RISK-BASED FOOD INSPECTION SYSTEM

Practical Guidance for National Authorities

World Health Organization

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Abbreviations

CCP	critical control point
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Points
MCDA	multicriteria decision analysis
MRL	Maximum Residue Limit
RTE	ready-to-eat
UHT	ultra-high-temperature
WHO	World Health Organization

Glossary

Critical control point (CCP): a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Control: an element of the food process that reduces, eliminates or removes a food safety hazard.

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.

Food business operator: the entity responsible for operating a business at any step in the food chain.

Food control: a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all food is safe, wholesome and fit for human consumption during production, handling, storage, processing and distribution; conforms to food safety and quality requirements; and is labelled honestly and accurately as prescribed by law.

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

Hazard Analysis Critical Control Point (HACCP): a system that identifies, evaluates and controls hazards that are significant for food safety.

High-risk foods: foods that may contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms 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 *(1)*.

High-risk food businesses: food businesses dealing with high-risk foods or high-risk production methods where the potential exists to put vulnerable groups, such as infants, elderly people, pregnant women and people who are sick, or large numbers of consumers at serious risk. Note: in the Association of Southeast Asian Nations (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.

Inspection: the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

Low-risk foods: foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals.

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

Medium-risk foods: foods that may contain pathogenic microorganisms but will not normally support their growth because of food characteristics; or foods that are unlikely

to contain pathogenic microorganisms because of food type or processing but may support the formation of toxins or the growth of pathogenic microorganisms *(1).*

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, and egg and egg products.

National food control system: the integration of mandatory regulatory approaches (i.e. official food control activities) with preventive and educational strategies that, along the entire food chain (including production, handling, storage, processing and distribution), ensure that food is safe, wholesome and fit for human consumption, conforms to food safety and quality requirements and is honestly and accurately labelled as prescribed by the law.

Risk-based inspection: inspection activities focused on food products and legal food businesses that pose the highest risk to consumers' health.

Risk categorization framework: a supporting tool to qualify and document the different risk categories that have been identified, and to subsequently insert the registered food business operators into a risk-based inspection programme.

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Preface

Foodborne illness is a major public health concern and contributes to loss of life, loss of work time, undue expense in terms of government health care and loss of productivity in the workforce. Globally, it is estimated that there are 600 million cases of foodborne diseases and 420 000 deaths each year due to the consumption of unsafe food. In the Western Pacific Region alone, there are an estimated 125 million cases of foodborne diseases and more than 50 000 deaths every year.

Food safety authorities implement regulatory activities to achieve the key objectives of food control throughout the entire food chain to protect the health of consumers against foodborne illness and ensure fair practices in the food trade. On this, governments are seeking to modernize and integrate their food control activities under harmonized Codex Alimentarius guidelines and to improve their efficiency, sustainability and robustness by applying the principles of national food control systems, including principles of risk analysis.

Risk-based inspection is an alternative that uses available resources more efficiently and modernizes inspection systems, through the application of a scientific and risk-based approach in inspection activities, focused on food products and legal food businesses that pose the highest risk to consumers' health. Risk-based food inspection, as opposed to traditional food inspection, provides opportunities to build systems to prevent food safety incidents by identifying risk factors and assessing the effectiveness of control measures in place.

The application of the scientific and risk-based approach to design and implement a risk-based food inspection system that uses the available resources efficiently is the scope of the current practical guidance.

This document is in line with:

The regional vision *For the Future: Towards the Healthiest and Safest Region* and fits under the priority area of "health security, including antimicrobial resistance";

The *Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSED III)* as it comprises its multisectoral approach, including food and water safety; and

The document also directly contributes to the implementation of the *Regional Framework for Action on Food Safety in the Western Pacific,* particularly in action area 2, risk-based food inspection and enforcement.

Executive summary

Food inspection plays an important role as part of food control activities, in ensuring that food businesses are implementing appropriate processes, collecting evidence, and verifying compliance with standards and requirements to ensure that the foods are safe and wholesome and fit for human consumption. Risk-based inspection is based on the application of a scientific and risk-based approach to focus inspection activities on food products and food businesses that pose the highest risk to consumers' health.

The purpose of this practical guidance is to assist national authorities on how to design, implement and communicate a risk-based food inspection system. This document provides step-by-step guidance, specific examples and case studies, as well as understanding risk prioritization tools to categorize the risk of food and establishments, and how to estimate the inspection frequency based on risk. In addition, guidelines for review and adjustment of an inspection plan are provided. Considering that the risks inherent in food and food processing are particular to each country and production chain, as well as the characteristics of the producing establishments, it is recommended that this guidance may be adapted to suit individual country needs. An annex is also included describing the main considerations that inspectors must take into account when preparing a food inspection. Finally, this document concludes that the keys to a successful risk-based inspection system start with political commitment and an adequate regulatory framework to support the process, designing the model based on the collection of adequate and relevant information, and periodically subjecting the model to a process of adjustment to allow for continuous improvement of the system.

1. Objective

This practical guidance provides a generic framework to assist national authorities on how to design, implement and communicate a national risk-based food inspection system. It provides step-by-step guidance, specific examples and case studies, as well as risk prioritization tools to categorize the risk of food and establishments, and how to estimate the inspection frequency based on risk.

Also, from an inspector-oriented approach, this guidance document will assist food inspectors in carrying out risk-based inspections. The guideline provides information on inspection elements and prompts for inspectors to make a risk-based assessment of food safety risks and control measures and determine an outcome, including specific guidance on the following.

Establishing the scope of the risk-based inspection system

Considerations for the collection of information on food establishments and food categories

Principles, tools (qualitative and quantitative) and practical examples for the risk categorization of food and food businesses

Determination of inspection frequency based on the results of the risk categorization

Considerations for implementation and communication of a risk-based system

Considerations for review and adjustment of the inspection plan

2. Introduction

Foodborne illness is a major public health concern and contributes to loss of quality of life as well as undue expense in terms of government health care and loss of productivity in the workforce.

REMEMBER: There are 600 million cases of foodborne diseases and 420 000 deaths each year due to the consumption of unsafe food. The Western Pacific Region has an estimated 125 million cases of foodborne diseases and more than 50 000 deaths every year. *(2,3)*

Food inspection plays an important role in ensuring that food businesses are implementing appropriate processes to ensure that the foods they produce are safe. National regulatory agencies develop inspection plans to schedule food inspections. The challenge faced by many countries is a lack of resources to inspect food establishments. A scientific and risk-based approach to design and implement a risk-based food inspection system that uses the available resources efficiently is the scope of the current practical guidance. While developed primarily for the Western Pacific Region, this document provides general guidance for any country looking to undertake the design, implementation and communication of a national risk-based food inspection system.

Government-appointed food inspectors have a crucial role to play by visiting food businesses to check food preparation areas, food-handling practices, food processes and equipment to determine compliance with food safety national regulation. These inspections are carried out at a certain frequency. The inspection frequency needs to be related to the food safety risk of the food being prepared and the inherent risk of the business facility (for example, equipment, personnel and separation of production areas). This is known as a risk-based inspection system, which is a method used for prioritizing inspection using a risk-based approach.

The aim of a risk-based inspection system is to assign inspection frequencies according to the assessed risk (food and facility). As a general principle, the higher the risk, the higher the inspection frequency. Thus, priority and focus of inspection should be placed on high-risk foods and processor facilities to minimize public health risk. The intent of this document is to assist national authorities on how to design, implement and communicate a risk-based food inspection system. It provides step-by-step guidance, specific examples and case studies, as well

as risk prioritization tools to categorize the risk of food and establishments, and how to estimate the inspection frequency based on risk. The guidance may be adapted to suit individual country needs.

Food safety regulatory agencies may need to work collaboratively with other governmental agencies/ministries, such as business licensing and regulation, primary industries, including agriculture, fisheries and horticulture, imported and exported foods, transportation, environment and industries, as relevant, to establish common goals in line with government priorities. Shared training and regular meetings between agencies allow common goals and priorities to be established. Sharing resources, including transport, can have economic benefits and allow for a more focused approach to food safety. It also provides clarity on the role of each agency. Data or intelligence information may provide an insight into food safety issues and problems. Resources for inspections can then be focused in areas where there is the greatest need. The sharing of information between government organizations and other support agencies is encouraged.

3. Generic framework of a risk-based food inspection system

This manual will explain step by step how to design, implement and communicate a national risk-based food inspection system. The information included in the present manual and framework has been also proposed by the Pan American Center for Foot-and-Mouth Disease and Veterinary Public Health of the Pan American Health Organization/World Health Organization (PANAFTOSA/VPH-PAHO/WHO) for the Latin America region.

The use of harmonized risk-based food inspection systems in different regions has many advantages as it standardizes the use of risk analysis principles in food inspection and allows countries to recognize inspection systems implemented by their trade countries. These actions will ultimately facilitate the safe trade of food products and reduce the public health impact of foodborne diseases. Fig. 1 shows the generic framework proposed by this manual for the implementation of a risk-based food inspection system.

Fig. 1 **Generic framework of a risk-based inspection system**

3.1 ESTABLISH THE SCOPE

Designing a new nationwide food inspection system can be challenging. The first step in designing a new risk-based inspection system is to decide on the scope. It is recommended that the country or regulatory agency address the following questions to orient themselves in defining the scope of the food inspection system.

Is the new risk-based inspection system intended for single or multiple food chains?

If the country is starting a new risk-based food inspection system, it is recommended that it is implemented in a specific food chain, such as dairy establishments, as a pilot and then revised, adjusted and replicated in other food establishments that produce other types of foods. The country can decide on the specific food chain to start the inspection system based on different criteria, such as the number of establishments, the total volume of production, exports or history of foodborne outbreaks and product recalls.

What is the minimum size of an establishment to be regulated under the new risk-based food inspection system?

The total number of establishments (large and small-scale) in a country can be overwhelming. The regulatory agency needs to decide what is the minimum size, taking into account such factors as the number of employees and annual production volume required to enter the risk-based food inspection system. It is recommended that small-scale and artisanal producers follow a different scheme and enter the new inspection system when they grow in business and their production volume is within the minimum required.

What type of establishments will be included in the food inspection system?

There are various food establishments, including abattoirs, ready-to-eat (RTE) meat establishments, convenience stores, restaurants, warehouses and fresh produce packing houses. Each type of food establishment has its own characteristics and risk profiles.

3.2 COLLECT INFORMATION

The second step in designing a new inspection system is to collect information on the characteristics of food establishments and the type of foods they manufacture.

3.2.1 Food establishments

Regulatory agencies need a database of food establishments nationwide that produce a specific food category, such as RTE meat products. To create the database, the following information is required:

- Total number of establishments within a specific food chain;
- Address of food establishment;
- Number of employees;
- Type of food categories produced;
- Annual volume of production per food category;
- History of noncompliance from previous inspections; and
- Product recalls related to food produced in the establishment.

3.2.2 Food categories

There are a large number of products and producing establishments in any given country. Each food chain, such as dairy products, RTE meat products, seafood and fishery, will have a high number of specific food products, including regionally different products, for example, various types of sausages. To facilitate this task, it is important to group the different foods by category, which is intended to group products that have similar raw materials, processes or technological characteristics. Food categories are defined in each food chain to reduce the total number of products to be categorized. Examples of ways to categorize foods produced in a country are as follows:

- Codex Alimentarius – Food categories *(4)*
  http://www.fao.org/gsfaonline/foods/index.html?print=true
- European Food Safety Authority – Food classification standardisation *(5)*
  https://www.efsa.europa.eu/en/data/data-standardisation
- United States Food and Drug Authority – Product categories and products *(6)*
  https://www.fda.gov/product-categories-and-products

- Food Standards Australia New Zealand – Priority classification system for food businesses *(7)* https://www.foodstandards.gov.au/publications/pages/theprioritycclassific352.aspx
- Department of Agriculture, Water and the Environment, Australian Government – Imported Food Inspection Scheme *(8)* https://www.awe.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis

Each product should be linked to only one category. For example, dairy product categories can be grouped by their manufacturing process and other process conditions, such as final product moisture, particular processing conditions (artisanal with raw milk), addition of post-heat treatment ingredients, among others. An example of dairy product categories is shown in Table 1.

Table 1 Example of dairy product categories

Group 1	Pasteurized milk, ultra-pasteurized milk, ultra-high-temperature (UHT) milk, evaporated milk, sterilized milk, pasteurized milk cream, UHT milk cream, sterilized milk cream, fluid ice cream mixtures
Group 2	Milk powders, instant milk powders, cream powders, cheese whey powders, buttermilk powders, whey protein concentrate, cheese powders, ice cream powders, powdered ice cream mixes, food preparations based on powdered dairy products
Group 3	Rennet edible casein, acid edible casein, lactic edible casein, edible caseinate
Group 4	Milk powders with dry additives
Group 5	Condensed milk, dulce de leche, milk caramel
Group 6	Butter, butter oil
Group 7	Yoghurt, fermented or cultured milk
Group 8	Low-moisture cheeses made from pasteurized milk

3.3 CATEGORIZE RISK

3.3.1 Principles of risk categorization

Risk categorization is defined as a risk management activity that uses a scientific process to identify food safety priorities and assign resources accordingly *(9)*. A definition that is important for regulatory agencies to understand is hazard and risk. These are two different terms, and Fig. 2 shows the definition and examples for both terms.

Fig. 2 Definitions of hazard and risk and examples

Hazard	Risk
• A biological, chemical or physical agent in food with the potential to cause an adverse health effect to the consumer. • Examples: *Salmonella* sp., *Trichinella spiralis*, mycotoxins, allergens, *Clonorchis* (liver fluke parasite).	• The combination of the probability of the hazard to be present in the food and the severity of the disease • Examples: What is the risk of acquiring an infection by *Salmonella* spp. from the consumption of raw or undercooked poultry?

REMEMBER: Hazards are agents that cause adverse health effects to the consumer. Hygiene and quality microbial indicators such as faecal coliforms, yeast and moulds, *Enterobacteriaceae*, among others, are not considered hazards as they are not directly related to illness. The indicators are mainly used to verify the hygiene conditions of raw materials, finished products, workers' hands, surfaces and water, with higher numbers indicating worse hygienic conditions and a higher probability for the presence of a pathogen.

Food safety risk can be calculated by using the following equation:

$$Food\ safety\ risk = probability \times severity$$

Probability can be defined as the occurrence of a hazard in the food. The occurrence of the hazard in a food product can be evaluated by a qualitative assessment (low, medium or high risk) or a quantitative assessment by calculating the prevalence of the

hazard in the food, that is, the percentage of positive samples for a pathogen in a food product or percentage of samples above the Maximum Residue Limit (MRL) for a chemical in a food product.

Severity can be defined as how serious the health symptoms of the disease are. Severity can be evaluated by a qualitative assessment (low, medium or high risk) or by using public health data from the official national statistics. In the case of a microbiological hazard, the severity can be evaluated from the following information:

- Health effects related to the pathogen such as gastrointestinal symptoms, sequalae
- Number of outbreaks and cases related to the pathogen
- Number of hospitalizations related to the pathogen
- Number of deaths related to the pathogen.

In case of a chemical hazard, the severity can be defined as:

- health effects related to the chemical hazard such as carcinogenic, organ toxicity, neurotoxic; and
- toxicity of the molecule with acceptable daily intake, tolerable daily intake defined as the maximum concentration of the chemical allowed to be consumed daily, expressed as µg/kg body weight/day.

Risk can be expressed in absolute risk or relative risk terms, and understanding the difference is important to interpret the meaning of the risk being evaluated. Fig. 3 shows the differences between both terms and how to use them. Relative risk will be used in this manual to rank foods and establishments based on the food safety risk they pose.

Fig. 3 Definitions of absolute risk and relative risk

Absolute risk	Relative risk
• Has a biological meaning and specific units • Quantifies the effect of the hazard in the population such as number of illnesses per year • It is used in quantitative risk assessment	• Does not have biological meaning or units • Uses an arbitrary risk scale (0–100) • It is used to compare or rank different scenarios, hazards or establishments

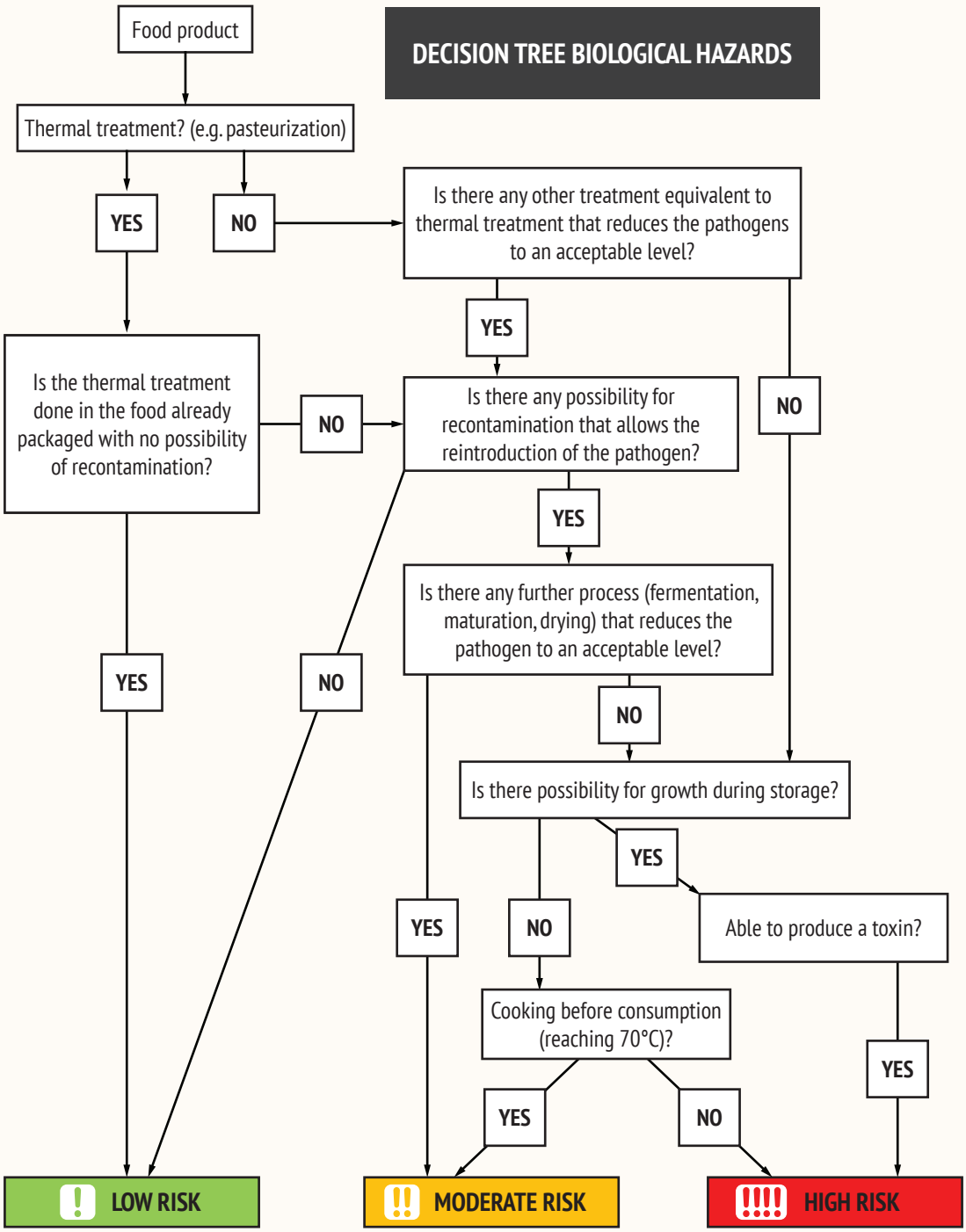
3.3.2 Risk categorization tools

3.3.2.1 Qualitative tools: decision trees

Decision trees are tools to qualitatively categorize (low-, medium- or high-risk) the food safety risk of different food products. Decision trees are built by using questions related to how the food is produced in an establishment and answering with a yes/no answer. This is a recommendable tool when the country does not have data on the prevalence of pathogens or chemical residues in different food products. Decision trees are very useful as well when the country must categorize many food products, and the tool can be used to identify foods that are low-risk and thus do not pose a risk to consumers. Fig. 4 shows an example of a decision tree to rank biological hazards in food.

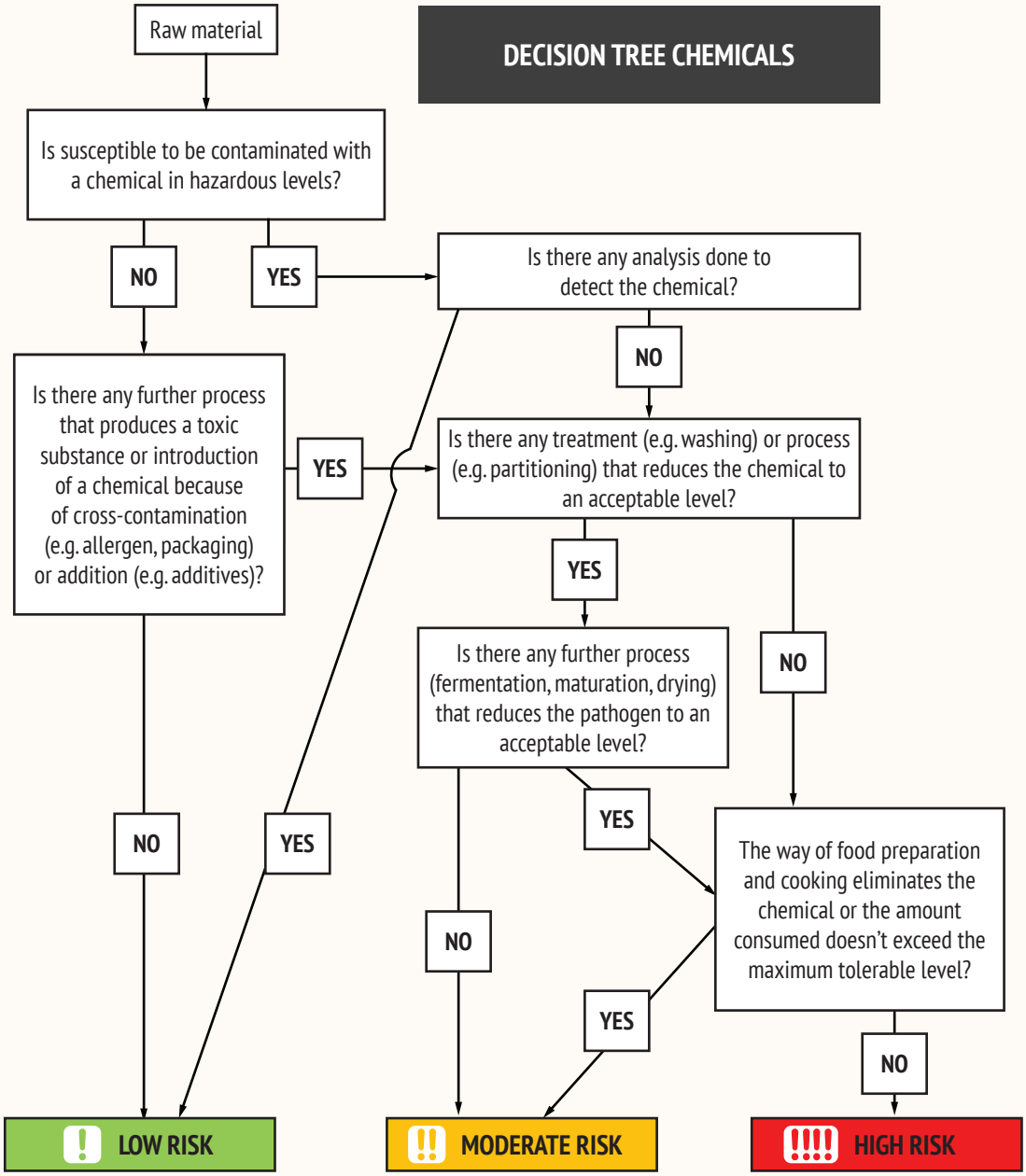
REMEMBER: When using a decision tree, the regulatory agency must consider that the establishment complies with Good Manufacturing Practices (GMP). For example, if the decision tree is used to categorize the risk of pasteurized milk, it is assumed that the establishment uses adequate temperature and time to pasteurize the milk and keep the milk refrigerated.

Fig. 4 Example of decision tree to rank biological hazards in food, by risk level



As shown in Fig. 5, a similar decision tree can be built for chemical hazards. In this case, there are few control points or strategies to reduce the presence of chemical substances as cooking will not destroy them.

Fig. 5 Decision tree to rank chemical hazards in food, by risk level



3.3.2.2 Quantitative tools: risk matrices

Risk matrices are tools to quantitatively categorize the food safety risk of different food products. It is recommended to use quantitative risk matrices over qualitative matrices due to being more objective and allowing a clear mathematical relationship between probability and severity. Risk matrices can also be used to categorize the establishments by their inherent risk (later in this manual).

REMEMBER: Risk matrices use relative risk, so the numeric scale that they use does not have biological meaning or units.

It is recommended that each country using this manual build its own risk matrices based on the examples provided in this manual. As each country has its own realities, such as information available, food production practices and food consumption, a generic risk matrix will not be suitable for all the countries. There are certain rules that need to be followed to build a risk matrix *(10,11)*:

1. Use the same scale for probability and severity (for example, between 0 and 1).
2. Use a numerical scale that reflects the nature of the risk to be assessed (such as prevalence 0–100%).
3. Use the equidistance rule in the levels of the numerical scale (for example, 0, 0.5, 1).
4. Define the numerical scale (for example, 0 = There is no evidence that the pathogen has been found in the food).
5. Define a mathematical relationship between occurrence and severity to estimate the final relative risk.
6. Define risk levels and their associated scores (for example, low risk <0.25).

A generic quantitative matrix can be built using the probability and severity concepts covered earlier in this manual. First, we need to define a numeric scale for probability and severity and then add the meaning of each level in the numeric scale. Probability is multiplied by severity to calculate the final score, and finally, different risk levels are assigned depending on the score (low-, medium- or high-risk). Table 2 shows a generic quantitative risk matrix where final risk is calculated by multiplying probability by severity.

Table 2 Generic quantitative risk matrix

		Severity		
		1	**10**	**100**
Probability	**1**	***1***	***10***	***100***
	10	***10***	***100***	***1000***
	100	***100***	***1000***	***10 000***

LOW RISK
1–10

MODERATE RISK
100

HIGH RISK
1000–10 000

Tables 3 and 4 provide examples of a numerical scale and definitions for probability and severity, respectively.

Table 3 Numerical scale and definitions for probability based on the prevalence of the hazard

Score	Definition
1	There is no evidence of the presence of the hazard in the food or it has been found sporadically (prevalence <1%).
10	There are reports of the presence of the hazard in the food (prevalence 1–10%).
100	The hazard is frequently found in the food (prevalence >10%).

Table 4 Numerical scale and definitions for severity

Score	Definition
1	Hazard results in hospitalization rate <1% and mortality <0.1%.
10	Hazard results in hospitalization rate up to 10% and mortality up to 1%.
100	Hazard results in hospitalization rate >50% and mortality >1%.

REMEMBER:

Biological hazards: In case of a pathogen, prevalence can be calculated by the number of positive samples:

$$Prevalence = \frac{Number\ of\ positive\ samples}{Number\ of\ samples\ analysed}\ x\ 100(\%)$$

Here is an example calculating the prevalence of Salmonella sp. in fresh chicken from a national surveillance study:

- Number of fresh chicken samples analysed: 1000 samples
- Number of positive samples for Salmonella sp.: 50 samples (assuming a positive sample as having more than 1 Colony Forming Units in 25 g)

$$Prevalence = \frac{50}{1000} = 0.05\ x\ 100 = 5.0\%$$

Chemical hazard: In case of a chemical hazard, prevalence can be calculated by the number of samples above the MRL or Maximum Level:

$$\%\ of\ sample\ above\ MRL = \frac{Number\ of\ samples\ above\ MRL}{Total\ number\ of\ samples\ analysed}\ x\ 100(\%)$$

Here is an example calculating the percentage of aflatoxin B1 samples above the MRL in raw milk from a national surveillance study:

Number of raw milk samples analysed: 500 samples

Number of samples higher than the MRL for aflatoxin B1: 10 samples (each country may have a MRL or may use the MRL established by Codex)

$$Prevalence = \frac{10}{500} = 0.02\ x\ 100 = 2.0\%$$

3.3.2.3 Quantitative tools: Multicriteria Decision Analysis

Multicriteria decision analysis (MCDA) is a quantitative tool to incorporate more variables than probability and severity. Countries use MCDA to calculate relative risk by incorporating different risk factors related to food production, public health and economic impact, among others. A typical MCDA exercise contains the following steps *(12,13)*:

1. Identification of the hazards/food categories to be classified
2. Definition of risk factors and numerical scale
3. Standardization of scores to make them comparable across factors
4. Obtaining weights for the different factors
5. Scoring and mathematical combination of the factors.

The first step is to identify the risk factors that may influence the final relative risk estimate. To assess the risk of a food, risk factors may include, among others: how the product is consumed (such as cooked, fresh or RTE); level of contamination of the raw material; target population; mitigation measures (including critical control points); possibility of recontamination; use of additives; presence of allergens; and possibility of cross-contact. Each risk factor identified should have a numerical scale to evaluate it following the rules and procedure seen in the risk matrix section of this manual. Table 5 shows two additional examples for evaluating the level of raw material contamination and the possibility of recontamination using a numerical scale.

Table 5 Examples of risk matrix to evaluate raw material contamination and the possibility of recontamination

A. Pathogen prevalence in the raw material/ingredient	Score	B. Possibility of recontamination	Score
>5%	1.0	There are more than two handling points* after heat treatment or equivalent critical control point**	1.0
1–5%	0.75	Two handling points exist after the heat treatment or equivalent critical control point**	0.75
<1%	0.50	There is only one handling point after heat treatment or equivalent critical control point**	0.50
<0.1%	0.25	No recontamination is possible, it is a closed system***	0.25

* Handling means any operation in which a piece of equipment, utensil or operator comes into direct contact with the food.
** Equivalent critical control point means a control measure in the Hazard Analysis Critical Control Points (HACCP) plan that controls the hazard to an acceptable level.
*** For example, milk pasteurization is an enclosed system where milk is always within a piping system and the product is never exposed to a worker or the environment.

Once the risk factors and the numerical scale have been identified, they should be combined to make a numerical estimate of the relative risk. For example, four risk factors identified (F*n*) can be combined by adding the scores obtained for each factor on a scale of 0.25–1:

$$\text{Relative risk} = F1 + F2 + F3 + F4$$

where F1 to F4 are risk factors. For example:

$$\text{Relative risk} = 0.25 + 0.50 + 1 + 1 + 1 = 2.75$$

REMEMBER: The value of 2.75 has no units, as it expresses a relative risk related to a numerical scale created by the user.

In the example shown, each risk factor is considered to have the same weight (for example, four factors with a relative weight of 0.25 or 25%). However, on many occasions, there are factors that may have more weight than others in the risk estimation. It is possible to assign weights to each factor as a percentage (%), bearing in mind that the sum of the weights should be 100%, and, therefore, the final risk score is between 0 and 1.

The different weights usually reflect the opinions of the risk manager (regulatory agency) and experts. For example, foodborne outbreaks and recalls that have occurred in the country usually have the highest weight in the risk estimation due to the impact they have on public health. The equation presented earlier in the manual can be modified to include different weights:

$$\text{Relative risk} = F1 \times P1 + F2 \times P2 + F3 \times P3 + F4 \times P4$$

where F1 to F4 are risk factors and P1 to P4 are weights. For example:

$$\text{Relative risk} = 0.25 \times 20\% + 0.50 \times 50\% + 1 \times 20\% + 1 \times 10\% = 0.6$$

The relative risk values obtained from the equation will be used to classify foods or establishments based on risk.

In summary, there are various risk categorization tools that a country can use, including decision trees, risk matrices and MCDA. The use of one specific tool will depend on the data available in the country and the level of expertise in using these types of tools.

3.3.3 Food risk categorization

Categorization of foods by risk is an important step in establishing inspection priorities. At this stage, the food categories in a country or specific food chain and the risk categorization tool (such as a decision tree) should have been defined by the regulatory agency. Each food category needs to be evaluated and a risk level assigned (for example, low, moderate or high). In general, risk levels depend on the likelihood that the

food may be contaminated with a pathogen or chemical hazard, the control measures used during processing to reduce the hazard (such as pasteurization and cooking) and the possibility of recontamination or growth during processing or shelf life. In turn, the fact that a food is ready for consumption may present a higher risk because it does not have a subsequent heat treatment that destroys pathogenic microorganisms.

REMEMBER: The process of assigning a risk level is done based on the food categories and not on each individual product.

An example of risk levels is shown below (Fig. 6). If using a decision tree to categorize each food by risk, a numeric score can be assigned to each level. Fig. 6 shows a score of four for high risk, two for moderate risk and one for low risk.

Fig. 6 Food risk definitions

High risk

- Food category that has a high probability of containing a pathogen or chemical hazard due to the way it is produced or consumed and thus causes adverse health effects.

Moderate risk

- Food category that has a moderate probability of containing a pathogen or chemical hazard but the way it is consumed (such as cooked) reduces the risk of causing adverse health effects.

Low risk

- Food category that has a low probability of containing a pathogen or chemical hazard, or the process lowers the hazards to an acceptable level.

In the event of having a significant number of food categories to evaluate, decision trees can be a very useful tool, as they allow foods to be classified by risk relatively quickly. At this stage, it is also important to identify the hazards associated with each food category, either by national or regional regulation, or by including emerging hazards not covered by the regulation.

REMEMBER: Food risk categorization is done based on the food manufacturing process, assuming that the industry adequately follows GMP. Each category yields a single risk level (low, for example), regardless of the hazards identified in the food.

Table 6 shows an example of categorization by risk of food from the fishery and aquaculture chain following the decision tree for biological hazards (Fig. 4) and chemical hazards (Fig. 5).

Table 6 Risk categorization of fishery and aquaculture products

Food category	Biological and chemical hazards identified	Risk level
Raw wild fish: fresh, frozen, glazed, with additives, minced or filleted	Biological hazards: *Salmonella*, *Staphylococcus aureus*, toxigenic *Vibrio cholerae* 01/0139, *Escherichia E.coli*, parasites (trematodes, nematodes, cestodes)	Low
	Chemical hazards: Mercury, cadmium, lead	Low
Wild fish and shrimp: salted and dried salted	Biological hazards: *Staphylococcus aureus*, *Listeria monocytogenes*, *Salmonella*, *E. coli*	Medium
	Chemical hazards: Mercury, cadmium, lead	Low
Live and raw bivalve molluscs	Biological hazards: *Salmonella*, *Staphylococcus aureus*, *Vibrio cholerae* toxigenic 01/0139, *E. coli*, *Listeria monocytogenes*	High
	Chemical hazards: Biotoxins [(okadaic acid (DSP), saxitoxins (PSD), domoic acid (ASP), azaspiracids (AZP)], mercury, cadmium, lead	High

3.3.4 Risk categorization of food businesses

Once foods have been categorized by their level of risk, proceed to the identification and selection of the factors that allow the categorization of establishments by risk by following the MCDA methodology (see *3.3.2.2. Quantitative tools: risk matrices*):

1. Identify the risk factors related to the establishment.
2. Assign numerical scales within each factor.
3. Combine the risk factors.
4. Establish a weighting on each factor (%).
5. Calculate the final risk score by combining the factors and weightings.

Among the risk factors that can be included in the evaluation of establishments:

- Degree of compliance with country regulations, including auto control systems (GMP or HACCP plan)
- Private third-party certifications
- Volume of production and/or number of employees
- Scope of marketing (local, national)
- Target population of food (local, national)
- Target population of the food (baby food, for example)
- Degree of food handling
- Plant layout, such as zoning and separation of areas and flows of personnel, raw materials, inputs and finished product
- Number of noncompliant samples for presence of pathogens or chemicals above the MRL
- History and degree of resolution of nonconformities detected during inspection
- Traceability plan
- Recall plan
- Allergen control
- Signs of fraud, counterfeiting or adulteration of products
- Hygienic zoning and environmental control of surfaces.

Once all risk factors have been identified, the scoring scale to be used to score each factor should be created (for example, 1 to 7 points). Additionally, depending on their

relative importance in the performance of the facility, each risk factor should be assigned a relative weight (for example, 5–50%).

One of the most important risk factors in the evaluation of establishments is the size and volume of production. Any contamination occurring in an establishment with a higher production volume will have a greater impact on public health. Below is an example of categorizing the size of an establishment by combining production volume and number of employees. Each country should adapt the matrix to the reality of its establishments.

Table 7 Classification of the size of establishments based on the number of employees and production volume

<table>
<tr><th></th><th>1–2 employees</th><th>3–19 employees</th><th>20–99 employees</th><th>100+ employees*</th></tr>
<tr><td><100 kg/month</td><td>Micro establishment</td><td>Small establishment</td><td>Medium establishment</td><td rowspan="4">Large establishment</td></tr>
<tr><td>100–200 kg/ month</td><td>Small establishment</td><td>Medium establishment</td><td>Large establishment</td></tr>
<tr><td>200–500 kg/ month</td><td>Medium establishment</td><td colspan="2" rowspan="2">Large establishment</td></tr>
<tr><td>>500 kg/month</td><td>Large establishment</td></tr>
</table>

* A food establishment with 100+ employees is always considered large regardless of the amount of food produced per month.

Table 8 shows another example of a risk categorization of establishments based on eight risk factors with their respective scores and specific weights depending on their influence on the final risk of the establishment. In order to obtain the weights of each factor, experts, inspectors and other risk managers can be consulted. The weight of each factor will be calculated by averaging all the responses obtained.

REMEMBER: To calculate the risk of the establishment the following calculation must be made:

$$\text{Risk} = F1 \times P1 + F2 \times P2 + F3 \times P3 + F4 \times P4$$

Where F1 to F4 are risk factors and P1 to P4 are weights, For example:

$$\text{Risk} = 0.25 \times 20\% + 0.50 \times 50\% + 1 \times 20\% + 1 \times 10\% = 0.6$$

Table 8 Example of a risk categorization of establishments

Risk factor (F)	Score	Weight (P)
Production volume	• Large (>2 million litres/month [L/m]) (7 points [pts]) • Medium (800 000–2 million L/m) (5 pts) • Small (200 000–799 000 L/m) (3 pts) • Micro (<200 000 L/m) (1 pt)	15%
Food safety management system	• Prerequisites programme (GMP, Sanitation standard operation procedures, good hygiene practices) (7 pts) • Previous item + HACCP (5 pts) • Previous item + export authorization (3 pts) • Previous item + international private scheme (1 pt)	20%
Compliance with GMP and/or HACCP	• 70–80% (7 pts) • 81–89% (5 pts) • 90–95% (3 pts) • > 95% (1 pt)	20%
Establishment of sampling programme	• No sampling programme (7 pts) • Has microbiological indicators in the finished product (5 pts) • Previous item + sampling for pathogens or chemicals in the finished product (3 pts) • Previous item + environmental monitoring (zoning 1,2,3) (1pt)	10%
Noncompliance with the official sampling plan	• More than two violating results in the last year (7 pts) • Two violating results in the last year (5 pts) • One violating result in the last year (3 pts) • No violating results in the last year (1 pt)	15%
Traceability	• No traceability plan (7 pts) • Only partial traceability (5 pts) • Full traceability (3 pts) • Full traceability and product recall plan (1pt)	5%
Manipulation	• More than two handling points after heat treatment or equivalent treatment (7 pts) • Two handling points after heat treatment or equivalent treatment (5 pts) • One handling point after heat treatment or equivalent treatment (3 pts) • The system is closed with no possibility of recontamination (1 pt)	5%
Status of the facility	• Older plants not remodelled (7 pts) • Older plants remodelled (5 pts) • Modern plants without zoning (3 pts) • Modern plants with zoning (1 pt)	10%

3.3.4.1 Example of a quantitative inspection checklist

One of the most important risk factors for evaluating the performance of establishments is the percentage of compliance with regulations and auto control systems (GMP or HACCP plan). For this, the regulatory body must design a scoring system for different items in the inspection checklist in order to quantify compliance.

For example, each checklist item can be divided according to its influence on the safety of the product (for example, critical, major or minor). Critical items are essential to ensure the safety of the final product, as well as all items that, because of their location in the plant (critical hygiene zones), in the process or are involved in direct contact with the product after heat treatment, may affect the safety of the final product.

In turn, during the inspection, the inspector assesses the degree of compliance of each item as follows:

Acceptable (A): the establishment fully complies with the item.

Deficient (D): the establishment does not fully comply with the item.

Once all the items on the checklist have been scored, the inspector sums up all A and D entries and then calculates the final compliance percentage by the following equation:

$$\text{Compliance percentage (\%)} = \frac{\textit{Number of items with A}}{\textit{Total number of items}} \times 100$$

Subsequently, the regulatory agency establishes the minimum percentage of inspection compliance (for example, 70%). The inspector then sums up all items with a D and, depending on if the D is from a critical, major or minor item, decides if the establishment passes the inspection. For example, the regulatory agency may decide that for an establishment to pass the inspection, it must comply with all the critical items and have only one D for a major item and only two Ds for minor items.

REMEMBER: Sometimes, not all items on the checklist are checked, and in that case, the percentage of compliance will be calculated taking into account the number of items checked in the inspection.

Table 9 Example of a quantitative GMP checklist

Number	Item	Category	Compliance
1	Equipment maintenance plan		
1.1	Compliance with the equipment maintenance plan	Major	A
1.2	Compliance with the critical equipment maintenance plan	Critical	D
2	Receipt and storage of raw materials, ingredients and packaging materials		
2.1	Verification of milk quality reports/corrective actions for deviations	Major	A
2.2	Inhibitor control/deviation actions	Major	A

TOTAL COMPLIANCE (%)	75%
Number of critical noncompliance	1
Number of major noncompliance	0
Results of the inspection	Failure to pass the inspection due to one critical noncompliance

3.4 DETERMINE THE INSPECTION FREQUENCY

Once the food and establishments have been classified by risk, the risk-based inspection system must be set up to assign inspection frequencies to the food-establishment combinations with the highest risk. These frequencies, as demonstrated later in this section, are established by each country according to its inspection capabilities.

To quantify the risk of food-establishment combinations, the food risk score (for example, 1, 2, 4) and the final score of the establishment must be mathematically combined. Following the methodology in section 3.3, Categorize risk, it is recommended to multiply both scores:

Overall risk = food risk score x establishment risk score

REMEMBER: If an establishment produces several food categories, the calculation should be made with the category with the highest risk.

Once the scores of the food-establishment combinations in the chain(s) we are evaluating have been obtained, the risk manager must establish the inspection frequencies in the country, according to the total risk scores. To do this, the manager must first decide how many inspection frequencies to implement, such as annual, semi-annual and monthly, which would be a frequency of three. The total risk score range must be divided by the number of frequencies. For example, if the risk manager decides that there will be three inspection frequencies and the range of the total risk score is between 5 and 95 (a range of 90 points), three scales (30 points each) will be applied to define the inspection frequencies that will go from five to 35, >35 to 65 and >65 to 95 points. Table 10 shows an example of inspection frequencies.

REMEMBER: Each country must establish its inspection frequencies.

Table 10 Example of inspection frequencies

Total Risk	Inspection Frequency
Less than X1	Annual
Between X2 and X3	Every 9 months
Between X4 and X5	Every 6 months

A food business operation within a specific risk category may have an assigned initial inspection frequency. This inspection frequency may increase or decrease depending on the compliance level following future inspections. It is recommended that the inspection frequency be increased for food businesses which have a poor compliance history and where food practices could pose an increased risk to human health. A compliant and well-operated food business may not need to be inspected as often; therefore, the inspection frequency may be reduced.

It is important to maintain the records of previous inspections to determine whether there are any issues that need following up or are a priority for the inspection. Any complaint information also must be reviewed.

Not every type of food business needs to be inspected at the same frequency. Food businesses that present a higher risk to human health should therefore be inspected more often.

Annex 1 contains information about how to prepare an inspector for an inspection.

REMEMBER: Inspection frequency is a dynamic variable and should be intensified when situations arise that increase the risk associated with the establishment (for example, a partial ban on operations due to failures in the hygienic and sanitary control of products).

3.5 IMPLEMENT AND COMMUNICATE THE RISK-BASED SYSTEM

Once the risk-based inspection system has been designed, a timetable for implementation and enforcement must be established. For this purpose, socialization meetings should be held within the organization to ensure that inspectors know and understand the new risk-based inspection system.

Communication channels should also be established with the industry and other actors in the production chain to explain the new model and establish a staggered implementation schedule. Finally, once the system is in place, annual reviews must be carried out to improve, adapt and correct aspects of the model following a process of continuous improvement.

There are different means to communicate the new risk-based inspection plan.

Communication channel	Purpose
Website	Publish the new inspection model on the website (including compliance dates)
In-person/virtual meeting	Explain the new risk-based inspection system to industry and producers allowing time for a Q&A session
Letter	Send a letter to industry/producers about the new risk-based inspection system

3.6 REVISE AND ADJUST THE PLAN ANNUALLY

Once the results of the inspections are obtained for the period considered, annual, for example, the team in charge of the operation plan must analyse the risk scores obtained from the system to assess the performance of each establishment and the situation of the entire sector or production chain, in order to set new inspection objectives and reformulate controls. To this end, those establishments that obtained a higher risk score, and will therefore be subject to more frequent inspection in the following year, should be identified. A "traffic light" colour code (such as red, yellow and green) can also be created by dividing establishments according to their risk score. The percentage of best, intermediate and worst-performing establishments can be calculated for the whole sector to set new targets within the operation plan for following years. For example, an official entity may identify reducing the percentage of high-risk establishments by 50% over a two-year period as a target. Fig. 7 shows an example of the traffic light system a regulatory agency may use to understand the level of risk among food establishments.

Fig. 7 Traffic light system indicating the food safety performance of establishments

High-risk establishments (40%)

- 40% of the establishments are categorized as high-risk and thus need more frequent inspection

Moderate-risk establishments (20%)

- 20% of the establishments are categorized as moderate-risk and thus need less frequent inspection

Low-risk establishments (40%)

- 40% of the establishments are categorized as low-risk and thus need lesser inspection frequency

In turn, an analysis of the results of the new system can indicate trends (improving or worsening) in the performance of each facility over time, allowing the frequency of inspection to be varied according to compliance results. An analysis of the results can also reveal differences in assessment attributable to the inspector during the inspection (which should be minimized by exchanging technical criteria) or "weak points" common to all establishments in the sector, which can be used by inspectors to emphasize areas for improvement and thus reduce risk.

Periodically, it is advisable to review the inspection checklist to check that all risk factors are included, and to include new regulatory aspects. At the same time, it is important to update the weighting or "weight" to be given to each factor in the establishment's risk matrix. For example, new aspects related to emerging hazards such as allergen management, history of noncompliance findings in finished product and pathogen verification programmes on food contact surfaces are some of the risk factors that can be considered for inclusion in the risk matrix for categorization of the establishment.

Finally, it is important to highlight that by taking into account the experiences of countries with implemented risk-based inspection systems, it has been possible to observe better performance of small establishments, as inspectors are present more frequently than before, which in itself represents a great achievement in the new risk-based inspection system.

4. Conclusion

Risk-based inspection models provide an opportunity for countries to modernize their inspection systems under a harmonized methodology and to improve their efficiency, sustainability and robustness by applying the principles of risk analysis. The examples presented in this handbook provide a starting point for countries to understand the steps and tools available to design a new risk-based inspection model. The risks inherent in food and food processing are particular to each country and production chain, as well as the characteristics of the producing establishments. In general, it can be concluded that the keys to a successful risk-based inspection system start with political commitment and an adequate regulatory framework to support the process, designing the model based on the collection of adequate and relevant information, and periodically subjecting the model to a process of adjustment to allow for continuous improvement of the system.

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Annexes

Annex 1. Preparing for an inspection

The inspector needs to prepare for the inspection. Some important aspects that need to be covered are inspection attire and inspection equipment.

A. Inspector attire

The inspectors need to be presented in such a way as to provide for effective inspection and to ensure that they themselves do not present a health and safety or hygiene risk to the areas being inspected. The inspectors should accordingly consider the following:

- Clothing should be clean and free of stains.
- A laboratory-type coat or other suitable overcoat is encouraged.
- Suitable enclosed and clean footwear should be worn.
- Containment of long hair and any loose clothing.
- Dangling jewellery should not be worn.
- A clean and well-maintained bag, case or clipboard may be brought into the food business.

B. Inspection equipment

Equipment required for inspection and any associated sampling will vary depending upon the type of inspection and the nature of the visit. The inspector needs to be familiar with the use of equipment and ensure that the equipment is kept clean, securely stored and maintained in good working order at all times.

Equipment commonly used by inspectors for routine inspections	
Item	**What is it used for?**
Clipboard for checklist	To provide a stable writing platform.
Pens	For note-taking and completing checklists. A spare pen as backup is recommended.
Camera	For taking photos as a visual record of conditions.
Flashlight	To view areas where lighting is limited, such as behind equipment and under shelving and other equipment.
Digital thermometer (probe-type and infrared)	For measuring temperatures of food being stored or displayed for sale. Thermometer calibration should be performed before inspection. Backup batteries are necessary.
pH meter or strips	To determine the pH of foods, which is especially important when pH additives are used as the sole preservation method.

Sampling and analysis equipment	
Item	**What is it used for?**
Sample notebook	To record the date and time of the sample taken, from whom and where it was taken. A sample number should be allocated to each sample.
Tape, labels and a permanent marker	To allow for a food sample to have an identification label. The sample number should be written on the label and also recorded in associated paperwork and notes.
Sterilized sample utensils, such as spoons and knives	To ensure that samples are not contaminated by other sampling equipment.
Small clean chopping board and sterilized knife	For inspection and portioning of a food item if required.
Food-grade sample bags or containers	Sample bags are for sampling foods. Sample bottles are for sampling liquids.
Ice or cool box with suitable refrigerant	To allow the food sample to be kept well chilled during transport.
Scissors	To open food bags and cut tape for re-sealing bags.
Tissues and wipes	For cleaning purposes.
Ethyl alcohol (70% w/v)	An effective method to sanitize surfaces. Prevents contamination from dirty surfaces. May also be used to sanitize hands.
Magnifying glass	For a detailed inspection of a sample for identification and assessment purposes.
Measurement ruler	Useful especially in relation to food complaints involving physical parameters such as size. Gives size perspective when included in a photograph.

C. The inspection process

The inspection process consists of an entry or opening meeting, familiarization tour, site inspection, reviewing findings and reporting, and closing meeting. This is followed by post-inspection activities including follow-up and corrective actions.

D. Entry/opening meeting

At this entry meeting, the inspector should be prepared and willing to answer questions about the laws and regulations empowering them and other relevant questions the food business operators may have. The inspector should be presentable and polite and identify themselves by showing official identification and proof of affiliation whenever necessary. The objectives of the inspection should be clearly stated.

During the opening meeting, the inspector should also mention the need to ask questions of employees in the facility and the confidentiality of the inspection and all records and documents involved. The applicable standards and codes or other regulations on which the inspection will be based should also be highlighted. A room for the inspector and assistant(s), if any, to meet and work on the report may be requested if needed.

The inspectors should obtain permission before proceeding with the inspection process. If there are some difficulties in communication between the inspector and the food business operator in relation to not speaking or understanding the same language, it is recommended to arrange for a translator before the inspection.

The owner/operator of the business or, if absent, the person with delegated responsibility needs to be identified. The inspector should ask to see the food licence or certificate of registration (if applicable) and check the following:

- the operator details are correct
- the approval status and any expiry dates are current.

If the legal owner or operator is different from that recorded on file, instruct them to renew the premises registration in the appropriate name.

The inspection process needs to be explained to the food business operator or person in charge and their collaboration requested. An outline of the scope and procedure of the inspection and the philosophy underlying the inspection should also be communicated at this stage. This is a good time to review the outcome of the previous inspection and discuss any outstanding requirements as well as to discuss how the food business is operating and if there have been any changes or planned changes to the process used within the food business.

During the entry meeting, it is important to arrange to meet with senior management/ owner of the food business at the completion of the inspection to discuss findings.

Any potential on-site work environment hazards including specific hygiene procedures such as the required wearing of protective clothing should be discussed at this stage.

E. Familiarization tour

The walk-through is a very important part of the inspection especially if it is a large operation. The walk-through should be conducted in a direction opposite to the flow of product so that the inspector will not become a potential source of cross-contamination by moving from raw to finished product areas. Care should be taken by the inspector to avoid being injured by equipment, conveyors, hooks and other hazards. The walk-through inspection should be timed to allow the inspector a complete view of the facility's processes, taking into account that certain operations such as reception of raw materials may take place only at certain times of the day. The inspector should take any necessary measures to ensure that they do not bring contaminants into the processing plant, including washing their hands and putting on a laboratory coat, as necessary.

In addition to specific aspects of the facility and processes that the inspector must pay attention to as they perform the walk-through inspection, there are various physical characteristics of food processing facilities that the inspector must keep in mind throughout the entire inspection, for example, the state of walls, floors, ceilings, doors and air quality.

F. Site inspection

Hazards and risk assessment

An inspector must conduct an inspection of the food business including all food-related areas and make an assessment from a risk-based perspective. Before the inspection of premises, the inspector should carefully consider the risk of the hazard and whether controls are in place to manage the hazard. Consider hazards from:

- Foods
- Processes
- People
- Environment.

The following four types of hazards may have an impact on the safety of food and are accordingly considered by the inspector with an overall perceived risk determined.

Microbiological hazards (M):
Bacteria, yeasts, moulds, viruses and parasites.

Chemical hazards (I):
Biocides, food additives, chemical residues during the process, contamination by cleaning chemicals, pest control substances and pesticides.

Physical hazards (P):
Foreign matter such as glass, sticks, stones, flakes of paint, packaging pieces, bolts, jewellery and pest droppings.

Allergen hazards (A):
Shellfish, fish, eggs, dairy, gluten, soybeans, sesame seeds, peanuts, tree nuts, lupin and sulphites.

The inspector assesses the types of foods being received, stored, prepared, processed, packaged, labelled and transported, and determines the critical control points (CCP) in addition to other important controls. A CCP is a step in food preparation in which control is crucial at that step in order for the food to be made safe. This is also the last step which is available to manage that particular hazard for that food item.

An example is the cooking step for poultry.

The heat step (cooking) is critical to ensure bacteria (commonly associated with foodborne illness) on raw poultry meat are destroyed. Research has proven that a temperature of over 75 °C will effectively destroy any such bacteria. This heat step is critical to ensure the safety of this food from potential microbiological hazards. This is a CCP. The CCP has a required temperature being a minimum of 75 °C; thus, the minimum temperature limit to control these hazards is 75 °C.

Control points include refrigeration or freezing of stored perishable food and also the keeping of foods at an appropriate temperature while on display. It is also important to be aware of these and assess them to determine whether hazards associated with these foods are being managed effectively by the operator. The use of a thermometer will allow temperatures to be measured by the inspector. All food storage and food preparation processes are to be considered by the inspector when determining hazards, risks and controls. The inspector will accordingly apply a risk-based approach to determine compliance.

The inspector needs to determine whether workers within the food business have a good understanding of the CCPs and associated controls. Remember to consider control of the following hazards:

- Microbiological hazards – control of bacteria from raw meats

- Chemical hazards – use of appropriate food additives, cleaning and storage chemicals
- Physical hazards – foreign matter, such as glass, metal, stones, flaking paint and hair
- Allergen hazards – awareness of ingredients in foods, allergen-free label assurance.

Food premises inspection checklists

The inspector needs to thoroughly assess the condition and operation of the food premises, and to identify factors which may affect the safety of the foods prepared or sold. For this, the inspector shall use a 'Food premises inspection checklist' to document the inspection outcomes (see Annex 5 for a model checklist). This checklist may be modified to suit inspection needs and country requirements. A notes section is included. It is recommended that the checklist is supported on a suitable clipboard.

The food premises inspection checklist allows the inspector to keep track of what has been inspected during the inspection and also record the outcome. The inspector may write additional notes relating to the CCP and management of risk, which serves as a useful record. This allows for information to be well documented and ready to relay to the operator at the end of the inspection. It also serves as an inspection record.

It is important that the inspector is familiar with the checklist and its requirements before the inspection.

The inspector also requires a clear understanding and awareness of the following before the start of the inspection.

- Food types being prepared or processed on the premises.
- Any foods being prepared at other locations.
- The food processes including the CCP required to keep foods safe.
- Controls to reduce risks associated with foods prepared or processed at the business
- How the operator ensures that food safety controls are effective.
- Whether foods are being sold/ distributed for further retail sale, and if so, confirm whether records show where the food has gone and also whether the food is appropriately labelled.
- Staff training levels: what training is provided and how the operator ensures that staff have the necessary knowledge to ensure that foods are prepared and maintained in a safe manner. The inspector may be able to offer advice as to what level of training is appropriate for the worker.

An inspection of the premises, work environment and surroundings of the premises is necessary to check for damage, wear and tear and cleanliness. The inspector needs to apply a risk-based approach to determine the risk imposed by the condition of the premises and how this affects the safety of the foods prepared/processed at the premises. The following aspects must be considered.

- Facilities and equipment are to be assessed for adequacy.
- The size of the premises, number of food workers and types of foods prepared will have a bearing on business requirements.
- Workers require adequate space to undertake their work and the premises must be adequately ventilated for hygiene reasons.

- The inspector needs to determine all potential hazards that may arise from staff activities, food processes and the general working environments.
- The headings detailed on the inspection checklist provide a prompt for the inspector as to what requirements are to be checked.

Insect and rodent controls should be assessed by looking for signs of pest activity which may include checking for potential entry points. Signs include rodent droppings, urine odour, partially eaten packaging or product or rodent baits eaten from traps. The inspector will determine required actions based on the risk-based assessment. Insects and rodents can carry disease and contaminate food areas, so this should be considered when requirements are imposed.

Refer to legislative mandate as a reference document to back up any requirements imposed.

NB: During the inspection, it is a good idea to ask food preparation staff what they consider are the most important points to ensure the safety of foods in the process.

Review findings and prepare reports

Once the inspection has been completed, the inspector reviews, collates and summarizes the findings. The data collected during inspections, including compliance outcomes, can be utilized to determine compliance action, follow-up inspection and when the next inspection should be scheduled.

The inspector makes sure all defects and noncompliances are thoroughly and accurately recorded. This may be useful in case evidence is required for any subsequent legal action. The non-conformity report is also prepared and is discussed in the closing meeting.

Closing meeting

A meeting is held with the food business operator (or delegated representative) at the conclusion of the inspection to discuss the findings. Attendance by all relevant departments should be encouraged. The inspector provides feedback to the operator or their delegated representative, which should include positive findings as well as a summary of areas that need to be corrected and the time frame for correction.

A discussion on the findings should include situations observed and the reasons for noncompliance, particularly in relation to critical control points, any noncompliance with a previously issued report or notice, any seizure of food and any recommendations (actions that reflect good food safety practice may be recommended). Discussion of actions is necessary to achieve compliance along with appropriate timelines for implementation. The corrective action plan must be agreed upon between the inspector and the food business management and written into the inspection report.

The inspector must record the outcome of the discussion and note any significant comments that may have a bearing on any subsequent inspections or enforcement action. It is necessary to hear and record any explanation given by the operator for any noncompliance. Their opinions are important in understanding the level of food safety awareness within the business and are useful for modifying and enhancing the inspection process. The inspector should then complete the inspection report, including the corrective action plan; if any corrective action is to be taken by the business, ask the management to sign

the report and provide the management with a copy.

This opportunity may also be taken to promote food safety. Information resources, wall charts with food-safe messages, stickers or any other food safe resources can be provided.

Corrective Action Plan and Improvement Notice

All noncompliance(s) should be recorded not only on the Food Premises Checklist, but also on the corrective action plan (see Annex 7 – Corrective Action Plan and Improvement Notice).

A Corrective Action Plan and Improvement Notice is a formal document provided to the operator of the food business and details what is to be addressed and also the due date for completion. It may be handwritten (preferably by duplicate carbon copy), or otherwise typed up and sent to the business at a later date. Substantial noncompliance(s) or ongoing issues may require a typed Corrective Action Plan and Improvement Notice detailing noncompliance, required actions and due dates for completion. Due dates for completion are based on the risk associated with the noncompliance and are determined by the inspector.

Any typed report must be checked for completion and accuracy before issue, making sure the matters detailed in the report are supported by recorded findings and are within the scope of the inspection.

High-risk situations are given a shorter time frame to correct the nonconformance compared to lower-risk issues. Any situation where there is an immediate risk requires immediate action. Other time frames may be from three days to six months. Any structural aspects that do not present a high risk are usually provided a longer time frame. This will also allow the business to budget for any structural upgrade.

It is advisable to discuss and agree on a due date with the food business operator, but if this is not possible, then the inspector shall assign due date(s).

Interim measures to safeguard foods may also be considered following the inspector noting a food safety concern. One such example could be to move to another location within the business premises to mitigate risk or otherwise protect foods. The inspector needs to have flexibility to allow for different compliance options if the end result is to mitigate the risk.

Improvement notices should not include any additional requirements that had not been discussed at the time of the inspection. Any food safety-related matter that is conducive to good practice but not required by current legislation should be listed on any report as a “recommendation” only.

Record-keeping/database

All documentation associated with the inspection should be fully completed, signed, dated, and then filed appropriately. The documentation should include as a minimum the completed Food Premises Checklist, the nonconformities, the Corrective Action Plan and Improvement Notice signed by both the inspector and the food business operator (FBO) management and copies of other pertinent documents deemed necessary by the inspector.

If a food inspection database is available, then the inspection details should be entered into the appropriate record fields in the database. This should be completed as soon as possible after the inspection takes place. All records shall be kept in a safe and

secure location. The next date for inspection or follow-up visit should be planned at this time.

Follow-up inspection visits

Proceed with this step when following up on the Corrective Action Plan and Improvement Notice. Follow-up inspections should be undertaken on or shortly after any completion dates recorded within a report/plan.

- Take the copy of the Corrective Action Plan and Improvement Notice. Write the date of re-inspection on the form and place a tick or a cross next to each item listed to indicate completion or otherwise. At the completion of this process, sign the Plan.
- Look for evidence during the inspection that the corrective actions have been satisfactorily implemented.

If all corrective actions have been satisfactorily completed and there are no further matters reported, sign the corrective action plan at the completion of this process and close the file.

If there are corrective actions that have not been completed to a satisfactory standard:

- Ask the food business operator for an explanation and note the details.
    a. If the explanation is reasonable and new completion dates are agreed upon, then record this (will require a further follow-up inspection).
    b. If the explanation is unreasonable, and it is considered that the failure to implement the corrective actions presents a continuing significant public health risk, then the inspector will report this to the food regulatory authority. The food regulatory authority may consider whether further legal actions are necessary. This should be dependent on the associated risk to the public.
- Record and report any new noncompliance or issues found during the re-inspection as per the normal procedure. This may involve the issue of a new Corrective Action Plan and Improvement Notice.

Further actions

A decision will need to be made by the food authority management as to whether further legal actions such as prosecution, revocation of approval or required food business closure are appropriate. In the first instance, advise management of the situation and keep them up to date with information. Further legal actions may be considered on a case-by-case basis.

The data collected during inspections, including compliance outcomes, can be utilized to determine the need for immediate compliance action, follow-up inspection needs and determine when the next inspection should be scheduled.

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