RISK-BASED FOOD INSPECTION MANUAL FOR THE CARIBBEAN

PAHO
Pan American Health Organization
World Health Organization
Regional Office for the Americas




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PANAFTOSA
Pan American Center for Foot-and-Mouth Disease and Veterinary Public Health

Risk-based food inspection manual for the Caribbean
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CONTRIBUTIONS AND ACKNOWLEDGEMENT

The Pan American Health Organization (PAHO/WHO) would like to express its appreciation to the people who have contributed to the preparation of this manual. While the manual is primarily conceived for use by Caribbean countries, PAHO/WHO is of the view that it may also be of use to other countries as a basis for developing or improving their national food control systems.

Leadership and coordination of this manual was provided by Dr. Alexandra Vokaty, Advisor, Veterinary Public Health, Caribbean PAHO/WHO Office in Trinidad and Tobago, supported by Drs. Simone Raszl and Margarita Corrales PANATOSA-PAHO/WHO.

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1 Report of Caribbean Sub-regional Workshop on Risk Based Food Inspection.

SECTION 1
INTRODUCTION

Countries are seeking to improve their food control systems consistent with guidance produced by Codex Alimentarius,[2] to improve food safety and reduce foodborne diseases. Improving food control systems generally requires a change of approach with respect to inspection on the part of government organisations with responsibility for food controls and food safety, (i.e., competent authorities) as well as by food businesses and food inspectors.[3]

For competent authorities, the changes mean a focus on a systematic, national approach that includes a risk-based planning and reporting process that is associated with performance measurement that contributes to collaboration, a reduction in duplication and continuous improvement.[4] For food businesses and food inspectors, it refocuses their relationship with inspectors from adversarial to collaborative, with the food business taking responsibility for producing safe food and the food inspector assessing both the food business controls and their implementation. The inspector's focus changes from simply verifying static (i.e., yes, no) compliance with regulations to a focus on assuring the food business has the appropriate processes in place to prevent food contamination, and that those processes will be working even when the inspector is not present.

It is recognized that, currently, each country has implemented its own unique approach to food business inspections. In moving to risk-based inspections, each country will need to develop a clear objective (e.g., a systems-based food control) and a multi-year plan for implementation. This requires a collaborative approach

2 The Joint FAO/WHO food standards program develops and publishes the "Codex Alimentarius" or "food code" a collection of international food standards, guidelines and codes of practice that contribute to food safety and fair-trade practices.

3 Risk-based food inspection manual, FAO Food and Nutrition Paper 89, Rome 2008.

4 Continuous improvement means that a national food control system has the capability to learn through a process of review and reform using mechanisms that evaluate whether the system can achieve its objectives (CAC/GL 82-2013).

to assessing its current situation (e.g., who is inspecting, what food business, how frequently). It also requires a country to have information on the types and classes of food businesses and the food they produce (i.e., the national food profile, see **Appendix 1** for further details), as well as the legal framework, the existing inspection services, and available financial and human resources. The multi-year implementation plan should include consultation with stakeholders (e.g., food businesses, consumers, academia), and could also include consultation with trading partners.

This manual contains guidance for risk-based inspections of food processing, preparation, retail and restaurants that countries can consult and adapt/adopt in developing a risk-based food business inspection program for their specific context.[5] It is intended to help countries implement risk-based inspection systems that are consistent with international standards. This document builds on the FAO Risk Based Food Inspection manual (2008)[1] and draws on the more recent guidance developed for governments by Codex Alimentarius, in particular, the Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013) and the General Principles of Food Hygiene (CAC/RCP 1-1969).[6] Where international standards are used in this document, they are listed both as a footnote and in the reference section.

The manual includes sections on guiding principles and terminology, risk-based planning and reporting, risk-based inspection, and appendices on rating guides and references.

5 The concepts and approaches set out in this manual could also be adapted to other inspection activities (e.g., farms, importers) although it would require development of specific guidance documents (e.g., good agricultural practices, good importing practices).

6 This manual also builds on other national risk-based inspection manuals (e.g., Trinidad and Tobago, Barbados, Bangladesh), the development of which was supported by PAHO and/or FAO.

SECTION 2

GUIDING PRINCIPLES AND TERMINOLOGY

This section provides some key principles that will help guide a country's inspection service(s) as they implement a risk-based food inspection program. It provides guidance for inspectors who undertake food inspections focusing on processes and practices for consistency and coherence. It identifies terms[7] that are used throughout this manual to simplify drafting as well as terms that are often established in national legislation that countries will have to consider in developing country-specific manuals. It **does not and is not intended** to re-define terms or words that are defined in national legislation or by Codex.

In adapting this manual, each country will have to adopt and adapt the appropriate terminology from their laws and regulations as appropriate within their own context.

GUIDING PRINCIPLES

Codex guidance on national food control systems[8] establishes a number of principles. When designing, implementing and managing risk-based food business inspection program or programs, consideration should be given to the following key principles:

7 A list of other terms from Codex and other sources can be found in the Glossary.

8 Principles and Guidelines for National Food Control Systems CAC/GL 82-2013.

RESPONSIBILITIES[9]

The maintenance and enhancement of health and safety is a responsibility shared between industry, consumers, and competent authorities.

- Food businesses have primary responsibility for the safety of any food product they manufacture, import, sell or distribute to the public or use in a manufacturing environment. They are responsible for sourcing, preparing, storing, labeling and selling food that meets legislative and regulatory requirements established by the competent authority and/or the government.[10]
- Consumers have a responsibility for the maintenance of their health and the safe use of food products. In addition, consumers should be provided with the opportunity, and be asked, to inform the competent authority of any problems that they encounter (e.g., hazards, adverse reactions and non-compliance) related to foods.
- The competent authority (ies) is/are responsible for promoting, monitoring and assessing compliance with established standards, and taking enforcement action, within the responsibilities assigned by the government in the case of non-compliance.

GUIDING PRINCIPLES FOR DECISION MAKING

In carrying out a risk-based inspection program, it is important to establish guiding principles for decision-making. Inspectors and other officials will be continually required to make decisions within the inspection program with respect to encouraging compliance or taking enforcement action. In taking such decisions, inspectors or other officials should take into consideration the following principles:

- The risk to health and safety and prioritizing the greatest risks.
- Fairness, equity and transparency.
- The powers and authorities set out in the legislation that authorizes the inspection activities.
- Consistency in the administration of the food safety programs to the greatest extent possible.
- Ensuring that inspection activities are carried out by qualified[11] personnel, professionally, in an unbiased and unprejudiced manner.

9 Principles and Guidelines for National Food Control Systems CAC/GL 82-2013.

10 In some countries, the competent authority has the authority to establish regulatory requirements, in others it is the elected officials (e.g. Parliament, national assembly) who are responsible to do so.

11 CAs and governments are encouraged to establish qualifications for inspectors and analysts, and other officials in the food control system.

While the primary objective is to address food safety, inspectors may also need to take into consideration the maintenance of fair practices in trade, in particular address the fraudulent sale of food (e.g., sale of agricultural products acquired by praedial larceny,[12] sale of illegally labelled[13] or produced products).

In addition to risk-based inspections and national monitoring or sampling programs, competent authorities, (e.g. inspectors, other officials) generally have a range of risk management activities that can be undertaken. Determining the most appropriate action requires consideration of the following points/answering the following questions:

- Will it resolve the risk to health and food safety?
- What is the chance of success based on the compliance history of the food business?
- What is the degree of cooperation by the food business?
- Did it act with indifference or premeditation?
- Is the food business likely to repeat the non-compliance?

Administrative actions (i.e., actions taken by the inspection services as authorized by legislation) are often the most effective means to achieve compliance and/or resolve non-compliance. Each action noted below should have a written procedure outlining the steps and consideration for implementation to maximise consistency and provide maximum transparency for food businesses. Actions may include:

FOOD SAFETY INVESTIGATIONS

Food safety investigations are intended to determine the source of a food safety issue. The investigation is a systematic determination to confirm if a problem exists, and if so, its cause (e.g., actions or inactions by the food business, retailer, consumer). It is undertaken as the result of a consumer or industry complaint, new national or international information indicating a food safety problem, trends identified by a national monitoring program, or sampling results. Should the food safety investigation confirm the source of the problem, an appropriate response can be developed and implemented by the food business, in cooperation with the competent authority.

12 Praedial larceny - the theft of agriculture produces (FAO sub regional office for the Caribbean, Issue brief #3 2013).

13 Guidance on labelling is included in Guidance 6 and more detailed guidance is provided in Annex 5.

WARNINGS

An inspector may issue a warning to a food business when it is believed that non-compliance has occurred or is occurring and the risk to human health or safety does not warrant stronger enforcement action. A warning may be issued verbally or in writing but information on the warning must be included in the food business file.

If the food business ignores the warning and does not resolve the issue, the competent authority should consider taking further risk management actions in order to maintain confidence in the effectiveness of the inspection program.

DETENTION

Detention is an agreement between a food business and an inspector to maintain control of a particular product, generally within the food business premises, until compliance is achieved. Detention is intended to control the product for a limited period of time, often to allow the product to be brought into compliance (e.g., relabelled).

INDUSTRY RECALLS

A recall is an action taken by a food business to remove a non-compliant food product from the market, because it may represent a risk to the health or safety of consumers.

PRODUCT WITHDRAWAL

Product withdrawal is a subset of an industry recall action, where a food business removes non-compliant food from warehouses and distribution centres prior to the food reaching the marketplace.

In many cases, the food business may be asked by an inspector to initiate the recall of a non-compliant food, but the business is responsible for implementing the recall. Where a food business implements a recall or product withdrawal, the competent authority will monitor the effectiveness of the recall.

PUBLIC ALERTS

When there is an imminent health hazard and the product is present in the marketplace, the competent authority may choose to inform the population at risk by means of a public alert. Public alerts must be factual and clearly state the problem, the identity of the food involved and why the public is being advised of the issue. They are generally reserved for situations where the risk to human health is high (e.g., potential for illness or serious injury).

SEIZURE (ADMINISTRATIVE)

An administrative seizure is an immediate and effective enforcement tool to control non-compliance consistent with legislative authority, whereby an inspector removes control, and in some cases, ownership, of the non-compliant product from the food business in order to address a food safety risk. In some legislation, the authority for seizure may also be associated with the authority to condemn and destroy. In some, but not all countries, the legislation may include the authority to seize equipment.

Decisions by an inspector to seize food products and/or equipment are generally made following discussions with supervisors or other designated officials within the competent authority.

NOTE:

An administrative seizure provides authority to control a food safety risk and must not be confused with an "evidentiary seizure", which provides authority to gather evidence as part of a criminal investigation. In executing an evidentiary seizure, the inspector, who would generally be accompanied by a police officer, would seize one or two items (e.g., labels, food products) as evidence to be presented before a judge. Evidentiary seizures are generally associated with prosecutions and/or injunctions.

REFUSAL TO ISSUE A CERTIFICATE

Where a country has established a process for issuing certificates (e.g., export, free sale, product), officials may refuse to issue and/or sign a certificate when there is evidence that the food business and/or the food to be certified is not in compliance with the specified requirements.

WITHDRAWAL OF AUTHORIZATION

In general, most national legislation requires that all or most food businesses be authorized (e.g., registered, have a license or have a certificate of free sale). This allows the inspection services to "know their universe of businesses", and also means that removing that authorization makes it illegal for the food business to manufacture and sell food.

Where a significant health risk exists and there is no indication that the food business will address that risk and bring itself into compliance with legislative requirements, then withdrawing authorization (i.e., making the operation of the food business illegal) may be considered. Such an action is not taken lightly, and it should

have clearly defined procedures. It is generally taken by senior officials within the competent authority, in consultation with the inspector.

It is recommended that the competent authority and the food business representative (e.g., owner, operator or other responsible personnel) meet to discuss the non-compliance and possible solutions prior to registration being withdrawn, as part of due process.

COMPLAINT OR DISPUTE RESOLUTION

Food businesses should be given the opportunity to provide input to the competent authority. This applies to specific situations pertaining to the food business, or to risk management activity taken by an inspector in response to non-compliance or other identified issues. The opportunity to provide input and allow discussion of the issue is intended to provide an opportunity for open and transparent communication and to resolve irritants and inconsistencies in the application of the requirements before these escalate to bigger problems.

In general, such input and/or discussion would take place with a representative of the food business, the inspector and a more senior official in the inspection services (e.g., supervisor, senior inspector).

This is an administrative procedure and does not preclude a food business or the government agency having recourse to the courts.

INFORMATION ON COMPLIANCE AND ENFORCEMENT ACTIVITIES

Transparency is a critical tool in improving food safety. Publishing information on risk management activities such as annual summaries of food safety inspections and/or analytical results can enhance understanding of food businesses and consumers of the food safety program and requirements.

Consideration should be given by the competent authority to make information on its compliance and enforcement activities available to the public and food businesses, subject to the provisions of legislation.

NOTE:

Some countries may choose to publish the list of licensed or approved food businesses. Publication provides consumers and other stakeholders with information to identify legal food businesses. A statement that the competent authority will be publishing the names of legal food businesses can be part of the licensing agreements. Where licenses are removed because of food safety concerns, the food business would also be removed from the list of licensed food businesses.

TERMINOLOGY

ANALYST

Analysts, including public analysts, are generally designated under national legislation. Their primary role within a food inspection system is to analyze samples and report on the results. The general term "analyst" is used to simplify drafting of this manual.

COMPETENT AUTHORITY

In general, countries will have multiple authorities responsible for managing the safety and quality of food, including but not limited to authorities such as health, agriculture, fisheries, consumer affairs, and standard setting. Each authority will operate under national laws and regulations and is considered the competent authority within their responsibilities. The term "competent authority" is used throughout the manual to simplify drafting.

A country's risk-based inspection manual should identify and list each competent authority and all the legislation and/or regulations or any other legal instrument under which they operate. An example of a template that could be used to list such information can be found in Chart 1 (see below).

CHART 1: TEMPLATE FOR LISTING COMPETENT AUTHORITIES AND LEGISLATIVE INSTRUMENTS

Competent authority	Legislation and/or regulations

FOOD

In general, countries have developed specific definitions of food and these definitions are set out in their laws and regulations. In developing a national manual, these legal definitions must be referenced. However, the term "food" is used throughout this manual to facilitate drafting and, as such, the definition of food in the Codex Alimentarius Procedural Manual is being included here:

> **Food**[14] means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum

14 CODEX ALIMENTARIUS COMMISSION Procedural Manual Twenty-Sixth edition 2018.

and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.

FOOD BUSINESS

Countries have generally developed specific definitions that apply to persons and businesses that produce, process, transport, distribute and sell food, including institutions such as hospitals and school feeding programs. These definitions are usually set out in their laws and regulations and may include terms such as farms, fishermen, distributors, food processing, stalls, food rooms, food establishments, processing plants, slaughterhouses, food premises, restaurants and markets.[15]

To facilitate drafting and readability of this manual, the term food business will be used as a general term.

FOOD HANDLER'S REGISTRATION

A food handler[16] is any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements. Where national legislation requires and authorizes requirements for food handlers, all the specified requirements (e.g., be registered, have a medical certificate, have specified food safety training) must be met.

To facilitate drafting and readability of this manual, the term food handler's registration will be used as a general term.

GOOD MANUFACTURING OR GOOD HYGIENE PRACTICES (GMPS OR GHPS)[17]

Food business practices and operations in all aspects of food production to mitigate risks and meet manufacturing specifications and statutory health, safety and compositional requirements. Codex, as well as some countries, may also use the term Good Hygienic Practice.[18]

In this manual, both GMP and GHP will be used.

15 In addition this term is also in the revised Codex Good Hygiene practices See the Report of the Codex Committee on food hygiene (50) http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-50%252FReport%252FREP19_FHe.pdf.

16 General Principles of Food Hygiene (CAC/RCP 1-1969).

17 Adapted from several similar international definitions including Codex and the USFDA.

18 The term "good hygienic practices" is based on the definition of food hygiene documented in the Codex General Principles of Food Hygiene (CAC/RCP 1-1969).

ILLEGAL FOOD BUSINESSES

This risk-based inspection manual is intended for competent authorities to inspect **legal food businesses** for compliance with national guidelines, specifications and regulatory requirements. Illegal food businesses should not be operating and should be referred to the police or other authorities for closure.

While each country will have its specific definition, an illegal food business is generally any food business that is not authorized under national legislation (e.g., registered, licensed, identified, permitted).

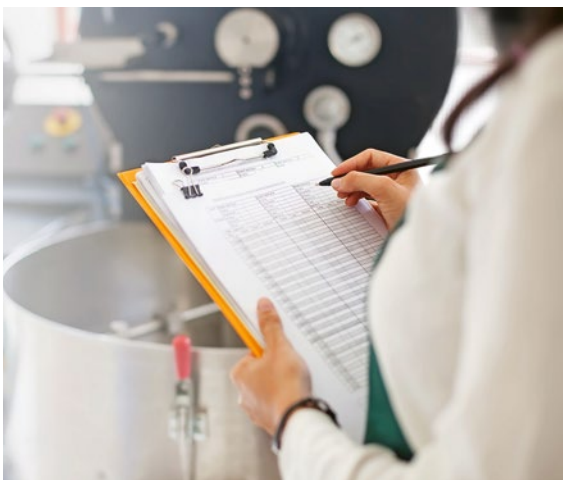
NOTE:

If there are a significant number of food businesses that, although considered illegal, have been operating for a significant period and are socially, economically or politically acceptable, then the competent authority should develop a strategy to legalize them.

INSPECTOR

Inspectors are designated under specific legislation. Their primary role is to monitor compliance and to enforce the relevant legislative requirements. They may be public health inspectors, food inspectors, district inspectors, veterinary inspectors, environmental health inspectors, agricultural inspectors or other similar titles.

The term "inspector" or "food inspector" is used to simplify drafting of this manual.



RISK-BASED INSPECTION

Inspection activities focused on food products and legal food businesses that pose the highest risk to consumers' health.

SALE

Sale is normally defined in the legislation and/or regulations of each country. In general, it will encompass concepts of sell, expose for sale or have in possession for sale whether or not for recompense. The inclusion of the definition of sale in any food inspection manual should be consistent with the legal definition(s).

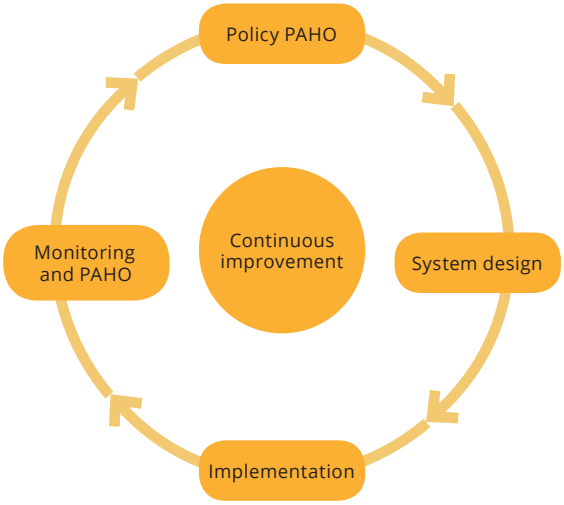
Each country should assess what activity is included in their legal concept of "sale", for example, produce sold at the farm gate may not be considered commercial sale, but is considered "personal consumption". This is similar to importation for personal use.

SECTION 3

RISK-BASED INSPECTION PLANNING AND REPORTING

Countries and their competent authorities must address a significant number of food safety issues within their food control programming. One of these is to identify the food/food business combination or combinations that present the highest risks. In general, national food control systems consider Codex guidance[19] and, in consultation with stakeholders, adopt a framework that includes policy setting, system design, implementation, monitoring, and system review – with an emphasis on continuous improvement.

FRAMEWORK FOR THE DEVELOPMENT OF A NATIONAL FOOD CONTROL SYSTEM (CAC/GL 82-2013).



The policy position is established by a country when it decides to implement a risk-based inspection program. Risk categorization, a systematic process to identify and assign risks to each food and each food business within the system design, often forms the basis of risk-based inspection planning and reporting. Written planning and reporting processes in this section and the results of inspection procedures set out in Section 4 provide the competent authority with information to monitor and review implementation and to support continuous improvement.

19 Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013.

This section is intended to provide a basic approach to risk categorization to assist competent authorities in establishing a country-based framework (i.e., identifying the risk associated with food, and the risks associated with a food business),risk-based inspection plans (use of risk categorization) and a reporting process which allows for performance assessment of the inspection activities. As countries implement the basic approach and framework, it is anticipated that they will further adapt and improve the process to their specific needs and requirements, such as including the results of foodborne disease surveillance linked to particular foods, the results of pathogen and contaminant monitoring programs, or refining the categorization of food businesses by taking into account the different types of operations.

This section outlines guidance on:

- Establishing food and food business profiles,
- Establishing risk categorization for food,
- Establishing risk categorization for food businesses,
- Using risk categorization in planning for domestic food business inspections,
- Establishing system reporting to assess the performance (i.e., what was done and if it made a difference).

NATIONAL FOOD PROFILES

Establishment of a countrywide, risk-based inspection system requires knowledge of food and food business profiles within the country, which means the competent authority (ies) have information on the production, processing, distribution and consumption of food. As each country has unique food consumption patterns, it is important to take that specific situation into consideration in the risk categorization process. Information about all food and all food businesses is needed for the planning processes.

In essence, a national food profile will list all the food businesses, the foods they sell, and the risk associated with the food, whether they are small, medium or large businesses, and the compliance status history of the food business. It may also break down the information on food businesses by inspection district. It is this national food profile that forms the basis of risk planning. For further guidance, please refer to Appendix 1.

Information about food and food business profiles may be developed over several years, should the information not be readily available to the competent authorities. In such cases, competent authorities should develop a plan or strategy to

gather the required information, including who would gather it, in what format, how and with what frequency it is to be collated at district and national level. The plan or strategy may be carried out over several years, as appropriate, based on the number of food businesses and inspection resources.

RISK CATEGORIZATION FOR FOOD

There are many factors that may be used in establishing the risks associated with food (e.g., microbial or chemical hazards, intended use, use by vulnerable populations, association with foodborne illnesses). With each additional factor, the process of risk categorization becomes more complex. Countries will have to consider what factors they will use in adopting this manual to their own national situation. For this manual, a two-factor approach to food risk is used:

- Food conditions that may result in microbiological and/or chemical hazards.
- Hazard mitigation (i.e., activities that reduce the potential hazard whether carried out by the food business or by the consumer (e.g., whether the food is ready to eat, or consumer cooked).

Each country will have to define each factor and assign a risk score within its own context. This means undertaking a review of the proposed definitions for food conditions and hazard mitigation as set out below. The conditions and any associated hazards should, be based on national or international scientific knowledge to the greatest extent possible.

NOTE:

Chemical contamination that is not the result of human actions (e.g., toxins such as paralytic shellfish poison, ciguatoxin, arsenic in plants from ground contamination) would be considered in this section, while chemical or physical contamination as the result of human actions (e.g., pesticide use, veterinary drugs, extraneous material) would be considered in the section on food businesses.

Physical hazards, such as presence of glass particles and animal hair, would also be associated with food business practices and considered under that section.

FOOD CONDITIONS
(Microbiological hazards and/or chemical/toxin hazards)

Based on the inherent conditions (e.g., water activity (aw), acidity (pH), temperature, conditions at source) of the food such that a potential for hazards exists (e.g., microbiological presence, toxins or chemicals from ground contamination).

→ **High risk (score 15):**

Potential for microbiological presence and growth or risk of toxin production.

→ **Medium risk (score 10):**

Potential for microbiological presence or risk of toxin presence or presence of ground-based, chemical contamination (i.e., no microbial growth, no toxin production).

→ **Low risk (score 5):**

Little to no potential for microbiological or chemical presence or toxin production.

HAZARD MITIGATION

Mitigation is whether the potential hazard associated with the food (e.g., microbiological contamination) is reduced by a particular process (e.g., cooking) prior to being consumed; or, in the case of chemical contamination, if it is reduced by monitoring processes (e.g., toxin sampling programs) that prevent contaminated food from entering the food chain.

For example, a product that is consumed raw with no cooking (i.e., raw, ready to eat) would have no mitigation. A ready-to-eat product where a potential hazard is reduced by some processing (e.g. pasteurization) would be considered to have some mitigation. A product where the hazard would be significantly reduced (e.g., consumer cooked, commercial sterilization) would have significant mitigation. The concept of "hazard mitigation" would be the second factor in food risk and defined and assigned a risk score as follows:

→ **High risk (score 15)** – no mitigation.

a. Ready to eat – raw/no processed.
b. Unknown conditions, or unknown or no control of over presence and/or growth of toxins or presence of natural chemicals (e.g., heavy metals).

→ **Medium risk (score 10)** some mitigation, e.g., processing reduces hazard.

a. Ready to eat – pre-processed.
b. Some monitoring programs for heavy metals, some controls over presence of toxins (e.g., appropriate growth, storage, transport controls).

→ **Low risk (score 5)** significant mitigation e.g., processing eliminates the hazard (e.g., commercial sterility, raw product that is consumer cooked.).

a. Not ready to eat (consumer cooked).
b. Monitoring program establishes absence of toxins, chemicals.

A systematic process should be put in place to identify the food risks which includes:

- Discuss and agree on the definitions and risk scores through a consultative process that should include representatives from all government organizations and may include representatives from academia and industry.
- Identify who will be responsible for identifying food risks, preferably include officials from all competent authorities and laboratories. Consideration should be given to including academia and/or industry representatives.
- Based on the food profile, identify and list all the foods to be assessed, starting with the highest volume foods.
- Assess each food for the two factors. A consensus should be reached and when in doubt, reference national or international information.
- Document the food risks in a chart that will be made available to all officials, industry and consumers. An example of such a chart can be seen in Chart 2 below.
- Establish a regular process, e.g., annually, to review and update the risk categorization process and include an ad-hoc process for updating the list should new information become available.

Developing a complete, food risk chart for a country may need to be carried out over several years. It is recommended that countries begin with the highest volume of food consumed by the population, as well as those associated with foodborne illnesses. Alternatively, countries could begin with available information, while developing a plan for gathering less accessible information. Countries may also choose to apply the food risk table to both domestic and imported foods.

To determine the risk associated with any food, add the two scores:

Food conditions	+	**Hazard mitigation**	=	**Risk score**

For example:

Consumer cooked chicken:	food risk 15 + mitigation 5 = total risk score 20
Pasteurized milk:	food risk 15 + mitigation 10 = total risk score 25
Bread:	food risk 10 + mitigation 5 = total risk score 15
Oysters:	food risk 15 + mitigation 15 = total risk score 30
Raw eggs	food risk 15 + mitigation 15 = total risk score 30
Ice	food risk 10 + mitigation 15 = total risk score 25

Appendix 2 provides some further examples.

It is important to verify that the food conditions and the hazard mitigation are scored according to the definitions. If there are significant concerns with the total scores, based on the knowledge of the assessors, then the definitions will need to be reviewed and potentially amended to better reflect the conditions in the country. Alternatively, the assessors may decide to add another factor in order to address the issue of concern, but each factor added to the assessment makes it more complex.

CHART 2: FOOD AND FOOD RISKS

When filling out the chart, the food should be carefully described (e.g., pasteurized milk, UHT milk, frozen meat, table eggs, eggs for further processing,) and any considerations used in categorizing the food should be listed in the comment section. For a food with multiple elements (e.g., tacos with condiments), each element should be scored separately.

Food	Food condition (Microbial/Toxin score)	Hazard Mitigation (score)	Total risk (score)	Comments

RISK CATEGORIZATION FOR FOOD BUSINESSES

There are many factors that may be used in establishing the risks associated with food business (e.g., the operations, use of documented food safety systems (e.g., HACCP, GMP, GHP, ISO), compliance history, size, distribution). With each additional factor, the process of risk categorization becomes more complex. For this manual, competent authorities are encouraged to use a two- factor approach:

1. Business size – used as a proxy for exposure, **the larger the business, the more the product is produced**, and the more customers served.
2. Compliance history – used as a proxy for the ability of a food business to meet regulatory requirements and sell safe food.

BUSINESS SIZE

The size of a food business may be calculated in different ways such as the number of employees, the quantity (kg) of food produced or the area (m2) used by the food business. Two examples of business size are set out below. The first is based solely on the number of employees, the second is a matrix that considers the number of employees and kilograms of food produced. Countries will need to consider the definition of food business size within their context.

Food business size: example 1

Micro businesses: 1 or 2 employees:
→ Risk score 5

Small business: 3 or more employees, but not more than 20:
→ Risk score 10

Medium businesses: 20 or more employees but not more than 100:
→ Risk score 15

Large businesses: 100 or more employees:
→ Risk score 20

Food business size: example 2

Principals underlying the matrix below:

1. Each country will have to consider the quantity of food and adapt it to their food businesses.
2. A food business with 100+ employees is always considered a large business regardless of quantity of food produced per month because the number of employees increases the potential food safety risk.
3. A micro business will only be considered as 1-2 employees with less than 100Kg food sold per month.

	1-2 employees	3-19 employees	20-99 employees	100+ employees
Less than 100kg per month	Micro business Risk score 5	Small business Risk score 10	Medium business Risk score 15	Large business Risk score 20
100-200kg per month	Small business Risk score 10	Medium business Risk score 15	Large business Risk score 20	Large business Risk score 20
200-500kg per month	Medium business Risk score 15	Large business Risk score 20	Large business Risk score 20	Large business Risk score 20
Greater than 500kg per month	Large business Risk score 20	Large business Risk score 20	Large business Risk score 20	Large business Risk score 20

FOOD BUSINESS COMPLIANCE

The risk score for food business compliance[20] is taken from the food business inspections, as per the procedures in Section 4, for assessing and assigning ratings to individual elements (Critical, Major, Minor, satisfactory) of operations.

- **Critical**: Contaminated food or significant risk of food contamination.
- **Major**: Unsanitary products, production and potential risk of food contamination.
- **Minor**: General conditions that present a low risk of food contamination but may affect product quality.
- **Satisfactory.**

NOTE:

Where critical non-compliance is identified during an inspection, the food business should not be allowed to operate unless it is under the authority of an inspector. Once the critical non-compliance is addressed, then the risk factor would be assigned as high .

COMPLIANCE RISK

→ **High risk (score 15)**

A major non-compliance identified in the last inspection – or a critical non-compliance that has been corrected.

→ **Medium risk (score 10)**

One or more minor non-compliances identified in the last inspection.

→ **Low risk (score 5)**

No non-compliance identified in the last inspection.

As each factor will be assessed by inspectors during their inspections, it is important that there be a consistent understanding among all inspectors and among inspection services. A systematic process should be put in place to identify the food business risks that includes:

- Discuss and agree on the definitions and the risk scores through a consultative process.
- Discuss and agree on the process for sharing the final list with officials and, where possible, food business and consumer representatives.

20 Note: chemical contamination or the presence of extraneous material is considered within the company specific factors. A company with poor controls over chemical contamination or extraneous material would have a critical or major non-compliance.

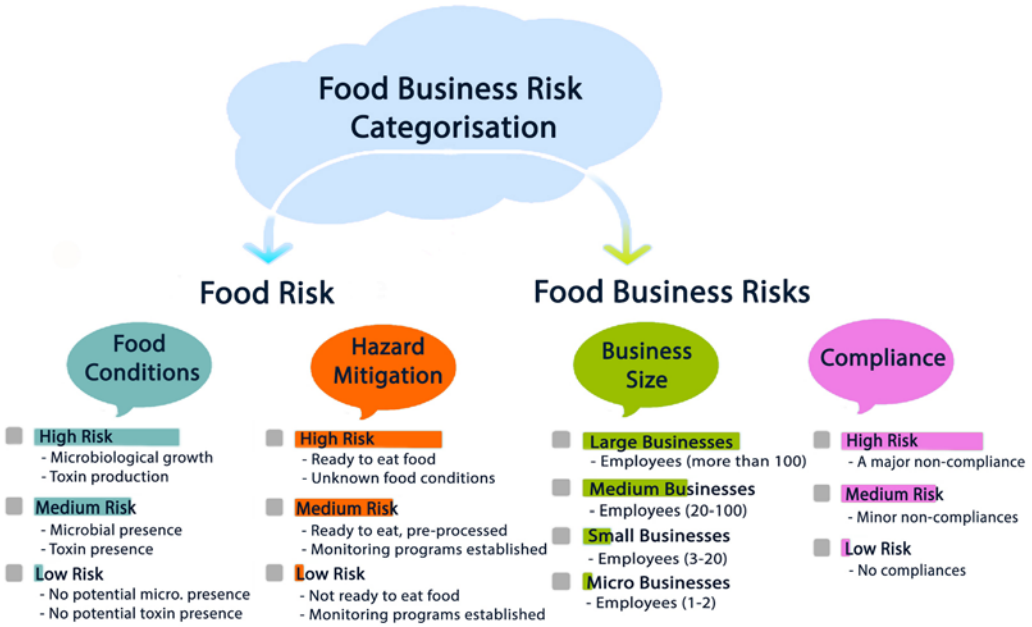
- Based on the food profile, identify the key food businesses to be categorized (e.g., largest food businesses, key categories of food businesses).
- Assign a small team of inspectors/officials to assess each food business in order to identify the food risk (always use the highest risk food produced) and then assess the two food business factors, ensuring there is good agreement within the team.
- Document the food/food business risks (An example of a form that can be used to document the food/food business risks is set out in Appendix 3) that can be maintained on file and updated regularly,
- Establish a regular process, e.g., annually, to review and update the risk categorization process and include an ad-hoc process for updating the list should new information become available.

To determine the risk associated with any food business, add the two scores:

Food risk score (Food risk + hazard mitigation)	+	**Food business risks** (Size and Compliance Risk)	=	**Food business risk**

For example:

1) A small bakery that only makes bread with a major non – compliance identified in the last inspection.	Total risk score 45 [Food risk score 15 (food risk 10 + hazard mitigation 5) + food business risk (size 10 + compliance risk 15)]
2) A large dairy that produces pasteurized milk with no non-compliance identified in the last inspection.	Total risk score 50 [Food risk score 25 (food risk 15 + hazard mitigation 10) + food business risk (size 20 + compliance risk 5)]
3) A medium producer of eggs used raw in dishes with minor non-compliance identified in the last inspection.	Total risk score 55 [Food risk score 30 (food risk 15 + hazard mitigation 15) + food business risk (size 15 + compliance risk 10)]



A combination of the food and food business risk scores are placed into one table, which then becomes the basis of the risk-based planning processes. An example of a chart that could be used to establish a national list of food and food business risks can be found in Chart 3 below.

CHART 3: FOOD AND FOOD BUSINESS RISK

1	2	3		4	5		6	7
Food business name/ identification number	Food (highest risk food)	Food risk factors		Total risk (food)	Food business risk factors		Total risk (food business)	Total risk (column 4 + column 6)
		Micro-bial/Toxin	Hazard Mitiga-tion		Size	Compliance history		

RISK-BASED INSPECTION PLANNING

GENERAL

Inspection planning is normally carried out on an annual basis, based on the fiscal year. This ensures that there is an ongoing assessment of inspection priorities that can be adapted over time based on results from previous years. It also allows for adjustments with respect to available resources and identifies any policy or program updates that are required.

An example of a planning cycle can be found in Section 4 of the FAO Risk Based Imported Food Manual (2016).[21]

In some cases, countries will not have sufficient resources to implement its risk-based program within a year, and these may choose to establish a multi-year schedule. For example, within a multi-year program, high risk food businesses may be inspected twice a year, medium risk food businesses may be inspected every year and low risk food businesses may be inspected every second year. However, even within a multi-year schedule, it is important that annual inspection plans be developed to ensure they consider the results of the previous year as well as any other issues that may arise (e.g., availability of inspectors, changes in the number of food businesses).

Where countries establish a multi-year inspection program but legislation requires annual licenses, they should have a written policy that sets out how licenses will be maintained and issued (e.g., a license will be issued based on the food business having had no critical and no major non-compliance in its last inspection).

ESTABLISHING INSPECTION PRIORITIES

Once the risk categorization framework has been developed and agreed upon, it forms the basis of the risk-based inspection planning. The various combinations of food and food business risk scores are used to establish the inspection priorities. Once all the food businesses are categorized, each one will have a risk score which establishes its priority for inspection.

The first step is to identify all the combinations of food risk scores. For example, with the 2 food risk factors, there are 9 combinations of risk scores. See Table 1 below.

21 FAO Risk Based Imported Food Manual (2016) English version http://www.fao.org/3/a-i5381e.pdf.

TABLE 1: FOOD RISKS (ALL COMBINATIONS)

Column 1	Column 2	Column 3	Column 4	Column 5
Microbiological /chemical risk	**Risk score**	**Hazard Mitigation**	**Risk score**	**Total combinations of food risk scores**
High	15	high	15	30
Medium	10	high	15	25
Low	5	high	15	20
High	15	medium	10	25
Medium	10	medium	10	20
Low	5	medium	10	15
High	15	low	5	20
Medium	10	low	5	15
Low	5	low	5	10

The second step is to identify all the combinations of the food business risk scores. For example, with the 2-food business factor, there are 12 combinations of risk scores. See Table 2 below.

TABLE 2: FOOD BUSINESS RISK SCORES (ALL COMBINATIONS)

Column 1	Column 2	Column 3	Column 4	Column 5
Business size	**Risk score**	**Compliance history**	**Risk score**	**Total combinations of food business risk scores**
large	20	high risk	15	35
Medium	15	high risk	15	30
Small	10	high risk	15	25
Micro	5	high risk	15	20
large	20	medium risk	10	30
Medium	15	medium risk	10	25
Small	10	medium risk	10	20
Micro	5	medium risk	10	15
large	20	low risk	5	25
Medium	15	low risk	5	20
small	10	low risk	5	15
micro	5	low risk	5	10

The third step is to identify all the risk scores identified in Column 5 from Tables 1 and 2 (i.e., there are 5 food risk scores and 6 food business risks scores. Thus, there are a total of 10 risk scores, or inspection priorities.

TABLE 3: COMBINATION OF TOTAL RISK SCORES.

65	60	55	50	45	40	35	30	25	20

The fourth step is to establish how many inspection priorities are required. Countries generally decide that establishing 10 inspection priorities from Table 3 would make development of a risk-based inspection plan, whether annual or multi-year, too complicated. It is recommended that they consolidate the scores into 2 or 3 categories.

For example: a country may choose to establish 3 inspection priorities as follows:

High:	risk score greater than 50
Medium:	risk score of 35 to 50 (inclusive)
Low:	risk score less than 35

For example: a country may choose to establish 2 inspection priorities as follows:

High:	risk score greater or equal to 45
Low:	risk score less than 45

For this manual, 3 inspection priorities are being used in the planning section.

Categorize all food businesses

In order to develop and implement a risk-based food inspection plan, the country needs to have assessed all food businesses and assigned each a total risk score. (i.e., establish a food business profile or knowing your universe). Assessing food businesses may need to be done over several months or even a year, depending on available inspection resources. Competent authorities should establish priorities for completing the categorization based on the food profile (e.g., food businesses producing the greatest amount of a particular food, foods with the highest risk, etc.).

Using the nationally agreed template (See Appendix 3 for an example), each district will assess all the food businesses for which they are responsible based on the national strategy and priorities. As districts complete the assessments, they should create a table (See chart 4 below) that lists the number of food businesses for each

risk score. The information on food businesses from each district will then be added into the food business numbers for the country. The use of software or common spread sheets will facilitate creating, maintaining and amending the list.

CHART 4: NUMBER OF FOOD BUSINESSES BY PRIORITY CATEGORY

Total risk scores		Food businesses (numbers per district)										Food businesses numbers (national)
		1	2	3	4	5	6	7	8	9	10	
High	65											
	60											
	55											
Medium	50											
	45											
	40											
	35											
Low	30											
	25											
	20											

Note: as per the discussion in the risk categorization section, this does not include food businesses with critical non-compliance as they should, in general, not be in operation without regulatory oversight (inspector in plant) because of the food safety risks.

DEVELOPING AN ANNUAL PLAN

Using the food business numbers from Chart 4 and taking into account the number of high, medium and low risk food businesses, as well as the number of inspectors, The competent authority should establish the inspection frequency to be used. (See examples below).

Example 1) If all food businesses are to be inspected within one year, a country may determine that high-risk food businesses will require 3 inspections per year, medium risk food businesses will require 2 inspections per year and low risk food businesses will require 1 inspection per year.

Example 2) If all food businesses are to be inspected within a two-year period, a country may determine that high risk food businesses will have 2 inspections per year, medium risk food business will have 1 inspection per year and low risk food businesses will have 1 inspection every two years.

Once the frequency of inspection is established, the annual inspection plan will need to be developed. At the national level, the annual plan establishes the total number of inspections, distributed over the year and by quarter.

To develop the annual plan, it is necessary to refer back to the food profile to take seasonality into account (e.g., a fish processing plant may only operate in one quarter because of fishing quotas; a market or a restaurant may only operate seasonally to cater to tourists). In addition, while scheduling, consideration should also be given to other factors such as the availability of inspectors, (e.g., vacations, school holidays, and statutory holidays or national festivals such as Christmas, or carnival), as well as distances (e.g., remote areas; little to no road access), or other specific factors applicable to the country and/or the competent authorities.

NOTE:

There may be other considerations in developing a country's inspection plan. For example, there may be food businesses or institutions that require continuous inspection (i.e., presence of a full-time inspector), or there may be agreements with trading partners that establish frequency of inspections, or there may be food businesses (e.g., street food vendors) that have two locations – the kitchen/cooking area and the vending area, that may be in two different locations.

It is very likely that the feasibility of the inspection schedule must also be discussed. In many countries, once all the food businesses have been categorized and the total number of food businesses are known, the time requirement to carry out inspections significantly exceeds the inspection resources. Should this be the case, a collaborative effort to distribute the inspection effort among competent authorities and across all districts[22] will enhance effective use of resources and minimize overlap and duplication. For example, if one specific district has significantly more food businesses than a second district, there may be an agreement between districts or between competent authorities to collaborate on inspections either on a continuing basis or as a specific project.

A country might develop an annual plan of scheduled inspections (national) as per the template in Chart 5 below.

CHART 5: TEMPLATE OF AN ANNUAL PLAN FOR SCHEDULED INSPECTIONS

Inspections	Number of food businesses for each score		Total annual inspections	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Planned inspections							
	High (x3)						
	Medium (x2)						
	Low (x1)						
	Continuous inspections						

22 The term "district" is used here as the basic geographical unit for the inspection service. There are other terms that may be used such as parish, municipality, ward and catchment.

Unplanned work

Countries will also have to build flexibility into the inspection plan. It is important that inspections are not scheduled for 100% of inspection resources, as this will ultimately lead to failure. Therefore, in addition to the planned work, the annual plan must also include unplanned work.

NOTE:

In many countries, food safety may be only one component of an inspector's responsibilities. Other responsibilities may include vector control, sewage and water assessment. In such cases, it is important to develop a plan for percentage of time that inspectors have available.

Unplanned work includes activities such as "pre-registration" inspections and follow- up inspections to verify the implementation of corrective action. They can also include requirements to issue certificates or other industry requirements such as referrals from other agencies or issuing food handlers' registrations.

These activities cannot be "identified in advance" but they can be estimated for scheduling based on historical information. To do so, establish an annual average for each activity, for example, estimate how many pre-registration inspections, how many certificates (e.g., free sale, export) were required, how many follow up inspections were carried out in the last 3 years and, using that number, develop an estimated number per year. This number will be your planning estimate for this year and will need to be updated during each planning session.

As a result, the annual plan might look like the example in Chart 6 below.

CHART 6: EXAMPLE OF AN ANNUAL PLAN THAT INCLUDES SCHEDULED INSPECTIONS AND UNPLANNED WORK.

Inspections	Number of food businesses for each score		Total annual inspections	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Planned inspections							
	High (x3)						
	Medium (x2)						
	Low (x1)						
	Continuous inspections						
Pre-registration inspections	Average # per year						
Follow –up inspections	Average # per year						
Certificates issued (e.g., export, free sale)	Average # per year						
Food handler's registration	Average # per year						

District and monthly inspection plans

The national plan is intended to identify inspection frequency and other activities, but it generally does not have enough detail for district inspection planning. A district plan will generally have two components:

- A high-level plan that is similar to the national plan using the template set out in Chart 7, and;
- A district level plan that establishes the details to be followed.

The detailed district inspection plans should identify each food business to be inspected each month, each week and by which inspector. This allows for seasonal operations, (e.g., fisheries) to be scheduled appropriately and ensures that the inspectors are available as required (e.g., audit trained inspectors for HACCP inspections). The detailed district plan might look like the example in Chart 7 below, where each business is scheduled to have an inspection during a specified week.

CHART 7: EXAMPLE OF A TEMPLATE FOR DETAILED DISTRICT INSPECTION PLAN

Identification		**score/priority**		**Scheduling**											
Food business name	**Food business registration number**	**Total score**	**Number of inspections**	**January - March**			**April - June**			**July - September**			**October - December**		
				1	2	3	4	5	6	7	8	9	10	11	12
1															
2															
3															
4															
5															

Districts should also include notes or comments that may assist in understanding and maintaining the detailed plan. For example, which food business may require a team of inspectors.

Developing a detailed plan will help in scheduling inspections and will allow the inspectors to ensure an adequate time allocation for each inspection. Time needed for reviewing the food business file, travel time and inspection time (opening meeting, inspection, closing meeting) report writing and filing) should be included. Time for each inspection step will vary based on the size and complexity of the

food business operations. For example, a small or micro business might require about 3.5 hours (½ hour review of documentation, 1hour travel time round trip, 1½ hour inspection time, ½ hour report writing/filing), while a large business might require around 8-10 hours (1-2 hours document review, ½ hour travel time, 5 + hours inspection time, especially for food businesses with HACCP systems, ½ hour travel time, 1-2 hours report writing).

If an inspection is to be carried out by a team of inspectors from one or more competent authorities, it should be determined in advance whether it is reported in the plan as one inspection by each inspector, or if the lead inspector would count the inspection, while the other team members would count as another activity (e.g., referral from another agency; food safety investigation). This is important for consistency in the planning and reporting activities.

Continuous inspection plans

In addition to the above noted plans, each district should develop a schedule of daily inspection activities for each food business under continuous supervision. For example, a food business under continuous supervision that is operating a HACCP plan 5 days a week might be inspected as noted in Table 4. If there are other food businesses or institutions (e.g., hospitals) with continuous supervision, then a similar table would have to be developed for inspection of those specific operations.

The inspector assigned to the food business will review those written documents each day for those particular areas prior to the daily inspection activities. The inspection activity groupings would be based on the elements in Section 4 Inspection procedures. These activities should be rotated so that there is no set pattern or time to their evaluation, but all activities are reviewed each week.

Consideration should also be given to rotating inspectors through food businesses with continuous inspection to minimize the possibility of the inspector developing a personal interest in the activities, often characterized by using the term “my plant”.

TABLE 4: AN EXAMPLE OF A CONTINUOUS INSPECTION PLAN

Day	1	2	3	4	5
Inspection grouping	**Premises:** Water/Ice/ Steam Quality, Protection and Supply Building design, Construction and Maintenance Lighting Ventilation Waste and Inedible/ Food Waste Disposal Hand washing Stations & Sanitizing Installations Outside Property Employees' Facilities Animal holding areas (construction/ cleaning)	**Operational Programs:** Process Flow Allergen Control Program Food Additives and Nutrients Food Processing Aids Foreign Material Control Program Processes Industry controls Industry inspection Government controls	**Transportation, Purchasing, Receiving, Shipping and Storage:** Purchasing/ Receiving/Shipping Storage, holding rooms, cooking and storage times/ temperatures Food Carriers **Recall:** Product Coding and Labelling Recall Plan	**Sanitation and Pest Control:** Sanitation Program General Slaughter area Processing areas Pest Control Program	**Equipment:** Equipment Maintenance and Calibration Design and Installation **Personnel** General Food Hygiene Program General Food Hygiene Training Program Technical Training

Review of the inspection plan

The detailed district inspection plan should be reviewed at least every month, but preferably every week in preparation for inspections. It is likely that, at various times throughout the year, modifications will have to be made to the plan, particularly where food safety issues arise, or due to unexpected issues (e.g., illness, injuries) with respect to inspectors. It is important that each inspector discusses and confirms any modification to the plan with their supervisor.

The following points should be taken into consideration when adjusting the delivery of the proposed activities:

1. Highest risk activities have priority. If some inspections cannot be completed in a specified week because of on-demand activities (e.g., recalls), they should be rescheduled for the following week or weeks, with the highest risk food business being inspected as a priority.

    b. If some inspections cannot be completed, lowest risk food business inspections should be dropped first (i.e., those requiring 1 or less inspections per year).

3. Advancing the schedule. If there are no "on-demand" activities required in a specified week, high-risk inspections from future weeks should be brought forward.

RISK-BASED INSPECTION SYSTEM REPORTING

Inspection activities will be reported in two different ways. The first is reporting the results of the inspection activities directly to the food business. The second is reporting the results of the food business inspection to a central organization to provide national data analysis. Reporting to individual food businesses is addressed in Section 4, this section addresses the system-based reporting.

System-based reporting is essential in order to assess whether the system is working as designed and to assess the system's performance.[23] Based on the information and the assessments, amendments may be made, either within the fiscal year or for the following fiscal year. These may include increasing the inspection effort to improve compliance in certain food sectors or reducing the effort where there is good compliance in a food sector.

System-based reporting is most effective where the inspection services have access to information management systems that assist in the dissemination and analysis of information. However, it can also be carried out based on paper-based systems or spreadsheet programs. Where no computer system is available, the information gathering and analysis should focus on a limited number of key elements, rather than gathering a lot of information that may never be analyzed.

In developing reporting processes, it is recommended that each district report on a monthly basis, with a national summary being developed on a quarterly basis, (generally the month following closure of the quarter).

The reporting process is intended to answer two questions:

1. Did we do what we said, and did we deliver the planned activities?
2. Did delivery of the planned activities make a difference?

DELIVERY OF PLANNED ACTIVITIES

In reporting on planned activities, districts should report the following information for analysis at national level on a quarterly or monthly basis, for paper-based reporting and on a weekly or monthly basis where the data is available in electronic format:

Program delivery (did we do what we said?)

- % of planned inspections delivered
- # of unplanned activities delivered
  - › pre-registration inspections
  - › follow-up inspections.

23 Although not included in this manual, many countries have developed quality assurance processes to complement the system or performance reporting.

Delivery Target

In the system design and planning process, the competent authority should have established a delivery target, generally within a specified range (e.g., delivery of 90-95% of planned inspections). Alternatively, the target could be 95% plus or minus 3%. Without an established target, it is more difficult for both the district and national levels to determine and successfully communicate the use of public resources.

The National and district authorities should collaborate to develop a reporting table and process that facilitate district reporting, national analysis and the development of a consensus on the meaning of the results and the steps to be taken. For an example of this, see chart 8 below. In general, district reports should be made on a monthly or quarterly basis while national reports should be produced annually for paper-based systems. Where data is produced and maintained on an electronic information management system, district and national reports may be produced more frequently (e.g., monthly) or on demand, to better monitor delivery.

NOTE:

Competent authorities are unlikely to deliver 100% of activities. The intent is to establish a range (e.g., 95% +/- 3%) as a target, because it is more likely to be met.

CHART 8: AN EXAMPLE OF PROGRAM DELIVERY REPORTING

Inspections	Number of food businesses for each score		Total annual inspections	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Planned inspections	High (x3)						
Delivered inspections							
% over (+) or under delivered (-)							
	Medium (x2)						
Delivered inspections							
% over (+) or under delivered (-)							
	Low (x1)						
Delivered inspections							
% over (+) or under delivered (-)							
	Continuous inspections						
Delivered inspections							
% over (+) or under delivered (-)							
Pre-registration inspections	Average # per year						
Delivered inspections							
% over (+) or under delivered (-)							
Follow –up inspections	Average # per year						
Delivered inspections							
% over (+) or under delivered (-)							
Certificates	Average # per year						
Delivered certificates							
% over (+) or under delivered (-)							
Food handler registrations	Average # per year						
Delivered registrations							
% over (+) or under delivered (-)							

Explanatory notes: The reporting form should also require districts to explain why there was under delivery (e.g., lack of inspectors, crisis response in a particular area) or over delivery (e.g., no major crisis, pre-delivery in advance of summer vacation).

The National and district authorities should also collaborate to follow up on under-delivery as these areas will be targeted in the next quarter and/or next fiscal year).

PROGRAM EFFECTIVENESS

In addition to reporting on delivery, inspection services need to assess whether the actions taken made a difference to food safety, (i.e., did it improve compliance, did it make a difference?). In reporting on whether the planned activities improved the compliance of food businesses, districts should report the following information for analysis at national level:

Program effectiveness (did it make a difference?)

Determine for each food business inspected the percentage and severity of non-compliance and whether the percentage represents an increase or decrease as follows:

- Percentage of food businesses with 1 or more element rated as critical, representing an increase/decrease from last quarter.
- Percentage of food businesses with 1 or more element rated as major, representing an increase/decrease from last quarter.
- Percentage of food businesses with 1 or more element rated as minor, representing an increase/decrease from last quarter.
- Percentage of food businesses with all elements rated as satisfactory, representing an increase/decrease from last quarter.

Performance Target:

In the system design and planning process, the competent authority should have established a program effectiveness target, generally within a specified range (e.g., 90-95% of food businesses will have no major or critical elements or that 95% plus or minus 3% of food businesses inspected will not have critical or major elements). It is unrealistic to target 100% compliance. Without an established target, it is more difficult to determine if the system is operating effectively and as designed, as well as facilitating communications.

The national and district authorities should collaborate on the development of a reporting table and process that facilitates district reporting, national analysis and developing a consensus on the meaning of the results and the next steps. For examples, see Chart 9 and 10 below. Chart 9 is an example of within-year reporting while Chart 10 is an example of reporting over 4 years. Data should generally be reported on a quarterly or monthly basis for paper-based reporting and on a weekly or monthly basis where the data is available in electronic format.

Effectiveness data, in contrast to delivery data is generally best assessed as a trend analysis (i.e., year over year data). In addition, where data indicates a change in compliance, this must also be correlated to the delivery data (e.g., was the change in compliance a result of over or under delivery).

Where the trend indicates increasing non-compliance, further analysis will be needed to assess the issue. For example, assess if there are sectors (e.g., dairy, fisheries, bakeries) that are problematic or if there are elements (e.g., pest controls, storage of ingredients) across all sectors that are problematic. Where increasing non-compliance is identified, actions to address it (e.g., education, food safety investigations) should be scheduled as part of the next planning cycle.

Generally, districts schedule and inspect food businesses in the same quarter every year which permits an analysis for each quarter against the same quarter the previous year. If this is not the case, then it is likely that the within year analysis will not provide much information and the year-over-year will be the most useful in determining performance effectiveness. In general, district reports should be made quarterly or twice a year, while national reports should be produced annually.

Other program effectiveness assessments over time could include:

- Percentage of certificates issued with no problems (e.g., number of certificates requested vs number of certificates issued).
- Percentage of food handler registration issued with no problems (e.g., number of food handlers requesting registration vs number of registrations issued).
- Percentage of pre-registrations issued with no problems (e.g., number of food businesses requesting registration vs number of registrations issued).

CHART 9: AN EXAMPLE OF A PROGRAM EFFECTIVENESS REPORTING TABLE (WITHIN YEAR)

Global Compliance				
	Q1	**Q2**	**Q3**	**Q4**
# of food businesses inspected				
% of food businesses with 1 or more element rated critical				
Increase/decrease from previous year				
% of food businesses with 1 or more element rated major				
Increase/decrease from previous year				
% of food businesses with 1 or more element rated minor				
Increase/decrease from previous year				
% of food businesses with all elements rated satisfactory				
Increase/decrease from previous year				

Explanatory notes: The reporting form should also include a requirement for districts to provide notes with respect to any change in food business compliance, particularly if these are the result of more elements rated as critical or major.

The national and district authorities should also collaborate on the follow-up actions to be taken to resolve the issues.

CHART 10: AN EXAMPLE OF A PROGRAM EFFECTIVENESS REPORTING TABLE (YEAR OVER YEAR)

Global Compliance				
	Year 1	Year 2	Year 3	Year 4
% of food businesses inspected				
% of food businesses with 1 or more element rated critical				
Increase/decrease from previous year				
% of food businesses with 1 or more element rated major				
Increase/decrease from previous year				
% of food businesses with 1 or more element rated minor				
Increase/decrease from previous year				
% of food businesses with all elements rated satisfactory				
Increase/decrease from previous year				

Explanatory notes: The reporting form should also include a requirement for districts to provide notes with respect to any change in food business compliance, particularly if these are the result of more elements rated as critical or major.

The national and district authorities should also collaborate on the follow-up actions to be taken to resolve the issues.

CONCLUSION

Implementing risk categorization, priority setting, planning and reporting will normally be a multi-year process. As noted in the introduction, it will generally begin with an assessment of what currently exists, what is working well and what processes need to be developed and implemented. During this process, countries and their competent authorities will assess what works best in their circumstances and adapt the processes from this manual or from other standards (e.g., Codex Alimentarius) to their specific situation.

It is recommended that countries identify a multi-year implementation strategy and establish on-going consultation processes with consumers and other stakeholders during implementation. This should improve stakeholders' understanding of the proposed risk-based inspection programming, roles and responsibilities.

SECTION 4

PROCEDURES FOR RISK BASED INSPECTION

This section outlines how risk-based inspection procedures are used to assess the food business's capacity to meet regulatory requirements and produce food that is fit for human consumption.

This section outlines guidance on:

- Types and categories of food business inspection.
- Preparation for a risk-based inspection.
- Seventeen guidance documents for inspection procedures.
  - Opening meeting.
  - Document review (for businesses with written documentation).
  - Exterior assessment (general).
  - Interior assessment (general).
  - Twelve operational specific guidance documents.
  - Rating individual elements.
  - Closing meeting/ Reporting back to the food business.
  - Scheduling follow-up inspections.

TYPES OR CATEGORIES OF FOOD BUSINESS INSPECTION

Within a risk-based inspection program, there are generally 3 types or categories of inspection.

- Pre-Registration.
  - › Export requirements.
- Monitoring/ongoing.
  - › Businesses with food safety management (e.g., GMP, GHP, HACCP, ISO) systems.
  - › Businesses without food safety management systems.
  - › Businesses that require certification (e.g., export, free sale).
- Follow up inspections.

PRE-REGISTRATION INSPECTION

Where legislation requires that food businesses be registered, it also normally requires that they be inspected to obtain a registration (before operations) and must meet all the requirements.

NOTE:

All food safety systems (e.g., HACCP system, GMP, GHP, ISO) should be developed and implemented by food businesses consistent with the Annex on HACCP in the General Principles of Food Hygiene. The process of developing food safety systems and appropriate controls should include food safety domestic or international experts or working with written protocols[25] developed specifically for that category of food business.

When the food business has a food safety system (e.g., HACCP system, GMP, GHP, ISO), all documents must be reviewed prior to approval. During the review, the documents should be assessed for compliance with specified regulatory requirements for that category of operation. Food businesses should review the appropriate guidance documents (e.g., General Principles of Food Hygiene (CAC/RCP 1-1969) and must engage the necessary experts, whether internal or external, to develop the written documentation for a food safety system.[24]

In general, inspectors should not evaluate the process of developing the food safety system, but if they have any concerns about the process or the control during a pre-registration inspection, they should request further evaluation from independent food experts.[26]

24 This manual does not provide guidance on the development of any food business safety system, but rather on assessing whether the food business is implementing the system as designed.

25 As, for example, those that can be found at https://www.fda.gov/Food/GuidanceRegulation/HACCP/default.htm.

26 FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses, FAO FOOD AND NUTRITION PAPER 86.

Where a business does not meet the specified regulatory requirements, the inspector may assist the owner by providing information but must not tell the food business what to do. Where the business cannot or will not meet standards, the food business should not be registered.

The pre-license inspection will follow the same approach as a regular inspection, (i.e., preparation, inspection, report and follow-up). The key difference is that there will be no food business file at the inspection office, nor any history about the production facilities.

Exporting food business

During a pre-licensing inspection, the inspector should determine if the business intends to export food and, if so, to which countries. In such instances, the food business shall be required to demonstrate that they know the requirements of the importing country and what systems are in place to provide assurance that the requirements can be met.

Food businesses that will require inspection for export certification in the future should be identified for inspection planning purposes.

MONITORING/ONGOING INSPECTIONS

These are the majority of inspections within a risk-based inspection program. These are the scheduled inspections intended to monitor food businesses and provide assurance that they are in compliance with regulatory requirements. Monitoring inspections may be complete or partial, depending on the country's specific program design. In a complete inspection, the whole food business is assessed whereas in a partial inspection, a segment of the food business is assessed. For example, if a food business produces both chicken and pork products, but only exports chicken products, a partial inspection for export certification may focus on the chicken operations only.

NOTE:

If during a partial inspection an inspector notes food safety issues with other operations, then the inspection will be expanded to a full inspection to address the issues.

Monitoring food businesses with food safety management systems

In general, where a food business has implemented a documented food safety management system (e.g., GMP, GHPs, HACCP, preventive controls), inspectors may choose to adopt an audit approach or a combination of audit and inspection to assess implementation.

Audit: Food safety audits are non-consultative, which means that the auditor does not advise or instruct the facility on how to meet requirements. The auditor reviews documentation (e.g., HACCP plans, procedures, training, pest control protocols, quality assurance plans); observes the physical conditions and implementation of plans and protocols, and assesses the records maintained by the food business. Any non-conformances observed during the audit are documented in the audit report. On conclusion of the audit, the food business is informed of all observed non-conformances.

Audit/Inspection: The inspector/auditor reviews documentation (e.g., HACCP plans, procedures, training, pest control protocols, quality assurance plans), compares them to regulatory requirements, inspects the physical conditions of the food business and its implementation of written documentation as well as reviewing records maintained by the food business. Elements deemed non-compliant are brought to the attention of the food business for resolution.

Monitoring food businesses without food safety management systems

Inspection: The inspector will review any available documentation (e.g., procedures, recipes, specifications) against regulatory requirements, inspect the physical conditions of the food business, question employees and, where available, review records maintained by the food business. Elements deemed non-compliant are brought to the attention of the food business for resolution.

Follow up inspections

Where non-compliance is identified and the food business and the inspector have agreed on both the appropriate corrective action and the timeframe for its implementation, the inspector will schedule a follow-up inspection.

In general, these follow-ups focus on the implementation of the specified corrective action, but should the inspector see or become aware of other non-compliance during the follow up, these would also be addressed.

GENERAL GUIDANCE

This section is intended to identify and provide guidance on the documents and information that need to be reviewed in preparation for an inspection. This information may include a review of:

- The key activities and guidance documents for that specific food business.
- The compliance history, food production operations, recalls, corrective action from previous inspections and any other pertinent information.

This manual identifies specific guidance documents which, based on Codex documents, identify each of the pertinent elements for both general and specific food business operations. Prior to an inspection, the inspector should determine which guidance documents are applicable to that inspection. During an inspection, each element of the guidance document should be considered. For example, in preparing for a dairy inspection, the inspector would consider and use the general guidance (6) and the guidance for dairies (12).

INSPECTION TECHNIQUES

Inspectors should use the following techniques while taking care not to be a source of contamination.

Personal actions:

- Use protective clothing similar to that used by employees (e.g., hair nets, laboratory coats, clean footwear).
- Do not leave papers or other inspection material on counters or food processing equipment.
- Ask food business personnel to open storage areas, lift parts of or open equipment to assess interior.
- Avoid touching raw materials, dirty walls, doors, equipment and finished products before packaging to prevent from inadvertently contaminating the product or being accused of doing so.
- Where examining ingredients, raw materials, cleaning chemicals, food or food labels, ask food business personnel to handle them.

Note taking:

- Review any documentation and note any associated areas to assess during the walk-through as well as questions to ask employees.
- Document observations, inspection results and questions and answers in a notebook as these are critical for ensuring a complete and accurate report.
- Document areas for improvement.
- Make relevant, factual and accurate notes.

Observation:

- Observe the process and procedures, the employees' implementation of process controls, the sanitation of the plant and the equipment.
- Be thorough when observing processes, products and equipment.
- Remember to look up, down and all around.

Physical/Visual Inspection:

- In carrying out any physical inspection, the inspector must ensure their equipment (e.g., thermometer, pH strips or meter) is sterile, that they have carefully washed their hands and/or ensure the appropriate use of disposable or sanitized gloves.
- Check and note down temperatures indicated by thermometers or charts.
- Check the cleanliness of equipment.
- Verify the ingredients in storage areas against the product formulation.
- During inspection, the inspector must not become a source of contamination.

Questioning:

- The inspector should talk to facility personnel about their specific duties and the procedures being followed and carefully note down the replies.
- Questions should generally be open-ended and are designed to enhance the inspector's understanding of the process.
  - "What are you doing?" or;
  - "Could you please explain the procedure?"

Sampling:

- Sampling is generally undertaken under the direction of a national sampling plan. For efficiency, the inspector may sample the product during the food business inspection.
- When sampling occurs during an inspection to supplement information about the conditions in the plant (e.g., sanitation, lack of appropriate processes), it should only be undertaken after consultation with supervisors and/or laboratory staff. Samples should not be taken where unsanitary conditions are determined through the inspector's observations as this may result in contradictory results (i.e., visual observation of unsanitary conditions exist but no contamination (e.g., pathogens, indicators) are found in the samples).

Generally, inspectors should write all their notes and observations in a notebook. The notebook should be bound, with numbered pages and all pertinent information should be included. It is not advisable to write notes on loose paper, as these may be misplaced, misfiled or easily lost. Alternative measures, such as dictating notes into a phone or taking pictures to supplement notes may also be considered. It is important not to simply use a "check mark" or an "x" to symbolize compliance or non-compliance for an element – as, there would be no comprehensive information for the inspector to review during following inspections.

It is these observations and notes that the inspector will use to assign a rating to each element, using the Rating Guide in **Appendix 4**.

PREPARATION FOR THE INSPECTION

This section will set out the approaches to preparing for an inspection of a specified food business based on the schedule.

CONSULT THE INSPECTION PLAN

Consult the district and/or individual inspection plan and determine which food business or businesses are to be inspected.

As per the guidance in section 3, where there are multiple food businesses scheduled for inspection, priority should be given to high-risk businesses, particularly those that are overdue for inspection or those that require follow-up inspection. For efficiency, consider whether micro or small food businesses (e.g., market vendors, street food, carts) at the same location can be inspected during the same time period.

For larger food businesses, verify if an inspection team or laboratory specialists are required. If so, identify participants for the team and confirm their availability. Recognize that the inspection might need to be rescheduled if they are unavailable. Ensure there is adequate time scheduled for the inspection(s), as larger businesses will require more time than smaller ones.

Verify if there is any educational material that should be distributed (e.g., information on new rules, good hygienic practices).

Review the annual sampling plans for product, ingredient or environmental samples. If samples need to be taken for chemical, microbiological or other reasons, contact

the sampling guidance or the laboratory to verify sample requirements, sample transport conditions and to coordinate for sample submission.

Verify that there is adequate time for any required sampling, including transport from the inspection site to the laboratory.

REVIEW INFORMATION FROM FOOD BUSINESS FILE

The inspector(s) should familiarize themselves with the operations of the food business to be inspected through a review of the information in the food business file that should include:

- Name of owner or representative, other key personnel, location.
- Products produced, processed and sold and the key food safety parameters to be assessed. If needed, review reference documents on food safety standards as well as whether the products are intended for export or domestic sale.
- Size and complexity of the processes used by the food business.
- Operating schedule (e.g. hours of operations, cleaning schedules).
- Previous food business inspection reports (e.g., report provided to the business, inspector notes, examples of labels, photos or other evidence).
- Verify any non-compliance and corrective action.
- Results of previous samples.
- Other pertinent documentation such as:
    - Information on the food safety management program and any documented procedures (e.g., Standard Operating Procedures, HACCP procedures) if available.
    - Any pending consumer or industry complaints.

Based on the file review, the inspector should be able to identify the guidance documents needed for the food business or businesses to be inspected.

Prepare inspection material and verify that it is clean and in good working order.

- Basic requirements for all inspections - notebook, pen, inspection checklist, flashlight, thermometer (sanitized), disinfectant.
- Appropriate clothing (e.g., lab coat for processing inspection).
- Specialized equipment that may be needed.

Prepare any reference materials required (e.g., legal references, food standards, guidance documents).

If required, prepare the appropriate sampling material based on the types and quantities of samples to be taken. If there are any questions, it is important to consult the laboratory.

- Cooler/icebox, ice packs, sterilized containers for water and ice collection, permanent marker pen for sample identification, sterile gloves, sterile swabs and sample bags/containers.
- Sampling protocols (e.g., finished product, ice/water, environmental swabs).
- Forms for sample submission to the laboratory.

Gather the appropriate quantity of information, educational and communication materials to be distributed.

NOTIFICATION

Notification of inspection can increase effective use of inspection resources and minimize delays in the process by ensuring that all required personnel and documentation are available. Inspections of medium or large food businesses are generally scheduled and announced, however inspections of small or micro food business do not generally require notification.

Notification is not generally used for a follow-up inspection or food safety investigation or where there are concerns the facility may attempt to conceal unsanitary conditions.

Notification may be given by telephone, letter or e-mail and a record of the notification (i.e., time, date, food business contact) should be placed in the food business file. Where notification is used, the inspector should confirm that the food business has received it, prior to leaving for the inspection.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INSPECTION GUIDELINES AND PROCEDURES

OPENING MEETING

This section will outline the key principles of the opening meeting between a food inspector (s) and the food business management prior to undertaking an inspection, including the rationale and the processes.

There are two guidance documents provided 1) for medium to large food businesses and 2) for small and micro food businesses. The key objectives are the same although the larger food businesses generally require a more formal approach.

GUIDANCE 1: OPENING MEETING (MEDIUM TO LARGE FOOD BUSINESSES)

	Opening meeting for medium to large food businesses
Objective:	To meet with designated representatives of the food business to discuss the inspection procedures, gather and/or validate basic information about the business and its operations and provide educational material.
Introduction	Opening meetings are generally held in offices or non-production spaces. They provide an opportunity for the inspector (s) and the food business representatives to start a good working relationship for the inspection processes.
Opening meeting	At the opening meeting, the inspector should: • Ask for the manager or the person in charge; write down the names, titles and contacts for key food business personnel. • Show official identification that provides legal authority for the inspection. • Explain the inspection schedule; outline the sequence of actions to inspect the processes. • Arrange to have an official representative present during the inspection, confirm commitment to protect confidential information. • Arrange to have a place to review all the food business documents.

	Opening meeting for medium to large food businesses
Preliminary (verbal) update Licenses	After introductions, the inspector should take the opportunity to review and confirm the information from the official files with the food business representatives to update any changes to personnel, foods produced and operations and also confirm that the food business continues to meet the basic regulatory requirements (e.g., licensing, food handler registration). If required by legislation: • Review the food business license (i.e., validity, up to date). • Verify that all food handlers are registered and have a certificate of good health. • Identify products that require free sale certificates (if required). Confirm the information from the food business file with the management and note down any changes: • To key personnel (e.g., quality assurance manager, supervisors, contact names and numbers). • To foods produced and sold, and whether this changes the risk category of the food business. • To production facilities and operations. Confirm that all corrective action from the previous inspection have been completed appropriately. Make note of all changes to the profile as the information will need to be: • Verified during the documentation review and the physical inspection. • Documented and maintained in the file at the inspection office.
Inspection Strategy	If the food business and food handlers, are required by law to be registered and they are not, or the products are required to have a free sale certificate and they do not, the followingInspection strategy[27] should be considered: • **1st inspection** – The inspector shall require that the food business and/or employees to apply for a registration, and the "product for free sale" certificate. • **2nd inspection** – The inspector shall issue a written warning to the food business and/or the employees requiring them to obtain a registration or free sale certificate. • **3rd inspection** – The inspector shall require that the food business cease operations until they and their employees are registered, products have a free sale certificate and consider prosecution.
Inspection schedule	During the opening meeting, the inspector should confirm the sequence of inspection steps (e.g., document review, walk through inspection, site evaluation, closing meeting). • Confirm food business representatives assigned to accompany the inspector. • Enquire about any specific requirements, particularly with respect to hygiene or operations. • Ask about a location for undertaking the document review. • Note the inspection techniques that may be used including note taking, observation, photos and asking questions of staff. Indicate if any samples will be taken. The inspector should confirm that the closing meeting will be held after the inspection is complete to discuss observations and findings. • Note if the written report will be provided during the closing meeting or at a specified time following it.

27 Based on the principle that food businesses are responsible for meeting requirements and the inspection services are not trying to "trap" the food business, inspection strategies should be measured, and consistent, but increase in severity if the food business is not willing or able to meet the requirements.

GUIDANCE 2: OPENING MEETING (MICRO AND SMALL FOOD BUSINESSES)

	Opening meeting micro and small food businesses
Objective:	To meet with owner or operator of the food business to discuss the inspection procedures, gather and/or validate basic information about the business and its operations, and provide educational material.
Introduction	In general, opening meetings will be held at the food business site (e.g., beside the market stall, outside a food cart).
Opening meeting	At the opening meeting the inspector should: • Introduce him/herself, • Show identification consistent with legal authority, • Confirm information including: › The general information on food being sold; › The owner and/or operator; › Location of operations and; › All information about food products and any changes. • Provide information on the inspection process in an informal manner, • Take the opportunity to discuss food hygiene and sanitation, to enhance awareness and provide educational material (if any), • The inspector should confirm the results will be provided after the inspection and there will be an opportunity to review the observations and findings. › A written report will also be provided, within the timeline established by the competent authority (e.g., no more than 2 weeks after the completion of the inspection.
Licensing, Registration	If required by legislation: • Review the license (i.e., validity, up to date). • Review that all food handlers are registered and have a certificate of good health.
Inspection strategy	If the food business and food handlers are required by law to be registered and they are not, the followingInspection strategy[28] should be considered: • **1st inspection** – The inspector shall require that the food business and/or the employees apply for a registration. • **2nd inspection** – The inspector shall issue a written warning to the food business and/or the employees requiring them to obtain a registration. • **3rd inspection** – The inspector shall require that the food business cease operations until they and their employees are registered and consider prosecution.
Process flow	The inspector should discuss the fundamental business processes of flow and specifications with the owner or operator. As written documents are unlikely in micro and small businesses, the descriptions are likely to be verbal and the inspector should take note of the information, especially any changes from previous inspections. **Process flow** • Process flow should be a straight line from reception to finished product sale and that the processes minimize the potential for cross contamination. **Specifications** • Discuss the sourcing of food, ingredients and packaging. • Discuss if the business uses written specification (e.g., recipes, quantities of ingredients (volume, weight, type, sequence) and processes (stir, chop, blend, cook) with the associated controls (time and temperature). In particular, take note of any handwritten documentation that might exist.

28 Based on the principle that food businesses are responsible for meeting requirements and the inspection services are not trying to "trap" the food business, inspection strategies should be measured, and consistent, but increase in severity if the food business is not willing or able to meet the requirements.

DOCUMENTATION REVIEW

This section provides guidance on the key issues to be reviewed, both procedures establishing the food safety systems and records that identify whether the system was implemented as designed. This guidance applies to food businesses that have implemented a written food safety management system that identifies active management processes to control risk factors such as maintenance schedules for equipment and facilities, sanitation procedures and operational procedures (i.e., standard operating procedures), particularly for important or critical steps in the process, training for personnel and record-keeping.

In some cases, a documentation review may also be undertaken for businesses with partial documentation but without a food safety management system. Partial documentation may include specifications or recipes for production of food products, sourcing requirements with invoices and supplier information and minimal cleaning protocols (e.g., the time, basis procedures).

NOTE:

For a food business that does not have a written food safety management system or any documentation, this guidance would not apply.

GUIDANCE 3: DOCUMENTATION REVIEW OF FOOD BUSINESSES WITH WRITTEN FOOD CONTROL PROCESSES

	Documentation Review
Objective:	The objective of the document review is to understand food business operations. There are generally 3 categories of documents that should be reviewed: 1. Process flow documents; 2. Quality management system (e.g., HACCP); Standard operating or process control documents, including specifications for raw materials and ingredients; 3. Records that demonstrate adherence to the firm's processes. Food businesses that are required to have a documented food safety system[29] (e.g., HACCP, ISO, GMP, GHP), either because of legislation or buyer requirements, will have written documents for review by the inspector. If required (e.g., by law, to meet HACCP/ISO requirements): • Verify that the documentation has been signed and dated by the responsible food business. • Verify that any changes have been submitted to the competent authority for review. • Verify that there has been an annual review by the food business. **Note**: if the food business is also inspected by other recognized organisations (e.g., KPMG, SGS) for ISO accreditation, or for international sales, consider reviewing the inspection reports from these organisations. The results could identify specific areas for consideration and/or reduce inspection time and effort.

29 As all written documents will have been determined to meet all regulatory requirements during the pre-registration review, the inspector's focus in these inspections will be to ensure the food business is meeting its own food safety system as written.

	Documentation Review
Inspection strategy	Food businesses should be encouraged to fully develop written documentation and to maintain records as part of their responsibility to ensure food safety requirements are met.
Process flow documents	Review the process flow used by the food business from incoming raw material to the shipment of final product. The process flow should be as straight as possible to minimize potential for cross contamination. • Does the process flow have any overlap between raw and final product processes? Spatial or temporal overlap? • Note differences from the last inspection, areas where changes have been made. Identify key control points in the process flow and/or diagram that may require further examination during the inspection. • During the inspection, focus on any possibility of cross contamination between raw and final product.
Inspection strategy	Where the process flow demonstrates a high potential for cross contamination, and that contamination or a high potential for contamination is confirmed during the inspection: All the food produced under the process flow should be rated as critical non-compliance and not permitted for sale. Where the flow chart has to be reviewed and signed off by the competent authority (e.g., by law): • Verify that the documentation has been signed and dated by the responsible food business. • Verify that any changes have been submitted to the competent authority for review. **Inspection strategy** Where a food business license requires the documentation and sign-off of the flow chart. • Where the food business is unable to produce documentation showing that the flow chart and amendments (if any) have been approved, this should be rated as critical non-compliance.
Food Safety Management Documents	Food businesses with food safety management systems such as HACCP, ISO must have developed written documents and employees must follow them. There are generally three categories of documents: **Specifications** • Specifications establish requirements for incoming raw materials and ingredients, and for the final products. **Procedures** • Procedures are detailed written instructions for employees to follow in carrying out their duties. Such written instructions are often called Standard Operating Procedures (SOPs). • SOPs are generally developed in the areas of manufacturing, sanitation and pest control. • There should also be SOPs for all food processes where the food is intended for export to ensure the food meets the importing countries' requirements. **Records** • Records are a historical record that demonstrate adherence to the specifications and procedures. • Records should be legible, permanent, and an accurate reflection of what happened at a specific time, signed and dated. For food businesses with partial documentation, they may have specifications or recipes that outline specific ingredients, mixing procedures, possibly time and/or temperature of cooking, or possibly other controls over operations. They are unlikely to have significant records. However, where food business documentation exists, the inspector should review and take note, to verify if the documentation is being followed by employees.

	Documentation Review
Inspection strategy	Where a food business has been licensed based on implementation of a food safety management system: • Lack of documentation and records and/or inability to demonstrate the documented SOPs are being followed should be rated as critical non-compliance. Where a food business has been licensed with authority to export food, based on specific SOPs. • Lack of documentation and records, and/or inability to implement their SOPs, they should not be eligible for export certification and should be rated as critical non-compliance.
Specifications	**Raw material, ingredients:** • Verify that there are validation protocols for water (e.g., use of municipal potable water) or valid testing protocols to ensure the water meets required standards. • Verify the specifications for raw materials. › Review the protocols for sourcing raw materials and ingredients. › Verify records to determine if the specifications and protocols are being followed. › Assess the ingredients, particularly additives, being used by the business. › Verify they are approved for use and are being used in appropriate quantities. **Packaging and labels** • Review specifications for packaging materials and proper labelling. › It is important to cross reference the ingredients written in the product specifications and the ingredients written on the label. • Verify that all the ingredients are noted on the label. **Note**: Further guidance on reviewing labels can be found in Appendix 6.
Inspection strategy	Where the ingredients in the product do not match the written specifications and/or do not match the ingredients on the label: • The food does not meet legal requirements and no sale should be permitted until the food business has investigated and resolved the issue. • The production of food that does not meet specifications should be rated as critical non-compliance.
Procedures	Review the written documents that establish the procedures for employees to follow. These documents will have been reviewed and approved during the food business licensing process. There should be written procedures for each product which will include the recipes (e.g., ingredients, (volume, weight, type, sequence) and processes (stir, chop, blend, cook) with the controls associated (time, temperature). Verify the documents: • Clearly identify the steps which are critical to the safety of food. • Outline the implementation of required control procedures at those steps. • Identify the required control procedures to ensure their continuing effectiveness. • Include periodic review of the control procedures and whenever changes in operations occur. Note specific areas, changes from previous procedures that should be examined during the walk-through inspection. Verify that there are specific procedures for product recall and disposal of the recalled product. • Verify that there is a procedure for determining if the product can be reworked and a procedure for controlling the product during the rework. • Verify that there is a procedure for disposal of all non-compliant products (e.g., complete denaturation, destruction) so the product is rendered unfit and unsaleable.

	Documentation Review
Inspection strategy	Where there are no written procedures, or employees following the written procedures: • The food does not meet legal requirements and no sale should be permitted until the food business has investigated and resolved the issue(s). • The product of food that was not produced according to written procedures should be rated as critical non-compliance.
Records	There should be written records of all activities in the food business to provide a documented history of that activity and to provide evidence that the actions were consistent with the written procedures. Verify that records exist for each specification and written procedure: • Assess the records against every step established by the procedure. • Are the records complete, permanent and legible? • Can you note any particular area of concern where the written procedure appears not to have been followed? › If so, discuss what happened with the food business. Why wasn't the process followed and what happened to the product being processed? • Verify the business has records of quantity and destination of each consignment. • Verify that the business has records of all recalls, including details as to the reason of the recall and the disposition of all the recalled products. Based on the records, note areas of particular importance to assess during the walk-through inspection.
Inspection strategy	Where the food business cannot provide records that the written procedures were followed, particularly for food businesses with food safety management systems: • The lack of records should be considered critical non-compliance. Where a food business does not have records to demonstrate they were following their established process for export requirements: • They should not be eligible for export certification.
Sanitation protocols	Review the written procedures for sanitation. Verify the detailed directions for the sanitation and cleaning of all areas of the food business, which should include the cleaning of equipment. Verify the detailed directions for inspection and cleaning prior to start of operations, as well as following maintenance (e.g., repairs, equipment maintenance). Verify protocols on waste management and disposal. These may be part of the sanitation protocols because of the waste disposal requirements or may be part of the operational procedures (handling of waste as part of operations) or both. Note when sanitation operations are scheduled and the times of the operations in case it is necessary to observe the process at a specific time. Determine what cleaning products are listed in the written procedures. • Verify they are approved for use in food plants (e.g., food grade, approved by the appropriate ministry). Note any training requirements for employees (e.g., handling of chemicals, knowledge of procedures). • Consider whether to verify by questioning the employees about their training background during observation of cleaning procedures. Note any specific concerns for reviewing during the walk-through inspection, such as verifying that the cleaning products in use, are those specified in the procedures. • Verify the records of the sanitation program to determine that the protocols have been implemented as designed.

	Documentation Review
Inspection strategy	Where there are no written sanitation procedures, or employees are not following the written procedures: • The food does not meet legal requirements and no sale should be permitted until the food business has investigated and resolved the issue(s). • For the period when unacceptable sanitation procedures were in place should be rated as critical non-compliance and all food deemed in non-compliance.
Pest control protocols	Review food business procedures for pest control. There should be detailed directions for all areas, including whether the food business has outsourced the process, or if it is implemented by their own employees. Note when pest control operations are scheduled in case it is necessary to observe the process at a specific time. • Verify what pest control products are listed in the procedures, that they are approved for use in food plants and that they are consistent with the manufacturer's directions. › Verify the records of the pest control program to determine that the protocols have been implemented. • Where countries require certification of pest control products, verify that products being used meet the required certification. Note any certification requirements if the process is outsourced for follow up with the pest control organization. Note any training requirements (e.g., handling of chemicals, knowledge of procedures). • Consider whether to verify by questioning the employees about their training background during observation of pest control procedures. During the walk-through inspection, verify that the pest control products in use are those specified in the written procedures.
Inspection strategy	Where there are no written pest control procedures, or employees are not following the written procedures: • The food does not meet legal requirements and no sale should be permitted until the food business has investigated and resolved the issue(s). • The product of food that was not produced according to written procedures should be rated as critical non-compliance.
Personnel requirements	Review all documentation that outlines the requirements for food handlers and other personnel in the food business. Where required by legislation, confirm the registration of all food handlers and/or have a certificate of good health: • Review documents for food hygiene training that ensures all personnel are aware of their role and responsibility in protecting food from contamination or deterioration. • Review the requirements for safe handling techniques for all personnel responsible for handling chemicals (e.g., cleaning material, pest control products). • Review the documentation pertaining to on-the-job injuries, (e.g., reporting). Identify key personnel requirements that may require further examination and clarification during the inspection. During the inspection, focus on any possibility of activities by personnel that may result in the possible contamination.
Inspection strategy	Where employees are not following the written guidance, or during the inspection, employees are not following the required processes for personnel hygiene. If the activities result in a high possibility of contaminated food, then it should be rated as critical non-compliance and all food produced deemed in non-compliance.

OUTSIDE REVIEW

This section provides guidance consistent with the Codex General Principles of Food Hygiene (CAC/RCP 1-1969) on the assessment of the exterior of the food business. Note: where a 3rd party service provider provides specific services (e.g., building maintenance), it is the responsibility of the food business to ensure that these services are provided and appropriate.

The key element food businesses need to consider in determining where to locate their operations is to identify any and all sources of contamination as well as any potential mitigation measures. This means food businesses should, in general, be located away from environmentally contaminated areas, industrial activities, areas prone to flooding or infestations of pests or areas where waste cannot be effectively removed.

In assessing the outside of a food business, the inspector will consider the same elements as the food business. The first review, generally associated with the pre-registration process, will of course be the most extensive. In subsequent inspections, while the review will be thorough, it will primarily focus on ensuring that there have been no changes from previous inspections and that the exterior building envelope continues to provide protection for the internal operations.

To minimize the possibility of the inspector being a source of contamination, the exterior inspection should be scheduled either prior to putting on protective clothing or after completing the interior inspection. In some cases, the inspector will be able to make a preliminary assessment as they are approaching the location, particularly in the case of small or micro food businesses.

GUIDANCE 4: FOOD BUSINESS: OUTSIDE EXTERIOR INSPECTION

Element	Food Business Outside Exterior Inspection
General	The exterior of a food business provides a protective envelope for the processes within. Holes, or lack of repair will allow entry of animals and pests in addition to dirt and fumes which can compromise food safety. Where buildings are owned by the food business, they must be kept in good repair and provided with adequate exterior services. Where buildings are rented, or where exterior services are provided by 3rd parties, it is important to assess the building maintenance and the delivery of services. Take note of the provider (e.g., private companies or other state organizations (e.g., municipal corporations) and review contract or delivery specifications.
Objective	To assess the exterior of the building where the food business is located to assess whether it is appropriate for the production of safe food.
Location	Verify the location of the food business and assess site for evidence of residential, environmental or industrial pollution and determine what mitigation factors (e.g., secure building envelope, no smoke or fumes inside the building) are in place. Where there is evidence of pollution and a lack of any mitigation measures, assess the likelihood that food being processed is contaminated: • If the food is contaminated, then this should be rated as critical non-compliance. • If the food is not contaminated but there is still a possibility of contamination, then rate it as major non-compliance. Assess site for evidence of flooding and, if found, determine which mitigation factors (e.g., raised building, flood controls) are in place. Assess site for adequate drainage for water/rain run-off. This is important to prevent flooding. Where there is evidence the building has been flooded and there are no mitigation measures to prevent flooding, assess the likelihood that food being processed will be contaminated during a flood: • If the food is contaminated, then this should be rated as critical non-compliance. • If there is a likelihood of contamination, then this should be rated as major non-compliance.
Illegal food businesses	Illegal food businesses as defined by legislation should never be inspected within a risk-based system. Rather, competent authorities, often in collaboration with police services, should develop national strategies such as: • Shutting down the food business. • Notices to the public. • Seizure of product. • Prosecution. • Legal injunctions. **Note**: In some countries, government policies (e.g., employment) may encourage food businesses to open although they may be unapproved or illegal under food safety legislation. In such cases, the competent authorities should develop a strategy to bring such businesses into compliance and therefore legal. This might require working with municipalities and/or police services, to ensure that such business is located in a safe, secure area (e.g., market) with access to appropriate personal hygiene facilities.

Element	Food Business Outside Exterior Inspection
Building envelope	Verify that the site, building design and construction are appropriate. Verify the building design, construction and maintenance to assure it is in a good state of repair and will prevent entry of pests and animals, including dogs, cats and birds. Verify signage (e.g., no dumping, no trespassing) and any other means of minimizing potential sources of contamination and/or waste accumulation from other people. Assess the building construction for its suitability for keeping dirt, debris and fumes from entering: • Where there is evidence the building envelope will not prevent entry of pests, dirt, debris or fumes, assess if the food being processed is contaminated. • If food is contaminated, then this should be rated as critical non-compliance. • If there are major holes, but no evidence of food contamination, rate as major non-compliance. • If the building envelope is mostly suitable, but there are some holes or other entry points for pests, rate it as minor non-compliance.
Power	Verify the building has access to a power source capable of providing power to the food businesses processing and storage (e.g., refrigeration) equipment. If not, it is important to assess mitigation measures during the inside inspection. Consider the processes being used as requirements for power for refrigeration would not apply where food businesses do not require it for their operations (e.g., warehouses that store products at room temperature). • Where power outages are frequent and there are no mitigation measures (e.g., use of ice, portable generators) to prevent food spoilage, rate this as critical non-compliance. • Rate it as major non-compliance if there is no evidence of unwholesome, spoiled food. If generators are used for power, verify that there is proper ventilation to ensure that any fumes are blown away from the building. • If there is evidence the fumes are entering the building, note the observation and rate this under building envelope.
Water supply	The building has access to potable water, whether from municipal sources, wells, or other approved sources. All water sources must be protected from contamination. Where the food business uses stored water, appropriate care must be taken to ensure that the water is suitable for use in processing (e.g., minimal time of storage, adequate chlorination, appropriate filtration). • Where there is evidence the water source is unapproved, unprotected and likely to be contaminated, this should be rated as critical non-compliance.

Element	Food Business Outside Exterior Inspection
Waste removal	Verify that the location allows access for the removal of waste products. Verify there is no evidence of any kind of garbage or waste (particularly food waste) accumulation on the grounds surrounding the food business. Verify there is adequate disposal of liquid waste whether it is on- site processing (e.g., miniature sewage plant), storage for later disposal or appropriate sewage connections. Verify who provides the waste removal service. If waste services are provided by 3rd party and are inadequate, meet with the food business representative to review the contract and service delivery.[30] In some cases, the food business may request intervention by the public health inspector to meet with the 3rd party service provider. Where there is evidence of garbage, waste accumulation or presence of pooling liquid waste or evidence of animals and pests, • If it is tracked into the operations area, rate it as critical non-compliance. • If it might be tracked into the plant, rate it as major non-compliance.

GUIDANCE 5: FOOD BUSINESS (WITHOUT A PERMANENT BUILDING) OUTSIDE INSPECTION

The objective and the intent of inspecting the location and exterior of a small or micro food business, for example operations are carried out in one room, a market stall, a vendor cart, food truck, remain the same. However, conditions may be very different as they are often located within a market site and may not have permanent walls and/or roofs.

NOTE:

Where a 3rd party service provider is used for specific services (e.g., waste removal), it is the responsibility of the food business to ensure that those services are provided and appropriate.

Element	Food business without a permanent building: outside inspection
General	In the case of micro or small food businesses that operate from market stalls, carts, trucks or otherwise without a permanent building, assessing the outside environment is important to assure the food can be produced safely. In most cases, because there is no building envelope, the key element will be location (i.e., within an authorized market, or other locations with adequate services (e.g., water, power, garbage removal).
Objective	To verify that the location of the food business allows production of safe food and is provided with adequate services.
Location and premises	During a site assessment (e.g., market stall selling fruits and vegetables, cooked food stalls, or food carts or trucks): • Verify that the design and construction of a vendor's premise, whether a permanent market stall or freestanding cart, is appropriate to prevent contamination from other adjacent operations. • Verify the premise is in good repair (e.g., no water leaks from roof) and verify that the layout is adequate for the intended operations to prevent contamination. • Verify the condition of walls, should they exist, in that they provide a protective envelope.

30 The food inspector should contact the environmental inspectors, about any concerns with potential non-compliance with environmental regulations (e.g., dumping of waste in a river, lake or other body of water), recognising in some cases the food inspector and environmental inspector may be the same person.

Element	Food business without a permanent building: outside inspection
Power	Verify the food business has access to a power source capable of providing power for its operations. Does the food business have access to continuous source of power? If not, assess whether there are any mitigation measures, such as a backup generator, use of ice. Where the food business sells food (e.g., fish) that must be maintained at refrigeration temperatures, has no continuous source of power and no mitigation measures (e.g., use of ice, portable generators) to prevent food spoilage: • If there is evidence of unwholesome or spoiled food. › Rate this as critical non-compliance. • If there is no evidence of unwholesome, spoiled food. › Rate as major non-compliance. • If there is evidence the fumes from portable generators would affect the food. › Rate as critical non-compliance. Where the food business sells food that does not require refrigeration, neither a continuous source of power nor mitigation measures (e.g., use of ice) would be required to prevent food spoilage, however: • If there is evidence of unwholesome or spoiled food, rate this as critical non-compliance. • If there are portable generators in use to provide lighting and if there is evidence the fumes would affect the food. › Rate as critical non-compliance.
Water supply	The food business has access to potable water, whether from municipal sources, wells, or other approved sources. All water sources must be protected from contamination. Where the food business uses stored water, appropriate care must be taken to ensure the water is suitable for use in processing (e.g., minimal time of storage, adequate chlorination, appropriate filtration). • Where there is evidence the water source is unapproved, or unprotected and likely to be contaminated. › Rate as critical non-compliance.
Waste removal	Assess areas surrounding the food business with respect to waste removal and hygiene. Verify that there is no accumulation of garbage, or waste, nor presence of pooling liquids. Some food businesses contract a 3rd party to provide waste services. If this is the case, and the service is inadequate, review the contract and service delivery standard with the food business representative and seek assurance that waste removal issues will be corrected.[31] Where there is evidence of garbage, waste accumulation or presence of pooling liquid waste that is being tracked into the operational area and/or evidence of animals and pests. › Rate it as critical non-compliance. Where the existence of garbage, waste and liquid creates the possibility of tracking it into the business, but there is no actual evidence of it being tracked into the operational area. › Rate this as major non-compliance.

31 Where the delivery of services is provided by another government agency, the inspector and/or supervisor may have to intervene to ensure appropriate service delivery before taking enforcement action against the food business.

INSIDE REVIEW

This section will provide guidance, consistent with the Codex General Principles of Food Hygiene (CAC/RCP 1-1969), as well as other Codex guidance, (e.g., Regional Code Of Hygienic Practice For The Preparation And Sale Of Street Foods (Latin America And The Caribbean) (CAC/RCP 43R-1995) Code Of Hygienic Practice For Precooked And Cooked Foods In Mass Catering (CAC/RCP 39-1993), Code Of Practice For Fish And Fishery Products (CAC/RCP 52-2003) on the assessment of the interior of the food business as well as the assessment of specific food business operations.

This section consists of guidance on:

- Food business site inspection: general (guidance 6);
- Bakeries (Guidance 7);
- Drinks (Guidance 8);
- Eggs (Guidance 9);
- Fish (Guidance 10);
- Market vendors, fruit, vegetables, spices, rice, pulses (Guidance 11);
- Milk, Dairy (Guidance 12);
- Poultry, Meat (Guidance 13);
- Restaurant/Cooked Food (Guidance 14);
- Retail (Guidance 15);
- Street food (Guidance 16);
- Warehouses (Guidance 17).

NOTE:

Where a 3rd party service provider is used to provide specific services (e.g., pest control, waste removal), it is the responsibility of the food business to ensure these services are provided and appropriate.

Inspectors should consult all pertinent guidance documents prior to and during an inside review. For example, in assessing a dairy, they would use Guidance 6 and 12; in assessing street food, they would generally use Guidance 16, as it is unlikely that much of Guidance 6 would apply.

At this point, the inspector would already have a good knowledge of the food business operations, having reviewed all the information prior to beginning the inspection, completed the opening meeting, and reviewed all appropriate documentation.

The inspector should undertake a **counter-flow inspection**, that is, the inspector should begin his/her review in the cleanest section of the food business (i.e., the finished product section) and proceed towards the least clean section (i.e., the raw material intake). In order to minimize the possibility for causing contamination, the inspector should avoid doubling back to the cleaner sections, without taking appropriate precautions (e.g., changing their protective clothing).

In small businesses, it is likely that all the operations will occur in a very small space, often with minimal walls. In such cases, the inspection of operations may well be carried out while the inspector is standing outside the space and observing operations within.

A food business representative (e.g., manager, supervisor or quality assurance personnel) should accompany the inspector in order to answer any questions and take immediate action where serious deficiencies are identified. The inspector must ensure that the representative does not pressure, rush or direct the inspection.

GUIDANCE 6: FOOD BUSINESS (INSIDE) INSPECTION

The guidance provided in the following table covers all sizes of food businesses, whether they operate from a permanent building or from a stall, market, cart etc. Where different approaches are required for the different types of operations or buildings, these are noted.

The term "food contact surfaces" used in the guidance documents is based on the draft Code of Food Hygiene (CX/FH 18/50/5)[32] and means "work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent, materials unless food business operators can satisfy the competent authority that they do not compromise the safety of the food provided such deviation does not result in food safety being compromised".

Element	Food business site (inside) inspection
General	During the inside inspection, the inspector should assess the food business's ability to produce safe food, meeting all established and written procedures and all conditions of registration (e.g., regulations). To do so, the inspector will discuss employees' work practices, especially key control procedures, such as temperature controls, sanitation and equipment maintenance. In addition, it is important that the inspector evaluate production steps while operations are ongoing, and cleaning and sanitizing operations while the cleaning and sanitizing activities are taking place. The inspector will rate each element to determine compliance, and, in particular, ensure there is no food contamination.

32 Proposed draft revision of the general principles of food hygiene (cxc 1-1969) and its HACCP annex.

Element	Food business site (inside) inspection
Layout and process flow	In carrying out a counter-flow review, the inspector must evaluate the potential for the final product contamination. This includes assessing the internal layout of the food business to verify appropriate separation to minimize cross-contamination. Do the actual operations/process flow correspond to the description provided in the opening meeting or during the document review? Where the two differ, bring this to the attention of management, seek clarification as to why there is a difference (e.g., documents not kept up-to date) and assess the actual operations. **For large food businesses**, the internal design, layout and process flow should ensure that: • Raw materials and final product are not co-located in the same room and/or area of the building. • Processing operations and packaging operations are separate from raw material intake and storage. • Non-food chemicals and cleaning material are not stored with food to prevent contamination. **For small food businesses**, particularly where operations are carried out in one room, a market stall or a vendor cart, the design layout and process flow should ensure that: • Raw materials and final products are stored separately, or that the area is appropriately cleaned after working with raw material and before handling final product. • No raw material is being handled or prepared during final product packaging. • There is no contamination from adjoining food businesses, market vendors or carts and the space around the stall is clear and permits easy access for cleaning. • Non-food chemicals and cleaning material is appropriately stored to prevent food contamination. During the assessment of manufacturing operations, verify that the equipment is designed and installed to allow cleaning and sanitizing, and that it is properly maintained. • Assess flow of employees and customers to determine if they are a potential source of cross contamination (e.g., tracking contamination on their shoes). **Inspection Strategy** If there is significant risk of food contamination, the process flow element should be rated critical non-compliance, and immediate corrective action should be taken by the food business.

Element	Food business site (inside) inspection
Internal Structures and fittings	Assess the internal structures to determine if they are appropriate for use in food operations. Verify that: • Internal walls, floors, ceilings and other structures are designed to prevent the entry of pests (i.e., no gaps or holes), water, (i.e., no evidence of leaks), built of durable materials and easy to maintain, clean and where appropriate, disinfect. • Surfaces of walls, partitions and floors are made of impervious materials and walls have a smooth surface. • Floors are constructed to allow adequate drainage and cleaning. • Ceilings and overhead fixtures are accessible for cleaning, to minimize the risk of dirt or condensation entering the processing area, food or food contact surfaces. • Windows are easy to clean and are designed to prevent the entry of pests (e.g., insects, rodents). • Doors have smooth, non-absorbent surfaces, are easy to clean and disinfect and are designed to prevent the entry of pests (e.g., insects, rodents). • Food contact surfaces are in good condition, durable and easy to clean, maintain and disinfect. In the case of market vendors with open-air stalls, or carts, there may not be any walls, windows or doors. However, the inspector should verify that: • Ceilings and overhead fixtures are accessible for cleaning, to minimize the risk of dirt or condensation entering the processing area, food or food contact surfaces. • Food contact surfaces are in good condition, durable and easy to clean, maintain and disinfect. • Where walls exist (e.g., market stalls) they should be built of durable material to prevent cross contamination from other operations in the market; allow for cleaning. • Floors are constructed to allow adequate drainage and cleaning. **Inspection Strategy** During assessment of the internal structures, the key element is to assess the potential for the final product contamination. Generally, the building construction will not explicitly contaminate food. If the condition of the plant demonstrates a high possibility of food contamination, the element should be rated major non-compliance.

Element	Food business site (inside) inspection
Cleaning facilities and procedures	Assess the cleaning facilities and procedures of the food business. The inspector should meet the person(s) responsible for cleaning procedures and obtain answers to the following questions: • Is the process described by employees consistent with written procedures or food hygiene principles and practices? • Is the frequency of cleaning processes and sequencing described by the employee consistent with written procedures or food hygiene principles and practices? Verify that the cleaning facilities are adequate for storing cleaning utensils and supplies with an adequate supply of hot and cold potable water or water approved by the competent authority. • For market vendors and market stalls, verify that cleaning facilities are available nearby, adequate and accessible to the vendor. › Storage of non-food chemicals (e.g., cleaning products, lubricants, paint) should minimize potential for food contamination and chemicals should be clearly identified. Verify whether the cleaning processes, including frequency, are being followed and assess whether the process is successful in removing gross debris, remnants of food, and presence of food waste, dust, and dirt from surfaces. • If yes, the inspector should verify the actual cleaning procedures and determine if: › a detergent solution is used to loosen soil and other material, › a detergent solution is followed by a water rinse with approved water, to remove the soil and detergent residues, › that following the water rinse, a disinfection process followed by rinsing is completed. • If no, assess the condition of food contact surfaces for the presence of gross debris, remnants of food, presence of food waste, dust, and dirt. **Note**: For food manufacturing processes where water-based cleaning should not or cannot be used6 (e.g., bakeries, dehydrated manufactured foods), assess the "dry" cleaning procedures used by the food business for removing and collecting residues and debris. See Guidance 7. Carefully assess the procedures used to clean the premises, the equipment, preparation, packaging, and serving surfaces to answer the following questions: • Are the employees following procedures? • Do the procedures being used remove gross debris from surfaces? • Is the use of detergent and/or disinfectant and subsequent rinsing to remove residue appropriate? • Are the manufacturer's instructions being followed regarding cleaning products? **Inspection strategy** The presence of gross debris or other matter on food contact surfaces is a significant risk of contamination and should berated as critical non-compliance and requires immediate corrective action. The presence of gross debris or other matter **on areas other than food contact surfaces creates** a high probability of contamination and should be rated as major non-compliance. The use of unidentified or unlabelled cleaning material (e.g., bleach in an unlabelled container) on food contact surfaces is a significant risk of contamination. This element should be rated as critical non-compliance and requires immediate action. The use of unidentified or unlabelled cleaning material (e.g., bleach in an unlabelled container) **on areas other than food contact surfaces creates** a high probability of contamination and should be rated as major non-compliance.

Element	Food business site (inside) inspection
Pest control procedures	Assess the pest control products and procedures used by the food business. The inspector should meet the person(s) responsible for pest control procedures and ask the following question about the process: • Is the process and frequency described by employees consistent with written procedures? Verify that the storage facilities are adequate for storing pest control products and minimize the potential for contamination. All pest control products should be clearly identified. • For market vendors and food carts, verify that storage facilities are available nearby, accessible to the vendor and adequate. › Verify that animals (e.g., dogs, cats) do not have access. Verify employee's knowledge of prevention and treatment to ascertain: • If the building or market stall is regularly inspected to ensure the building prevents pest access. • If potential breeding sites are eliminated, that food ingredients, food and all waste is stored in pest proof containers. • If there is ongoing assessment of the building, or market stall, including surrounding areas for evidence of infestation. • When necessary, treat with appropriate and authorized chemical, physical or biological agents. • Assess pest control products being used to determine if they are approved in food businesses and that manufacturer's instructions are followed. • Where countries require certification of pest control products, verify that products being used meet the required certification. **Inspection strategy** The presence of pests or evidence of pests or the use of unidentified or unlabelled pest control material on food contact surfaces is a significant risk of contamination and this element should be rated as critical non-compliance and require immediate action. The presence of pests, evidence of pests or the use of unidentified or unlabelled pest control material **on areas other than food contact surfaces creates** a high probability of contamination and should be rated as major non-compliance.

Element	Food business site (inside) inspection
Personnel hygiene facilities and practices	The inspector should verify the hygiene facilities and personal hygiene practices. Verify that personnel hygiene facilities are available for employees either on site or, in the case of market vendors and food carts, available nearby. There should be: • Adequate hand-washing facilities with hot and cold water. • Adequate toilets or lavatory facilities. • Adequate changing facilities for personnel where protective clothing is provided. • Appropriately located and maintained facilities to encourage proper hygiene and minimize the potential for cross contamination. Assess personnel cleanliness of food handlers, including: • Appropriate use of suitable protective clothing, head covering, and footwear. • Handwashing at the start of food handling activities, immediately after using the toilet and after handling raw food or any contaminated material including money, where this could result in contamination. • Observe employee personnel hygiene and sanitation practices, such as handwashing, appropriate use of sanitizers and the use of clean and appropriate protective clothing. Where gloves are part of the protective clothing, ensure they are used appropriately and not as a substitute for proper hygiene, handwashing etc. Verify the personnel behaviour of food handlers to ensure they are not: • Using gloves inappropriately (e.g., reusing single-use gloves, touching contaminated product, touching final product without changing gloves). • Smoking. • Spitting. • Chewing or eating. • Sneezing or coughing over unprotected food. • Wearing personal effects (e.g., jewellery, watches, false fingernails) if these may contaminate food. Verify the movements of employees to ensure there is no circulation between raw and finished product areas. **Inspection strategy** Where employee practices, or a lack of good practices (e.g., no handwashing prior to handling food, sneezing or coughing over unprotected food, employees from raw material sections handling finished food etc.) are a significant risk of contamination, rate this element as critical non-compliance and that it requires immediate action. Where employee practices, or a lack of good practices (e.g., not wearing protective clothing in non-production areas) are a potential risk of contamination, rate this element as major non-compliance.

Element	Food business site (inside) inspection
Internal environment and storage	**Note**: The lighting, temperature and ventilation elements are generally not applicable to food businesses operating out of non-permanent buildings, such as market stalls or food carts. The food business facility should provide the appropriate environment (e.g., lighting, temperature, storage) to ensure the production of safe food. In assessing the facility environment, the inspector should: • Verify lighting throughout the facility to ensure it is adequate to enable operations, (e.g., colour, intensity) and that fixtures are protected to ensure food is not contaminated in the case of breakage. • Verify the temperature in the food business facility is appropriate and that equipment ensures appropriate temperatures in dedicated areas (i.e., heating, cooking, refrigeration and freezing). • Verify the temperature of the refrigeration units, and the freezers. • Verify the equipment used to cook, heat, treat cool, store or freeze food is designed to reach the required temperatures as rapidly as needed and to maintain that temperature. • Verify the equipment can be and is monitored and controlled appropriately for temperature, airflow, humidity and any other required characteristics that need monitoring (e.g., HACCP critical limits). • Verify that equipment function has been validated (e.g., cooking at appropriate temperature, refrigeration or freezing at appropriate temperatures) and is periodically revalidated. • Verify the ventilation in the food business facility is sufficient to remove air borne contamination, control odors and humidity. • Verify that all ventilation equipment is clean (e.g., no evidence of grease or gross debris) and in good repair to minimize the potential for contamination. • Verify there are adequate storage facilities for food and ingredients, and that the storage equipment (e.g., shelving) is installed to facilitate maintenance and cleaning. › Are there separate storage facilities for raw product and finished food in order to prevent contamination? › Are the storage facilities in good repair and able to prevent access by pests, maintain appropriate temperature and humidity and temperature control to minimize deterioration? **Inspection strategy** Where there is a lack of protective covering for lights over food production areas, where equipment is not designed or operated within established production parameters (e.g., heating, cooling, storage temperatures), or where raw and finished product are stored in the same areas, there is a significant risk of contamination and this element should be marked as critical non-compliance. Where there is a lack of protective covering for lights in non-production areas, where the operation of equipment requires constant mitigation strategies to ensure performance, mark this element as major non-compliance.

Element	Food business site (inside) inspection
Water and Ice	The food business must have access to and use approved water. The inspector should: Verify that there is an adequate supply of potable water or water from a source approved by the municipality or other appropriate government authority. • If bulk water is used by the premise and stored on site in containers, verify the containers protect water from contamination (i.e., covered) and that utensils do not contaminate the water. • Water should not be re-used as it significantly increases the risk of contamination. Where non-potable water is used in fire control systems, steam production, refrigeration, verify the non-potable water systems are clearly identified and do not connect to potable water systems. Ice that comes into contact with food must be made from potable water and be produced, handled and stored to protect it from contamination. • Ice used for raw material should never come into contact with ice used for final product or used for any other purpose. • Steam used in direct contact with food or food contact surfaces must be generated from approved water. **Inspection strategy** The use of contaminated or unapproved water, particularly for food ingredients and products, or for food contact surfaces, will result in contaminated food or a significant risk of contaminated food and should be rated as critical non-compliance and immediate corrective action should be taken. The use of contaminated or unapproved water for any other use has a high probability of contaminating food and should be rated as major non-compliance.
Equipment	Equipment used to produce food must be built from appropriate material, kept clean and in good repair. In assessing equipment, the inspector should: • Verify that equipment is located so that it functions in accordance with its intended use, allows for good hygiene practices and can be appropriately cleaned and maintained. • Verify the cleanliness of all equipment, in particular, food contact surfaces. There should be no gross debris or any waste remaining on the surface or on any other part where the debris or waste might fall on the surface or in the food. • Verify the cleanliness of all equipment, utensils, knives, pans, ovens etc. › Equipment should be moved or disassembled as needed to ensure adequate cleaning, maintenance and/or inspection (e.g., pest control). › Material, especially any food contact surface, is made of nontoxic material and will not contaminate food. **Inspection strategy** The presence of dirt, debris or waste on food contact surfaces or where it may fall onto food or food contact surfaces poses a significant risk of contaminating food and should be considered critical non-compliance and immediate corrective action should be taken. The presence of dirt debris or waste on non-food contact surfaces or where it is unlikely to fall onto food or food contact surfaces has a high probability of contaminating food and should be considered a major non-compliance.

Element	Food business site (inside) inspection
Drainage, waste, inedible substances	All food business must have adequate processes for ensuring that liquid and solid waste is not and does not become a source of contamination. Where there are waste removal protocols or procedures, employees should follow them. Verify that all waste is removed frequently, stored appropriately, and not allowed to accumulate in food handling, food storage, and other working areas as well as the adjoining environment. Verify that all waste containers have lids, and are being used appropriately (e.g., not cross used for ingredients), and that the floor of the premise is waste-free. Verify that containers for waste, by-products and inedible substances are readily identifiable and appropriately constructed. Verify frequency of waste collection and disposal (e.g. by business association, market authority). Verify the adequacy of drainage and that the design and construction of the drainage minimizes the risk of contaminating food or the potable water supply. • Assess if there is any standing water in the food production and handling areas, or in other areas (e.g., storage). • Assess if there is there any evidence or potential for the presence of sewage in the premise. **Inspection strategy** The presence of significant waste or pooling sewage in the processing areas, or cross utilization of storage containers between waste and food poses a significant risk of contaminating food and should be considered critical non-compliance and immediate corrective action should be taken. The presence of significant waste in non-food producing areas, cross- utilising waste containers in non- food producing areas or pooling water or sewage in non-food producing areas has a high probability of contaminating food and should be considered major non-compliance.

Element	Food business site (inside) inspection
Raw Material and ingredients	All raw materials and ingredients must meet food safety standards. The use of contaminated material presents a significant risk that the final product will also be contaminated. Assess the raw material and ingredient procedures used by the food business. The inspector should: • Ask to meet the responsible person(s) and ask questions about the process to verify if: › The process described by employees is consistent with written procedures. › There is appropriate verification of reception records (e.g., supplier, lot identification, testing). • Verify the condition of the reception area (e.g., cleanliness, temperature) to verify: › The reception process and ascertain if appropriate stock rotation occurs. › There is adequate inspection and sorting of raw materials and ingredients on reception and before processing. › There are records of inspection results, (e.g., rejections because of unacceptable raw materials or ingredients, laboratory results). **Stock management** Verify the rotation of raw materials and ingredients that the 'first in/first out" process is in place. Verify food ingredients and additives in the storage areas to ensure they are approved for use and that they are appropriately stored to prevent cross contamination. • Cross reference ingredients and additives in the storage areas with information on final product label. **Transport** Ask what processes are used to verify that ingredients and raw material were protected during transport to the vendors site. • Verify that product to be cooked was separated from ready-to- eat product during transport. • Verify that the food was not transported in containers or vehicles previously used for non-food products to minimize potential contamination. **Small and micro food businesses** are unlikely to have specifications or raw material documentation but should still be able to provide information about the source of raw material and ingredients. The food business should be able to provide the name of their supplier and to ensure the product is fresh and wholesome to meet their responsibility to source food that meets the requirements. **Note**: Requiring that food businesses know and are able to identify their supplier (s), is a key element in investigating any praedial larceny. Verify that any ingredients and additives being used are approved for food use. **Assess storage of raw materials** • Verify storage location of dry goods and raw material. These should be on shelves, not on the floor. • Verify whether raw ingredients are effectively separated from cooked or ready-to-eat foods. • Verify raw material temperature control: › If refrigeration, verify the temperature of the equipment. › If ice, verify there is sufficient ice and observe whether product is protected from melted water. • Use a thermometer to check the temperature of product (disinfect thermometer between use).

Element	Food business site (inside) inspection
Packaging and labelling	Packaging should be of appropriate quality to ensure it is not a source of contamination, and to protect the final product from contamination during transport and sale. Labels should meet all regulatory requirements and provide the required information to the buyer (e.g., common name, weight, ingredients). **Packaging** Verify the storage of packaging material is appropriate to protect it from any contamination. Verify the packaging on site is consistent with the specifications and that it is non-toxic. Verify that reusable packaging should be appropriate to the product, easy to clean and disinfect as appropriate. **Lot identification, handling and labelling** Verify that each container of food is permanently marked to identify the producer and the lot. Verify that all food products are accompanied by adequate information, or that this is available, so that the person receiving the product knows how to handle, store, prepare and use the product appropriately. Is the food labelled appropriately (e.g., common name, list of ingredients) to inform purchasers of the content of the packages? Further guidance on labelling review can be found in Appendix 6.
Transport of final product and records of sale	Verify the condition of final product shipping area, (e.g., cleanliness, temperature). • Note the shipping process and ascertain if appropriate stock rotation occurs. • Is there adequate inspection of final product prior to shipping? • Are there records of inspection results, (e.g., rejections because of damaged packaging, leaking units, laboratory results)? Verify that there are records for every lot sold by a food business, quantity and purchaser. Verify that the business has processes to handle all returned material, including recalled products, and has records as to the reason for the return and the disposition of all the products. **Transport** Ask what processes are used to verify that final product is adequately protected during transport to the buyer's site. • Verify that product to be cooked was separated from ready-to- eat product during transport. • Verify that the food was not transported in containers or vehicles previously used for non-food products to minimize potential contamination.

GUIDANCE 7: BAKERIES

This guidance is provided to address specific considerations for the inspection of bakery operations, particularly with respect to the use of low moisture foods. It does not repeat the considerations set out in guidance (6).

Element	Bakery (inside) inspection
General	Flour is a key ingredient used by bakeries and its use creates dust both in the processing area and throughout the premises. Because flour is considered a low moisture product,[33] bakeries must take this into account. Cleaning is generally accomplished through dry cleaning that removes food residue, dirt, grease or other objectionable matter by actions such as wiping, sweeping, brushing, scraping or vacuuming the residues without the use of water and detergents. Where bakeries use other high-moisture products (e.g., meat for pies, sandwiches, fruits or vegetables), the specific requirements for those products must also be addressed and cross contamination between raw and finished product must be minimized.
Process flow	In assessing the process flow in a bakery, the inspector's objective is to understand the sequence of operations and to assess the potential risk of contamination of the final product. Confirm the process flow being used. A general description of a process flow, from reception to sale will be: Receive → store → process (mix, cook/freeze) → hold → serve/sell/distribute Verify that the process flow of the plant assures the separation (e.g., physical or temporal) of raw and cooked food. It is important to verify that the layout and the hygienic design ensure that areas intended for dry cleaning remain in a dry state and receive only dry cleaning and disinfection. **Inspection Strategy** During assessment of the layout and process flow, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination due to an inappropriate process flow where raw and final products are juxtaposed, the element should be rated critical non-compliance and immediate corrective action should be taken.

33 Code of Hygienic Practice for Low-Moisture Foods CXC 75-2015.

Element	Bakery (inside) inspection
Reception of raw materials and ingredients	Similarly, to the general guidance, the inspector should verify the sanitary condition of ingredients and raw material, and that perishable materials were refrigerated or put on ice at reception. Verify that flour and any other ingredients are packaged appropriately and are free from insects and other pests/foreign material and are stored appropriately (i.e., in closed containers, on shelves).
Equipment	In addition to the general guidance: the inspector should verify the cleanliness of equipment being used in low moisture environments, that is: • All parts of equipment are accessible for inspection and cleaning. • Designed to facilitate cleaning with little or no water, or; • Designed to be removed easily to a separate location for wet cleaning and should ensure rapid and complete drying to prevent microbial growth and microbial harbourage sites. Other criteria include: • Push buttons, valve handles, switches and touch screens should be designed to ensure product and other residues (including liquid) do not penetrate or accumulate and become a harbourage site. • Verify that mixing or other equipment is designed and maintained to prevent flour or dough accumulation and is free from insect infestations. • Verify pans and other utensils are not stacked on floors, which can lead to cross contamination. **Inspection strategy** During assessment of bakery equipment, particularly for processing flour, the presence of harbourages, dough accumulation, insects and standing water in low-moisture processing areas, present a significant risk of food contamination and the element should be rated critical non-compliance and immediate corrective action should be taken.
Food Preparation and processing	In addition to general guidance 6, it is important to verify that there are adequate control measures in the food preparation areas. The inspector should verify that: • There are processes in place to prevent increases in humidity in order to prevent condensation from contaminating products or create conditions that allow the proliferation of pathogens such as Salmonella within the production environment. • There are dedicated workers and equipment, including utensils and cleaning tools, assigned to this area. • Employee traffic into the area is controlled and personnel follow established hygiene procedures prior to entering. **Inspection Strategy** During assessment of the food preparation, the key is to evaluate the potential for final contamination. If there is significant risk of food contamination, similar to the element on equipment, this element should be rated critical non-compliance and immediate corrective action should be taken.

Element	Bakery (inside) inspection
Cleaning	Verify that the low-moisture product and preparation areas are designed and constructed to facilitate dry cleaning and the avoidance of water. Verify that non-fixed equipment or utensils that require washing are cleaned outside the dry clean areas. Verify that dry cleaning tools for removing dust and other material are cleanable, durable and dedicated to use: • Tools used for cleaning food contact surfaces are not used to clean non-food contact surfaces. • Filters are properly maintained on a regular basis and replaced when necessary. Verify that, in order to limit the introduction of water in the processing areas requiring stringent hygiene controls, handwashing and footbath (if used) stations are located outside, at the entrance of this area.
Packaging, storage and display	As with all food businesses, the most stringent hygienic practices should be in place for the packaging of cooked products to prevent recontamination. Verify that the finished products are appropriately packaged and stored. Verify refrigeration temperatures of final product display. Verify appropriate temperatures for distribution to other sites.

GUIDANCE 8: BOTTLING DRINKS

This guidance is provided to address specific considerations with respect to bottling plants. The focus is on reception of raw materials and ensuring the bottles are clean and do not become a source of contamination. Other more general considerations are provided in guidance (6).

Element	Bottling drinks
General	When bottling drinks, all the requirements for sourcing primary product under general guidance 6 must be met whether for juice, soft drinks or alcoholic drinks There are also some additional requirements for the packaging of bottled drinks, particularly, the preventing contamination of the bottles that are addressed in this guidance.
Plant construction	Verify that the filling / bottling room is separated from other plant operations and storage areas to protect against contamination, either by physical location or by time. Verify where a conveyer is used to transport containers or bottles from one room to another and that the opening is minimal (i.e., allows passage of the conveyer and the bottles). Verify that washing and sanitizing of containers or bottles is separated from the filling stations, either by physical location or by time.

Element	Bottling drinks
Sourcing product	Verify that raw product is from reputable sources: • Vegetables, fruits, or their concentrates for juices should be sourced from reputable producers and are inspected and culled when needed (e.g., removal of decomposed products, removal of dirt and any extraneous material). • Water for bottling meets the potable water standards (e.g., either domestic water supply, certificate of analysis) established by the competent authority.
Fruit or vegetable processing	Verify that the fruit or vegetables are inspected before pressing and that decomposed or contaminated product is discarded. Verify that the filter cloths and presses are designed for purpose, maintained in a sanitary manner and are cleaned and inspected prior to each pressing. Verify that all produce residue and waste is disposed of appropriately following each pressing.
Operations	**Bottles or containers** Where bottles or containers are re-used (multi-use), verify that these are cleaned and inspected before use or reuse. Where single source containers or bottles are used, verify that they are inspected prior to use. Verify that filling, capping, closing and packaging operations are completed so as not to contaminate the final product. This includes: • Verification and inspection of empty and filled containers. • Verification that there are no glass fragments in the containers, either from broken containers or other broken glass. • Verification that there is adequate protection (e.g., empty bottles stored upside down, empty or filled bottles held under protective cover) of open bottles before and after filling and before capping, to prevent physical contamination in the event of bottles breaking during filling.
Aseptic processing and packaging	Where drinks are produced under aseptic conditions: **Aseptic processing and packaging**[34] mean the processing and packaging of a commercially sterile product into sterilized containers followed by hermetically sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product. Aseptic processing and packaging differ from canning in that, in canning, the food is placed in the can, sealed and heat processed in that order. Verify that prior to production, all piping, valves, pumps, surge tanks, product fillers and other product contact surfaces downstream from the hold section or tube are brought to a condition of commercial sterility, and that this is maintained until production is completed. Verify that the aseptic zone of filling and packaging equipment must be cleaned and brought to a condition of sterility prior to the initiation of product filling and must be maintained in a condition of sterility throughout production. The aseptic zone should be re-sterilized when conditions occur which may result in loss of sterility. Verify that the product steriliser is equipped with appropriate number of temperature and time/temperature recording devices at the required locations and verify operation and records. • Where pressure is a critical factor in the processing schedule, verify that there is a pressure sensor/recorder and verify operation and records. Verify processing time and temperature is consistent with the documented and validated process. Verify that final product is inspected for defects, including sealing. Verify that each container is marked with an identifying code that is permanent, legible, and does not adversely affect the container integrity. Verify that final product is handled in a manner that protects containers and closures from damage and minimizes potential defects and subsequent microbial contamination.

34 Code of hygienic practice for aseptically processed and packaged low-acid foods CAC/RCP 40-1993.

GUIDANCE 9: EGGS

This guidance is provided to address specific considerations for the sorting, grading, processing and distribution of eggs and egg products and does not repeat the considerations set out in the general guidance (6) when possible. In this section, table egg is defined as "an egg destined to be sold to the end consumer in its shell and without having received any treatment significantly modifying its properties."

Element	Eggs
General[35]	Eggs can be contaminated internally during egg formation as well as externally (e.g., filth). Eggs presented for sale to consumers should be wholesome, stored appropriately and not subject to contamination by pests, animal or other means.
Process Flow	Objective: to understand the sequence of operations. • Confirm the process flow being used specific to each operation. Receive → handling/clean/prepare → store/hold → sell
Reception	Verify that eggs have been sourced from primary producers[36] with good agricultural practices consistent with food safety and hygiene. They should also have implemented appropriate animal husbandry practices to assure the proper animal health of the flocks is maintained. Verify that eggs are inspected on reception to ensure they have been stored and transported in a manner that minimizes damage, thus avoiding potential for contamination. Verify that eggs intended for sale as table eggs are not broken or leaking, are not contaminated with fungus or faeces and that unacceptable eggs are rejected. Verify, if legislatively required, all accompanying documentation about the eggs and their production at farm level, including a veterinary certificate. The veterinary certificate or documentation can include: • Prevention and control of avian diseases with an impact on public health. • Identification and movement of birds and eggs. • Use of agriculture and pest control chemicals. • Nature and source of feed, feed ingredients and water. • Use of veterinary drugs and medicines. • Results of testing where testing is performed. • Health status of personnel. • Cleaning and disinfection. • Traceability/product tracing and recall. **Note**: if the inspector has any concerns about the documentation accompanying the eggs at reception, they should take steps to confirm the information, generally in collaboration with Agriculture or Veterinary inspectors.

35 Code of hygienic practices for eggs and egg products (CAC/RCP 15-1976).

36 This document addresses the sale of eggs, for guidance on primary production, refer to CAC/RCP 15-1976.

Element	Eggs
Handling, clean, prepare	Verify that eggs are handled in a manner that avoids damage, minimizes moisture on the shell surface and prevents contamination. If intended for the table egg market, verify that the eggs are visibly clean prior to sorting, grading and packing. Where eggs are washed, verify that the cleaning process: • Ensures that eggs are not soaked prior to or during washing. • That the water (e.g., water temperature, pH, and quality) meets the written standards to minimize contamination. • That eggs are dried to minimize moisture on the surface of the shell. • The shell is sanitized effectively. Verify that cracked, dirty, and unsafe/unsuitable eggs are segregated from clean and intact eggs and identified as not suitable for table eggs. • Verify that eggs segregated for processing are suitable (e.g., candled). Verify conditions during handling and preparation in that moisture is minimized on the shell surface. • If required by law, verify that eggs are maintained at refrigerated temperatures, or as specified by authorities.
Display and sale of table eggs	Assess the wholesomeness of the eggs: • Cracked eggs, eggs with mud, dirt, litter or other material should not be sold. • Eggs with foreign odors, abnormal color sand moldy should not be sold. Verify that eggs are adequately protected from pests, animals or other contamination during storage prior to and on offer for sale. Verify that eggs are stored at the appropriate temperature[37] as established by the specific country. • Where eggs are required to be refrigerated, verify that eggs offered for sale are labeled and maintained at the appropriate temperature. Assess stock rotation to ensure fresh eggs are being offered for sale.

37 To establish the appropriate temperature in their manual, each country should refer to their laws and regulations as well as consulting international standards such as the CARICOM standard for Grading and Quality Requirements for Table Eggs (draft 2004).

GUIDANCE 10: FISH AND FISH PRODUCTS

This guidance is provided to address specific considerations for fish and fish products whether wild-caught or from aquaculture farms and, as much as possible, does not repeat the considerations set out in the general guidance (6).

Food businesses should also be encouraged to consult the guidance provided by Codex.[38]

Element	Fish (inside) inspection
General	Fish, including shellfish, and fish products are highly perishable foods that need careful handling and appropriate storage conditions (e.g., temperature). Temperature is the single most important factor affecting the rate of fish and shellfish deterioration and multiplication of micro-organisms. Food business facilities and procedures should therefore be designed to facilitate rapid processing and subsequent storage at the appropriate temperatures. Where fish is intended for international trade, the inspection should not only assess the ability of the food business to meet national requirements but also to meet the those of the destination country. **Inspection strategy** Where a food business does not have or does not meet their established process to meet export requirements, they should not be eligible for export certification.
Flow through	Where the food business is required to have a documented food safety plan (e.g., HACCP), carefully review all the documentation as per guidance 3. Verify that the process has a product flow-through pattern designed to prevent potential sources of contamination, minimize process delays (which could result in further reduction in essential quality), and prevent cross-contamination of finished product from raw materials. For food business without HACCP, or without a written food safety system, verify the process flow and verbally confirm if the process flow provides adequate separation to prevent cross contamination. For example: • Fishing/Transport/Reception; • Storage; › (On ice) or refrigerated; › Live, in chilled water. Processing (optional as fish may be sold as is): • Heading/gutting; • Descaling; • Trimming, filleting, skinning; • Washing; • Refrigeration or Freezing (optional); • Weighing and Packaging. **Inspection strategy** During assessment of the layout and process flow, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination, or the food business is not following its documented (e.g., HACCP) process flow, the element should be rated critical non-compliance and immediate corrective action should be taken.

38 Code of Practice for fish and fishery products, CAC/RCP 52-2003.

Element	Fish (inside) inspection
Sourcing	Verify that fish and shellfish are sourced from reputable businesses including: • Aquaculture fish are sourced from businesses operating based on, or in compliance with, the recommendations of the Code of Conduct for Responsible Fisheries (FAO, Rome, 1995), and section 6: Aquaculture Production of the Code of Practice fish. • Molluscan shellfish are sourced from fishing areas approved by government organizations and are grown in clean sea water, minimizing the potential for molluscs to concentrate contaminants. And harvest areas for shellfish and roe on scallops have appropriate controls for biotoxins. • That wild caught fin fish are sourced from licensed or approved fishermen. **Inspection strategy** If the food business cannot identify the source of the fish or shellfish, it may have been caught or harvested illegally and should be treated as an illegal product, as the food business will be unable to provide assurance the product meets requirements. • In particular, where the supplier and harvest area of molluscan shellfish are not known, it should be considered as contaminated, and not permitted for sale. Rate this element as critical non-compliance.
Reception	Verify that all fish and shellfish are assessed on reception for suitability, including: • That live fish and shellfish are actually alive, and not diseased and that dead lobsters and crabs are not processed. • That they are at the appropriate temperature. • That the organoleptic characteristic (e.g., appearance, odor) is appropriate to ensure they are not decomposed. Verify that shrimp are being inspected on reception, that they are well-iced, deep frozen and that they are not decomposed.
Holding / Storage/ Temperature	Temperature is the single most important factor affecting the rate of fish and shellfish deterioration and multiplication of micro-organisms. Verify that the fish, shellfish and their products are chilled at reception, and that the temperature is verified on reception. Verify that the fish is kept chilled to about 0°C as much as possible. Verify that fresh fish and shellfish, sold at markets or direct to consumers, are iced or refrigerated to prevent decomposition or, if held without ice, that the fish is sold immediately. **Molluscan shellfish** Storage periods should be kept as short as possible before processing or sale. **Lobster, Crab** Verify that there is a process to ascertain that they are still alive and to ensure that dead lobsters or crabs are not processed. Verify that live animals are stored in appropriate tanks, wells, crates, open weave bags or boxes covered with wet sacking and held at as low a temperature as practical. Verify that the tanks and wells for pounding live lobsters are placed and constructed so as to maintain the animals in a live state. • Verify that lobsters and other species that mutilate each other have their claws banded.

Element	Fish (inside) inspection
Processing	**Molluscan shellfish** Verify molluscan shellfish are handled carefully during processing so as not to damage the shells, which increases the risk of contamination and deterioration. Verify the outsides of the shells are washed free of mud, and all soft- adhering organisms, and as much as is possible, hard adhering ones, are removed. Verify that the washing is carried out with clean (sea) water. Verify that only live molluscs are shucked, that dead ones are disposed of and that shucking is done carefully to minimize the potential for contamination. **Scallops** Verify that scallop adductor muscles are not stored in a manner to absorb excess water (i.e., should not be in contact with freshwater, or melting freshwater ice,), which can result in consumer fraud). **Shucking** Verify that scallops are examined prior to shucking and that those showing evident signs of death (e.g., shell gaping, lack of response to percussion, sour odor, and/or viscera exposed outside the shell, picking of muscle or mantle, evident signs of decomposition or damage) are disposed of in a proper manner. Verify that the viscera and roe are completely removed from scallop meat. For Roe-on Scallop Meat, verify that the viscera are completely removed. **Fin fish or fish products** Processing of fresh, frozen and minced fish may range from presentation of whole, dressed, fillets or minced fish to be distributed in markets and institutions or used in processing facilities. In some cases, processing of fresh, frozen and minced fish may be an intermediate step for other fish products (e.g., smoked fish, frozen breaded or battered fish). • Verify that the required fish processing (e.g., gutting, descaling, trimming, filleting, skinning, washing) is done without delay and with care to avoid contamination. • Verify that pieces of bones, scales, skin or any other matter (e.g., scales and viscera) are cleaned as frequently as necessary, and that a thorough cleaning is undertaken at the end of the day. • Verify fish is moved to chilled storage or frozen storage as appropriate, as quickly as possible: › Fish should be chilled at a temperature of 0 to +4°C. › Fish should be frozen at -18°C or colder. • Verify inedible material is placed in closed waste containers. › Fish that falls on the floor should be considered contaminated and appropriately disposed of. Verify there is an adequate supply of clean seawater[39] or potable water to wash: • whole fish, to remove foreign debris and reduce bacterial load prior to gutting, • gutted fish, to remove blood and viscera from the belly cavity, • surface of fish, to remove any loose scales, • gutting equipment and utensils, to minimize build-up of slime, blood and offal. For fin fish known to have parasites, verify that there is a candling process in place and the process is effective (e.g., adequate lighting, skilled personnel).

39 For the definition see Code of Practice for Fish and Fishery Products CAC/RCP 52-2003.

Element	Fish (inside) inspection
Battered fish	Coating and battered fish can vary significantly in process, but key inspection steps are outlined here: • Verify the storage of the coating, batter or the ingredients to ensure sanitary conditions. • For battered shrimp, verify peeling, deveining and butterflying (as appropriate) processes minimize the possibility for cross contamination. • Verify the written procedures for battering fish, including preparation of the batter, time and temperature controls of the batter to minimize bacterial growth. • If battered fish is cooked or partially cooked, verify scheduled time and temperature of cooking is followed. • Verify battered fish is frozen to -18°C immediately after cooking.
Shellfish (lobster, shrimp, prawns)	Verify the written procedures for the production of raw- frozen or cooked-frozen shellfish and the implementation of the procedure including: • That peeling, deveining, trimming washing of lobster tails or shrimp is done quickly, to prevent contamination and product spoilage. **Note**: in some processes, peeling may be done after cooking or not at all. • If product is to be cooked, verify that the cooking schedule is tailored to the size of the shellfish and that there are records of the time and temperature used and that, after cooking, the product is chilled quickly to minimize microbial growth. If product is frozen, verify the use of quick-freezing methods, followed by glazing to protect against dehydration and packaging.
Waste disposal	Verify that adjacent areas are free from trash, and that any waste is promptly and properly removed and disposed of. Verify that all waste containers are tightly covered and appropriately labelled to prevent access by animals and to prevent cross utilization. **Solid waste** • Fish including scales, skin, viscera, fish heads and carcasses (fish bones). • Assess disposal of solid waste. Waste should be disposed of into appropriate lidded, dedicated waste containers. • Verify if any animal by-products are being sold for further use (animal/fish feed;). If so, verify they are being handled separately from waste and protected from contamination. **Liquid waste** • Blood and contaminated wash water must be disposed of so as not to contaminate the food facility and the food. • Liquid waste containers must be clearly identified and have close fitting lids. They must be used for waste only.
Processing areas	Verify that dogs, cats, wild birds and all live animals are prevented from entering the processing environment. Verify that all equipment used in processing is clean and well maintained. Verify that processing supplies, and materials are securely stored to prevent damage or contamination and they are inspected prior to use.
Packaging and labelling	Verify that packaging is carried out without unnecessary delay and under conditions that will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms. Verify the packaging material is appropriate for the product and conditions of storage and will provide protection from damage and contamination.

GUIDANCE 11: MARKET VENDORS, BULK SALES OF FRUIT, VEGETABLES, SPICES, RICE, PULSES

This guidance is provided to address specific considerations for the inspection of market vendors of bulk product and does not repeat the considerations set out in the guidance (6) as much as is possible.

Element	Market Vendor (inspection)
General	Bulk sale vendors in this case refer to individuals or individual businesses that sell in bulk, non-refrigerated and the primary controls are to purchase from reputable sources, protect from pests and other contaminants during storage and sale, and dispose appropriately of unwholesome product.
Process Flow	For market vendors, confirm the process flow, generally verbally. Receive → store → clean/prepare → hold → sell
Product wholesomeness	During assessment of persons selling fruit, vegetables, spices and pulses, the inspector should: • Discuss stock rotation with vendor. • Ascertain how long the products are stored and how the vendor ensures product is not spoiled prior to being sold. • Verify that cut fruits or vegetables being offered for sale are protected (e.g., in a display counter or plastic wrap). Assess the wholesomeness of the food beings sold, verify that unwholesome food is not sold, but is appropriately disposed of. Verify that spices, rice, pulses and other bulk products are being stored in clean containers, are free from insects and other foreign material and are stored and displayed appropriately (i.e., on shelves, not on the ground). Fruits, vegetables and spices should be sourced from reliable vendors[40] to ensure they have been produced and harvested under sanitary conditions. Verify that products are protected from the elements, from pests such as flies and rodents and that they are not subject to contamination from any activity, (e.g., sprinkling fresh produce with water, any nearby activity), both during display for sale and during storage. • If market stall is not emptied overnight, discuss how produce is protected.

40 Products should be sourced from vendors that meet the Code of Hygienic Practice for Fresh Fruits and Vegetables CXC 53-2003.

Element	Market Vendor (inspection)
Product wholesomeness (continuation)	**Inspection strategy** If unwholesome, rotten or contaminated food is being sold, this should be marked as critical non-compliance. If lower quality food is sold, then it is a minor non-compliance. The presence of vermin, particularly disease-carrying vermin that has a significant possibility of coming into contact with food, should be considered critical non-compliance. If the vendor cannot identify source, the product may and should be treated as an illegal product as the vendor will not be able to guarantee it meets requirements. • **1st time** – remind the vendor that they must source from reputable suppliers, and that they should get a written document (e.g., bill of sale). • **2nd time** – written warning. • **3rd time** consider seizing product (after consultation with supervisors), as product from unknown source may be contaminated.
Waste removal	Verify that there is appropriate waste removal of trimmings and unwholesome foods, and that there is no accumulation of product or other waste either around the market stall or around the vendor's feet.

GUIDANCE 12: MILK, DAIRY

This guidance is provided to address specific considerations for milk and milk products and as much as is possible, does not repeat the considerations set out in the guidance in documentation (3) and general guidance (6). Food businesses should also be encouraged to consult the guidance provided by Codex.[41]

Element	Milk Dairy (inside) inspection
General	Milk is a highly perishable product and must be handled carefully across the entire food chain from farm practices through to final sale. Food businesses (dairies) generally process pasteurized or UHT/shelf stable milk,[42] which Codex defines as the processing and packaging of a commercially sterile product into sterilized containers followed by hermetically sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product. Most countries require that dairies have an official and validated procedure for every aspect of preparation, production, packaging and storage. As with guidance 3, the inspector's role is to verify that the dairy is following that procedure, maintaining records and taking corrective action where there are deviations from the procedure. For dairies using HACCP or other food safety management systems, inability to follow the established procedures should be considered a critical non- compliance.

41 Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004.

42 *Details on the establishment of thermal processes designed to render milk or milk products commercially sterile can be found in the* Code of Hygienic Practice for Low- Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979) and the Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods (CAC/RCP 40–1993).

Element	Milk Dairy (inside) inspection
Process Flow and Documentation	Verify the process flow for milk within the specific dairy establishment, particularly that it minimizes any potential for cross contamination: Raw milk reception → storage → standardization/homogenization → heat treatment → packaging and labelling → storage → distribution and sale Verify written documents, including: • Requirements for storage of milk on reception (e.g., temperature, time). • Principle of 1st received, 1st processed to minimize potential for microbial growth. • Process document from a recognized authority with validation data including preparation, processing, aseptic packaging and storage requirements. • Cleaning procedures. • Validation of bacteriological analysis.
Reception	Verify that milk is sourced from reputable suppliers, from farms that practice Good Agricultural Practices. **Note**: May require coordination with Agriculture inspectors. Verify that milk is subject to visual inspection and other inspections (e.g., temperature, acidity and appropriate microbial and chemical tests) and verify records. Verify that the dairy can receive and maintain at the necessary temperatures (e.g., refrigeration, or immediate processing) to minimize any increase of the microbial load of the milk. Verify that milk is not accepted on reception when the product is deteriorated or spoiled or contains any substances, matter or agent that result in spoilage or is unfit for use in any way. • Determine what corrective actions were taken when milk was below inspection standards.
Steam, Air and other connections	Verify that the steam supply to the thermal processing system supplies sufficient pressure during processing, and the corrective action that is taken if the pressure drops during processing. Verify that air or other appropriate gas used in the process is sterile, either by filtration (e.g., double filtration within one filter housing or two separate filter housings) or by a combination system such as incineration followed by filtration. Verify that filters are installed, maintained and changed in accordance with the manufacturer's instructions, their performance is periodically verified using appropriate test methods and records maintained. If incineration is used, verify that critical factors such as final air temperature and flow rate are controlled and recorded. Verify that all connections are appropriate: • No direct connections between pasteurized and raw milk or milk products. • No direct connections between milk or milk products and cleaning systems and/or cleaning solutions.
Packaging and labelling	Verify that packaging is appropriate for product being packed (e.g., meets manufacturer specifications) and has been stored and handled appropriately (e.g., clean). Verify that the packaging material is inspected prior to use. Where the dairy uses in-line formation of containers, verify that process follows specifications, maintains container integrity and prevents aseptic zone and container contamination.

Element	Milk Dairy (inside) inspection
Processing	Verify that the scheduled processing procedures are followed. **Note**: Codex considers that UHT treatment is normally in the range of 135 to 150 °C in combination with appropriate holding times necessary to achieve commercial sterility. **UHT/Commercial Sterility**[43,44] **UHT** (ultra-high temperature) **treatment** of milk and liquid milk products is the application of heat to a continuously flowing product using high temperatures for such time that renders the product commercially sterile at the time of processing. When the UHT treatment is combined with aseptic packaging, it results in a commercially sterile product. Verify that prior to production, all piping, valves, pumps, surge tanks, product fillers and other product contact surfaces that are downstream from the hold section or tube are brought to a condition of commercial sterility, and sterility it is maintained until production is completed. Verify that the aseptic zone of filling and packaging equipment is cleaned and brought to a condition of sterility prior to the initiation of product filling and is maintained in a condition of sterility throughout production. Verify that the aseptic zone is re-sterilized whenever there is a potential for loss of sterility. Verify that the product sterilizer is equipped with the appropriate number of temperature and time/temperature recording devices at the required locations and verify operation and records. • Where pressure is a critical factor in the processing schedule, verify that there is a pressure sensor/recorder and verify operation and records. Verify that processing time and temperature is consistent with the documented and validated process. Verify that final product is inspected for defects, including sealing. Verify that each container is marked with an identifying code that is permanent, legible and does not adversely affect the container's integrity. Verify that final product is handled in a manner that protects containers and closures from damage and minimizes potential defects and subsequent microbial contamination. **Pasteurization Batch** Verify processing time and temperature is consistent with the documented and validated process: • For example, 30 minutes plus filling time, if product pre-heated, plus emptying time if cooling began before emptying. • No product added after start of holding time. Verify indicating, recording and airspace thermometers comply with specifications, are appropriately installed and are working. Verify agitator is appropriately installed, and working as required. **Pasteurization – High temperature** Verify processing time and temperature is consistent with the documented and validated process. Verify indicating and recording thermometers comply with specifications, are appropriately installed and are working. Verify flow diversion and flow promoting devices are appropriately installed and that there are processes and procedures to ensure the product is not adulterated with added water.

43 Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004.

44 Code of Hygienic Practice for Aseptically Processed and Packaged low-acid foods CAC/RCP 40-1993.

Element	Milk Dairy (inside) inspection
Deviations	Verify that employees understand the procedures for handling deviations. (i.e., failure to meet any factor identified by the process authority as being critical to the production of a commercially sterile food product). Verify records to assess compliance with procedures.
Cleaning	Verify that employees are following the established cleaning processes and procedures: • For transport vehicles and/or milk containers (e.g., milk churns) in reception. Verify that all food product contact surfaces, including internal piping and equipment, by-pass valves and sampling valves, have been adequately cleaned.
Validation	Verify that all equipment controls have been periodically validated (e.g., thermometers, temperature recorders) and there are appropriate records to demonstrate validation. Verify that the validation procedures are being followed (e.g., products subjected to commercial sterilization are microbiologically stable at room temperature, either measured after storage until end of shelf life or incubated at 55° C for 7 days (or at 30° C for 15 days) in accordance with appropriate standards). Verify there are appropriate records to demonstrate validation.

GUIDANCE 13: POULTRY AND MEAT

This guidance is provided to address specific considerations for meat and poultry products and, as much as possible, does not repeat the considerations set out in the guidance on documentation (3) and general guidance (6). Food businesses should also be encouraged to consult the guidance provided by Codex.[45]

Element	Poultry /Meat (inside) inspection
General	Meat and the animals from which meat is derived have been and continue to be viewed as a source of microbial contamination and, consequently, the source of foodborne disease. As a result, countries generally give oversight authority to those organizations responsible for human health (e.g., Ministry of Health) and those responsible for animal health (e.g., Veterinary services).[46] Where there is more than one government organisation responsible, integration and coordination are needed to prevent duplication of activities and maximize efficiencies. There are generally two types of operations: food businesses that operate every day with assigned personnel and food businesses that operate on demand for processing poultry and meat. In either situation, the roles and responsibilities for food safety and veterinary services should be clearly established. • Where the food business is under continuous inspection, verify the inspection plan to determine which parts of the process are scheduled for inspection. **Inspection strategy** Where a food business does not have, or fails to meet, their established process for export requirements, they should not be eligible for export certification. **Note**: this guidance is intended to assess the potential for food contamination. Any national standards pertaining to animal handling and welfare should be read in conjunction with this manual.

45 Code of hygienic practice for meat (CAC/RCP 58-2005).

46 Linkages should also be made to the standards, guidelines and recommendations contained in the OIE Terrestrial Animal Health Code.

Element	Poultry /Meat (inside) inspection
Licenses	Countries often establish multiple license requirements for meat processing facilities. If this is the case, verify that the food business has all applicable licenses (e.g., Slaughterhouse License, Meat processing license) and others (state if applicable). **Note**: this is generally reviewed during the opening meeting, as set out in guidance (1).
Procedures Ante mortem	Slaughterhouses should have written documents setting out the specific procedures for the ante-mortem inspection systems. These procedures should include: • The process for taking information from the primary production, e.g. declarations from the primary producers relating to the use of veterinary drugs. • Identification of all animals suspected as being unsafe or unsuitable for human consumption and the process for how these are to be handled (e.g., held in special facilities, more detailed inspection, diagnostic tests, and/or treatment). • The process for communicating the results of ante-mortem inspection to those responsible for post- mortem inspection. › Particular procedures where a suspect animal is allowed to proceed to slaughter under special hygiene conditions. Verify the process for identification and handling of animals condemned as unsafe or unsuitable for human consumption, including those that have died in transit, are not sufficiently clean, or in which an zoonotic disease posing a threat to humans or animals is present or suspected, as well as recording the reason for condemnation. Verify that condemned animals are not slaughtered in the slaughterhouse and, once killed, they and any other dead animals are moved immediately to the inedible areas which are separated from all edible meat products.
Veterinary services	Every establishment should have an assigned official Veterinarian and may have other veterinarians assigned as needed. The veterinarian is not required to be present at all times, however, they must be satisfied that information on animals/flocks is available and that no food safety issues are present. The animal's health status must be satisfactory, and their welfare must be ensured. The vet must be available within a reasonable period to fulfil his/her specific veterinary tasks, taking into consideration various risk factors including: • Animal status (compromised animal, emergency, welfare, behaviour). • Nature of disease (OIE listed diseases, zoonosis). • Animal status (e.g., transport conditions, distress). • Contamination (risk of contamination or propagation, residue program, tissue deterioration). • Operation (volume, holding capacity, assistance, information, impact on normal operation). Carcasses rejected and condemned during post-mortem inspection may be retained for later veterinary diagnosis and disposal, or may be handled by the operator as condemned material.
Process flow General	Where food businesses used fresh or frozen meat or poultry parts to produce sausages or other categories of meat products, they should have developed a specific validated process. These processes should be consistent with the specified parameters approved by the competent authority.[47]

47 Paragraph 100 Code of hygienic practice for meat (CAC/RCP 58-2005).

Element	Poultry /Meat (inside) inspection
Process Flow Poultry	Confirm the general process flow being used for poultry. It is important that the processes be separated physically or in time to prevent cross contamination: › Reception and handling of live birds; › Slaughtering (ante mortem inspection); › Bleeding; › Scalding; › De-feathering/Plucking; › Evisceration; › Washing and Rinsing; › Chilling and dripping/holding; › Processing whole or parts; › Preparing for sale (post-mortem inspection). • Verify that the layout and process flow provide adequate separation between live animal holding pens, slaughter and meat or poultry processing areas. • Identify the practices used to prevent cross contamination (e.g., regular cleaning and disinfection of surfaces, disposal of waste into closed waste containers). **Inspection Strategy** During assessment of the layout and process flow, the key is to evaluate the potential for final product contamination. If there is significant risk of this, the element should be rated critical non-compliance and immediate corrective action should be taken.
Process Flow Meat	Confirm the general process flow being used for meat. It is important that the processes be separated physically or in time to prevent cross contamination: › Reception and assessment of health status (ante mortem inspection); › Stunning and bleeding; › Hoof and hide removal /de-haring / scalding as appropriate; › Evisceration; › Carcass inspection (post-mortem); › Carcass splitting; › Washing; › Chilling; › Processing. Verify that the layout and process flow provide adequate separation between live animal holding pens, slaughter and meat, or poultry processing areas. Identify the practices used to prevent cross contamination (e.g., regular cleaning and disinfection of surfaces, disposal of waste into closed waste containers). Verify separation of animals (e.g., different classes, types of slaughter) where appropriate. **Inspection Strategy** During assessment of the layout and process flow, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination, the element should be rated critical non-compliance, and immediate corrective action should be taken.

Element	Poultry /Meat (inside) inspection
Transport of live animals to slaughter facility	Verify that transport vehicles[48] are constructed in a manner that allows: • Animals to be loaded, unloaded and transported easily and with minimal risk of injury to the animal or between or among animals. Verify that vehicles are appropriately constructed (e.g., use of floor gratings, crates) to limit soiling and cross-contamination; provide adequate ventilation during transport and allow for easy cleaning and sanitizing.
Animal holding areas	**Poultry, live animals** Verify that live animal or poultry holding, and adjacent areas are clean, well-drained and free of litter. Verify they are of sufficient size and/or quantity to accommodate the peak number of animals and that the holding areas and associated areas are appropriately constructed (e.g., fences, walls, chutes/ramps, floors, (drained, scored, provide appropriate footing,) and are thoroughly cleaned. Verify that there is an adequate supply of approved water for drinking, cleaning, and for feeding (if appropriate). Verify that live animal or poultry holding areas are separate from slaughter and processing areas and that they are operated in a manner to minimize the potential for soiling and contamination of the animals. Verify that there are appropriate areas for ante-mortem inspection and handling condemned animals.
Reception Animal health: ante mortem	Verify that live animals and poultry have been or are assessed to ensure they are in good health (not diseased) before slaughter. • Verify that only live animals are presented for slaughter unless specific conditions have been established by authorities. Verify that there are processes to ensure that animals presented for slaughter are sufficiently clean, and that the animals maintain their identification (either individually or as flocks/lots) until slaughter. Verify that all poultry presented for slaughter has been authorized by a competent person whether on an individual or lot basis (e.g. ante mortem performed on animals within 24 hours). • If antemortem performed at farm, then all animals must be accompanied by a flock sheet or other documentation certified by an official. In the event that no official is available, the slaughter of animals that have already received official ante-mortem inspection may proceed in the normal manner. • Each animal should be inspected and any lots or individual animals that show deviations from normal behaviour or appearance should be set aside to ensure appropriate inspection before slaughter. Verify that ante-mortem inspections correspond to the written procedures, are risk-based and take into consideration: • Organoleptic procedures and examinations for relevant meat-borne risks, clinical signs of illness and grossly detectable abnormalities. • Procedures that can be tailored to the spectrum and prevalence of diseases and defects that may be present within the country for a specified animal and the primary production conditions. **Note**: the processes for antemortem inspections may be reviewed during the documentation (guidance 3) review. If so, the inspector should review implementation of the process at this stage.

48 OIE World Organisation for Animal Health, Terrestrial Animal Health Code (2018), Chapters 7.1-7.4 (transport).

Element	Poultry /Meat (inside) inspection
Facility	Verify that dogs, cats, wild birds and all live animals are prevented from entering all areas in the facility (reception, slaughter, processing etc.). Verify that there is separation between stunning and bleeding activity and dressing activities (either physically, in time), so that cross-contamination of animals is minimized. Verify that the appropriate scalding, dehairing, defeathering, scraping and singeing (or similar operations) are also separated from dressing operations.
Slaughter area	Verify that operations are implemented to minimize any cross contamination, including: • That feathers and other matter are cleaned from the area as frequently as necessary, and that thorough cleaning is undertaken at the end of the slaughter process or at the end of the day. • That all pieces of bones, fat, meat, skin or any other matter is cleared from the area as frequently as necessary and that any inedible material is placed in closed waste containers. Verify that there are separate rooms or separate areas for different species and classes of animals. Verify that there is sufficient and adequate drainage, with capacity to prevent blockage when animals are bled. Verify that blood for edible purposes, if collected, is done in an appropriate manner, so that the blood is not exposed to contamination and identity is maintained until post-mortem inspection. • Birds, animal carcasses, or meat that falls on the floor should be considered contaminated. The facility should have a written protocol for disposal and/or where appropriate corrective action should be taken. **Inspection Strategy** During assessment of the slaughter area, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination, the element should be rated critical non-compliance, and immediate corrective action should be taken.
Holding rooms	Verify that holding rooms meet requirements for capacity, loading rates, stock rotation, specifications for temperature and relative humidity; regarding air circulation, minimize cross contamination via dripping of fluids from carcasses or from overhead equipment.
Product cooling and storage time	Verify that product is cooled to and held at refrigerated temperature (e.g., iced) immediately after processing. Verify that poultry chill tanks, if used, have adequate ice. Verify length of holding time for freshly slaughtered meat and poultry: • Freshly slaughtered meat and poultry must be sold within 4-8 hours of slaughter (if not refrigerated). • Fresh slaughtered meat and poultry may be held at less than 5°C for no more than 4 days. Verify that all animal by-products for further use are placed in closed containers and appropriately protected from contamination.
Personal hygiene	Verify that personnel wash hands frequently when handling live or processed poultry, meat or any viscera, waste or by-products. Verify that there is no circulation of personnel from live animal areas to processed product areas.

Element	Poultry /Meat (inside) inspection
Waste disposal	Verify that all areas adjacent to the premises are free from trash, blood, feathers and faecal material and that any such waste is promptly and properly removed and disposed. Verify that all waste containers are tightly covered and appropriately labelled to prevent access by animals and to prevent cross utilization for useful by-products. **Solid waste** • Meat may include heads, hooves, hide, viscera, and carcasses (bones). › Where any item or part of any item noted above is considered an edible by-product rather than waste, it should be handled to maintain hygiene and minimize any potential for contamination until further processing. • Poultry includes heads, feet, feathers, viscera, and carcasses (bones). › Assess disposal of solid waste. Waste should be disposed of into appropriate lidded, dedicated waste containers; › Assess if there are any animal by products sold for further use (animal/fish feed; feathers). If so, verify these are being handled separately from waste and protected from contamination. **Liquid waste** • Blood and contaminated wash water must be disposed of so as not to contaminate the food and food facility. › Where blood is considered an edible by-product rather than waste, it should be handled to maintain hygiene and prevent contamination until further processing. Liquid waste containers must be clearly identified and have close- fitting lids.
Post-mortem inspections	Post-mortem inspections should be designed to determine the safety and suitability of the animal or animal part and may include if these are: • Safe and suitable for human consumption either directly or subject to a specified process. • Requires further tests for judgment held on suspicion of being unsafe or unsuitable, pending the outcome of further procedures and/or tests. • Unsafe for human consumption but either suitable for processing for other purposes (e.g., pet food), or requires condemnation and destruction. Verify that the procedures for post-mortem inspections are being implemented appropriately, including visual inspection of the carcass and relevant parts as soon as possible after dressing, confirmation of proper stunning and bleeding, palpation and/or incision of the carcass and other relevant parts, (e.g., multiple incisions of lymph nodes as necessary); other organoleptic inspection procedures, (e.g. smell, touch); and removal of specified "risk parts" as required (e.g., risk parts associated with BSE).[49] Verify that meat judged as safe and suitable for human consumption is removed from the area, and that it is handled in a manner to protect it from contamination and under conditions to prevent deterioration. **Note**: the processes for post-mortem inspections may be reviewed during the documentation (guidance 3) review. If so, the inspector should review implementation of the process at this stage.

49 Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, is a neurodegenerative cattle disease.

Element	Poultry /Meat (inside) inspection
Freezing	Verify that for meat being frozen: • If it is not in cartons, it is hung or placed on racks or trays that allow adequate circulation of air; and minimizes the potential for cross- contamination via dripping; • If it is in cartons, these are stacked to allow adequate circulation of air; • If it is on trays, there is adequate circulation of air to minimize potential for cross contamination and physical contact with the base of an upper tray. Verify that frozen meat: • Is stored to maintain hygiene, not stacked on the floor, has adequate air circulation; • Is frozen and maintained at the appropriate temperature. Verify the freezer is being operated and maintained (e.g., temperatures recorded and monitored, adequate inventory control) appropriately.
***Trichinella* control**	Each country will establish the specific controls for parasites that are likely to be present in a particular animal species. The following outlines controls for *Trichinella spp*. Verify that the food business has controls for *Trichinella spp.*, if it slaughters *Suidae* (pigs) and that the controls are acceptable to the competent authority. • Freezing regimes that ensure lethality for all *Trichinella spp*. that may be present in the meat or carcass. • If freezing controls are used, pig carcasses should not be hung with other meat carcasses. • Heat process treatments that either alone or in combination with other parameters are sufficient to destroy *Trichinella spp.*.
Processing areas	Verify that dogs, cats, wild birds and all live animals are prevented from entering the processing environment. Verify that all equipment used in processing is clean and well- maintained. Verify that processing supplies, and materials are securely stored to prevent damage or contamination and that the vendor or alternate inspects them daily prior to use. Verify that there are adequate and secure containers for any animal by- products that will be used for further processing (e.g., feathers, blood). **Poultry**: verify chill tank to ensure temperature is maintained between 0.5 and 4.5°C – add ice to maintain temperature. The chill tank should reduce temperature to 4.5°C or lower within 4 hours of evisceration. **Inspection Strategy** During assessment of the processing areas, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination, the element should be rated critical non-compliance, and immediate corrective action should be taken.
Deboning	Verify that meat /poultry to be cut or de-boned, pre-rigor is transported directly to the processing area, which is appropriately temperature-controlled and provides an appropriate level of hygiene. Verify that it is only brought into the work room as needed and is not allowed to accumulate on worktables. Verify that cutting-up, de-boning and packing is done without delay.

Element	Poultry /Meat (inside) inspection
Further processing	Following post-mortem procedures, meat and poultry carcasses may, instead of being butchered and sold as chilled or frozen meat or poultry, be further processed to produce consumer products such as: • Raw ground or comminuted e.g. pork sausage; • Meat with secondary inhibitors / non-shelf stable e.g. cured corned beef; • Heat treated / not fully cooked, non-shelf stable e.g. partially cooked patties; • Fully cooked / non-shelf stable e.g. cooked ham; • Non-heat treated / shelf stable e.g. dry salami; • Heat treated / shelf stable e.g. beef jerky. Each food business should have a documented process for each product and that written process should be reviewed (see guidance 3) annually and be acceptable to the competent authority. Verify that there are documented procedures, developed, validated and implemented for cooked meat products, commercially sterile, hermetically sealed products, pasteurized meat products to assure product safety. Verify that the process for thawing frozen meat or poultry for further processing is carried out in a controlled environment so it will not result in growth of micro-organisms or the formation of toxins. It should also include adequate drainage of liquid run-off. Verify that the process flow ensures adequate rotation (e.g., a first in/first out approach) and avoids possible cross-contamination, e.g. between raw materials and ready-to-eat products. Verify the hygiene controls in place to minimize potential for growth of micro-organisms or formation of toxins when frozen raw meat is thawed for further processing. Verify that the procedures are consistent with the written procedures for product formulation (e.g., distribution of antibacterial ingredients throughout cooked sausage emulsions, addition of cultures, adjustment of pH), and procedures (e.g., fermentation, partial heat treatment, drying, maturing and curing process), that may include correct pH after fermentation, correct time/temperature schedules during and after heating or smoking, correct moisture / protein ratio after drying, correct formulation and application of nitrite as a cure ingredient. **Mincing** Verify that meat/poultry used for mincing is made from parts of animals approved for use (e.g., striated muscle and adherent fatty tissue) or as approved by competent authority, does not contain skin or bones or abnormal tissues. Verify that minced meat is subject to a process for detecting metal fragments or other extraneous material. **Cooked product** Verify that the time /internal temperatures for cooked products are consistent with the written validated procedures to achieve specified pathogen reduction and other performance criteria. **Verify that the product is adequately cooled** Where final pH, heat and/or other processing treatments are not sufficient to ensure the stability of the product, the product should be cooled to an appropriate storage temperature and in a manner that ensures product safety is not compromised as a result of germination and subsequent growth of pathogenic spore formers. Verify that dried products are protected from environmental contamination and from reabsorption of moisture.

Element	Poultry /Meat (inside) inspection
Inedible parts	Verify that all parts judged unsafe or unsuitable for human consumption are: • Immediately put into identified chutes, containers, trolleys, or other handling facilities; with clear identification as to the type and end use of the tissue. • Handled in rooms reserved for that purpose and conveyed in a secure manner to a place of disposal (e.g. rendering station) in the case of condemned material.

GUIDANCE 14: RESTAURANT/ COOKED FOOD[50]

This guidance is provided to address specific considerations for food businesses that are restaurants or otherwise provide cooked food and is not intended to repeat the considerations set out in the general guidance (6). The guidance for street food, which has overlaps with restaurant food, can be found in guidance 15.

Element	Restaurant (inside) inspection
Restaurants/ other food business cooked food	As there is a wide range of businesses that prepare and cook food for direct sale, it is important to tailor the inspection to the type of business and the food being sold. Most of the key assessments (e.g., personal hygiene, sanitation) are covered in general inspection guidance 6.
Process Flow	Process flow should be close to a straight line to minimize cross contamination. Confirm the process flow being used specific to each operation. Receive → store → prepare → hold → serve/sell Receive → store → prepare → cook → hold → serve Receive → store → prepare → cook → cool → reheat → hold hot → serve **Note**: some process flows may include a transport step between cook and serve. Where a food business operates in two locations, the inspector must have access to information about conditions in both locations (e.g., prior to inspecting a serving area, the inspector will review a copy of the inspection pertaining to the preparation area). **Inspection Strategy** During assessment of the layout and process flow, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination, the element should be rated critical non-compliance, and immediate corrective action should be taken.
Licensing	Verify that restaurants or other businesses selling cooked foods have a license and a food handler's certificate of good health. • Ask what food safety and hygiene training is provided to staff. **Note**: in general, restaurants can have a high turnover of staff, thus it is important to verify that food handlers meet all requirements and have a good understanding and/or training in food safety.

50 Code of Hygienic Practices and the Code of Hygienic Practices for Pre-cooked and cooked foods in mass catering CAC/RCP 39-1993.

Element	Restaurant (inside) inspection
Cooking, handling and serving	**Objective**: verify that preparation, handling and serving minimize food safety risks. • Assess quantity of raw materials – they should correspond to business needs and fit in storage capacity. • Assess preparation of raw materials: › Is there any evidence of gross dirt on raw vegetables and fruit or have they been appropriately washed? › Determine if the raw, ready-to-eat foods (e.g., leafy greens) are maintained separately to prevent cross contamination. › Determine if raw foods are washed prior to cooking and, if so, verify what processes are used to prevent cross contamination with other foods, particularly ready-to eat- foods. › If any waste is diverted to animal feed, assess handling of waste that will be sold (e.g., vegetable, animal trimmings) to ensure it is handled to prevent contamination of both the animal feed and human food. • Thawing: › Verify that, where possible, product is cooked from frozen (e.g., frozen vegetables). › Where products are thawed, verify they are thawed at refrigerated temperatures, under running water or another process that will thaw products quickly and minimize potential for cross contamination. • Assess cooking processes: › Does the vendor have a specified time and temperature of cooking? Note it down. › Are cooked foods kept hot? Verify temperature of cooked foods (are they 60°C or above?). • Assess handling of prepared food: › How is food stored prior to serving? (If frozen, it should be kept at -18°C or below with regular monitoring of temperature). › Is it stored on appropriate shelves? Verify it is not stored on the floor. › Are ready-to-eat foods, including salads and vegetables, kept cold? (4°C or below) Verify the temperature of foods. › Use thermometer to check product temperature (disinfect thermometer between use). › Is cooked rice served hot (above 63°C) or within 2 hours? › If not, rice should be cooled quickly to 7°C or below. › Is ready-to-eat food and prepared food kept separate from raw material? › Verify how long the food will be held for sale. If sale is prolonged (3+ hours), assess whether the processing is done in smaller quantities more frequently to minimize potential for pathogen growth. › Verify how leftovers are managed at the end of the day. • Assess transport of cooked food: › Food should be protected against dust, dirt or other contamination. › Cooked (hot) food should be maintained at 60°C at least, while cooked chilled food should maintain a temperature of 4°C.

Element	Restaurant (inside) inspection
Cooking, handling and serving (continuation)	• Assess reheating processes: › Is it reheated rapidly? Does it reach 75°C within one hour? › Is it served to the consumer quickly after reheating? • Assess how food is served: › Verify utensils or disposable gloves are used to serve food. › Verify that in self-service operations (i.e., buffets), the serving system should be such that the foods offered are protected from direct contamination, including from the consumer. The temperature of the food should be either below 4°C or above 60°C. › Some restaurants use time control (e.g., food only offered for 2 hours) rather than using a thermometer for temperature. In such instances, verify that the food business has validated the temperature for the entire time period and that there are records of periodic validation. › Verify that packaging materials are approved. › Verify handwashing of food handlers, particularly if they also handle money. **Inspection Strategy** During assessment, the key is to evaluate the potential for final product contamination. If there is significant risk of food contamination, the element should be rated critical non-compliance, and immediate corrective action should be taken.
Unsold food	Verify that at the end of the day, the food business has an appropriate process for any remaining food and beverages, for example: • It is properly stored at refrigeration temperatures, or frozen or; • Food which can not be properly stored indisposed of. Leftover food that will be reheated can generally be safely stored at refrigeration temperatures and, if reheated appropriately, will not cause food safety issues. Pay particular attention to leftovers, ready- to-eat foods such as leafy greens, condiments and prepared salads that will not be reheated. These foods, unless they have been consistently held at refrigeration temperatures, should be disposed of. Verify how the food business disposes of leftover food (e.g., compost, garbage) and estimate if disposed of quantities matches leftover food. **Inspection Strategy** During assessment, the key is to evaluate the potential for contamination of leftover food being offered in future sale. Food that is reheated has a lower risk than ready-to-eat food. If there is significant risk of food contamination because ready to eat food has been improperly disposed of, or improperly stored, the element should be rated critical non-compliance, and immediate corrective action should be taken.

GUIDANCE 15: RETAIL

This guidance is provided to address specific considerations for retail food businesses and is not intended to repeat the considerations set out in the general guidance (6). Where retail businesses also sell food that is prepared and cooked on the premises, inspectors should also consult guidance (13).

Element	Retail (inside) inspection
General	As there is a wide range of retail businesses, it is important to tailor the inspection to the type of business and the food being sold. Most of the key assessments (e.g., personal hygiene, sanitation) are covered in the general inspection section. The two key elements in retailing are sourcing from reputable suppliers and managing stock (i.e., rotation).
Sourcing	As retailers generally do not manipulate or process foods, rather they sell pre-packaged consumer goods, it is critical that such goods be sourced from reputable suppliers. Verify the retailer can identify the suppliers and that all products offered for sale are sourced from a legal (e.g., registered) food business. If required under national legislation, verify that domestic pre-packaged products have a free sale certificate issued by the appropriate government organisation (e.g., Food and Drugs, National Standards association). **Inspection strategy**: (Country specific) Where food businesses are required to be registered, products sourced from non-registered food businesses should be considered illegal. Where pre-packaged foods are required to have a free sale certificate, such products purchased without a certificate should be considered illegal. In particular, where food is sourced directly from farms/distributers, it is the retail business' responsibility to ensure they are purchasing from reputable farms and not purchasing stolen farm products. • **1st inspection** – request the business determines and documents the source of products and prove they are registered/have free sale certificates. • **2nd inspection** – written warning requiring the food business to determine source of products and if they are registered/have free sale certificates. • **3rd inspection** – consider seizing products sourced from illegal food business or without appropriate documentation, and/or closing the retail store.
Stock management	During the assessment of retail operations, the inspector should: Verify that food products are adequately protected from damage (e.g., physical, water) or contamination. Verify that the storage conditions are appropriate (i.e., freezers, refrigeration). Verify stock rotation (first in/ first out). Verify unsafe or unwholesome food products are disposed of appropriately.

Element	Retail (inside) inspection
Labelling	Retail inspections are also an opportunity to assess packaging and labelling of pre-packaged products and to identify products illegal in the country (e.g., products not labelled in mandatory language, not meeting national labelling standards). Choose a selection of pre-packaged products to verify that they are correctly labelled. See Appendix 6 for guidance on a general approach to labelling. **Inspection strategy** Where products are illegal, (i.e., they are not labelled in the mandatory language), the product should be detained and/or seized for corrective action (i.e., disposed of, relabelled).

GUIDANCE 16: STREET FOOD

Street food is common in most countries and is often an integral part of the lifestyle of the country. In general, street food can be considered ready-to-eat food prepared and/or sold by vendors in public places from carts, tables, benches, and vehicles with or without wheels.

This guidance is provided to address specific considerations for street food businesses and is not intended to repeat the considerations set out in general guidance (6) (e.g., permits, hand washing, construction).

Where the food is prepared in a separate location (e.g., small kitchen; home kitchen) those kitchens should be inspected using Guidance 14 (restaurants). The results from the inspections of both locations will provide the complete inspection.

Element	Street food inspection
General	Street food, whether sold from food carts and stalls or any other structure, should meet minimum sanitary requirements.[51] In general, street food can be considered ready-to-eat food prepared and/or sold by vendors in public places from carts, tables, benches, and vehicles with or without wheels.
Licensing	Verify that street food vendors have a license and a food handler's certificate of good health.

51 Regional Code of Hygienic Practices for the Preparation and Sale of Street foods (Latin America and the Caribbean) (CAC/RCP 43R-1995).

Element	Street food inspection
Temporary Mobile premises	Verify that the temporary or mobile premise is sited, designed and constructed to protect food from contamination and to avoid harbouring pests as much as is possible.
Equipment	Verify that cooked and uncooked foods are handled with separate utensils. Verify washing procedures for utensils, (e.g., washing them in warm water containing soap and then either immersing them for one-half (1/2) minute in boiling clean water or, for two (2) minutes in potable water at a temperature of not less than 77°C, followed by draining. • Alternatively, use potable water, wash soap or detergent and a running-water rinse where previous methods are unattainable. Verify washed and clean utensils and crockery are handled, stored or transported separately from unclean and used utensils and crockery and other sources of contamination. Verify that napkins, towels and hand wipes are disposable and there are sufficient waste containers to dispose of them.
Access to personnel Hygiene facilities	Verify hygiene facilities are available nearby. There should be: • Adequate hand washing facilities with hot and cold water; • Adequate toilets or lavatory facilities.
Serving food	Verify that vendors: • Purchase from licensed and reliable sources; • Don't handle food with bare hands. Clean tongs, forks, spoons or disposable gloves should be used; • Use clean and dry crockery; • Don't stack plates filled with food on top of each other during display, storing or serving; • Offer beverages for sale in their individual, original, sealed containers or from taps fitted to bulk containers with lids; • Protect any food such as cut fruit in an enclosed display case, cabinet or under plastic wrap; • Avoid handling food after handling money. If unavoidable, ensure hands are washed before handling food again; • Protect ready-to-eat foods from environmental contamination and keep at the following holding temperatures: › for food served hot: 60°C or above. › for food served cold: 7°C or below. › for frozen food: -18°C or below.

Element	Street food inspection
Unsold food	The food business should only prepare food to be sold in one day, thus avoiding possible leftover food. Verify that at the end of the day, the food business has an appropriate process for any remaining food and beverages, for example: • They are properly stored at refrigeration temperatures or frozen; • They are disposed of if cannot be properly stored. Leftover food that will be reheated can generally be safely stored at refrigeration temperatures, and reheated appropriately (i.e., to 75°C). This is not the case with leftover, ready-to-eat foods such as leafy greens, condiments and prepared salads that will not be reheated. These foods should be disposed of by the food business. Verify how the food business disposes of leftover food (e.g., compost, garbage) and estimate if quantities disposed of matches leftover food. **Inspection Strategy** During assessment, the key is to evaluate the potential for contamination of leftover food in future sale. Food that is reheated has a lower risk than ready-to-eat food. If there is significant risk of food contamination because ready to eat food has been improperly disposed of, the element should be rated critical non-compliance, and immediate corrective action should be taken.
Transport	Verify that vendors transport street foods to the point of sale in well- protected, covered and clean container(s) to avoid contamination. Also: • That vehicles used in transport are clean and in good condition and provide protection from environmental contamination; • That foods are transported in temperature-controlled containers (i.e., thermal boxes); • That perishable foods such as milk, and milk products etc. should be transported to the point of sale in an insulated container maintained at a maximum temperature of 4°C. Prepared foods and ready-to-eat foods should not be transported together with raw food and ingredients, animals, toxic substances and any other materials that may contaminate the food.
Waste	Verify that waste bins or containers are not kept in the food handling area and have a lid. Where possible, these should be fitted with an automatic closing device. Verify that wastewater is collected and disposed of separately from solid wastes. • Verify that, to the greatest extent possible, it is disposed of in the public drainage system, verify it is not thrown onto the ground and/or into surface waters such as rivers and lakes. Verify that solid waste, recyclable and non-recyclable materials are kept separate until they reach their final destination, as per official requirements. Verify that disposal of food waste minimizes the attraction of insects and animals, such as flies, rodents, dogs and cats.

GUIDANCE 17: WAREHOUSES, STORAGE FACILITIES

Food businesses often use public warehouses or storage facilities to maintain product. Space is rented in these buildings from the owner, who is responsible for maintaining the building.

Element	Warehouses, Storage facilities
General	The condition of the building, i.e., maintaining the outside and inside, should be considered the responsibility of the warehouse owner. Management of the product would be the responsibility of the food business owner.
Outside of the warehouse	Use guidance 4.
Layout and Process flow	Assess the layout of the warehouse. It should be appropriate for operations, i.e., sufficient space to allow a logical flow of materials, products and personnel, and to ensure that food can be managed under the first in/first out (FIFO), or first expiry/first out (FEFO) principle. • Verify that there is adequate space for food storage to allow for appropriate food storage and management. • Verify there is separation between food storage areas and all other areas (e.g., employee washrooms, cleaning and sanitation products). • Verify there is appropriate reception (e.g., loading and unloading points) that facilitates movement of imported food and these points are protected from pests, rain etc. **Inspection Strategy** • During assessment of the layout, evaluate the potential for stock management. In particular, verify that there is access to all the stored food. Where product access is restricted, verify how employees implement the first in/ first out principle, ensuring that there is no expired product on the premises. • If layout of food storage is restricted, and there are no mitigation measures (e.g., detailed documentation to manage food rotation), assess if any food has passed its expiry date: › Food passed its expiry date shall be deemed non-compliant and detained. It must not be sold, and layout should be rated as critical. • If food storage is not adequately separated or protected, assess potential for contamination: › If food is contaminated, rate as critical non-compliance. › If there is a high potential for contamination, rate as major non-compliance. **Note**: the inspector will have to verify responsibility for stock movement, whether it is the warehouse operator or the food business owner who determines stock movement and management.

Element	Warehouses, Storage facilities
Internal structures and fittings (similar to a food business in guidance 6)	Assess the internal structures to determine if they are appropriate for use in food operations. This includes: • Walls, floors, ceilings and other structures prevent the entry of pests (i.e., no gaps or holes), and water, (i.e., no evidence of leaks). They should be built from durable materials and easy to maintain and clean. • Flooring is made of impervious materials and allows adequate drainage and cleaning. • Ceilings and overhead fixtures are accessible for cleaning, to minimize possibility that dirt or condensation fall on stored food, in particular, where there is bulk stored food. • Windows and ventilators are easy to clean, and prevent the entry of pests (e.g., insects, rodents). • Doors have smooth, non-absorbent surfaces, are easy to clean and disinfect as well as prevent the entry of pests (e.g., insects, rodents). **Inspection Strategy** During assessment of the internal structures, determine the potential for imported product contamination. Generally, the building construction will not, explicitly contaminate food. If the condition of the warehouse results in a high possibility of food contamination, the element should be rated major non-compliance.
Facilities environment	Verify the warehouse has the appropriate environment (e.g., lighting, ventilation) to maintain the food. In assessing the facility environment, the inspector should: • Verify lighting to ensure it is adequate (e.g., color, intensity) and that fixtures are protected; • Verify the temperature in the warehouse is appropriate for food storage; • Verify ventilation is sufficient to remove airborne contamination, control odors and humidity; • Verify that all ventilation equipment is clean (e.g., no evidence of grease, or gross debris) and in good repair to minimize the potential for contamination. Are there separate storage facilities for raw ingredients?
Equipment	Verify that equipment, including storage racks, freezers and fridges: • Is located so that it can be, and is, appropriately cleaned and maintained; • Is made of non-toxic material and will not contaminate food; • Fridges and freezers achieve and maintain required temperatures and are appropriately monitored. › Verify the temperature of the refrigeration units and the freezers. • Verify that storage conditions and equipment will prevent spoilage (e.g., food is stored away from walls, off the floor on pallets or racks). **Inspection strategy** In the presence of spoiling, rotten or contaminated food due to storage in unsanitary conditions, or because fridges or freezers are not working properly, rate as critical non-compliance.

Element	Warehouses, Storage facilities
Cleaning facilities and procedures	Assess the cleaning facilities and procedures. The inspector should: • Verify with person(s) responsible for cleaning procedures: › That process and frequency described by employees are consistent with written procedures or food hygiene principles and practices. • Verify the cleaning facilities are adequate: › For storing cleaning utensils and supplies; › That there is an adequate supply of hot and cold water; › That non-food chemicals are clearly identified and minimize potential for contamination. • Assess cleaning and sanitation procedures: › Are the employees following procedures? › Assess cleaning products being used to determine if manufacturer's instructions are followed.
Pest control procedures	Assess the pest control products and procedures. The inspector should: • Verify with person(s) responsible for pest control procedures: › That process and frequency described by employees are consistent with written procedures. • Verify that the storage facilities are adequate: › For storing pest control products; › To minimize potential for contamination. • Verify employees' knowledge: › Of prevention: » The building is regularly inspected to ensure it prevents pest access; » Potential breeding sites are eliminated, that food ingredients, food and all waste is stored in pest-proof containers; » That there is on-going assessment for evidence of infestation. • Of treatment – when necessary with chemical, physical or biological agents. › Assess pest control products being used to determine if they are approved for use in food businesses and that manufacturer's instructions are followed.

Element	Warehouses, Storage facilities
Personnel hygiene facilities and practices.	The inspector should verify the hygiene facilities and personal hygiene practices. For most storage facilities where there is little or no manufacturing and most, if not all, product is protected, the primary verification is of personnel hygiene facilities. Where there is production, all parts of this element should be assessed. • Verify that personnel hygiene facilities are available for employees: › That there are adequate hand washing facilities with hot and cold water; › That there are adequate toilets or lavatory facilities; › Where protective clothing is provided, there are adequate changing facilities for personnel; › For both on-site hygiene facilities or where facilities are located nearby, verify that the facilities are appropriately located and maintained to encourage proper hygiene and minimize the potential for cross contamination. • Assess personnel cleanliness of food handlers including: › Appropriate use of suitable protective clothing, head covering, and footwear. • Observe employee personnel hygiene and sanitation practices, such as: › Hand washing; › Clean and appropriate protective clothing. • Verify and observe food handlers to ensure they are not: › Smoking; › Spitting; › Chewing or eating; › Sneezing or coughing over unprotected food; › Wearing personal effects (e.g., jewellery, watches).
Drainage, Waste/ inedible substances	Verify that the warehouse has appropriate processes for liquid and solid waste including: • That waste containers have lids and are readily identifiable and appropriately constructed; • That waste is removed frequently and stored appropriately (i.e., does not accumulate on floor or other surfaces). Verify frequency of waste collection and disposal (e.g. by business association, market authority). Verify the adequacy of the design, construction and operation of drainage to: • Assess if there is any standing water or settled water in the warehouse, or in other areas (e.g., storage); • Assess if there is any evidence or potential for the presence of sewage on the premises. **Inspection strategy** The presence of food contamination from sewage, garbage or cross utilisation of waste containers should be considered critical non-compliance and immediate corrective action should be taken.

Element	Warehouses, Storage facilities
Transport.	• Ask what processes are used to verify that the food was protected during transport to the warehouse site. • Verify what processes are used to protect the food during distribution to clients/direct accounts. • Ensure that the food was not transported in containers or vehicles previously used for non-food products to minimize potential contamination. • Where food is transported to or from the warehouse in unprotected vehicles, in an unprotected state or, in the case of refrigerated or frozen food, in vehicles without refrigeration or freezer capacity, rate this as critical non-compliance.
Records	• Verify that there are records for every lot maintained in the storage facility (i.e., identification, quantity, date and purchaser.) Verify that food is sold within established best-before or expiry date (i.e., food can be sold by client.

CLOSING MEETING, REPORTING AND FOLLOW UP

This section will outline the key principles of the closing meeting between a food inspector (s) and the food business management following an inspection, including identification of non-compliant elements, negotiation of follow-up and date of completion.

There are two guidance documents provided: 1) for medium to large food businesses and 2) for small and micro food businesses. The key objectives are the same, however the larger food businesses generally require a more formal approach.

GUIDANCE 18: MEDIUM TO LARGE FOOD BUSINESSES

	Closing meetings
General	The objective of the closing meeting should be to review all the inspector's findings during the inspection, to seek clarification from the food business representative of the findings and to negotiate the required corrections and time frame.
Assessment of findings	The inspector should review all the notes taken during the inspection and document non-conformances/non-compliances and, if necessary, discuss with their supervisor. For larger businesses, this is generally done at the same location used for the document review and/or the opening meeting and prior to meeting with food business representatives. It may also take place at the inspection services office, if the inspector has to undertake significant review (e.g., labels, food additives), or in order to consult the appropriate texts and /or experts.

	Closing meetings
Assessment of findings (continuation)	During this assessment, the inspector should identify all elements considered non-compliant and assign ratings (Critical, major, minor or satisfactory), as per Appendix 3. • Non-compliance **must relate to** documented observations from the inspection. The inspector must identify and establish the priority of the items to be corrected.
Closing meeting	At the closing meeting, the inspector should: • Ensure that management personnel are present, particularly those responsible for plant operations; • Highlight the key observations, including corrective requirement action, to the facility personnel who were at the opening meeting; • Ensure the facility management agree on the required corrections and time frame for completion. Critical issues should be addressed immediately, while less significant issues may be addressed over several months. Use the official report form (for an example, see Appendix 4) to provide a written report to the company, or advise the facility when it will be provided (e.g., following a review by their supervisor): • If providing a written report, all corrective actions should be included, and the food business representative should sign the report; • Where the written report will be provided at a future meeting, establish a date and time to deliver and discuss the report. The corrective action plan developed by the food business should: • Include a description and the action to correct and prevent any further occurrence. This may include process re-design, training, re-formulation, new procedure or any combination of these. The corrective action plan should also identify the responsible person and the timeline for completion.
	Documentation of the inspection consists of two parts: • The company report with a specified format that is generally provided to the food business at the closing meeting; • The full inspection report that is filed at the inspection office and generally includes: Inspector notes, lists of non-compliance with associated ratings, a copy of the report provided to the food business. It should also include examples of labels, any photos or other evidence, any samples taken, and results. The report should be: • Clearly written, contain all pertinent information and be accessible; • Focused on objective evidence, contain observations with the use of clear and concise statements; • State the facts and avoid stating inspector opinions; • Include all information pertinent to the inspection, including sample collection and corrective actions.

	Closing meetings
Follow – up inspection	The follow-up inspection should be scheduled based on the rating of the identified non-compliance. A general schedule is provided in the section on risk categorization for food businesses. The inspector should schedule a time for a follow-up inspection and include it as one of the unplanned activities in the inspection plan. The follow-up inspection is intended to verify that the corrections identified by the food business have been implemented. While most of the elements are the same (e.g., preparation, opening meeting, document review, walk-through inspection, the focus of the inspection is to seek assurance that the plant has implemented the corrective action.

GUIDANCE 19: SMALL AND MICRO FOOD BUSINESSES

	Closing meetings
General	The objective of the closing meeting should be to review all the inspector's findings during the inspection, seek clarification from the food business owner/operator and to negotiate the required corrections and time frame.
Assessment of findings	The inspector should review all the notes taken during the inspection and document non-conformances/non-compliances and, if necessary, discuss with their supervisor. During this assessment, the inspector should identify all elements considered non-compliant and assign ratings (Critical, major, minor or satisfactory), as per Appendix 3. • Non-compliance **must relate to** documented observations from the inspection. The inspector must identify and establish the priority of the items to be corrected.
Closing meeting	At the closing meeting, the inspector should: • Highlight the key observations, including corrective requirement action. • Ensure that there is agreement on the required corrections and time frame for completion. Critical issues should be addressed immediately, while less significant issues may be addressed over several months. Use the official report form (for an example, see Appendix 4) to provide a written report to the company including all corrective actions. The food business representative should sign the report. The corrective action plan developed by the food business should: • Include a description of the non-conformity and the action to correct and prevent any further non-conformance. This may include process re-design, training, re-formulation, a new procedure or any combination of these. The corrective action plan should also identify the responsible person and the timeline for completion.

	Closing meetings
	Documentation of the inspection consists of two parts: • The company report with a specified format that is generally provided to the food business at the closing meeting; • The full inspection report that is filed at the inspection office and generally includes: Inspector notes, lists of non-compliance with associated rating and a copy of the report provided to the food business. All documents should be: • Clearly written, contain all pertinent information and be accessible; • Focused on objective evidence, observations with the use of clear and concise statements; • State the facts and avoid stating inspector opinions; • Include all the information pertinent to the inspection, including sample collection and corrective actions.
Follow – up inspection	The follow-up inspection should be scheduled based on the rating of the identified non-compliance. A general schedule is provided in the section on risk categorization for food businesses. The inspector should schedule a time for a follow-up inspection and include it as one of the unplanned activities in the inspection plan. The follow-up inspection is intended to verify that the corrections identified by the food business have been implemented. While most of the elements are the same (e.g., preparation, opening meeting, document review, walk-through inspection, the focus of the inspection is to seek assurance that the food business has implemented the corrective action.

APPENDIX

APPENDIX 1:

NATIONAL FOOD PROFILES

In order to implement and manage a food control program, countries will need to develop and maintain national food profiles.

National food profiles set out, for the whole country: who is producing, selling and distributing what foods, when and how. They may also include information on inspection services, (e.g., the names of the ministries (competent authorities), numbers of inspectors, nationally and by district) to identify the inspection resources available.

Collecting this information and assembling it into a national database for use in planning, implementing and reporting on food controls will generally take significant time and inspection resources. Therefore, careful consideration should be given to how the required data should be collected. The processes should also include building on existing data and information that is already part of the current food inspection system.

For example, if a country has limited resources and/or are working with a paper-based process, they may choose to initially focus on the medium and large food businesses selling the highest volume foods consumed within the country. Alternatively, a country with national registration of all food businesses may choose to develop a profile for all food businesses and all foods.

The information should be collected in a systematic manner (such as using a common form as per Appendix 2), and in collaboration with all competent authorities. It may also be collected during the inspection processes.

INFORMATION ON FOOD BUSINESSES

The profile will require knowledge of all food businesses in the country and can include the number of businesses by sector (e.g., bakeries). It can also include the number of large, medium, small or micro food businesses by sector. Some countries may also include the number of food businesses with written food safety systems. See Chart 11 and Chart 12 for examples for national and district profiles.

Once established, the food profile will assist in national planning as the authorities will know the total number of food businesses nationally and be able to break them down by category, size, etc. It can also promote discussion on distributing the inspection plan among competent authorities.

- How many food businesses by category? (e.g., dairy, restaurant, bakery);
- How many food businesses by size? (e.g., large, medium, small, micro).
- Number of food businesses with written food safety systems?
- If primary production is included, then number of farms, fishermen etc. should also be included.

CHART 11: AN EXAMPLE OF A NATIONAL PROFILE TABLE

Category of food business	Number of food businesses /Number of food businesses with written food safety system	Large	Medium	Small	Micro
Bakeries					
Dairies					
Eggs					
Fish and seafood					
Market vendors					
Meat and Poultry*					
Restaurants					
Street food					
Retail					
Farms**					
Fishermen**					

* Consider whether subcategories are needed (e.g., slaughter businesses, processing businesses).
** If primary production is included.

As the national profile is built on district information, each district will also develop and maintain their own food profile i.e., a list of all food businesses within a district by category, size etc.

- How many food businesses by category? (e.g., dairy, restaurant, bakery).
- How many food businesses by size? (e.g., large, medium, small, micro).
- Food businesses with written food safety systems.
- If primary production is included, then number of farms, fishermen etc. should also be included.

CHART 12: EXAMPLE OF A DISTRICT PROFILE

Category of food business	Number of food businesses /Number of food businesses with written food safety system	Large	Medium	Small	Micro
Bakeries					
Dairies					
Eggs					
Fish and seafood					
Market vendors					
Meat and Poultry					
Restaurants					
Street food					
Retail					
Farms					
Fishermen					

APPENDIX 2:

FOOD RISKS (INFORMATION AND EXAMPLES)

INFORMATION ON FOOD

Similarly, information on food consumption and the associated risks also needs to be collected, analyzed and maintained in a systematic manner, and on a national basis.

Knowing the food risks is important in implementing a national inspection program and classifying them in a systematic manner will enhance consistency across the program. Classification of food should be undertaken in a collaborative manner, bringing together people with different knowledge and expertise and from different organizations. It is recommended that the team established to categorize food meet on a regular basis to discuss and categorize new foods as needed.

FOOD CONDITIONS (Microbiological hazards and/or chemical/ toxin hazards)

→ **High risk (score 15):**

Potential for microbiological presence and growth or risk of toxin production.

→ **Medium risk (score 10):**

Potential for microbiological presence or risk of toxin presence or presence of ground-based, chemical contamination (i.e., no microbial growth, no toxin production).

→ **Low risk (score 5):**

Little to no potential for microbiological or chemical presence or toxin production.

HAZARD MITIGATION

→ **High risk (score 15)** – no mitigation.

a. Ready to eat – raw/no processed.
b. Unknown conditions, or unknown or no control of over presence and/or growth of toxins or presence of natural chemicals (e.g., heavy metals).

→ **Medium risk (score 10)** some mitigation, e.g., processing reduces hazard.

a. Ready to eat – pre-processed.
b. Some monitoring programs for heavy metals, some controls over presence of toxins (e.g., appropriate growth, storage, transport controls).

→ **Low risk (score 5)** significant mitigation e.g., processing eliminates the hazard (e.g., commercial sterility, raw product that is consumer cooked).

a. Not ready to eat (consumer cooked).
b. Monitoring program establishes absence of toxins, chemicals.

To tailor the profile to the country, list the top foods consumed within the country. In addition to the top foods, include any foods that have been associated with a food borne illness, whether nationally or internationally.

Once the list has been established, each one should then be categorized according to potential for microbial or chemical (toxin) contamination and end uses (See section 3). Once categorized, the table should be distributed widely as it will be used in determining the total risk score of food businesses as part of the inspection planning processes.

FOOD RISKS (EXAMPLE)

Food		Food conditions	Hazard mitigation	Total risk score	Comments
		Microbiological/ chemical hazards			
Milk - pasteurized		15	10	25	
Milk unpasteurized		15	15	30	
Milk unpasteurized but boiled by consumer before use		15	5	20	
Rice – raw		5	5	10	
Rice –cooked		15	10	25	
Corn meal		15	5	20	Aflatoxin risk
Vegetables – eaten raw		10	15	25	
Vegetables – cooked before eating		10	5	15	
Fruit – eaten raw		10	15	25	
Fruit cooked before eating		10	5	15	
Fish: fresh, wild caught		15	5	20	
Meat: fresh, (consumer cooked)		15	5	20	
Meat: baked, cooked (e.g., sliced meats, fully cooked ham)		10	10	20	Eaten as is (RTE)
Frozen cooked foods that are to be reheated (e.g., pizza, frozen dinners)		10	5	15	
Fresh salads (Ready to eat)		15	15	30	No mitigation
Hamburger patties served	Rare	15	15	30	
	Medium	15	10	25	
	Well done	15	5	20	
Juice	Raw	15	15	30	
	Pasteurized	15	10	25	
	UHT	15	5	20	
Tacos with condiments	Tacos	10	5	15	
	Filling	15	10	25	
	Condiments	15	15	30	

APPENDIX 3:

FOOD BUSINESS RISK SCORES (DRAFT) FORM

Food Business Name			**License #**
Address			
Owner/Operator			
Contact information (email, telephone no.)			
Food (s)	**Note**: list all food produced/sold by the food business to the extent possible use the naming conventions from the national food risk table		
Food Risk	Details	Risk points	Notes/comments
Risk Factor (Food)			
Risk Factor (End use)			
Total Food Risk Points			
Food Business Risk	Details	Risk points	Notes/comments
Volume			
Compliance			
Total Control Risk Points			
Total Risk score			
Any further observations, notes, comments			

APPENDIX 4:

RATING GUIDE

During the site inspection and the walk-through inspection, there will be notes and observations for every element in the guidance documents that will need to be considered to determine if the business practices conform to the required standards. In addition, where there are any documented procedures, such as Standard Operating Procedures or HACCP systems, the inspector should note any deviations from the processes and bring them to the attention of the food business representative and/or management.

Where the inspector is of the view, based on the observations and facts, that there is a deviation from the required standards (e.g., legislative standards), they should:

1. Verify the standard (i.e., look up the standard in an inspection manual, program document or the appropriate law or regulation) to confirm the food business is not meeting it and verify the written documents (e.g., approved HACCP program).
2. Take into account all the observations and facts, determine if the deviation for that element is:
    a. Critical non-compliance – significant risk of imminent or occurring contamination that will result in adulterated, contaminated or unsanitary food, includes not following established HACCP procedures;
    b. Major non-compliance – high probability that the food may become contaminated;
    c. Minor non-compliance – low risk that the food will become contaminated, but food quality may be affected.

Where critical non-compliance is identified, the inspector must advise the responsible individual, and the food business management must take immediate corrective action. Document the identified issue and the corrective action taken.

A food business with critical non-compliance, that has not taken appropriate corrective actions:

- should not be operating without regulatory oversight;
- should not be eligible for license renewal;
- should not be eligible for any export certificate.

EXPORT CERTIFICATION

Where the inspector is of the view, based on the observations and facts, that there is a deviation from the required procedures and processes to meet the conditions of export (i.e., meet the specified condition of an importing country), the inspector should advise the food business that they are no longer eligible for export certification until corrective action has been taken.

3. Assess the critical, major and minor non-compliance to determine the schedule for follow-up inspections and for updating the risk profile of the food business.

NOTE:

A food business that has corrected a critical non-compliance will be deemed a high risk within the Risk Categorization guidelines.

During an inspection, it is expected that a wide range of conditions will be observed pertaining to the construction and sanitary operation of food business. Many of these conditions will be entirely satisfactory, while many others could negatively affect the production of food. The inspector should take detailed notes of any observations that could potentially impact the safety of food.

During the inspections, the primary objective is to assess the possibility that any condition or combination of conditions could render the food unsafe or unsanitary.

While it is impossible to provide for all the conditions that might be encountered, it is useful to follow a structured process in determining whether the food business is meeting its regulatory requirements.

As the inspection program is risk-based, there must be a link between the rating and the health risk.

DECISION TREE FOR RATING LEVEL OF NON-COMPLIANCE.

The inspector will assess every element identified in the appropriate checklist. This includes the interior and exterior of the facility, ingredients, raw materials, and equipment among others. As the inspector reviews each element, they should assess whether the food business is in compliance or determine the level of non-compliance based on the health risk. Following the steps laid out below provides a systematic approach to decision making.

1. **Contaminated food or significant risk of food contamination**

   In your view, does the condition or practice being assessed result in a high health risk associated with the production of unsanitary, adulterated or unsafe food by that business?

   - Yes - assess the element as critical non-compliance.
   - No – go to 2.

   See example situations in the table below.

2. **Unsanitary products, production and potential risk of food contamination**

   In your view, does the condition or practice being assessed decrease the food business's ability to produce food under sanitary conditions, prevent proper plant sanitation or have a high probability of resulting in the production of unsanitary, adulterated or unsafe food?

   - Yes = assess the element as major non-compliance.
   - No – go to 3.

   See example situations in the table below.

3. **General conditions that present a low risk of food contamination but may affect product quality**

   In your view, do the conditions or practice being assessed have a low probability of affecting sanitary production of food, although they may affect food quality?

   - Yes = assess the element as minor non-compliance.
   - No = Go to 4.

   See example situations in the table below.

4. **Satisfactory**

   In your view, does the condition or practice being assessed meet the required standards and will result in safe food?

   - Yes = satisfactory.

ASSIGNING RATINGS AND TIMEFRAMES FOR FOLLOW UP.

The ratings are determined by the relative potential health risk represented by the overall inspection findings and serves to identify the timeframes for all follow-up activity. Inspections with at least one critical element or multiple major elements receive the highest priority for follow-up activities.

A food business with one critical element is deemed out of compliance and should not be operating without regulatory supervision.

- License should be suspended and not reissued.
- No export certificate or certificates of free sale should be issued.

A food business with multiple minor deficiencies that are not corrected (i.e., that the owner or operator is unwilling or unable to correct) is deemed out of compliance.

- License should not be reissued.
- No export certificate or certificates of free sale should be issued.

RATINGS AND TIMEFRAME FOR FOLLOW-UP INSPECTION.

Criteria	Risk categorisation rating	Timeframe for follow up
At least one element rated critical non-compliance	Not applicable Close until corrected	Immediate
At least one element rated as major non-compliance, but no elements rated as critical non-compliance	15 points	Within one month
At least one element rated as minor non-compliance, but no elements rated as major non-compliance and no elements rated as critical non-compliance	10 points	Within six months
All elements rated as satisfactory	5 points	Scheduled inspection

FURTHER GUIDANCE FOR CATEGORIZING DEFICIENCIES.

EXAMPLE SITUATIONS

Element		Minor non-compliance	Major non-compliance	Critical non-compliance
Contamination of food	1	Processing (e.g., cleaning, washing, paring) that may affect quality	Food not protected from contamination during storage and processing	Contaminated, unwholesome, decomposed food
	2	Extraneous material that may affect quality but not heath[52]	No process for protecting food from extraneous material during storage	No protection from extraneous material during processing (e.g., potential for glass in bottles, breakage from overhead fixtures)
	3		Presence and/or evidence of insects or animals inside food business	Evidence of insects, or animals on processing surfaces or contaminating food Or evidence of disease carrying vermin/insects
	4	Leaks that don't contaminate food	Leaks, pooling water in raw material areas	Leaks, pooling water, contaminating food
	5	Poor drainage but no evidence of pooling water	Water pooling on floors, draining toward processing areas	Drains backing up into plant
	6	Cracked windows	No example	Broken windows, glass, other foreign material that contaminate food
Establishment with HACCP plan		N/A	Plan not being followed at non -CCPs	Plan not being followed at CCPs
Process flow	7	Delays in process flow such that product quality could be affected	Business does not ensure full separation by time or space of post-process product from pre-process product	Close association of raw and processed products
Construction materials	8	Wood, metal, plastic that is difficult to maintain and clean used in construction is generally in good condition	Wood, metal plastic used in construction shows some damage, but generally wouldn't contaminate food	Wood, metal plastic used in construction damaged, broken providing little or no protection and posing a contamination risk
Walls /Ceilings	9	Non-permanent material (e.g., tarpaulin, plastic) used as a permanent wall	Very rough painted wood, or other cracked, scored or rough surface	Wood, metal plastic used in construction damaged, broken providing little or no protection and posing a contamination risk
	10		Use of non-permanent material in poor condition used as a permanent wall	

52 For examples see The Food Defect Action Levels Levels of natural or unavoidable defects in foods that present no health hazards for humans.

Element		Minor non-compliance	Major non-compliance	Critical non-compliance
Overhead fixtures (e.g., ceiling fans, pipes)	11	Accumulation of condensation, moulds in areas where product or packaging may be exposed and cannot be easily cleaned	Condensation from cooler unit dripping on or splashing into processing area (not product)	Condensation, material, hydraulic fluid, lubricants leaking into product
	12	Condensation from cooler unit or other refrigeration/freezing equipment not piped to a drain	Overhead fixtures that are not clean that could fall into processing area	See above
Floors (dry or wet)	13	Unsanitary (e.g., presence of dirt, debris) in non-production areas	Unsanitary floors which may result in the production of unwholesome product	Unsanitary floors that expose product to contamination, compromise the assurance that food is processed under sanitary conditions or presents a threat to the health and safety of the consumer
Disposal of liquid waste, including drains	14	Liquid waste disposed in drains with missing covers, presence of rusty drain covers	Liquid waste disposed in drains have insufficient capacity, resulting in water pooling	Liquid waste disposed directly onto floor with or without drains
	15	Drains with missing covers, presence of rusty drain covers	Drains used not properly connected to sewers, permits entry of gases	
	16		Drains potential entry for rodents, pests	
	17		Liquid waste stored in closed containers within the building	Liquid waste stored in open containers within the building
	18		Process effluent disposed of in a manner which attracts pests to the facility	Process effluent disposed of in a manner which impacts the general sanitation of the facility
Disposal of solid waste	19	Limited number of garbage containers, but no evidence of waste accumulation	Lack of colour coded waste containers	Waste containers identical to food containers
	20	Lack of garbage bags in appropriate waste containers	Broken, damaged waste containers in processing area	
	21	Closed full waste containers remaining inside food business	Open waste containers, or overflowing waste containers in processing areas	Storage of food in containers coded for solid waste or vice versa
	22		Inadequate or infrequent removal of waste leading to waste accumulation either inside or outside food business	

Element		Minor non-compliance	Major non-compliance	Critical non-compliance
Assessment of exterior grounds	23	Pallets, totes, boxes stored near exterior walls	Uncovered garbage near exterior of food business	Business located and built such that water, exhaust from other facilities will enter premises
	24		Presence of animal pests found in debris and garbage outside food business	
	25	Entrance to facility has no drain but no pooling water, mud that can be tracked inside	Entrance to facility has poor drainage, pooling water and mud that is being tracked inside	Entrance has pooling water, sewage or garbage being tracked inside
Equipment Maintained to minimize contamination	26	Damaged hoses	Flaking, pitted or rusty equipment	Equipment flaking, pitted, damaged such that it will contaminate food
	27	Non-processing areas difficult to access and clean	Processing areas difficult to access and clean	
	28	Presence of clutter, old equipment or other material that prevents access for cleaning and maintenance		
Equipment (Unsanitary conditions)	29	Unsanitary equipment (e.g., forklifts,) that is not used for food processing	Not applicable	Unsanitary equipment that exposes product to contamination, compromises the assurance that the food is processed under sanitary conditions or presents a threat to the health and safety of the consumer
Packaging material	30	Packaging storage cluttered, crowded, lack of space	Packaging material not protected (e.g., accessible to pests, exposed to potential contamination)	Contaminated packaging
Ingredients	31	Ingredient storage cluttered, crowded, lack of space	Ingredients not protected (e.g., accessible to pests, exposed to potential contamination) Ingredients not stored at appropriate temperatures	Contaminated ingredients

Element		Minor non-compliance	Major non-compliance	Critical non-compliance
Packaging, chemicals, Ingredients	32	Not generally applicable	Presence of unacceptable packaging materials, chemicals, or other ingredients – but not in use	Unacceptable packaging materials, chemicals, or other ingredients being used
Labelling, Storage		Ingredients stored where they can affect quality	Ingredients stored where they can become decomposed or otherwise affect safety Chemicals not properly labelled or stored where spills could contaminate product, ingredients or packaging (e.g., processing areas.	Ingredients storage has resulted in decomposition, adulteration or unsafety
Chilling, refrigeration, freezing	33	Not generally applicable	Refrigerator cannot maintain temperature (4 °C); Freezer cannot maintain frozen food Perishable food not iced or refrigerated, but no evidence of decomposition	Perishable food not iced or refrigerated, but evidence of decomposition; Perishable food stored at room temperature during container inspections (e.g., at ports)
Transportation	34		Transport of frozen or chilled food or food ingredients without appropriate refrigeration or temperature controls; (e.g., in open pickup trucks) but no evidence of decomposition	Food transported from one place to another in open trucks without protection or in trucks that have previously transported live animals, chemicals or other sources of contamination
Water, Ice	35	Not applicable		Food business is using unapproved source of water and ice
	36		Inadequate water supply for processing, cleaning and handwashing	No water available or contaminated water used for processing, cleaning and handwashing
	37		Lack of hot water for hand-washing	Water treatment (e.g., chlorination) not functioning

Element		Minor non-compliance	Major non-compliance	Critical non-compliance
Acceptable sanitation procedures (e.g., removal of gross debris, disinfection and rinsing)	38		Sanitation practices that may spray or come into contact with food products	Gross hygiene practices (e.g., no removal of gross debris)
	39		Reuse of single- use cleaning products	Sanitation practices that contaminate food products with cleaner or disinfectant Connections between pasteurized and raw milk or milk product or between milk or milk products and cleaning systems and/or cleaning solutions result in contamination
Sanitation facilities	40	Toilets and facilities not located conveniently	Insufficient number of toilets and facilities	No toilets available
	41		Toilets backed up and overflowing – waste material collecting in containers	Toilets located where plumbing leaks will contaminate processing area
	42			Toilets overflowing waste material on floor, not removed
Employees Health	43	Not applicable	Employees' actions (e.g., coughing, spitting) may contaminate food	Sick or ill employees working in processing areas, high likelihood of contamination
Employees Clothing (includes clothing, boots, head gear)	44	Protective clothing not worn properly	Dirty clothing worn in plant (protective or street)	Clothing contaminated with waste material (e.g., blood, offal) worn in processing area

APPENDIX 5:

INSPECTION REPORT AND CORRECTIVE ACTION FORM

(PROPOSED)

Food Business Inspection Report	**Report #** _____
Food Business Name _____	Registration number _____
Food Business Owner _____	
Address _____	Telephone (Business) _____
Street Number and Name _____	Telephone (Manager/Owner) _____
County/Town _____	
Manager/Operator (if different from owner) _____	Inspection Date (if different than report date) _____
Name, Title _____	Inspection type Scheduled, Follow-up, Food Investigation
Facility type (e.g., dairy, bakery, market vendor, food service, retail)	Food Products _____
Inspector _____	Date & signature _____

Food Business Inspection Report (Non-compliance)			Report #
#	Inspection element	Rating	Observation
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Food Business Inspection Report (Corrective Action)		Report #
#	**Corrective Action**	**To be completed by:**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Business Commitment to Implement Corrective Action and Inspector Agreement

Responsible agent _____ Date _____ / _____ / _____

Inspectors signature _____ Date _____ / _____ / _____

APPENDIX 6:

GUIDANCE ON LABELLING REVIEW (GENERIC)

As every country will have its own laws and requirements with respect to labelling, this check list will need to be adapted to its specifications. Nevertheless, this provides a generic approach as a starting point. This checklist primarily applies to pre-packaged product destined for sale to the consumer and not to bulk packages.

The checklist should be read in conjunction with the element on packaging and labelling in **Guidance 6**.

General labelling requirement: all label information provided must be truthful and not misleading.

Element	Criteria
Language	**Is the language used on the label for the mandatory requirements in the designated official language (s)?** Yes – continue. No – detain, product is illegal and should not be sold until official language requirements are met (e.g., relabelled; sticky added).
Common name	**Is the common name present on the label as per mandatory requirements? Is it the acceptable common name as per law and/or standard?** Yes – continue. No – detain product until common name, as specified in law and/or standards is added to label (e.g., sticky added). **Is the common name on a place and/or manner that is readily visible to the consumer?** Yes- continue. No – determine if re-labelling of the lot is required; or if the food business is required to implement corrective action prior to producing the next lot.

Element	Criteria
Net quantity	**Is there a net quantity declaration present as per mandatory requirements? Is it presented in metric units as per requirements? Is it the appropriate metric (e.g., volume, weight, count for that specific product)?** Yes – continue. No – detain product until net quantity, as specified in law and/or standards is added to label (e.g., relabelled; sticky added). **Is the net quantity on a place and/or manner that is readily visible to the consumer?** Yes- continue. No – determine if re-labelling of the lot is required; or if the food business is required to implement corrective action prior to producing the next lot. **Inspection strategy** During inspections at manufacturers and importers, verify23 that the net quantity on the label corresponds to the net quantity in the packaged food. If the net quantity does not correspond, detain product and investigate other lots to determine the extent of the problem. Assess if it is a deliberate fraud, a result of mislabelling or other operational issues. All product that does not meet required net quantity is illegal and should not be sold until appropriately labelled and net quantity is truthful (e.g., relabelled; sticky added).
Ingredients	**Is there a list of ingredients on the label as per mandatory requirements? (e.g., descending order of proportion by weight or percentage?** Yes – continue. No – detain product until list of ingredients, as specified in law and/or standards is added to label (e.g., relabelled; sticky added). **Are any of the ingredients listed considered prohibited in food?** No- continue. Yes -detain, product is illegal and must not be sold. **Are the ingredients listed using the required terms and/or names?** Yes – continue. No – detain product until list of ingredients, as specified in law and/or standards is added to label (e.g., relabelled; sticky added). **Inspection strategy** During inspections at manufacturers, verify that the ingredients listed on the label correspond to the ingredients in the storage areas, and to the ingredients added to the product during manufacturing. Also verify that the proportions of the ingredients are consistent with the specifications used to produce the product. If the ingredients used to produce the product do not correspond to the ingredients on the label, detain product and investigate other lots to determine the extent of the problem. All product with mislabelled ingredients is illegal and should not be sold until appropriately labelled and truthful (e.g., relabelled; sticky added).

Element	Criteria
Presentation	**Is the label legible? This means is a consumer reasonably able to read the information? Is the print sufficient size and the background, border or other parts of the label do not prevent the consumer from reading the information on the label?** Yes – continue. No – determine if re-labelling of the lot is required; or if the food business is required to implement corrective action prior to producing the next lot.
Responsible food business	**Does the label identify the responsible food business as per law and/or standard?** (for example: produced by [Name], address, phone or contact; or imported by [Name], address, phone or contact). Yes – continue. No – detain product until food business contact, as specified in law and/or standards is added to label (e.g., relabelled; sticky added).
Date markings	**Is the required date marking (i.e., best before; packaged on, expiration date) present on the label as per law and/or standard?** Yes – continue. No – detain, product is illegal and should not be sold until date marking requirements are met (e.g., relabelled; sticky added).
Storage instructions	**If storage conditions are required (e.g., keep refrigerated, keep frozen), are they on the label?** Yes – continue. No – detain product until storage instructions, as specified in law and/or standards are added to label (e.g., relabelled; sticky added).
Country of origin	**Is country of origin required for imported product? Is it declared on the label?** Yes – continue. No – detain product until country of origin, as specified in law and/or standards is added to label (e.g., relabelled; sticky added). **Inspection strategy** During importer inspections, cross reference and verify that the country of origin on the label corresponds to the information from the import documentation.
Nutritional labelling	**If nutritional labelling is required, verify that it is in the form and content that meets the requirements of law and/or standard.** Yes – continue. No – detain product until the nutritional label is added to the label, as specified in law and/or standards (e.g., relabelled; sticky added). **Inspection strategy** During food business inspections, cross reference and verify that there is appropriate documentation to support the nutritional labelling.
Any other mandatory labelling requirements	Verify all other mandatory labelling requirements are as per legislation and/or standards of the country (e.g., irradiation, allergen labelling).

APPENDIX 7:

PLANNING EXAMPLE

Every country will have a unique planning process based on the specific conditions within the country. This will generally take into consideration timing (i.e., the fiscal year, number of competent authorities, number of districts, available resources (e.g., inspector, laboratory, financial), industry profile, food risk and any other factors the country deems appropriate.

National planning

In developing a national plan, all competent authorities should collaborate to develop a national profile and to establish anInspection strategy (e.g., frequency of inspections).

For example, if a country has 10 inspection districts and has developed the followingInspection strategy based on its profile and inspection resources:

- Every food business will have one licensing inspection a year.
- High-risk food businesses will have one extra inspection.
- Medium-risk and low-risk businesses will only have the licensing inspection.

NUMBER OF FOOD BUSINESSES BY PRIORITY CATEGORY

Total risk scores		Food businesses (numbers per district)										Food businesses numbers (national)
		1	2	3	4	5	6	7	8	9	10	
High	55-65	17	10	1	1	8	25	14	2	13	2	94
Medium	35-50	25	70	90	30	95	10	60	100	45	75	600
Low	20-30	61	35	27	25	44	29	72	99	54	42	488

Each food business is categorized as to risk – there is a list of food business and based on that risk categorization there are:

- 94 high-risk businesses.
- 600 medium and 488 low-risk businesses.

Most vacation is taken in Quarter 3 (both inspectors and small/micro businesses), the high-risk businesses are mainly the large and medium businesses and they operate throughout the year.

NATIONAL PLAN

Inspections	Number of food businesses for each score		Total annual inspections	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Planned inspections							
	High risk (x2)		184	46	46	46	46
	Medium risk (x1)		600	200	200	50	150
	Low risk (x1)		488	150	188	0	150
	Continuous inspections		0				

District 4 has 2 food inspectors. Based on the national plan and for the food businesses in the district, there would be a plan for each inspection district.

Inspections	Number of food businesses for each score		Total annual inspections	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Planned inspections							
	High risk (x2)	1 food business	2				
	Plant a			1	1		
	Medium risk (x1)	30 food businesses	30	10	8	2	10
	Each food business would be listed by name						
	Low risk (x1)	25 food businesses	25	8	10	1	6
	Each food business would be listed by name						

APPENDIX 8:

CASE STUDIES

CASE STUDY 1: RETAIL

The inspection schedule includes a small retail store (Store A) for inspection. To prepare, review the documentation in the file (small retail attached to a house, selling pre-packaged food, operating 6 days a week (closed Monday) from 7am to 7pm, primarily selling snacks and convenience food (e.g., chips, cookies, crackers, cereals, candies) and some staples (e.g., rice, canned food), stored at room temperature. There is one household refrigerator for drinks (milk, pop, juices, water).

The last inspection identified issues with sanitation and the toilet was not working, but these issues had been corrected at the follow-up inspection. Food products are primarily sourced from larger retail stores.

The risk score (using the highest risk food (milk) from the last inspection was:

Food	Food risk		Food business risk		Total risk score
	Food risk	Hazard Mitigation	Size	Compliance history	
Milk	15	10	5	15	45

Prepare inspection documentation

This includes a review of the guidance or taking the documentation with you to consult during the inspection.

- Guidance document 2: opening meeting (review);
- Guidance document 4: outside review (consider taking);
- Guidance document 6: general;
- Guidance document 14: retail (take with you);
- Guidance document 19 closing meeting (review);
- Inspection form;
- Notebook, pencil, pen or other appropriate writing material.

There is no new requirement to deliver educational material, and no samples are required.

Inspection is scheduled for Tuesday 10am

Walking up to Store A, you review all the exterior elements and make notes:

- Location: no evidence of pollution or flooding,
- Building envelope appears to be in good repair,
- Power: an electrical line provides power to the store,
- Water: no visible water supply but, from the file, you know that the business has approved municipal water,
- Waste removal: there is a garbage can near the entrance that is full but not overflowing. You make a note to discuss frequency of waste removal with the owner.

Conclusion

Exterior elements appear satisfactory.

Opening Meeting

Inside the store, you introduce yourself to the person ask if they are the food business owner/operator, show your identification and ask to see the food license. Review licensing conditions.

Inside inspection

Sourcing: owner provides documentation identifying sources (e.g., invoices). Take note of the sources: but verify that it is appropriate.

Internal structures:

- Windows, walls and ceilings are in good repair, well maintained and appropriate.
- Floors are appropriately constructed, but are dirty, and there is litter accumulating in the corners. Point this out to the owner and ask about cleaning.
- Cleaning facilities: Ask about cleaning facilities and frequency of cleaning. Owner notes that cleaning is generally done after the store closes but the floors have not been washed for several days. The cleaning products are in a separate area and are labelled. Rate as minor – as the store only sells pre-packaged product, there is little chance of food contamination.
- Personal hygiene facilities: You verify the toilet facilities and note they are clean and working. None of the issues in the last inspection have re-occurred.
- Internal environment and storage: The lighting, ventilation and environment are suitable for retail stores. Food is appropriately stored on shelves and there are no unsafe or unwholesome, decomposed food on the shelves.
- Stock: labels meet language requirements, are not expired. But the owner does not have a policy of first in/first out when selling product. Recommend that they regularly review products to ensure they are all sold within their expiry dates.
- Equipment: the home refrigerator is not working, products that require refrigeration are being stored at room temperature. The fridge smells of sour milk. Rate as critical and require immediate action. Owner should remove and dispose of all products that require refrigeration. Products such as water and pop may be reconditioned through washing, but the others should be disposed of.
- Water: water supply is from an approved source; owner provides documentation from the water control authority about the annual testing and it is acceptable.
- Waste removal: ask about the frequency of outside waste collection and note this is done weekly. Collection is the next day. Note this down.
- Records of sale: As these are direct sale to consumers, there is no documentation, nor is it required.

Prepare an inspection report noting the key elements for follow up:

#	Inspection element	Rating	Observation
1	Equipment Food	Critical	On inspection, the fridge used to store drinks, – milk, water, juice, pop, was not functioning. The milk and juice had spoiled and was not fit for consumption.
2	Floors	Minor	The floors were dirty, presence of mud, dirt and dust throughout, there was snack wrappers and chip bags in the corners of the store and under several of the shelves.
3	Stock rotation	Minor	The food business does not have a procedure to verify and ensure that stock is sold before the due date. And, if it is not, that expired product is properly disposed of.

Discuss the non-compliance with the owner and ask them to fill in and sign the corrective action report:

#	Corrective Action	To be completed by:
1	The product in the fridge has been disposed of and the products needing refrigeration will be stored in the home fridge until a new one is bought. New fridge to be installed within 3 days.	
2	The garbage has already been collected and floors will be washed tonight.	

On return to office, file all the notes, the inspection report and the corrective action report. Schedule a follow-up inspection the next day to ensure that the corrective action is in place.

Update the risk score for Store A and include it in the file:

Food	Food risk		Food business risk		Total risk score
	Food risk	Hazard Mitigation	Size	Compliance history	
Milk	15	10	5	15	45

CASE STUDY 2: SMALL MANUFACTURER OF CONDIMENTS

The inspection schedule includes a small manufacturer that produces condiments, particularly pepper sauces (Food business B) for inspection. To prepare, review the documentation in the file (small manufacturer with 5 employees producing condiments in a small commercial building, selling pre-packaged condiments directly to consumers in markets stalls, with some distribution to local restaurants and small retailers, operating 4 days a week (closed Friday to Sunday), from 7am to 3pm.

The manufacturer's pepper sauce – 3 varieties - is made with hot peppers, various other ingredients (e.g., onions, spices, herbs) and, depending on the variety, vinegar. All of these are mixed, cooked and pureed and then hot packed into bottles and sealed. The product is labelled and then put on shelves for storage until sale.

The last inspection identified minor non-compliance, namely some clutter in storage area, ingredients storage lacks space and presence of a temporary wall between storage and processing areas.

Food	Food risk		Food business risk		Total risk score
	Food risk	Hazard Mitigation	Size	Compliance history	
Hot sauce	10	10	10	10	40

There is no new requirement to deliver educational material, and no samples are required.

Inspection is scheduled for Monday at 11am and the food business has been notified.

Prepare inspection documentation

This includes a review of the guidance or taking the documentation with you to consult during the inspection.

- Guidance document 2: opening meeting (review),
- Guidance document 4: outside review (consider taking),
- Guidance document 6: general (consider taking with you),
- Guidance document 19 closing meeting (review),
- Inspection form,
- Notebook, pencil, pen or other appropriate writing material.

Walking up to Food Business B, review all the exterior elements and make notes:

- Location: no evidence of pollution or flooding, located in a commercial area, with other food businesses, no industrial smells.
- Building envelope appears to be in good repair, make a note to confirm the conditions on the inside (because of the temporary wall).
- Power: The building is connected to a power source (electrical power line).
- Water: The business has an approved municipal water line and does not use storage tanks for water.
- Waste removal: There is a garbage dumpster located near the food business, the lid is on the dumpster and there is no evidence of litter or waste. Make a note to ask if the food business uses this dumpster.

Conclusion

Exterior elements appear satisfactory.

Opening Meeting

Inside the food business, introduce yourself and ask to meet the person in charge. On meeting the person, show your identification and suggest meeting in the office. In the office, you review the food license and licensing conditions (e.g., food handler's registration).

During the discussion, confirm that only the 3 varieties of hot sauce are being produced, that the food business still operates from 7am to 3 pm and that there are only 5 employees. The owner notes that there are now 7 employees as they are producing 5 days a week, but still working from 7-3.

During the discussion, ask about the process flow – how ingredients are brought in, where they are sourced from, and the recipes being used.

According to the owner, the process has not changed, the ingredients are all mixed, cooked, cooled, pureed and bottled (you note that previously this was a hot pack). Reviewing the recipe, there are handwritten instructions changing this to a cold pack. The owner says hot pack was too difficult, so it is cooled before packing. There haven't been any complaints about the product.

- Note the change for review during inspection and for the file. Also, to follow up to see if there have been any complaints.

The owner indicates that the hot peppers and other fresh ingredients are sourced locally, the vinegar and dried ingredients are bought from the retail store.

- You note this information for review of storage and ingredients during the inspection.

Inside inspection

You start in the storage of the final product, which is stored on shelves, clearly labelled and organized. Product is easily accessible. The internal structures (walls, floors, ceilings) are in good repair and clean.

You note that half the storage area has empty vegetable boxes, but they are separated on the other side of the storage rooms and on other shelves. Owner notes that there is no refrigeration for fresh product, they buy fresh product on a daily basis and use it all on the same day.

- You make a note to ask employees about storage of fresh product.
- You make a note that the next inspection should be earlier in the day to allow for inspection of raw materials.
- You make a note to verify whether the employees handle raw ingredients while packaging final product – especially now there is a cold pack.

You review the ingredients on the shelves (e.g., vinegar, spices) and they are all acceptable for use in food.

In the operations room

You observe the internal structures, the walls, floors and ceilings are in good repair and well-maintained. The temporary wall has been replaced with a permanent wall. You ask what is on the other side and are informed that it is the toilets and the cleaning material. You make a note to inspect after reviewing the operations.

The processing environment has appropriate lighting, it is hot and 2 of the 4 windows are open with no screens. There are some flies and other insects in the processing room.

- You note the need for screens on the windows, if they are to be opened. Rate the lack of screens as major because you also note that the product is cooled on counters without lids.

Water source is confirmed as approved municipal water – and monitored regularly by the water authority. No ice is used.

The equipment being used (pots, pans) is appropriate for the product and the counters used for chopping vegetables and to measure other ingredients is clean. There is significant vegetable waste in a large box near the processing station with no lid. The employees mention that this is emptied in the dumpster at break, at lunch and at the end of the day.

You ask about the knives for chopping product, and the measuring, stirring equipment. The knives and measuring equipment are noted as being clean, but the spoons are simply left beside the stove and are reused. Note this as critical because of the potential for cross contamination. The owner agrees that the spoons should be placed in a container or spoon rest that is cleaned between each batch.

There is product being cooled to room temperature – as noted above – with no lids.

You ask the employees about the process being used and they indicate the product is brought to a boil and cooked for 30 minutes before the vinegar is added, it is cooled to a safe handling temperature and packaged.

- This process is consistent with the recipes.

Packaging

You ask the employees how the product bottles are prepared. They indicate all the bottles are washed and dried and then brought into the processing room to be filled. You note there are no bottles in the room now and are told that the product is still cooling and not ready for packing.

Personal hygiene facilities, storage of cleaning material

You move to the back room and review the storage areas and the toilet facilities.

You note the toilet facilities are properly situated, as they open onto a corridor and not the processing room. You check the water, and note there is only cold water, no hot water. You also note there is no soap for handwashing and no sign that reminds employees to wash their hands.

- You mark this as critical and note the requirement to check the water in the equipment cleaning area.

You review the cleaning equipment asking about who cleans up and how often. The response is that cleaning of the counters and equipment is done as they are used, but once all the product is packaged, floors and everything else are cleaned.

- You note the presence of a very dirty rag on a counter, and an employee confirms that it is used to wash the floor and the counters. You note this as critical and require that it be disposed of.
- You check the water in the cleaning area and sinks and find that there is sufficient hot water.

Prepare an inspection report noting the key elements for follow up:

#	Inspection element	Rating	Observation
1	Envelope	Critical	Lack of screens allowing for entry of insects and possibly other animals.
2	Processing	Critical	Re-use of spoons and utensils after having been placed on counters or stove top.
3	Personal facilities	Critical Minor	Lack of hot water and soap in the toilet. Lack of signage reminding employees to wash their hands.
4.	Cleaning	Critical	Use and reuse of cleaning mops and rags on counters (food contact surfaces) and floors.

Discuss the non-compliance with the owner and ask them to fill in and sign the corrective action report:

#	Corrective Action	To be completed by:
1	Windows were closed when the issue was identified by the inspector. New screens to be installed within a week.	Immediately 1 week
2	Containers for the spoons and utensils were found and placed on the counters and by the stove top.	Immediately
3.	Soap was immediately put into the toilet – a plumber will be brought in to fix the problem with hot water in the toilets. Signage put up within a week.	Next day
4	Review of all cleaning equipment and classification to ensure rags are not used on both floors and food contact surfaces. All rags to be washed and sanitized daily.	Immediately Immediately

On return to office, file all the notes, the inspection report and the corrective action report. Schedule a follow-up inspection the next day, to ensure that the corrective action is in place.

Update the risk score for Food business B and include it in the file:

Food	Food risk		Food business risk		Total risk score
	Food risk	Hazard Mitigation	Size	Compliance history	
Hot sauce	10	10	10	15	45

CASE STUDY 3: STREET FOOD (DOUBLES)

Based on a study published in Food Microbiology,[53] there is a public health initiative to inspect doubles vendors for adherence to good hygienic practices. Inspectors are being directed to inspect doubles vendors to determine if they meet the street food guidance and the specific guidance for doubles.

Key standards are:

1. Product must be sourced from a kitchen that is licensed, has been inspected and has no critical or major non-compliance.
2. Product must be transported to point of sale in an insulated container that is capable of keeping the product warm (above 60°C).
    a. There should be a means of maintaining the temperature above 60°C at the site.[54]
3. Condiments and spices must be prepared in a sanitary manner, must be served in appropriate containers with lids, and a separate utensil used for each condiment.
4. All leftovers much be discarded, doubles, filling and condiments.

53 Bacteriological quality of "doubles" sold by street vendors in Trinidad and the attitudes, knowledge and perceptions of the public about its consumption and health risk, Food Microbiology 20 (2003) 631-639.

54 For advice on the transport and serving of street food, consult CAC/RCP 43R-1995 Regional code of Hygienic Practice for the Preparation and Sale of Street Food (Latin America and the Caribbean).

5. Vendor sites must have acceptable water for handwashing. If municipal water is not available on site, they must bring water for handwashing. There should be separate handwashing for the vendor and for customers.
6. To ensure that vendors do not prepare a double after handling money, the food business should:
    b. Have a 2nd person to handle all money or,
    c. Only use tongs and utensils to handle the doubles or,
    d. Must wash hands after preparing a double and after handling money prior to preparing the next double. If they use gloves, they must only use them once and dispose of them after use.

The inspection schedule includes a doubles vendor (street food C) for inspection. To prepare, review the documentation in the file, micro size (1 person), food prepared at home and transported to site for sale. You verify the results of the last "kitchen" inspection provide by the inspectors in a neighboring district and see that it was deemed in compliance.

The last inspection of the site identified critical non-compliance, in particular the lack of handwashing water, and contamination from cross-utilised utensils.

Food	Food risk		Food business risk		Total risk score
	Food risk	Hazard Mitigation	Size	Compliance history	
Doubles	15	15	5	15	50

Prepare inspection documentation.

This includes a review of the guidance or taking the documentation with you to consult during the inspection.

- Guidance document 2: opening meeting (review),
- Guidance document 16: street food (take with you),
- Guidance document 19 closing meeting (review),
- Inspection form,
- Notebook, pencil, pen or other appropriate writing material.

Source the required educational material and prepare a cooler and sampling equipment to take samples as per the established sampling plan. Confirm with the laboratory that you will be delivering the sample by 4pm that afternoon.

Walking up to Street food C, you review all the exterior elements and make notes:

- Location: very close to the road, subject to exhaust fumes, note that there is space to move the stand further off the road, minor.
- Building envelope: The stand has a cover to protect the food while it is being sold.
- Power and water: none: mobile stand.
- Waste removal: There is an overflowing garbage bin beside the vendor, minor.*

Conclusion

Exterior elements, minor non-compliance.

If possible, take the opportunity to watch the vendor serving customers, pay particular attention to handwashing and cross contamination.

Opening meeting

Choose a time when the vendor is not overwhelmed with customers as you want to have their full attention. Introduce yourself to the vendor, show your identification and review the food license and licensing conditions (e.g., food handler's registration). Confirm that the source of the food is Kitchen D, and cross reference address with list of approved and licensed kitchens. Provide the vendor with the educational material, go over it with the vendor to ensure it is understood and confirm you will be taking a "double" as a sample to be analyzed at a laboratory.

Utensils: you note that each condiment and the products have a separate utensil and they are not cross utilized. However, you cannot see any place for storing or washing dirty utensils. The vendor shows you his transport vehicle, where he has stored extra clean utensils and the dirty ones. He confirms the utensils are taken back to the kitchen for washing.

Handling: The vendor is using spoons and tongs to prepare the doubles, holding the double on a single use paper for delivery to the consumer. However, he does not wash his hands after preparing the double, nor after handling money.

Transport: The product is brought to the site in a cooler, and all the spices are also transported to the site in a cooler on ice.

NOTE

This as critical and require vendor to prepare a handwashing station near the serving area.

Food storage: All the drinks are maintained in coolers, on ice. Extra food and extra condiments are also stored in a thermal container and maintained at a temperature of at least at 60°C. The condiment containers have lids, but they have been taken off and are not used. There is a high likelihood of cross contamination.

NOTE

This as critical and require vendor to ensure all the condiments are covered.

Unsold food: The vendor confirms that all unsold food is disposed of at the end of the day and placed in the garbage bin. At that point, all the garbage is picked up and taken back to the kitchen for disposal.

Handwashing water is disposed of at the side of the road. While not ideal, it is not prohibited for doubles stands and note this as an observation only.

Closing meeting

Prepare and take the scheduled samples as per sanitary requirements.

1. One double,
2. One sample of each condiment,
3. One sample of ingredient.

Put the samples on ice.

Prepare an inspection report noting the key elements for follow up:

#	Inspection element	Rating	Observation
1			
	Handwashing	Critical	No handwashing by vendor after preparing double or handling money.
2	Food cross contamination	Critical	Condiments are not covered when not in use.
3	Garbage	Major	Presence of litter and overflowing bin.

Discuss the non-compliance with the owner and ask them to fill in and sign the corrective action report:

#	Corrective Action	To be completed by:
1	Handwashing Vendor established a hand washing station, beside serving area.	Immediately
2	Lids were placed on the condiments.	Immediately
3.	Garbage was picked up and vendor put out new bag and washed hands after touching garbage.	Immediately

On return to office, file all the notes, the inspection report and the corrective action report. Schedule a follow-up inspection the next day to ensure that the corrective action is in place.

Update the risk score for street food C (as per the table below) and include it in the file:

Food	Food risk		Food business risk		Total risk score
	Food risk	Hazard Mitigation	Size	Compliance history	
Doubles	15	15	5	15	50

GLOSSARY

Certificate

The term certificate has different meanings and should be considered in a country-specific context. The term certificate may mean:

- Free Sale certificates attest that the food can be freely sold in the country of origin, meaning it is deemed safe and suitable for human consumption, (i.e., produced under sanitary conditions, is edible, free from contamination and is not labelled in a false, misleading or deceptive manner). Free sale certificates may be used to facilitate international trade as they may be a requirement of importing countries.
- Certificate[55] (Export) are the paper or electronic documents which describe and attest to attributes of consignments of food destined for international trade.
- Product certificates attest that the process used to manufacture food ensures it complies with specific standards for safety, quality, sustainability or performance, and is generally carried out by certification, standardization or accreditation bodies (e.g., ISO or other accreditation bodies).

Compliance

Compliance is a state where a food business meets all established guidelines, specifications or legislation. Therefore, non-compliance is a state where a food business does not meet the established guidelines, specifications or legislative requirements.

Conformity is a state where a food business is assessed as meeting an individual element within established guidelines, standards or legislative requirements. Therefore, non-conformity is a state where a food business is assessed as not meeting an individual element within established guidelines, standards or a legislative requirement.

Compliance monitoring

Systematic action (e.g., inspections, audits, investigations, sampling and analysis) within a food control program that are undertaken by a competent authority to verify that food and food businesses are in compliance.

55 Guidelines for design, production, issuance and use of generic official certificates CAC/GL 38-2001.

Documents

There are generally 3 categories of documents:

1. Process flow documents.
2. Quality management system (e.g., HACCP); Standard operating, or process control documents, including specifications for raw materials and ingredients that are detailed written instructions for employees to follow in carrying out their duties.
3. Records that demonstrate adherence to the firm's processes.

Enforcement

Enforcement is the range of activities undertaken by competent authorities and/or designated inspectors to compel a food business to comply with legislative requirements.

Follow-up inspections

Follow-up inspection are scheduled to review implementation of specified corrective action, but should the inspector see or become aware of other non-compliance during the follow-up, these would also be addressed.

Food contact surfaces

The term is based on the Code of Food Hygiene draft (CX/FH 18/50/5)[56] and means « work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent, materials unless food business operators can satisfy the competent authority that they do not compromise the safety of the food provided such deviation does not result in food safety being compromised.

Food hygiene[57]

In this document, this means the conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.

56 Proposed draft revision of the general principles of food hygiene (cxc 1-1969) and its HACCP annex.

57 CODEX ALIMENTARIUS COMMISSION Procedural Manual Twenty-Sixth edition 2018.

Food safety[58]

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Hazard[59]

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

Hazard Analysis Critical Control Points (HACCP)[60]

A system which identifies, evaluates and controls hazards which are significant for food safety. This system may be voluntarily implemented by a food business or mandatory, where required by a competent authority.

Note: GMPs/GHPs and HACCP are examples of food safety management systems that can be defined as a network of interrelated elements that combine to ensure that food does not cause adverse human health effects.[61]

Monitoring/ongoing inspections

Scheduled inspections intended to monitor food businesses and provide assurance that they are in compliance with regulatory requirements.

National Food and Food Business Profile

A food and food business profile may be stated in general as knowledge about which food business is producing, selling, distributing, etc., which foods.

Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to hazard(s) in food.

Risk categorization

A systematic process to identify and assign risks to each food and each food business within the system design.

58 General Principles of Food Hygiene (CAC/RCP 1-1969).

59 Principles and Guidelines for The Conduct of Microbiological Risk Assessment CAC/GL-30 - 1999.

60 General Principles of Food Hygiene (CAC/RCP 1-1969).

61 ISO 22000 (2005) Food Safety Standard (in plain English) http://praxiom.com/iso-22000.htm.

Risk categorization for food

Food conditions (Microbiological hazards and/or chemical/toxin hazards). Based on the inherent conditions (e.g., water activity (aw), acidity (pH), temperature, conditions at source) to the extent that there is a potential for hazards including microbial presence, toxins or chemicals from ground contamination.

Hazard mitigation
Mitigation is whether the potential hazard associated with the food (e.g., microbiological contamination) is reduced by a particular process (e.g., cooking) prior to being consumed; or in the case of chemical contamination, if this is reduced by monitoring processes (e.g., toxin sampling programs) that prevent contaminated food from entering the food chain.

Risk categorization for food businesses

Business size – used as a proxy for exposure, the larger the business the more product produced, and the more customers served.

Compliance history – used as a proxy for the ability of a food business to meet regulatory requirements and sell safe food.

Temperature

Refrigeration: The lowering of product temperature to limit microbial activity[62] generally recommended to be 4°C or below. In this document, the temperatures noted in the Guidance are based on the temperatures included in the Codex codes. In adopting temperatures in their national manual, countries will have to review the various temperatures provided as well as their legislation.

In Codex codes of practice, the refrigeration temperatures vary, for example:

- Fish: Temperature approaching that of melting ice, or as close as possible to 0°C, storage between 2°C and 10°C (molluscs), temperatures between 1°C and 4°C.
- Mass catering: chilled food storage should not exceed 4°C, but during transport may rise to 7°C; heated food should be held above 60°C.
- Street food: below 5°C.

62 Code of Hygienic Practices for Milk and Milk Products (CAC/RCP 57-2004).

The International Commission on the Microbiological Specification for Foods has various recommendations:

- Meat less than 5°C,
- Poultry less than 4°C,
- Fish (melting ice (~0°C),
- Intact vegetables are product specific while cut vegetables should be at less than 4°C.

Traceability/Product Tracing[63] is the ability to follow the movement of a food through specified stage(s) of production, processing and distribution. The ability to follow the movement of a food using, for example, bills of sale and receipts, from a farm source to a distributor or market to a processor to a retail store, enables inspectors to ensure that food is appropriately sourced and address praedial larceny.

63 Principles for Traceability/product tracing as a tool within a food inspection and certification system (CAC/GL 60-2006).

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PAHO

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World Health Organization
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PANAFTOSA
Pan American Center for Foot-and-Mouth Disease and Veterinary Public Health

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