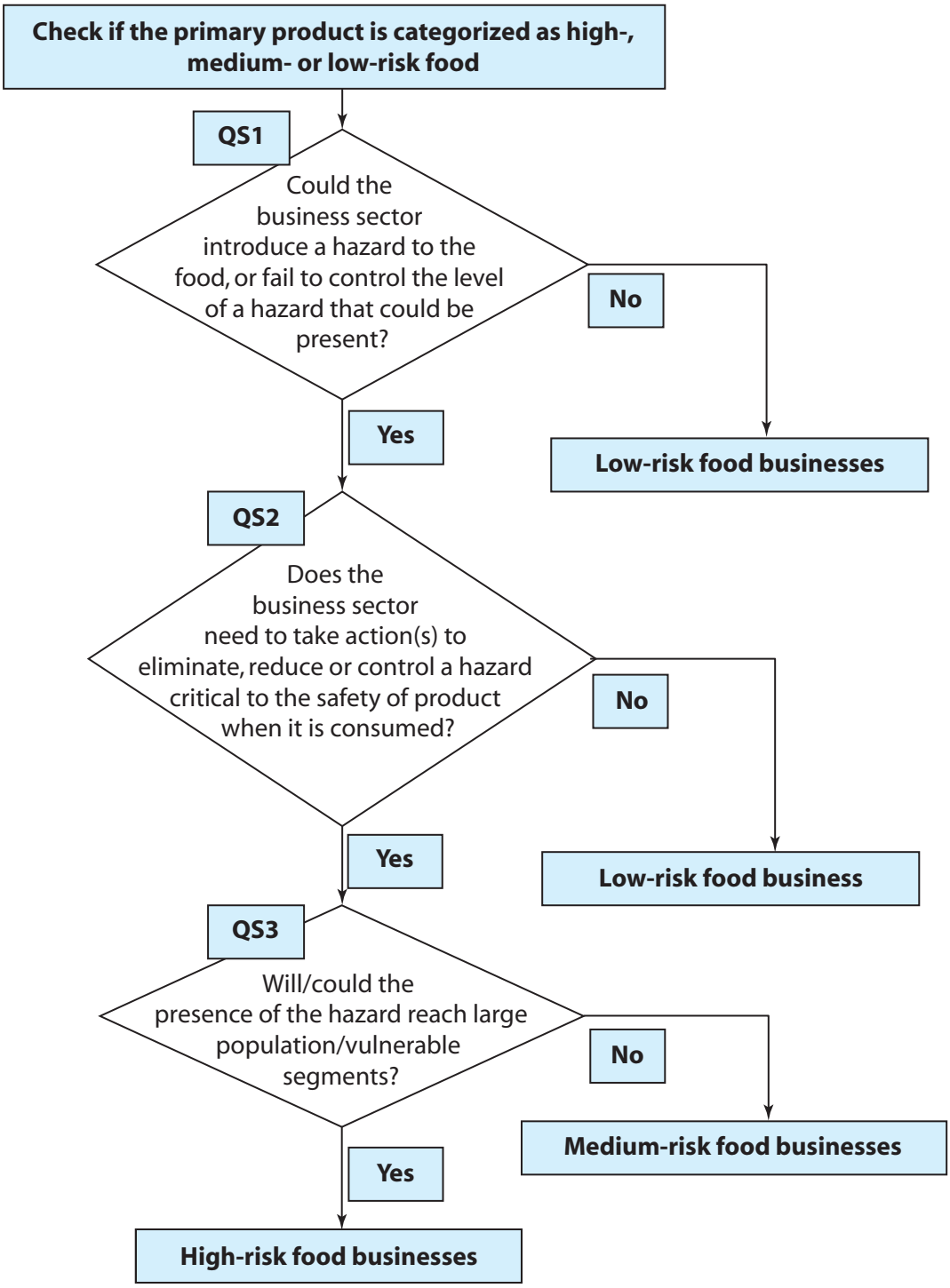
Note: QP = Question in decision tree for businesses dealing with primary foods

Figure 2. Decision tree for risk categorization in *businesses dealing with primary foods*



Note: QS = Question in decision tree for businesses dealing with secondary foods

Figure 3. Decision tree for risk categorization of businesses dealing with secondary foods (in particular, manufacturers and retailers)



Note: QP = Question in decision tree for businesses dealing with secondary foods

Figure 4. Decision tree for risk categorization in *businesses dealing with secondary foods* (in particular, the food service sector)

to the flowchart given in the figures. Each answer ('yes' or 'no') is placed in the appropriate column in the table and the risk category (either high, medium or low) can be determined according to the answers obtained.

Table 1 shows the results of risk categorization of businesses dealing with primary foods using a decision tree model with four questions (QP1, QP2, QP3, and QP4). Tables 2 and 3 show the results of risk categorization of businesses dealing with secondary foods using a decision tree model with three questions (QP1, QP2, and QP3).

It is realized that the conditions of food businesses in any one ASEAN country may differ from those in another country. The types of businesses dealing with primary and secondary foods may also differ. Therefore, it is suggested that the results of food businesses risk categorization as shown in tables 1 and 2 may be reviewed and revised if needed according to the actual conditions in each ASEAN country. Each ASEAN country may also add to or delete from the list of types of businesses dealing with primary or secondary foods according to the food businesses present in the country.

Basically, these guidelines are designed as a means of general observation in categorizing food businesses on the basis of risk. Therefore, if further assessment is required, for example when the frequency of inspection has to be determined, the authority in each country may prepare additional questions based on specific risk factors such as compliance history related to Good Agricultural Practices (GAP) or Good Manufacturing Practices (GMP) or the implementation of a food safety management system and its certifications.

Table 1. Risk categorization in *businesses dealing with primary foods*

Businesses dealing with primary foods	Main activity	QP1	QP2	QP3	QP4	Risk-category		
						High	Medium	Low
Beef cattle	Animal husbandry, slaughtering, fresh handling	yes	no			X		
Piggery	Animal husbandry, slaughtering, fresh handling	yes	no			X		
Dairy farm, small-scale	Animal husbandry, milking	yes	no			X		
Poultry farm, small-scale	Farming, butchering, fresh handling	yes	no		yes	X		
Freswater fish farm	Farming, fresh handling	yes	yes	yes			X	
Captured fish	Catching, fresh handling	yes	no		yes	X		
Vegetable farm	Farming, harvesting, packaging, fresh handling	yes	yes	yes			X	
Rice farm	Farming, harvesting, threshing, drying	no						X

Note: QP1, QP2, QP3, and QP4 = questions in decision tree for primary food business sector.

Table 2. Risk categorization in *businesses dealing with secondary foods*

Businesses dealing with secondary foods	Main activity	QS1	QS2	QS3	Risk-category		
					High	Medium	Low
Manufacturer							
Dairy products							
• Pasteurized milk	HTST processing, aseptic packaging	yes	yes	yes	×		
• Sterilized milk	UHT processing, aseptic packaging	yes	yes	yes	×		
• Sweet condensed milk	Formulating, heat processing, packaging	yes	yes	no		×	
• Milk powder	Pasteurization, spray drying, packaging	yes	yes	no		×	
• Ice cream	Formulation, freezing, packaging	yes	yes	yes	×		
• Yogurt	Formulation, fermentation, packaging	yes	yes	yes	×		
• Cheese	Curdling, fermentation, packaging	yes	yes	yes	×		
Fats and oils and fat emulsions							
• Cooking oil	Oil extraction and refining, bottling	yes	no				×
• Butter	Fat separation, packaging	yes	no				×
• Margarine	Hydrogenation, packaging	yes	no				×
Edible ices, including sherbet and sorbet							
• Popsickle	Formulation, freezing	yes	yes	no		×	
Fruits and vegetables							
• Dried fruit	Cutting, sugar mixing, drying, packaging	yes	no				×
• Fruit in vinegar, oil, or brine	Cutting, deeping in vinegar, oil or brine	yes	no				×
• Canned or bottled (pasteurized) fruit	Cutting, blanching, filling in can or bottle, pasteurization	yes	yes	no		×	
• Jams, jellies, marmalades	Cutting, pressing, sugaring, cooking, setting, packaging	yes	no				×
• Candied fruit	Formulation with sugar, dehydration	yes	no				×
• Pickled vegetable	Cutting, brining, fermentation	yes	no				×
Confectionary							
• Cocoa and chocolate products	Grinding, formulating, refining, counching, moulding, packaging	yes	yes	no		×	
• Chocolate with nuts	Grinding, formulating, refining, counching, moulding, packaging	yes	yes	yes	×		
• Candy	Formulating, heating, moulding, packaging	yes	no				×
• Chewing gum	Formulating, heating, moulding, packaging	yes	no				×
Cereals and cereal products							
• Rice	Drying, milling, packaging	yes	no				×
• Wheat flour	Grinding, separating, packaging	yes	no				×

Table 2. *(continued)*

Businesses dealing with secondary foods	Main activity	QS1	QS2	QS3	Risk-category		
					High	Medium	Low
• Starch	Grinding, separating, drying, grinding, packaging	yes	no				×
• Pasta	Formulating, extruding, drying, packaging	yes	no				×
• Breakfast cereals	Formulating, extruding, drying, packaging	yes	no				×
• Noodle	Formulating, extruding, drying, packaging	yes	no				×
• Other flour	Drying, milling, packaging	yes	no				×
Bakery wares							
• Breads and rolls	Formulating, dough making, fermenting, baking, packaging	yes	no				×
• Breads and rolls, frozen dough	Formulating, dough making, fermenting, freezing, packaging	yes	yes	no		×	
• Bakery products with fillings: meat, milk, poultry, cream, other perishable foods	Formulating, dough making, fermenting, baking, packaging	yes	yes	yes	×		
• Biscuits and cookies	Formulating, moulding, baking, packaging	yes	no				×
• Cookies with nuts	Formulating, moulding, baking, packaging	yes	yes	yes	×		
• Cakes	Formulating, moulding, baking, coating (cream, butter etc.), packaging	yes	yes	no		×	
Meat and meat products							
• Frozen meat	Cutting, fresh handling, packaging, freezing	yes	yes	yes	×		
• Canned meat, ready-to-eat	Cutting, curing, cooking, packaging, sterilizing	yes	yes	yes	×		
• Sausage, ready for cooking	Formulating, grinding, filling, heating or smoking, packaging, freezing	yes	yes	no		×	
• Dried meat, ready for cooking	Cutting, formulating seasoning, drying, packaging	yes	yes	no		×	
• Meat ball, ready for cooking	Formulating, grinding, cooking, packaging, freezing	yes	yes	no		×	
• Frozen chicken, ready for cooking	Cutting, fresh handling, packaging, freezing	yes	yes	yes	×		
• Chicken nugget	Formulating, coating cooking, packaging, freezing	yes	yes	no		×	
Fish and fishery products							
• Frozen fish	Fresh packaging, freezing	yes	yes	yes	×		
• Smoked fish, ready for cooking	Fresh handling, smoking, packaging, freezing	yes	yes	no		×	
• Salted fish	Fresh handling, salting, drying, packaging	yes	no				×
• Canned fish, ready-to-eat	Cutting, cooking, packaging, sterilizing	yes	yes	yes	×		

Table 2. *(continued)*

Businesses dealing with secondary foods	Main activity	QS1	QS2	QS3	Risk-category		
					High	Medium	Low
Eggs and egg products							
• Salted egg, ready-to-eat	Cleaning, salting, boiling	yes	yes	no		×	
• Salted egg, ready for cooking	Cleaning, salting	yes	no				×
Sweeteners							
• Cane sugar	Extracting, filtrating, refining, crystalizing, drying, packaging	yes	no				×
• High fructose syrup	Extracting, filtrating, trating with enzyme, separating, packaging	yes	no				×
• Honey	Collecting, separating, packaging	yes	yes	no			×
• Coconut sugar	Collecting, cooking, moulding, packaging	yes	no				×
Salts, spices, soups, sauces, salads, protein products							
• Fermented soy sauce	Fermenting, grinding, pressing, filtrating, formulating, cooking, packaging	yes	no				×
• Salad dressing, ready-to-eat	Formulating, heating, packaging	yes	yes	no		×	
• Dried soup	Formulating, cooking, drying, packaging	yes	yes	no		×	
• Dry seasoning, ready for cooking	Formulating, cooking, drying, packaging	yes	no				×
Foodstuffs intended for particular nutritional uses							
• Infant formula	Drying, formulating, packaging	yes	yes	yes	×		
• Baby food	Drying, formulating, packaging	yes	yes	yes	×		
Beverages, excluding dairy products							
• Drinking waters	Filtrating, inactivating microbes, bottling	yes	yes	yes	×		
• Paseurized fruit and vegetable juices	Extracting, filtering, pasteurizing, cooling	yes	yes	no		×	
• Sterilized friut and vegetable juices	Extracting, filtering, sterilizing, aseptic packaging	yes	yes	no		×	
• Fresh fruit juice/ sugarcane juice	Cutting, extracting, filtering, pasteurizing, aseptic packaging	yes	yes	no		×	
• Carbonated beverages	Filtering, carbonating, bottling or canning	yes	yes	no		×	
• Alcoholic beverages	Extracting, brewing, filtrating, bottling or canning	yes	no				×
Distributor							
Prepackaged foods	Collecting, distributing	no					×
Fruit and vegetables	Formulating, processing, serving						
Meat and meat products	Formulating, processing, serving	yes	yes	yes	×		

Table 2. *(continued)*

Businesses dealing with secondary foods	Main activity	QS1	QS2	QS3	Risk-category		
					High	Medium	Low
Milk and milk products	Formulating, processing, serving	yes	yes	yes	×		
Retailer							
Prepackaged foods	Selling	no					×
Bakery	Formulating, dough making, fermenting, baking, serving	yes	no				×
• Bakery products with fillings: meat, milk, poultry, cream, other perishable foods	Formulating, dough making, fermenting, baking, serving	yes	yes	no		×	
Ice cream	Formulation, freezing, serving	yes	yes	yes	×		
Confectionery	Formulating, processing, serving	yes	no				×
Confectionary with added nuts	Formulating, processing, serving	yes	yes	no		×	
Fruit and vegetables, raw	Collecting, selling	yes	no				×
Fruit and vegetables	Formulating, processing, serving	yes	yes	no		×	
Refill drinking water	Filtrating, inactivating microbes, selling	yes	yes	yes	×		
Ready-to-eat food stalls	Collecting, selling	yes	yes	yes	×		
Raw meat stall	Collecting, selling	yes	yes	no		×	
Fresh fish stall	Collecting, selling	yes	yes	no		×	
Food service							
Hotels	Preparing various ready-to-eat foods	yes	yes	yes	×		
Restaurants	Preparing various ready-to-eat foods	yes	yes	yes	×		
Caterers	Preparing various ready-to-eat foods	yes	yes	yes	×		
School canteens	Preparing various ready-to-eat foods	yes	yes	yes	×		
Street food vendors	Preparing various ready-to-eat foods	yes	yes	yes	×		
Manufacturers selling directly to the final consumer							
Breads and rolls	Formulating, dough making, fermenting, baking, packaging	yes	no				×
Bakery products with fillings: meat, milk, poultry, cream, other perishable foods	Formulating, dough making, fermenting, baking, packaging	yes	yes	yes	×		
Ice cream	Formulation, freezing, packaging	yes	yes	yes	×		
Coconut sugar	Collecting, cooking, moulding, packaging	yes	no				×

Note: QP1, QP2, and QP3 = questions in decision tree for secondary food business sector.

5. Frequency of inspection

The frequency of inspection should be based primarily on the risk category of the particular food business. Principally, food businesses categorized as higher-risk businesses should be inspected more frequently than those categorized as lower-risk businesses. However, the frequency of inspection may be reduced or increased depending on whether or not compliance and checks are satisfactory during the inspection visit. Some criteria that should be considered for example are risk category of the business, past compliance record, prerequisite activities and application of HACCP. A matrix to assign a priority to the establishment has been suggested (FAO, 2008).

1. Top inspection priority – when the establishment compliance profile is low and the product risk profile is high.
2. Medium inspection priority – when the establishment compliance profile is low and the product risk profile is low. Also, when the establishment compliance profile is high and the product risk profile is high.
3. Low inspection priority – When the establishment compliance profile is high and the product risk profile is low.

The suggested frequencies of inspection for high-risk, medium-risk, and low-risk food businesses are given in table 3. The frequency of inspection as suggested here may vary depend on the inspection results from the previous visit to the food business. Several factors will determine the need for frequent inspection such as compliance history to GAP or GMP and the performance of food businesses in implementing food safety management systems and their certification. For example, it may be enough to inspect a high-risk food business once every 12 months, however, it may need more inspections (every 3 months) if noncompliance inspection items have not been resolved or improved.

Table 3. Suggested frequencies of inspection

Risk Category	Frequency of Inspection (every × months)*		
	Starting point	Maximum	Minimum
High-risk food businesses	6	3	12
Medium-risk food businesses	12	6	18
Low-risk food businesses	18	12	24

* Based on inspection findings of factors such as compliance history to GAP or GMP and the performance in implementing food safety management system.

6. Summary

Classifying food businesses according to risk category is an important step in allowing the regulatory agency responsible for food inspection to prioritize inspections of food businesses on the basis of the potential risk to the population if the safety of food is not ensured. Risk factors related to both food and food businesses are important factors that will determine the food business risk category. Although microbiological contaminants have been known to be a high risk factor in causing food-borne diseases all over the world, the fish-borne zoonotic trematodes as well as chemical contaminants common to many ASEAN countries are also considered high risk factors.

Risk categorization of food businesses is a complex process that may be influenced by a number of factors. Therefore, different approaches have been used in classifying food businesses on the basis of risk category, such as: (i) an approach using risk categorization model questionnaires; (ii) an approach using a scoring system; and (iii) an approach using a decision tree model.

Food business risk categorization applicable to ASEAN countries using a simple desicion tree model is suggested in these guidelines so it can be applied readily in ASEAN countries. These guidelines are designed as a general approach to categorizing food businesses on the basis of risk. If a more comphrehensive approach to food business risk categorization is needed additional questions based on specific risk factors may be added.

A decision tree model has been applied in categorizing both businesses dealing with primary and secondary foods, including high-risk, medium-risk, and low-risk food businesses. However, the national authority in each ASEAN country may review and revise the categorization procedures if needed, according to the food business conditions existing in the country concerned.

The risk category of a particular food business will determine the frequency of food inspection with food businesses categorized as high risk businesses to be inspected more frequently than those categorized as low risk businesses.

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ANNEXES

Annex 1. Comparison of existing definitions from various agencies

Federal Provincial Territorial Committee on Food Safety Policy, Canada (2007)	FSAI, Ireland, 2001, 2006	Department of Health and Ageing, Australia (2007)	ANZFA, 2000
Classification of foods based on risk category			
High-risk foods: Foods or groups of foods that are frequently the cause of microbial food-borne illnesses. Foods may contain and support the growth of micro-organisms and are intended for consumption with or without further treatment to destroy micro-organisms.	**High-risk foods:** Foods that support the growth of harmful and potentially harmful micro-organisms and that will not be subjected to any further heat treatment or processing that would remove or destroy such micro-organisms prior to consumption. Ready-to-eat foods are high risk foods.	**High-risk foods:** foods that may contain pathogenic micro-organisms and will support formation of toxins or growth of pathogenic micro-organisms (*see* "potentially hazardous foods" *q.v.*). Examples include raw meat, poultry and fish, unpasteurized milk, oysters, tofu, fresh filled pasta, meat pies, frankfurts, cooked rice and lasagne.	**High-risk foods:** foods that may contain pathogenic micro-organisms and will support formation of toxins or growth of pathogenic micro-organisms. Examples are raw meat, fish, oysters, poultry and milk. Other examples include tofu, fresh filled pasta, meat pies, frankfurters, salami, cooked rice and lasagne (these foods pose a particularly high risk if they are not processed or cooked adequately).
Medium-risk foods: Foods or groups of foods that are less frequently the cause of microbial food-borne illnesses. Foods may contain micro-organisms but will not normally support their growth because of food characteristics or are unlikely to contain pathogenic micro-organisms because of their processing, but may support their growth.		**Medium-risk foods:** those that may contain harmful natural toxins or chemicals introduced at steps earlier in the food supply chain, or that may contain pathogenic micro-organisms but will not normally support the formation of toxins or growth of pathogenic micro-organisms because of food characteristics; or are unlikely to contain pathogenic micro-organisms because of food type or processing but may support the formation of toxins or growth of pathogenic micro-organisms. Examples include fresh fruits and vegetables, orange juice, pasteurized milk, canned foods, salami, vegetables stored in oil, peanut butter, shell eggs, milk-based confectionary and hard-frozen ice cream.	**Medium-risk foods:** foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing but may support formation of toxins or growth of pathogenic micro-organisms. Examples are fruits and vegetables, orange juice, canned meats, pasteurised milk, dairy products, ice cream, peanut butter and milk-based confectionery.

Low-risk foods: Foods or groups of foods that are seldom the cause of food-borne illnesses. Foods are unlikely to contain pathogenic micro-organisms or will not support the growth of pathogenic micro-organisms because of food characteristics.		**Low-risk foods:** those that are unlikely to contain pathogenic organisms and will not support their growth (*see also* "potentially hazardous foods") and are unlikely to contain harmful chemicals or foreign matter. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionary, dried fruit, alcohol and fats and oils.	**Low-risk foods:** foods that are unlikely to contain pathogenic micro-organisms and will not normally support their growth because of food characteristics. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionery, alcohol and fats and oils.
Classification of food business based on risk category		Priority classifications for primary producers and priority classifications for food business sector*	Priority classification
	Food business: any undertaking, whether for profit or not, and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.		
High-risk establishment: An establishment that has a high likelihood of a food-borne illness outbreak occurring, based on the evaluation of the eight risk factors provided in the risk categorization questionnaire.	**High-risk business:** food business operations dealing with high-risk foods/production methods and/or where the potential exists to put vulnerable groups (infants, the frail, elderly, pregnant women and the sick) or large numbers of consumers at serious risk.	**Priority 1** **Priority 2**	High risk business score: 65 or more
Moderate-risk establishment: An establishment that has a moderate likelihood of of a food-borne illness outbreak occurring, based on the evaluation of the eight risk factors provided in the risk categorization questionnaire.	**Medium-risk business:** businesses involving operations with the potential to pose a significant risk to consumers.	**Priority 3**	Medium risk business score: 40–64

Low-risk establishment: An establishment that has a low likelihood of a food-borne illness outbreak occurring, based on the evaluation of the eight risk factors provided in the risk categorization questionnaire.	**Low-risk business:** business where the potential to cause harm to consumers is low.	**Priority 4**	Low risk business score: 39 or less

* **Priority classifications for primary producers:**

Priority 1: A primary producer whose product could contain hazards which, if not controlled by the primary producer, could lead to a serious or severe public health risk in foods derived from that product (e.g. oysters contaminated with Hepatitis A virus).

Priority 2: A primary producer whose product could contain hazards which, if not controlled by the primary producer, could lead to a moderate public health risk in foods derived from that product (e.g. *Salmonella* in broiler chickens).

Priority 3: A primary producer whose product could contain hazards that if not controlled on the farm, or at the harvest site/time, could, at worst, lead to a "low" public health risk from foods derived from that product either because:

- the safety hazards that can be controlled "on-farm" induce mild illness only and would only affect a small number of consumers; or,
- the hazard is reliably controlled by normal handling or processing at a subsequent step in the food supply chain (e.g. game meat harvesters).

Priority 4: A primary producer whose product, or a food derived from it under normal conditions of use and handling:

- does not, or could not be anticipated to contain any known food safety hazard; or
- may contain a hazard that cannot be controlled by actions by the business sector but is reliably controlled by normal handling or processing of the product at a subsequent step in the food supply chain.

Priority classifications for the food business sector:

Priority 1 and Priority 2: This classification relates to business sectors that will, characteristically, handle foods that support the growth of pathogenic micro-organisms and where such pathogens are present or could, from experience or literature reports, be expected to be present. Their handling of food will, characteristically, also involve at least one step at which control actions must be implemented to ensure the safety of the food.

Priority 1: Business sectors are further characterized by known risk-increasing factors, such as the potential for inadequate/incorrect temperature control (e.g. reheating or "hot-holding" of food), a consumer base that includes predominantly immune-compromised populations, the scale of production/service and others factors identified in the *National Risk Validation Project* (FSA & ME, 2002).

Priority 3: Business sectors that will only handle "low risk" or "medium risk" foods. A medium risk food is one that may contain harmful natural toxins or chemicals introduced at steps earlier in the food supply chain, or that:

- may contain pathogenic micro-organisms but will not normally support the formation of toxins or growth of pathogenic micro-organisms because of food characteristics; or
- is unlikely to contain pathogenic micro-organisms because of food type or processing but may support the formation of toxins or growth of pathogenic micro-organisms.

Priority 4: Business sectors that will normally handle only "low risk" foods, i.e. those that are unlikely to contain pathogenic organisms and will not support their growth, and will not introduce microbial, physical or chemical hazards to the foods they sell or handle.

Annex 2. Risk level matrix for fish and fishery products (FAO, 2009)

Fish/fishery product	Characteristics that increase risk			Events that are reasonably likely to occur and that will increase risk			Risk level
	No terminal heat application	Bad safety record	No CCP identified for a hazard	Harmful recontamination or contamination	Abusive handling-time-temp	Growth or accumulation of hazard	
Molluscan shellfish live and eaten raw	×	×	×	×	×	×	High
Fermented <8% NaCl	×	×		×		×	High
Semi preserved >6%, pH <5	×				×	×	Medium
Frozen freshwater finfish					×	×	Low

Annex 3. Prioritizing establishments based on establishment type and product profile (FAO, 2009)

Establishment type	Compliance	Product	Priority
Fish landing	**High**	Fresh fish for processing and direct consumption after cooking	**Low**
Aquaculture producer	**Low**	Molluscan shellfish for consumption raw	**High**
Processing plant	**High**	Frozen fish fillets	**Low**
Retail fish market	**Low**	Variety of fresh and processed products some of which are consumed without further processing	**High**

Annex 4. Food business risk categorization approaches

1. Approach using risk categorization model questionnaires

Risk categorization is a complex process that may be influenced by a number of factors. Therefore, different approaches have been used in classifying food businesses on the basis of risk category. One approach developed by FPTCFSP, Canada (2007) using risk categorization model (RCM) questionnaires is commonly used in categorizing food businesses on the basis of risk. Basically this approach is started by designing questionnaires for assessing food-borne disease risk factors in a food business. Furthermore, the assessment results will be scored, and the score will determine the food business risk category.

In this model the following eight risk factors are assessed:

- types of food and intended uses;
- food preparation and processing;
- equipment and facilities;
- management and employee food safety knowledge;
- food safety management programme;
- regulatory compliance;
- volume of food; and
- typical patronage.

Each risk factor has corresponding weighted values or scores based on the level of risk posed by the situation noted during an inspection.Table 1 below is an example of RCM questionnaires for all eight risk factors. By checking one of a, b, c, or d on table 1 the inspector scores each of all eight risk factors. Once a score is given to each risk factor, the scoring process using RCM questionnaires is continued with the remaining risk factors. The total scores will determine whether food businesses fall into a high-risk, moderate-risk or low-risk category.

Table 1. Example of RCM questionnaires for all risk factors (FPTCFSP, Canada, 2007)

1. Types of food and intended uses	**Check one of a, b, c, or d**	**Circle corresponding score**
a) High-risk foods that are ready-to-eat when served or sold to the consumer		40
b) Medium-risk foods that are ready-to-eat when served or sold to the consumer		25
c) High- or medium-risk foods that are not ready-to-eat		25
d) Low-risk foods that may or may not be ready-to-eat		10
2. Food preparation and processing	**Check one of a, b, c, or d**	**Circle corresponding score**
a) Extensive handling or preparation of high- or medium-risk foods		40
b) Limited handling or preparation (cooking, serving) of high- or medium-risk foods		25
c) Handling or preparation of unpackaged low-risk foods		25
d) a, b, or c do not apply		0

Table 1. *(continued)*

Additional factors	**Check one of a, b, c, or d**	**Circle corresponding score**
e) Manufacturing cooked/chilled foods; small-scale cooked		20
f) Provides catering services offsite		20
3. Equipment and facilities	**Check all that apply**	**Circle corresponding score**
a) Insufficient refrigeration equipment or hot holding equipment to maintain food temperatures at correct standards, facilities that are under re-occurring boil order advisories, or, if in place, drinking water treatment systems for microbial contamination are poorly maintained		15
b) Food preparation area or kitchen is small, insufficient space, has poor layout, inadequate lighting or ventilation		15
c) Equipment or facility surfaces are not easily cleanable, in disrepair or need replacing		15
d) Equipment and facilities are satisfactory or better		0
4. Management and employee food safety knowledge	**Check only one**	**Circle corresponding score**
a) Demonstrate little or no knowledge/training of food safety practices		30
b) Demonstrate some knowledge/training of food safety practices		15
c) Demonstrate good knowledge/training of food safety practices		0
5. Food safety management programme	**Check only one**	**Circle corresponding score**
a) No documented food safety management programme in place where warranted		30
b) Documented food safety management programme in place without an audit programme		15
c) Audited food safety management programme where all HACCP principles are applied		0
d) Not applicable because of the type of foods (1d) or the amount of handling and preparation (2d)		0
6. Regulatory compliance	**Check only one**	**Circle corresponding score**
a) Non-compliance usually with three or more critical items during inspections; continual non-compliance with non-critical items		40
b) Non-compliance with two critical items during inspections; continual non-compliance with non-critical items		30
c) General compliance usually with one or no critical items in non-compliance during inspections; some non-compliance with non-critical items; conditions being maintained or improved		15
d) High compliance; may have some non-compliance with non-critical items		0
Additional factors		
e) A clinically confirmed or epidemiologically linked outbreak has occurred at the facility within the last year under the same ownership/management		30

Table 1. *(continued)*

7. Volume of food	**Check only one**	**Circle corresponding score**
a) Food service serving more than 250 meals per day or food retail employing more than 10 people		20
b) Food service serving less than 250 meals per day or food retail employing 10 or fewer people		10
8. Typical patronage	**Check only one if presents**	**Circle corresponding score**
a) Provides food service primarily to vulnerable populations including **immuno-compromised individuals** (e.g. in hospitals and nursing homes)		30
b) Provides food service directly to vulnerable populations that **do not** include **immuno-compromised individuals** (e.g. in child care centres and residential care facilities)		15
Total score for 8 risk factors		

Table 2. Risk categorization based on the total score obtained with questionnaires

Risk	Score	Total score
Low	105 or less	
Moderate	110–160	
High	165 more	

2. Approach using scoring system

ANZFA (2000) developed a scoring system to classify food businesses into risk categories based on:

- type of food
- activity of the business
- method of processing
- customer base.

The tools in the scoring system are given in table 3. Scoring is conducted by ticking only one of several choices listed in the table. Based on this method each of all four risk factors will be scored and the total score will determine the priority classification. With scores of 39 or less, 40-64, and 65 or above, food businesses are classified as low-risk, medium-risk, and high-risk respectively (table 4).

Table 3. Example of scoring system in classifying the food business risk (ANZFA, 2000)

1. Food type and intended use by customer (tick only one)	**Score**	√
High-risk foods that are ready-to-eat	35	
Medium-risk foods that are ready-to-eat	25	
High-risk foods that are **not** ready-to-eat	15	
Medium-risk foods that are **not** ready-to-eat	5	
Low-risk foods that may or may not be ready-to- eat	0	
Business score		
2. Activity of the food business (tick only one)	**Score**	√
High- and medium-risk ready-to-eat foods are handled during processing or manufacturing of food	25	
High- and medium-risk ready-to-eat foods are only portioned before receipt by the customer	20	
Low-risk or non-ready-to-eat foods are handled during processing or manufacturing of food	15	
Storage, distribution or sale of pre-packaged food only	5	
Business score		
Additional point	**Score**	√
A catering business prepares and serves food at different locations	15	
Business score		
3. Method of processing (tick only one)	**Score**	√
A pathogen reduction step is performed during processing by the food business prior to sale	10	
A pathogen reduction step is not performed during processing by the food business prior to sale	0	
Business score		
4. Customer base (tick only one)	**Score**	√
The food business is **not** a small business	10	
The food business is a small business	1	
The food business is a charitable organization	0	
Business score		

Table 4. Priority classification

Risk	**Score**	√	**Business score**
Low	39 or less		
Medium	40–64		
High	65 or more		

3. Approach using a decision tree

The Department of Health and Ageing, Australia (2007) developed the decision tree approach to consider:

- the nature of the potential risk that might exist or arise from products *sold* by the business sector and considering both the *inherent* risk (i.e. in the absence of existing controls) and the *managed* risk (i.e. reliability of existing risk management actions; and

- whether there are steps that are susceptible to the introduction of hazards, or processes that are critical to the safety of the product at the time it is consumed.

In the decision tree there are three key questions that must be answered sequentially, as follows:

1. Could a hazard realistically be present in the food?
   ("NO" – Priority 4, "YES" go to Question 2)
2. Does the business sector have a crucial role in controlling the hazard?
   ("NO" – Priority 3, "YES" go to Question 3)
3. Are there known "high risk" factors associated with the sector?
   ("NO" – Priority 2, "YES" – Priority 1).

Thus, the three basic considerations lead to four risk categories, namely, Priority 1, 2, 3, and 4. According to definitions of the four risk categories, Priority 1 and 2 can be classified as high-risk food business, Priority 3 as medium-risk food business, and Priority 4 as low-risk food business.

4. Comparison of three approaches

In the approach using RCM Questionnaires developed by FPTCFSP, Canada (2007) eight risk factors were selected as the main criteria to categorize the food business risk. This approach is rather complex and the level of risk category of a food business can only be determined after a thorough onsite assessment using eight sets of questionnaires. Each questionnaire is scored and the assessor can categorize the risk of food businesses on the basis of the total score obtained with the questionnaires. ANZFA (2000) developed a scoring system which is a simpler approach in classifying risk category of food businesses using only four risk factors. In each risk factor scoring tools were prepared and on the basis of this method each of the four risk factors is scored and the total score determines the priority classification or risk category. In categorizing the risk of food businesses these two approaches use the total score as the basis for risk category determination. Although the scoring system used in both approaches is different, in each system the higher the score obtained the higher is the risk.

The Department of Health and Ageing, Australia (DHAA, 2007) developed an alternative approach known as the decision tree approach. In this approach basically there are three key questions that have to be answered sequentially leading to a decision regarding food business risk categorization. Four food business risk categories, namely, Priority 1, 2, 3, and 4, are determined, and according to definitions, Priority 1 and 2 can be classified as high-risk food business, Priority 3 as medium-risk food business, and Priority 4 as low-risk food business. The reader may review the "Business sector food safety risk priority classification framework" endorsed by the Food Regulation Standing Committee on 16 March 2007 (DHA, Australia, 2007) for detailed use of a decision tree to categorize food business risk.

FAO Regional Office for Asia and the Pacific
39 Phra Atit Road, Bangkok 10200 Thailand
Tel: (66 2) 697 4000 Fax: (66 2) 697 4445
E-mail: FAO-RAP@fao.org
Website: http://www.fao.org/asiapacific

ISBN 978-92-5-107056-7

9 789251 070567

I2448E/1/11.11