ISSN 0254-4725

Risk-based food inspection manual

FAO
FOOD AND
NUTRITION
PAPER
89

For further information, please contact:

Food Quality and Standards Service
Nutrition and Consumer Protection Division
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00153, Rome, Italy
Fax: +39 06 570 54593
E-mail: food-quality@fao.org
Web site: www.fao.org/ag/agn/agns/
.

Risk-based food inspection manual

FAO
FOOD AND
NUTRITION
PAPER

89

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2008

ISBN 978-92-5-105976-0

Contents

Contents iii
Table of figures vi
Acronyms vi
Acknowledgements vii
Foreword ix
Introduction to the manual 1
1. Scope of the manual 2
2. Objectives 2
3. Descriptive terms 2
4. Target audience 3
5. Contents and use of the manual 3
1. Concepts and approaches of modern food inspection 5
1.1. Role and responsibilities of stakeholders in the food chain 5
1) Government 5
2) Consumers 5
3) The food industry 5
1.2. General inspection philosophy and approach 5
1.3. Social and economic impact of food control 6
1) Food-borne disease and food control 6
2) Economic impact 7
3) Social impact 7
1.4. Quality and safety management systems 7
1.5. The role of inspection in food control 8
1.6. Food chain approach to food control 8
1.7. Risk-based food inspection 9
1.8. Shifting from product-based inspection to risk-based inspection 12
1.9. Establishment registration and identification 12
1.10. Establishment categorization 13
1.11. Prioritization for inspection based on establishment and product profiles 14
2. General inspection procedures 16
2.1. Introduction 17
2.2. Objectives 18
2.3. Inspection of food business system components 18
2.4. Organization of the inspection 19
2.5. Authorization, rights and responsibilities 19
2.6. Prerequisite plan 20
2.7. Regulatory action plan 22
1) Product and process standards 22
2) Ingredients and packaging materials 22
3) Labelling 22
2.8. HACCP plan, traceability and recall plan 23
1) HACCP plan 23
2) Traceability and recall programme 23
2.9. Inspection closing, reporting and documentation 23
3. General inspection approach for primary production facilities 25
3.1. Introduction 26
3.2. Objectives 26
3.3. Inspection approach 26

3.4. Preparing the inspection 26
3.5. Initiating the inspection 27
3.6. General process flow 27
3.7. Walk-through inspection 28
1) Facility assessment 28
2) Monitoring and record keeping 30
3) Training 30
4) Production and harvesting practices and raw product transportation 30
5) Packaging and labelling 31
6) Storage and transportation of finished product 31
7) Corrective action and recalls 31
3.8. Closing meeting 31
4. General inspection approach for food processing facilities 34
4.1. Introduction 35
4.2. Objectives 35
4.3. Scope of inspection 35
4.4. Organization of the inspection 35
1) Inspection approach 35
2) Inspection scheduling 36
3) Response to consumer and trade complaints 36
4) Overall preparation 37
5) Opening meeting 37
6) Closing meeting 38
7) Inspection techniques 39
8) Inspection equipment 39
4.5. General process flow 41
1) Product list, production lines and flow diagrams 41
2) Critical control points (CCPs) 42
3) Critical limit(s) per CCP 42
4) Process validation 43
5) CCP control records 43
4.6. Counter-flow walk-through inspection 43
1) Facility assessment 44
2) Product assessment 46
3) Manufacturing equipment assessment 46
4) Employees and staff assessment 49
5) Employee facilities assessment 50
6) Raw materials assessment 51
4.7. Site assessment 52
1) External environment, building design and construction 52
2) Zoning and separation 53
3) Plant services 53
4.8. Food additives 53
1) Approvals 53
2) Specifications 53
3) Use 54
4) Labelling 54
4.9. Non-food chemicals 54
1) Receiving 54
2) Storage 54

4.10. Packaging materials 54
1) Approval 54
2) Storage 54
4.11. Sanitation and pest control 55
1) Sanitation protocol and schedule 55
2) Pest control protocol and schedule 55
3) Pest barriers 55
5. Enforcement and compliance 57
5.1. Regulatory base for effective quality and safety management systems 58
1) Applicable food law(s) 58
2) Other pertinent regulation(s) 58
5.2. Knowledge and skill requirements for food inspectors 58
1) Thorough knowledge of food law(s) and pertinent regulations 59
2) Background in the field of food safety and quality 59
3) Prerequisite sanitation, hygiene, and pest control practices 59
4) HACCP principles 59
5) Inspection techniques 60
6) Sampling techniques for product testing 60
7) Compliance verification skills 60
8) Communication and other skills 60
9) Original training certificate and required certificate updates 60
5.3. Compliance and enforcement policy 61
1) Responsibilities 61
2) Principles 61
5.4. Response to non-compliance and violations 62
1) Corrective action plan 62
2) Corrective action follow-up and verification 63
3) Corrective action closure 63
5.5. Enforcement actions and appeal process 64
1) Enforcement policy and approach 64
2) Product recall 64
3) Appeal process 65
6. Annexes 66
Annex 1: Sample primary production facility inspection checklist 67
Annex 2: Sample food processing facility inspection checklist 71
Annex 3: References and further reading 76

List of tables and figures

Figure 1 Inspection of a primary production facility 32
Figure 2 Inspection of a food processing facility 55

Table 1. Matrix to assign a priority rating to the establishment 14

Acronyms

CAC	Codex Alimentarius Commission
E. coli	*Escherichia coli*, an enteric bacterium
FAO	Food and Agriculture Organization of the United Nations
GAHP	Good Animal Husbandry Practices
GAP	Good Agricultural Practices
GHP	Good Hygienic Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
RtoF	Right to Food
SOP	Standard Operating Procedures
SPC	Statistical process control
SSOP	Sanitary Standard Operating Procedures
US FDA	United States Food and Drug Administration
WFS	World Food Summit
WHO	World Health Organization

Acknowledgements

FAO would like to express its appreciation to the many people who provided advice and guidance during the preparation of this publication. This document was prepared for the Food Quality and Standards Service (AGNS) of the Food and Agriculture Organization of the United Nations (FAO). The original document was drafted by the FAO international consultant, Ricardo Molins, Ph.D., and further developed by Maya Pineiro, Ph.D., Senior Officer, and Masami Takeuchi, Ph.D., AGNS/FAO. Several people in AGNS and other units in FAO and in the Department of Food Safety, Zoonoses and Foodborne Diseases of the World Health Organization (WHO) provided comments and suggestions and their inputs are gratefully recognized.

We would like to express our deep appreciation to the national consultants, Mr Faustine Masaga from Tanzania, Mr Edward Nsimbe Bulega from Uganda and Ms Nancy Gitonga from Kenya, for their valuable contributions on their national food control systems, in particular on food inspection. The experiences gathered during the food control system assessments were incorporated into the manual to make it responsive to the needs of developing countries. Our gratitude is also extended to the Kenyan, Tanzanian and Ugandan participants in the FAO Sub-Regional Workshop for Eastern Africa on "Strengthening National Food Control Systems", held on 4–8 December 2006 in Bagamoyo, Tanzania, for their enthusiastic review of the manual and thoughtful suggestions for improvement. FAO is also grateful to the international experts who participated in the final peer review process, namely Guilherme Antonio da Costa Junior, Ministerio de Agricultura, Brazil, and Yvonne Robinson, Food Standards Agency, United Kingdom. Last, but not least, FAO would like to thank the Government of Norway, which provided financial support for the development and publication of this document under the FAO Norway Partnership Programme.

Foreword

Food safety and quality and consumer protection against food fraud relate to basic human rights advocated by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), and also have major social and economic implications for all member countries. Conscious of the mandate given to FAO by the World Food Summit (WFS)[1], which highlighted the Right to Food (RtoF), that is, "the right of everyone to have access to safe and nutritious food", FAO has been at the forefront of efforts to upgrade the capacity of member countries to establish and implement appropriate food safety and quality control systems.

National governments have a mandate to ensure the health of the population, including the provision of a sufficient and safe food supply. To do so, a national food control system needs to be in place that includes a modern and effective legal and regulatory base addressing safety issues throughout the food chain, including food production, handling, storage, processing and distribution (a "farm-to-table" approach), protecting the consumer's health and also protecting against fraud[2]. A mechanism must also be in place for enforcement. The best legal and regulatory system is rendered useless in the absence of proper enforcement.

National food control systems are a key area in which improvements are necessary to ensure the safety of food throughout the food chain. This includes the need to base food safety regulations on risk and to harmonize them with Codex Alimentarius and other relevant international standards.

Worldwide, it is recognized that the application of the Hazard Analysis and Critical Control Point (HACCP) system[3] throughout the food chain has clear benefits, including the potential to enhance food safety and prevent food-borne diseases. However, implementation of this system can be a long-term activity and requires consideration of the specific characteristics of each situation (e.g. prerequisite conditions). While this is occurring, food inspection can be improved to focus on issues that will reduce food-borne disease. However, it is important that the development of inspection systems is not seen as the end point. National governments need to aim for the implementation of HACCP systems, as appropriate, throughout the food chain. Guidance on how to achieve this is available in the *FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses*[4] as well as other FAO and WHO publications[5].

As the overseer of the safety of the food supply and enforcer of food safety regulations, the regulator must have adequate procedures for inspecting, sampling and auditing the quality and safety management system put in place by food producers, suppliers and processors, to ascertain that these businesses are implementing adequate food control measures. To a large extent, national food control systems rely on food inspection to ascertain that food safety and

[1] FAO. 1996. World Food Summit. Rome declaration on world food security. Rome, Food and Agriculture Organization (available at: http://www.fao.org/docrep/003/w3613e/w3613e00.htm).
[2] FAO/WHO. 2003. Assuring food safety and quality. Guidelines for strengthening national food control systems. FAO Food and Nutrition Paper 76 (available at: ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf).
[3] FAO/WHO. 1969. Recommended International Code of Practice. General principles of food hygiene. Codex Alimentarius Commission CAC/RCP 1-1969, Rev. 4-2003. Annex. Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application (available at: http://www.codexalimentarius.net/web/standard_list.do?lang=en).
[4] FAO/WHO. 2006. FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses. Food and Nutrition Paper No. 86 (available at: ftp://ftp.fao.org/docrep/fao/009/a0799e/a0799e00.pdf).
[5] FAO. 1998. Food quality and safety systems. A training manual on food hygiene and the Hazard Analysis and Critical Control Point (HACCP) system (available at: http://www.fao.org/docrep/W8088E/W8088E00.htm). See also the FAO and WHO web pages on HACCP at http://www.fao.org/ag/agn/agns/foodcontrol_assurance_en.asp and http://www.who.int/foodsafety/fs_management/en/ respectively.

quality regulations are being complied with. However, the basic concept underlying regulatory inspections in many developing countries has not progressed from the old, product-based, reactive modality to the modern, preventive type of risk-based food control system. Furthermore, the food control system of many countries is not centralized but is composed of multiple institutions with diverse agendas. These institutions have their own separate inspection systems covering specific food sectors with frequent overlaps or gaps between them; they do not coordinate actions with each other and often use widely varying inspection procedures.

Therefore, to help facilitate the necessary transition from the old to the new concept and harmonization of food inspection procedures nationally and internationally, FAO implemented a project entitled "Improved Food Safety and Quality at the National Level and Along the Food Chain", and envisioned the development of an integrated generic inspection manual for use under multiple scenarios and for a variety of primary food handling operations and food processing establishments.

To ensure that this manual responds to the real needs and circumstances of developing countries, the above-mentioned project first conducted an assessment of the capacity building needs of the food control systems of five countries[6], paying particular attention to food inspection procedures in general, and to inspection of fish and fishery products in particular. The information collected from these assessments, especially that related to food inspection, has been used to emphasize various areas in the manual where weaknesses and gaps were observed, to redirect the focus of food inspections towards a risk-based process rather than a product-based process, and to introduce the concept of modern and preventive risk-based food inspections.

[6] Tanzania, Uganda, Kenya, Lao PDR and Cambodia.

Introduction to the manual

1. Scope of the manual

This manual deals with risk-based inspection of primary production operations and food processing establishments. Although it does not address retail food service and food preparation operations specifically, some of the material may be suitable for such applications. National food inspection procedures should be integrated across the different types of food sector, including imported, exported and domestic products; however the manual does not cover food import and export inspections, for which the Codex Alimentarius Commission (CAC) has published specific guidelines[7,8]. The implementation of HACCP and auditing processes are not covered by this manual. Food quality inspection has been included in this manual to assist countries who undertake inspection of both food safety and quality issues. National governments should determine if it is appropriate for their countries to focus on both food safety and quality or only on food safety.

2. Objectives

In order to support capacity building in the development of effective national food control systems, FAO, in collaboration with many international, intergovernmental and governmental bodies, has supported the development of many standardized guidelines. This manual was developed to assist countries in strengthening national food inspection systems, and the specific objectives of the manual are:

- to provide food inspectors in developing countries with practical guidelines for conducting the modern style of risk-based inspections;
- to provide a roadmap for food inspectors that can be used in their inspection of primary production or processing operations across the entire food sector, regardless of the specific product(s) handled or manufactured by the inspected establishment;
- to reorient food inspection from a product-based process to a risk-based process;
- to serve as a training and reference tool for food inspectors.

3. Descriptive terms

For the purposes of this document, the following terms are clarified (they are not official definitions).

- **Quality and safety management system** is an integrated system of procedures and operations to assure both safety and quality of products in food industry[9]. It includes food safety management systems[10], and it does not refer to the wider national food control system[11]. Also see related terminology defined by others[12].

---

[7] FAO/WHO. 1995. Principles for food import and export certification. Codex Alimentarius Commission CAC/GL 20-1995 (available at: http://www.fao.org/DOCREP/005/X4489E/x4489e02.htm#bm2).

[8] CAC. 1997. Guidelines for the design, operation, assessment and accreditation of food import and export inspection systems. Codex Alimentarius Commission CAC/GL 26-1997. Rome, Food and Agriculture Organization of the United Nations.

[9] Orris, G.D. 1999. Equivalence of food quality assurance systems. *Food Cont*., 10(4–5): 255–260.

[10] "A holistic system of controls that manage food safety in a food business. It includes GHPs, the HACCP system, management policies and traceability/recall systems". FAO/WHO. 2006. FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition Paper 86. ISBN 978-92-4-15903-2 (available at: ftp://ftp.fao.org/docrep/fao/009/a0799e/a0799e00.pdf).

[11] FAO. 2006. Strengthening national food control systems: Guidelines to assess capacity building needs. ISBN 92-5-105536-X (available at ftp://ftp.fao.org/docrep/fao/009/a0601e/a0601e00.pdf).

[12] For example, "Quality Assurance (QA)" is defined as "a set of activities whose purpose is to demonstrate that an entity meets all quality requirements. Quality assurance activities are carried out in order to inspire the confidence of both customers and managers, confidence that all quality requirements are being met." International Organization for Standardization (ISO), under ISO 9001.

- **HACCP system** is a system that identifies, evaluates and controls hazards that are significant for food safety, described in the Annex to the Codex General Principles of Food Hygiene[13].

- **Good hygienic practices** are all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain[14].

4. Target audience

This manual is for use by food inspectors in charge of ensuring the adequacy and efficacy of food control systems in primary production operations and food processing plants. Food control authorities may also find this manual useful in the training of new inspectors and in refocusing food inspection practices on a risk-based process.

5. Contents and use of the manual

The manual is composed of six parts. The first part, *Concepts and approaches of modern food inspection*, describes the concepts, approaches and frameworks of the modern food inspection process. The second part, *General inspection procedures*, introduces the overall concept of risk-based inspection and describes basic principles and components of food inspection, including organization of an inspection, authorization, rights and responsibilities of an inspector, prerequisite plan, regulatory action plan, traceability and recall plan and the closing, reporting and documentation of an inspection. The third part, *General inspection approach for primary production facilities,* explains the generic inspection procedures covering primary production. The fourth part, *General inspection approach for food processing facilities*, covers the generic inspection procedures for food processing operations. The fifth part, *Enforcement and compliance*, covers general aspects of food inspection as the regulatory base of food safety and quality, the knowledge and skills needed by food inspectors and the compliance, enforcement, appeal and recall processes. Finally, the sixth part comprises the *Annexes*, which include a sample primary production facility inspection checklist, a sample food processing facility inspection checklist and references/further reading.

This manual is designed to be used as a guide in conducting risk-based inspections in primary production operations and food processing plants. For inspectors to undertake their role effectively it is important that they receive formalized training as outlined in this manual. However, because achievement of this in all countries will be a long-term process, this guide may be used as a training tool for inspectors.

[13] FAO/WHO. 2003. General principles of food hygiene. CAC/RCP 1-1969, Rev. 4-2003 (available at: http://www.codexalimentarius.net/download/standards/23/cxp_001e.pdf).
[14] The term "good hygienic practices" is based on the definition of food hygiene documented in the Codex General Principles of Food Hygiene (CAC/RCP1-1969, Rev. 4[2003]).

1. Concepts and approaches of modern food inspection

1.1. Role and responsibilities of stakeholders in the food chain

To place the manual in context, it is essential to point out that, from farmers or fishers to food collectors and other intermediaries, distributors, processors, retailers, consumers and regulators, everyone participating in the food chain has a role to play and some responsibility for food safety and quality.

1) *Government*

   National authorities have the responsibility of protecting public health by reducing the risk of food-borne disease and providing food safety education and information to consumers and the food industry.

2) *Consumers*

   Consumers are entitled to safe, wholesome food. Consumers also have responsibilities regarding food safety: observing good hygienic practices when handling food, storing food properly and following manufacturers' recommendations on labels; however they cannot be expected to be the sole providers of food safety. Many consumers, through no fault of their own, lack adequate education concerning appropriate food handling practices[15] in the home and may have only limited or no access to information on these practices.

3) *The food industry*

   Ultimate responsibility for food safety lies not with the regulator nor with the consumer but with food producers, processors, retailers, preparers and servers. Whereas any individual or firm has the right to produce, process, prepare, serve, import and export food, this right comes with the inseparable responsibility to ensure that such food is wholesome and safe and that the conduct of their business is within all applicable laws, including those regarding fraud. The capacity of producers and processors – and, although not included in this manual, also of retailers and food preparers – to fulfil their roles adequately depends on their ability to understand, establish and follow effective food control systems.

1.2. General inspection philosophy and approach

This manual strives to convey to the food inspector not only a set of techniques and procedures to facilitate his/her work and harmonize it with that of other inspectors in their own or related institutions who are involved in verification of compliance with food safety and quality regulations in their country, but also to foster food safety partnerships between the inspector and food processors. This approach is derived from many experiences in countries where such partnerships have contributed greatly to the active involvement of inspectors in the improvement of existing quality and safety management systems. The approach requires a change of philosophy regarding the inspector's traditional regulatory role, which is generally limited to verifying that regulations are complied with, to a vision of him or herself as a food safety professional actively contributing to improving the system through incremental changes that are meaningful with regard to enhancing the safety of food products. Thus, the

[15] WHO has developed a global food hygiene message with five key steps that promote health, the *Five keys to safer food* (available at: http://www.who.int/foodsafety/consumer/5keys/en/index.html).

philosophy relies on placing the inspector's emphasis on factors that are likely to lead to food-borne disease.

The traditional regulatory inspection seeks only to obtain correction of food safety concerns that already exist rather than to prevent future violations from occurring. Although this approach may have helped to improve sanitation in the past, it emphasizes reactive rather than preventive measures. In contrast, the method proposed herein is based on prioritizing inspections using a risk-based approach. This new approach has proven effective in changing the attitude of the regulated to a new level of respect towards the inspector.

In addition to a new philosophy and approach to food inspection, this manual attempts to refocus the inspector's attention from environmental aspects and end product testing to a risk-based process. That change of focus is from the simple (and often unfounded) "verification" of the compliance of a product or premises with dated prescribed regulations to an assessment of the controls put in place in the operation to address food-borne disease risk factors that could put the processor's products at risk (i.e. cause disease).

1.3. Social and economic impact of food control

1) Food-borne disease and food control

Food-borne disease is a scourge that has plagued humanity since time immemorial. However, recent trends in global marketing of foods, animals and plant material and the high mobility achieved by humankind have made food-borne diseases equally global. Other factors, such as population concentration in large urban areas, environmental contamination and poor sanitary conditions, poverty, changes in food production towards intensive agriculture and animal rearing and in processing and distribution chains covering ever longer distances, and the emergence of highly virulent micro-organisms, some of them resistant to antibiotics, have placed strains on the safety of the food supply that were hitherto unknown.

The full impact of food-borne diseases on the social and economic fabric of many nations is unknown and very hard to assess or estimate for several reasons:

a. Lack of surveillance systems

Compiling statistics on food-borne disease requires advanced food-borne disease surveillance systems to be in place. To be effective, such systems require adequate diagnostic training of health care providers as well as tools and timely reporting, which most developing countries and also some industrialized ones lack.

b. Under-reporting of food-borne disease

Even when food-borne disease surveillance systems do exist, the true number of food-borne disease incidents in a country may never be known because of various factors. For example, it is estimated that in highly industrialized countries only 10 percent of all food-borne disease cases are ever reported because outbreaks, but not individual cases, are reported and investigated (three individual cases are

necessary to determine the possible origin of a food disease outbreak). In addition, many people suffering from enteric diseases recover after a few days and do not visit a doctor. Furthermore, doctors are often ill-prepared to diagnose the exact nature of the disease correctly and either do not take samples for laboratory confirmation or fail to report such diseases. Moreover, the impact of diseases caused by chemical contamination of food, which may be substantial, is largely unknown.

2) *Economic impact*

Given the lack of statistics that could be used to estimate economic impact, food-borne disease continues to be a major obstacle to economic development that frequently goes unnoticed by planning and economic authorities unless massive outbreaks or environmental disasters occur. Nevertheless, sometimes the internal economic cost of food-borne diseases for a country can be estimated indirectly by considering the number of work hours lost, medical and health care costs and especially deaths caused by such diseases. In addition, real or perceived contamination of food with disease-causing agents – whether chemical, biological or physical – can be devastating for countries whose economies rely heavily on food exports. For example, the disruption of livelihoods and economic losses caused by the European Union ban on fish exports from East African countries in the late 1990s affected more than 80 000 fishers and hundreds of thousands of their family members.

3) *Social impact*

Food-borne diseases adversely affect the social fabric of a country. Dysentery, for example, is one of the leading causes of child mortality in many developing countries, while epidemics of such highly contagious diseases as cholera have, in the past, altered the life of entire nations. Food-borne diseases are also significantly more prevalent among the poor because of unsanitary surroundings, habitual and necessary reliance on street-vended foods of dubious origin and quality, and lack of education regarding safe handling of foods. Malnutrition continues to afflict people in many developing countries, while the food control system fails adequately to regulate addition of nutrients to certain foods or adherence to labelling requirements to prevent fraud and enable consumers to make informed choices about foods.

Food control, therefore, is essential to the well-being of the people and constitutes, or should constitute, a top priority for national governments. The front line of the food control system, in turn, is the food inspector. This manual is dedicated to him or her.

1.4. Quality and safety management systems

Implementation of a quality and safety management system by the food business is not a passive but an active managerial system. To provide active managerial control of risk factors, producers and processors can emphasize various areas and procedures of relevance to the safety and quality of their food products and/or establish specific requirements, such as the following:

- facility design and maintenance schedule;

- equipment design and maintenance schedule;
- instrument calibration (e.g. thermometers, timers);
- standard sanitation operating procedures (SSOPs) for clean-up operations;
- standard operating procedures (SOPs) for critical steps during processing;
- specifications for purchase of raw materials;
- periodic health certification of employees;
- exclusion of and compensation for ill employees;
- training of managers, supervisors and employees;
- record keeping.

Note that this manual assumes that such a quality and safety management system does not necessarily correspond to a Hazard Analysis and Critical Control Point (HACCP) system, which is the ideal quality and safety management system. Instead, this manual attempts to promote the introduction in developing countries of concepts that underlie and precede the HACCP system, the establishment of which should be the ultimate goal.

1.5. The role of inspection in food control

Food safety and quality control are primarily, though not solely, the responsibility of food producers and processors who benefit economically from selling their products. Because the public is entitled by right to safe and wholesome food, governments must ensure that this right is preserved, and to do so, governments enact regulations and verify compliance with these regulations through enforcement actions.

Legislation and complementary regulations are some of the fundamental components of a national food control system. However, the enforcement of regulations determines whether a national food control system is effective or not. The best food safety and quality regulations are worthless in the absence of proper enforcement. Consequently, because it is central to the enforcement process, inspection plays a critical role in food safety and quality control.

Because of the impact of inspections on the safety and quality of foods, mere confirmation that primary food operations and food processing operations are observing proper sanitation practices is far from enough to ensure food safety. Yet this is essentially what many national food safety control systems do. In some other systems, samples of products are taken during the inspection supposedly to determine whether they comply with safety and quality standards. However, samples are often taken during inspections without a clear plan of the analyses to be performed because there is no defined standard to meet and also without a plan of action on how to react to the results. In addition, when there are standards, these often focus on cosmetic characteristics of food products rather than on their safety. Moreover, samples are frequently taken improperly because of lack of sampling procedures, tools and plans or are mishandled during transportation to the laboratory. Laboratories, in turn, are often not equipped to conduct the necessary analyses or do so improperly because of scarcity of resources, lack of staff training or both. These considerations have weighed heavily on the modern trend to shift from product-based inspection to risk-based inspections that focus on prevention.

1.6. Food chain approach to food control

The food chain extends from the farm or water through various stages that may include transportation, selection and packing, slaughter and dressing, processing for transformation

into new, value-added products, distribution and retail, all the way to the home of the consumer or the ultimate food preparer and server. Opportunities for contamination of food throughout this chain are multiple. Although the levels of some potential contaminants are sometimes reduced by processing (e.g. pesticide residues and possibly mycotoxins), microbial contaminants may increase as the food is handled unless a killing step (e.g. heat) is applied at some point. Even after sufficient heat has been applied during processing or cooking and pathogenic micro-organisms of concern have been inactivated, there are many opportunities for recontamination of cooked products on their way to the table. In addition, toxigenic micro-organisms that are allowed to proliferate in or on a food prior to heating may produce heat-resistant toxins that can make consumers ill long after the culprits themselves have been inactivated by heat treatments.

In a different scenario, thoroughly washed fresh produce cleaned at a field packing station, for example, may be handled and re-contaminated at retail or may be cross-contaminated with pathogens from raw meats, poultry or other sources by cutting boards, dripping juices and contact during refrigerated storage or by unwashed hands during preparation prior to serving. Fresh produce is often consumed without prior heating.

Until the advent of modern food safety control systems based on preventive rather than corrective measures, it was common to expect processors to "clean up" food contaminated at origin during production or harvesting and transportation to the processing plant. However, this is not always possible with current technology and processing methods. Such is the case with *Escherichia coli* (*E. coli*) O157:H7, which may be carried by cattle and later found on fresh meat originating even from abattoirs where the best available decontamination methods for animal carcasses are in place. The situation is just as serious with fresh produce contaminated on the field. In addition to potential long-term consequences to consumer health from ingestion of pesticide residues, more acute diseases may result from microbial pathogens in produce consumed without a prior inactivating step. This group of foods is rapidly becoming the major recognized source of food-borne disease in many countries. Farmers and subsequent handlers cannot escape the responsibility for diseases caused by their produce. A measure of the consequences of producer responsibility in food-borne diseases is the proliferation of international standards for fresh produce, including private standards, which exporters worldwide are finding themselves subjected to. For these reasons, this manual includes guidelines for inspection of primary production facilities.

Similarly, food control systems that include food safety and quality assessment must be in place at the other end of the processing chain: during transportation, distribution, retail and preparation of food (even in the home). This is what is meant by approaching food safety from "farm-to-table", that is, along the entire food chain. This approach is all the more logical because food safety is the responsibility of all stakeholders in the food chain. This manual does not specifically address food control systems at these final stages of the food chain, but the material presented herein may be applicable to food retail and preparation operations.

1.7. Risk-based food inspection

Traditional food inspection has centred on determining compliance by food processing establishments with a number of regulations that may or may not be up to date. To a large extent, the effectiveness of this method of inspection depends on the time available to inspectors to check the facility under inspection and particularly its products physically. It is

common in many countries to find an inordinate number of establishments to be inspected compared with the number of available inspectors, especially when inspectors must cover primary production facilities (e.g. packing houses), food processing plants, food preparers (institutional, catering) and food serving establishments (restaurants). In some countries, inspectors must also add public markets and street vendors to their inspection portfolio.

Non-compliance and violations thus revealed usually have been dealt with by serving the establishment with notices and/or fines and demanding corrective action, which may or may not follow depending on the legal framework and/or policy of the corresponding regulatory authority. The method is, therefore, corrective. Furthermore, because the corrective action demanded cannot go beyond bringing the offending establishment up to the standard indicated by the regulations, which may be obsolete, there is no assurance after this type of inspection that there will not be recurrence of the violation.

By focusing inspection on risk factors that may cause food-borne disease, on the other hand, the inspector will make better use of his/her scarce time allocation to each processor, without overlooking existing non-compliance and violations of regulations. Furthermore, by using the occurrence of risk factors to determine the adequacy of a processor's quality and safety management system, the inspection will be based on risk and will thus fulfil its ultimate purpose of safeguarding the consumer. Ensuring that the food control system works all the time so that safe products are consistently produced also reduces the problem of sampling. Thus, product samples will be collected and analysed only for verification purposes and no longer as a means to ensure product safety.

To be able to focus inspection on risk factors for food-borne disease it is necessary first to determine what these factors are. Whereas many factors pertaining to the physical characteristics of food-processing facilities and their operations may be contrary to good manufacturing practices (GMPs), accepted sanitary guidelines, regulatory requirements or other benchmarks of adequate food processing and handling, there are some factors that have been found frequently to be implicated as causes of food-borne diseases. It is on these factors that the inspector must concentrate during inspections to have a meaningful impact on food safety. *Food-borne disease risk factors are those factors that may cause food-borne disease in consumers if left uncontrolled.*

Food-borne disease risk factors may be common to many countries and types of foods and food processing operations or unique to a particular country, food or operation because the origin, nature or traditional processing and handling methods of specific food products may differ. To determine food-borne disease risk factors, national food control systems rely on various techniques and programmes. **Epidemiological surveillance by health authorities** is a primary element in determining risk factors for food-borne disease by linking food-borne diseases with their origin through investigation of outbreaks. Unfortunately, this type of surveillance is lacking in many countries and such data are not available.

Contaminant monitoring programmes for foods in the marketplace are another source of information that allows connections to be made between particular food products and food-borne diseases. Examples of such programmes are *Vibrio cholerae* monitoring of fish and seafood (such as that conducted in East African countries on Nile perch from Lake Victoria), and monitoring of mycotoxins in cereal and grain products and enteric pathogens such as *Salmonella* spp. in fresh produce. As mentioned before, many countries unfortunately do not have routine programmes to monitor the presence of contaminants in the food supply.

Environmental considerations are a third element in determining food-borne disease risk factors for specific foods or processes. Examples of this include the quality of water used for irrigating green leaf vegetables and other produce: the use of served waters or water contaminated with animal or human faeces for irrigation has been implicated in most outbreaks of food-borne disease stemming from fresh produce; the abundance of flies in areas historically prone to outbreaks of dysentery; the use of traditional animal husbandry practices such as pasturing of cattle in orchards, a practice known to have caused contamination of fruit with *E. coli* O157:H7.

A fourth consideration in determining food-borne disease risk factors are **product and producer/processor histories**. For example, fresh seed sprouts are widely known to be fertile ground for growth of *Salmonella* spp., and raw chicken is known frequently to harbour *Campylobacter* spp. and *Salmonella* spp. the world over. Similarly, ready-to-eat cold cuts of processed meats that have a long shelf-life under refrigeration have been repeatedly implicated in cases of listeriosis. Therefore, product history, in the context of each particular country's experience, should be an important aspect considered during risk-based inspections. Producer history is also important because a record of non-compliance, of consumer complaints, or worse yet of documented instances linking cases of food-borne disease to specific processors should raise alert flags before an inspection. Hence the importance of careful record keeping and of reviewing the establishment's inspection record in advance of any new inspection.

Finally, national food control authorities can undertake studies to determine the **frequency of non-compliance** with regulations by primary food operations and food processing operations that result in unsafe foods. This is usually a complex procedure but it is more precise than relying on food-borne disease surveillance data because of the gross under-reporting of food-borne diseases[16].

In the absence of information on or from one or more of the above, the inspector is not helpless. Various important food-borne disease risk factors have been identified in many countries and thus can be considered "universal". Some examples of widely identified risk factors for food-borne disease are presented in Box 1.1.

Box 1.1. Examples of food-borne disease risk factors.

- Cross contamination (e.g. from a raw to a ready-to-eat product).
- Food from unsafe sources[17].
- Inadequate cooking[5].
- Improper holding temperatures[5].
- Contaminated equipment[5].
- Poor personal hygiene[5].
- Food handlers' health status.
- Water quality.
- Presence of pests.

[16] An example of this type of exercise can be accessed online at the following website: http://www.cfsan.fda.gov/~dms/retrsk.html
[17] CDC. 1996. Surveillance for food-borne disease outbreaks -- United States, 1988-1992. *Morb. Mort. Weekly Rep.,* 45 (SS5): 1–66. Centers for Disease Control and Prevention (available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm).

1.8. Shifting from product-based inspection to risk-based inspection

The old concept of product-based or premises inspection presents several drawbacks that risk-based inspections have overcome. Because inspection, in essence, is a snapshot of what is taking place in the food processing establishment at the time of the inspection, the panorama presented to the inspector during an inspection is not necessarily complete. Situations may occur throughout the day that the inspector does not see, especially when the inspected establishment is notified in advance about the impending inspection. Therefore, ascertaining that samples of products taken during the inspection present the expected safety and quality characteristics does not mean that all products from the plant are equally safe or have the same quality characteristics.

The need to analyse product samples brings forth another set of problems, not the least of which is the lack of modern laboratories, adequately staffed and having the necessary information and resources not only to perform the analyses but also to determine what to assay, based on the type of product. Secondly, to be statistically valid, sampling of products for analysis usually requires large numbers of units and tests, especially in large operations, that neither the processor nor the inspecting agency want to forfeit or to pay for, respectively (most food analyses are destructive). As a result, unless there are gross violations resulting in extensive and continuous product contamination or faulty processing, the probability of finding offending samples is very small. Ironically, the sampling problem grows as a processor's operation improves and the quality of the products increases; more and more samples are needed to find a possible violating unit because fewer and fewer units are defective (i.e. contaminated or otherwise compromised). Eventually, to ensure fully that all products are safe under this scheme, all products would have to be tested and there would be none left to sell.

In contrast, risk-based inspection departs from the premise that when all necessary control measures are implemented – which by definition must fully control all identified food-borne disease risk factors associated with the product – the safety risks associated with the resulting food products are minimized. Therefore, if the above-described quality and safety management system is adequate and fully implemented, it follows that all products should meet the requirement of the safety and quality characteristics. This risk management approach in the food industry is consistent with the principles of risk management[18] and is essentially equivalent to the extremely successful zero-defect system implemented long ago by other industrial sectors. In the event that faulty products are found, risk-based inspections require an examination to determine where the system is or was at fault, or what hazard in the process is or was not being properly controlled. This demonstrates the importance of in-plant record keeping. Sampling under this scheme is done only for verification purposes.

1.9. Establishment registration and identification

The national food control system of most countries requires that food processing establishments obtain registration before starting operations. The ideal situation is to analyse the planned establishment layout before construction of the establishment. This makes it possible to identify non-compliances, which can cause for example cross-contamination, and corrections can be made to the project without high costs for the enterprise. An inspection of the premises is customarily required as a prerequisite for registration. Upon approval

[18] FAO/WHO. 1997. Risk management and food safety. Report of a Joint FAO/WHO Consultation. Rome, Italy, 27–31 January 1997. FAO Food and Nutrition Paper 65 (available at: http://www.fao.org/docrep/W4982E/W4982E00.htm).

following the initial inspection, a licence is issued that in most cases has to be renewed annually and a unique establishment registration number may be issued. Some countries may require that establishments undergo a new registration process whenever major changes to the facility (e.g. remodelling, expansion, replacing machinery) or a change in processing are introduced, but the registration number remains unchanged. The inspector must ascertain that the registration is up to date and use the establishment registration number to consult the records before an inspection and to identify the inspection report.

1.10. Establishment categorization

The various industries that process foods are not equally likely to be sources of food-borne diseases because the type of product they handle or the processes they use may have different food-borne disease risk factors. There is, therefore, a process/product-related set of risk factors for food-borne disease that the inspector should have in mind before an inspection so that the time dedicated and intensity applied during the inspection will be appropriate for the particular set of food-borne disease risk factors. Thus, a bakery producing only bread, for example, does not present the same risks that may exist in another bakery that produces pastries with cream fillings (historically notorious as source of intoxication with *Staphylococcus aureus* toxin A). Another example is the difference in risk factors presented by processing plants producing foods that will be cooked prior to consumption (e.g. raw chicken or meat) and others that produce ready-to-eat products (e.g. cold meat cuts) that will not be cooked prior to consumption.

By identifying high-risk foods or high-risk food preparation processes, the inspector can focus on those foods or processes that are most likely to cause food-borne disease if uncontrolled. Products such as raw chicken are high-risk foods because they naturally carry a high load of pathogenic bacteria. Therefore, if such products are used, practices related to cross-contamination and cooking should be a priority during the inspection. If there are foods that go one or several times through the temperature "danger zone" (4.4–60°C or 40–140°F), at which pathogenic micro-organisms are most likely to proliferate, cooling and holding practices must be reviewed.

In addition, there are risk considerations related to the number of expected consumers. A product having wide distribution and large consumption is more likely to cause extensive outbreaks of food-borne disease than one with reduced market reach.

The inspector's experience and academic training should serve as guides to the level of risk presented to consumers by the products from each establishment to be inspected. Box 1.2. presents some important types of primary food operations and food processing operations.

Box 1.2. Some important types of primary food operations and food processing operations.

- Animal rearing, slaughtering, or processing operations:
  - animal rearing operation
  - abattoir
  - egg production operation
  - egg processing operation
  - milk production operation
  - dairy processing operation

- fresh and/or frozen meat or poultry packer
- meat or poultry canning
- ready-to-eat meat or poultry product processing.

- Produce growing/packing operations:
  - fruit and/or vegetable growing operation
  - fresh produce packing operation
  - fruit and/or vegetable canning operation
  - fruit and/or vegetable juice processing.
- Fisheries and/or fish and other seafood processing operations:
  - fishing operation
  - shellfish depuration operation
  - fresh and/or frozen fish and other seafood processing operation
  - fish and/or shellfish or other seafood canning operation
  - shellfish processing operation
  - aquaculture operation.

1.11. Prioritization for inspection based on establishment and product profiles

When the number of establishments to be inspected is large enough to overwhelm the national or local food control system, some type of prioritization is necessary to ensure that products that pose greater risk to consumers and establishments that have a poor record of compliance are given special attention and inspected more frequently. A technique that can be used to establish a priority list of primary production and food processing establishments to be inspected relies on establishment of product "profiles". Box 1.3. shows the procedure for applying this selection methodology.

Box 1.3. The procedure for prioritization.

1. The history of compliance by the establishment with its quality and safety management system and pertinent regulations – the establishment profile – is designated "High" (good) or "Low" (bad) in accordance with existing inspection records.
2. The establishment's products are profiled on the basis of the level of food-borne disease risk factors they present (i.e. inherent microbiological, chemical and marine toxin risks) and marketing characteristics (e.g. large volumes reaching all populations, destined for children or infants, speciality products to niche markets). A "High" or "Low" risk classification is assigned to the product profile.[19]

The results of the above procedure are compared with the following matrix to assign a priority rating to the establishment (Table 1).

[19] For further information, see Section II of the WHO food safety inspection guidelines. WHO Regional Office for the Western Pacific (WPRO).

Table 1. Matrix to assign a priority rating to the establishment.

Establishment compliance profile	Product risk profile	Inspection priority*
Low	High	1
Low	Low	2
High	High	2
High	Low	3

*1 = top priority; 2 = medium priority; 3 = low priority.

The establishment categorization or priority level for inspection thus obtained should be reviewed and updated after each inspection if there have been changes in the establishment profile (e.g. non-compliance and violations are reported) or product profiles (e.g. new products, new formulas, new processes).

2. General inspection procedures

2.1. Introduction

Risk-based inspection starts with the consideration of hazards associated with the food and a review of the control measures in place to determine if they are adequate. For example, some relevant food-borne disease risk factors associated with the relatively simple primary food operations of a typical fruit packing station are presented in Box 2.1.

Box 2.1. Example: Food-borne disease risk factors at a typical fruit packing station.

- Incoming fruit contaminated with pesticide residues and/or enteric pathogens.
- Contaminated wash water.
- Poor design of facility: toilets open into packing area, packing station open to dust, poor drainage of floor, floors and/or walls are cracked or absorb water.
- Presence of pests or other animals.
- Sick employees or staff.
- Lack of personal hygiene (e.g. dirty clothes, shoes), failure to wash hands or improper washing.
- Dirty boxes/crates.
- Recontamination during transportation to market.

In order to address the identified food-borne disease risk factors, the quality and safety management system may require the items showed in Box 2.2 to be present.

Box 2.2. Example: Items required for the quality and safety management system of a typical fruit packing station.

- Management (i.e. the operation supervisor) understands the importance and objectives of the controls in place in the business and is able to explain them to labourers. He/she has received training.
- Fruits come from properly managed fields (regulations on pesticide use and withdrawal periods are observed) and irrigation water that is clean and free of enteric bacteria is used. Pre-qualification of fruit providers is required and periodic verification visits are made.
- Fallen fruits are excluded.
- Cattle and other animals are excluded from orchards.
- Fruits are thoroughly washed after selection.
- Staff have been trained to an appropriate standard in food hygiene and personal hygiene.
- Employees are healthy; sick employees (especially those with enteric diseases) are excluded from food handling activities and the processing environment.
- There are toilets and hand washing facilities separated from the packing area and employees have been instructed about proper hand washing.
- Employees properly wash their hands after exiting the facility and re-entering, and after using the toilet.
- Employees wear clean clothes.
- The facility is free of dust, pests (cockroaches, flies, rodents, etc.) and other animals (cats, dogs, birds, etc.).
- The packing area is screened to keep insects and animals out.
- The wash water is potable.

- A high enough level of chlorine (previously determined) is maintained in the fruit wash tank at all times (requires periodic monitoring throughout the day).
- The chlorine level in the wash water is periodically checked and readjusted as needed.
- The boxes or crates for the fruit are new or properly washed and sanitized if reused.
- The fruit is kept from being contaminated during transportation.

Furthermore, having established the quality and safety management system, it is imperative that management actively promote and monitor compliance. Besides supervision, management may enhance compliance by posting signs reminding personnel to wash their hands and to indicate the level of chlorine to be maintained in the wash tank, and by periodically sending water samples for microbiological analysis (especially when using water from wells or other private sources).

2.2. Objectives

The objectives of assessing the hazards and controls associated with food processing during an inspection are:

1. To ascertain that the establishment's quality and safety management system adequately addresses all identified food-borne disease risk factors associated with the establishment's product(s).
2. To examine possibilities for improving the systems that are in place and progression to a HACCP-based process when appropriate.

2.3. Inspection of food business system components

The inspector must prepare for an inspection. If a full HACCP system is in place then an audit (assessment/evaluation) should be performed. Preparation includes consulting the food control authority's records to gain an insight into the background of the operation to be inspected, its history of compliance and the product(s) it handles. This advance knowledge will accomplish the following.

- Help the inspector to prepare a list of potential food-borne disease risk factors identified for the type of product and facility to be inspected.
- Help the inspector to prepare the necessary inspection wear (unless it is provided by the establishment), tools and equipment.
- Help the inspector to make an adequate time allocation for the inspection based on the size and complexity of the operation.
- Inform the inspector about the registration status, the identification number of the facility, and, hopefully, the name(s) of the person(s) to communicate with before, during and, if necessary for follow-up, after the inspection.

Preparation also involves taking care of personal aspects such as obtaining protective clothing (unless provided by the inspected establishment), and preparing the necessary equipment (e.g. flashlight, thermometer), sampling tools, note-taking materials and official forms.

2.4. Organization of the inspection

The inspector must consider the task at hand and organize each inspection. Unless the inspection is a follow-up to a complaint or known violation, in which case a non-announced visit is in order, establishments should be notified of inspections in advance so that management will be available to accompany the inspector during the inspection and the necessary records will be available. The notion that this will result in pre-inspection fixing of problems in the inspected establishment may be countered with the argument that if the inspection serves to fix something that is wrong, it is worth it. After all, the sooner non-compliances and violations are corrected, the better.

The inspector should plan an opening meeting to get to know the management, explain the objective and scope of the inspection and the procedure to be followed, go over the relevant regulations, review existing records, discuss the quality and safety management system and ask pertinent questions. This should be followed by a walk-through to assess hazards and the associated controls and to observe the performance of and talk to members of staff and floor personnel. Finally, an exit meeting should allow an opportunity to go over non-compliance and violations, suggest solutions and agree on a time frame for corrections.

Box 2.3. Summary: Organization of the inspection.

- Notify establishment in advance (except for follow-up inspections).
- Consult the establishment's records.
- Prepare clothing, equipment, tools and official forms.
- Schedule an opening meeting.
- Conduct a walk-through (counter to product flow).
- Plan a closing meeting.

2.5. Authorization, rights and responsibilities

The inspector and assistants, if any, must be properly authorized to enter the facility and conduct the inspection. The inspector must produce official proof of his/her identity and affiliation and those of any assistants at the beginning of the inspection.

The establishment has the right to demand such identification, to be informed of the law and regulations empowering the inspector, and to ask questions and defend its procedures and practices. The establishment also has the responsibility to open the relevant records to the inspector and provide pertinent information upon the inspector's request.

Box 2.4. Summary: Authorization, rights and responsibilities.

- The inspector must be properly authorized to enter an establishment.
- The inspector (and any assistants or team members) must have official identification.
- The inspector must know the applicable laws and regulations (including any requirements related to the timing and duration of the inspection, and the length of advance notice required).
- The staff of the establishment have the right to ask questions.
- The establishment has the responsibility to provide pertinent records and information.

2.6. Prerequisite plan

The prerequisite plan consists of various aspects that some national legislative bodies group under "Good Hygienic Practices" (GHPs) and "Good Manufacturing Practices" (GMPs). Some of the main aspects covered under GHPs and GMPs include: 1) plant construction and equipment programme, i.e. the physical characteristics of the facility; 2) Standard Operating Procedures (SOPs), the established procedures for conducting specific processing operations; 3) Sanitary Standard Operating Procedures (SSOPs), the plant and equipment sanitation schedules and procedures; 4) pest control programme; 5) management review: the training received by management and the knowledge that managers have about food safety; 6) personnel hygiene; 7) training programme; 8) customer complaints and handling; 9) suppliers' specifications and control; 10) record keeping.

The inspection must cover all the above components with enough detail to enable a fair assessment of the adequacy of the prerequisite plan. A detailed description of the characteristics that would qualify as "adequate" in the prerequisite plan is given later in this manual. However, some general considerations regarding each of these components are provided in Box 2.5, as an introduction.

Box 2.5. Some general components and considerations of the prerequisite plan.

1) Plant construction and equipment programme

This component of the prerequisite plan addresses physical aspects of the primary production or food processing facility and their maintenance. It begins with the facility's surroundings, as these have a bearing on such environmental issues as air quality and presence of pests, and the general layout. Then it proceeds to building materials and structural characteristics, facility maintenance, design and materials of equipment and utensils – aspects that influence ease of cleaning and sanitation – maintenance and calibration schedules, and general operational status.

2) Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) describe how critical processing operations such as heating or cooling, instituted with the purpose of addressing a food-borne disease risk factor, are to be carried out.

3) Sanitary Standard Operating Procedures (SSOPs)

Sanitary Standard Operating Procedures (SSOPs) describe how, with what and how frequently the facility and equipment must be cleaned and sanitized, and how the effectiveness of cleaning and sanitizing will be ascertained.

4) Pest control programme

The pest control programme describes the measures taken to prevent pests from entering the establishment and premises, and the procedures followed periodically for controlling those pests that may have gained access. It must include a description of the training required of pest control operators.

5) Management review

The inspector must take note of the establishment's chain of command with regard to the actions specified in the procedures. The inspector also needs to learn what the responsibilities of each link in the management chain are and what every individual is authorized to do, so that the adequacy of each individual's training may be measured against his/her responsibilities. This knowledge facilitates the assessment by the inspector of the facility management's commitment to improving the safety and quality of the products.

6) Personnel hygiene

This aspect includes the facility's policy regarding sick workers, the employees' general appearance of cleanliness, the clothing they wear and the policy regarding hand washing. It also includes employees' facilities (toilets, hand washing stations, showers, locker rooms and eating areas).

7) Training programme

The inspector must take note of the facility's policy regarding training of management, staff, floor labourers and other employees and must examine the training records. These should include academic, on-the-job and continuing education training. The frequency and level of training for each step in the establishment's organizational structure should also be reviewed.

8) Customer complaints and handling

This aspect covers the establishment's policy concerning consumer complaints and follow-up. Records of such complaints should be available, as well as of the action taken to address them (including compensation when applicable).

9) Supplier specifications and control

Supplier specifications for all raw materials received by the primary operation or processing plant, including packaging materials, must be available. The specifications should address food-borne disease risk factors inherent to such materials. When relevant, evidence of supplier compliance with specifications, such as copies of certification and laboratory analyses, should be at hand.

10) Record keeping

The establishment must have implemented a system for keeping records of all actions taken to address identified risk factors for food-borne disease. These records should be kept at the establishment and be available during inspections. If records are required, local regulations may determine how long these records are to be kept readily available at the establishment before they can be archived (six months to three years is commonly required, depending on such parameters as product shelf-life and other considerations)[20].

Box 2.6. Summary: Prerequisite plan.

Covers aspects that some national legislative bodies group under Good Handling Practices and Good Manufacturing Practices:

- plant construction and equipment programme;
- Standard Operating Procedures (SOPs);
- Sanitary Standard Operating Procedures (SSOPs);
- pest control programme;
- management review;
- training programme;
- customer complaints and handling;
- supplier specifications and control;
- record keeping.

- The inspection must cover all of these components

2.7. Regulatory action plan

The regulatory action plan lists the regulations that the establishment must comply with[21]. It includes product and process standards (if the product is standardized), ingredient and packaging requirements (if any), including food additives, the controls that are implemented to ensure compliance with the standard, and the labelling requirements.

1) *Product and process standards*

As part of the regulatory action plan, the establishment must have at hand any standard(s) that are applicable to the processes used or products manufactured by the facility, provided such standards are mandatory. If there are such mandatory standards, the regulatory action plan must describe the controls that are in place to ensure compliance with the standard(s).

2) *Ingredients and packaging materials*

The regulatory action plan must describe the controls that are in place to ensure that all ingredients and packaging materials comply with regulatory requirements.

3) *Labelling*

The regulatory action plan also describes the controls that are in place to ensure that labelling of products (and codes and dates when required) complies with regulations,

[20] FAO/WHO. 2001. Codex Alimentarius. Food hygiene basic texts, 2nd edition. Joint FAO/WHO Food Standards Programme (available at: http://www.fao.org/docrep/005/Y1579E/Y1579E00.HTM).
[21] Example: Canadian Regulations, Chapter 3, Subject 4, QMP Reference Standard and Compliance Guidelines, Section 4. The Regulatory Action Points (RAP) Plan (available at: http://www.inspection.gc.ca/english/anima/fispoi/manman/fimmii/chap3su4e.shtml).

is truthful, legible and does not mislead consumers. Labelling should also allow product tracing by means of a code indicating batch or lot number and production date.

Box 2.7. Summary: Regulatory action plan.

- Covers mandatory product and process standards.
- The establishment's controls must comply with the standards.
- Specifications and controls for ingredients and packaging materials.
- Labelling.

2.8. HACCP plan, traceability and recall plan

1) HACCP plan

If the facility follows the HACCP system and has a HACCP plan in place, it should be available to the inspector. If a HACCP is in place, an audit will be undertaken, not an inspection.

2) Traceability and recall programme

The traceability and recall programme comprises all the techniques and procedures in place at the facility to (a) maintain records of incoming materials, indicating date, lot number, supplier, carrier, amount and condition, and (b) implement a recall programme that allows products to be traced to retail in case they need to be withdrawn from the marketplace. This requires coding of all products, keeping records of lot and/or batch numbers and keeping distribution records.

Box 2.8. Summary: HACCP plan, traceability and recall plan.

- Records of incoming materials.
- Traceable codes, labelling and records.
- Recall programme.

2.9. Inspection closing, reporting and documentation

Upon completion of the inspection, the inspector and the establishment's management should have a closing meeting to discuss any non-compliance findings (and in this case, to agree on a timetable for correction), discuss possible ways of improving the process, gather any missing information and answer the management's questions. For example, the inspector may point out that recent urbanization of areas surrounding the establishment has brought more traffic, dust and insect pests, and that if this trend continues, it will be necessary to install air conditioning throughout the plant or, at a minimum, in the final product packaging area to replace the current natural air flow. Therefore, the management should start thinking about this improvement.

The particulars of every inspection must be recorded in an appropriate form (see Annex 1 for an example of an inspection checklist and record form) and documented with copies of any pertinent documents the inspector deems necessary. Management must sign the original of the

form to signal having seen it and discussed its contents, and the original form must then be entered in the national food control system files for future reference. If corrective actions are scheduled, a copy of the inspection form should be kept separately in a "pending" file organized by month to ensure timely follow-up. Such follow-up may include an unannounced, limited inspection to ascertain that corrective actions agreed upon during the previous inspection have been implemented.

Box 2.9. Summary: Inspection closing, reporting and documentation.

- Conduct an inspection-closing meeting.
- Discuss non-compliance findings.
- Discuss ways of improving food safety and quality in the future.
- Record the observations and document them as needed.
- Have management sign the original and keep a copy of the inspection form.
- File the original of the inspection form with the food control authority.
- File a copy of the inspection form in a "pending" file if follow-up is necessary.
- Conduct an unannounced visit to ensure corrective actions have been taken.

3. General inspection approach for primary production facilities

3.1. Introduction

The importance of inspecting primary production facilities lies in the fact that food such as fresh produce is often consumed without any further processing. Therefore, there is no "kill step" to inactivate potential microbial pathogens contaminating these products before they reach the consumer. The massive outbreak of *E. coli* O157:H7 in 2006 caused by Californian spinach is an example of the potential risk posed by these products.[22] In addition, following the farm-to-table approach to food safety, risk factors that can be addressed at the farm should be so addressed. Operators who grow, handle, store and/or transport raw produce are responsible for the safety of the products under their control and should implement hygienic production practices and other available measures at all steps in their operation to reduce the risk posed by the identified hazards.

3.2. Objectives

In accordance with the stated goal of basing food inspections on risk, the objectives of inspecting primary production facilities such as fresh fruit or vegetable packing stations, or milk collection stations are listed below.

1. To ascertain that controls adequately address all identified food-borne disease risk factors associated with the establishment's product(s).
2. To examine possibilities for improving the systems that are in place and for progression to a HACCP-based process when appropriate.
3. To improve the quality and safety management system continuously.

3.3. Inspection approach

Inspection of primary food production facilities should follow the basic approach proposed in this manual: the inspection should be based on identified risk factors for food-borne disease. Moreover, the inspector should conduct the inspection in a spirit of partnership to foster continuous improvement of the controls in place that ensure food safety and quality.

Box 3.1. Summary: Inspection approach (primary production).

- Base inspection on risk factors.
- Foster continuous improvement of food safety and quality through partnership.

3.4. Preparing the inspection

The inspector should prepare for inspecting a primary production facility and organize the inspection in the same manner as he/she would do for inspecting a food processing plant. Pre-announcement of the inspection should be made and records of previous inspections should be retrieved and examined. Previous non-compliance and violations, in particular, should be noted for later checking during the inspection.

[22] FDA. 2006. FDA statement on food-borne *E. coli* O157:H7 outbreak in spinach. September 21 2006. United States Food and Drug Administration (US FDA) (available at: www.fda.gov/bbs/topics/NEWS/2006/NEW01460.html).

Preparation for the inspection must include selection of appropriate clothing, protective devices (if needed) such as coat, goggles, gloves and a hard hat, common tools such as a calibrated thermometer, calibrated pH meter and/or wide-range pH paper, flashlight, sterile tongs, spatulas, tweezers, sterile bags, cooler, ice or dry ice, labels, marker and sampling devices, if needed. In accordance with the principle of setting an example, the inspector should not conduct an inspection while suffering from any disease that could be transmitted during a food inspection.

An opening meeting with the manager or supervisor should be scheduled. The inspector should be prepared and willing to answer questions about the laws and regulations empowering him/her and to present the required identification and proof of official affiliation.

Box 3.2. Summary: Inspection preparation (primary production).

- Foster partnership with the operator.
- Prepare for the inspection.
- Announce the inspection.
- Schedule an opening meeting.
- Examine establishment inspection records.

3.5. Initiating the inspection

The inspector should be punctual and presentable. The inspection should begin with the inspector's identifying himself/herself and showing his/her official identification.

During the opening meeting, introductions should be made and the objectives of the inspection should be clearly stated. An outline of the scope and procedure of the inspection and the philosophy behind the inspection should be communicated to the manager in a friendly manner and his/her collaboration should be requested.

Box 3.3. Summary: Initiating the inspection (primary production).

- Identify yourself and your team.
- State the objectives of the inspection.
- Sign facility register.
- Outline the inspection procedure.
- Request management collaboration.

3.6. General process flow

It is very useful to have a sketch of the process flow at the beginning of any inspection. If the process flow chart is not available, the inspector should prepare one in collaboration with the manager or supervisor during the opening meeting. This sketch consists of a graphic depiction of all major operations that the product undergoes within the facility. A brief glance at the various stages should give the inspector initial guidance concerning specific operations that may be critical for product safety (e.g. washing, cooling). Operators must be able to describe in detail all the steps performed, identify the steps critical to food safety and point out the measures that have been taken to control the identified food-borne disease risk factors.

Box 3.4. Summary: General process flow (primary production).

- Obtain or prepare a process flow chart.
- Use the flow chart to anticipate critical steps in ensuring product safety.

3.7. Walk-through inspection

In all walk-through inspections of food handling or processing facilities, and as a matter of principle, the inspector should begin at the finished product and proceed counter-flow, because the inspector must not become another potential vector of cross-contamination by moving from raw to finished product areas. The various aspects that the inspection must cover are presented below in concordance with the direction of the inspection (i.e. opposite to product flow).

The inspector should be accompanied by the manager or supervisor during the walk through. This allows questions to be asked as the inspector observes the process, thus facilitating thoroughness, reducing the amount of notes to be taken and cutting down the number of items to be dealt with later during the closing meeting. The inspector should feel free to question floor personnel about how they perform specific operations and tasks and to measure their level of awareness about the impact of what they do on the safety of the product. The inspector should also use the walk-through inspection to observe how the personnel go about their tasks, particularly with regard to hygiene practices.

Box 3.5. Summary: Walk-through inspection (primary production).

- Walk through from the end product to the start of the process.
- Be accompanied by the manager or supervisor.
- Question floor personnel.
- Concentrate on addressing food-borne disease risk factors.

The following is a list of general checkpoints for a walk-through inspection. It is important to note that it is for guidance only, and the actual requirements should be appropriate for the risks associated with the specific food items produced.

1) Facility assessment

a. Premises

The premises are the building(s) and the surrounding area. Premises should be kept clean and free of weeds, dust and materials that could harbour pests and/or contribute to product contamination, and be properly designed and maintained.

Floors, walls and other surfaces should be smooth, free of cracks or peeling paint and amenable to cleaning and sanitizing. Floors in wet areas should be impermeable to water and adequately drained. Roofs and/or ceilings should be designed and maintained in such a way as not to contribute to product contamination.

b. Equipment

The design and material of equipment that comes in direct contact with the product must be such that the equipment does not contribute to product contamination and allows adequate cleaning and sanitizing.

An equipment maintenance plan and implementation records must be available and must include calibration of instruments (e.g. thermometers) and controls. Equipment cleaning and sanitizing procedures and a schedule based on the characteristics, function and potential of the equipment for contaminating the product must be available and be implemented by trained personnel.

c. Ventilation

Natural or mechanical ventilation should keep the ambient temperature cool and not contribute to product contamination by dust, aerosols, odours or condensation. Air must not flow from contaminated areas to final product areas.

d. Water

Water that comes into contact with the product and equipment must be potable. Documented proof that such water is potable must be at hand (i.e. a certificate of analysis from a recognized laboratory), especially when the water comes from a well or other private source. A schedule should be in place to monitor water quality and a contingency plan should exist in case the water is found to not be potable.

If the washing process requires disinfection with chlorine, there should be a clear procedure for monitoring the level of chlorine in the wash water periodically and replenishing it to within target range. This procedure should be performed by a trained individual.

e. Maintenance, sanitation and pest control

Premises, facilities and equipment must be adequately maintained to prevent contamination of the product. A schedule and procedure for cleaning and sanitizing the facility by properly trained personnel must be in place. Cleaning and sanitizing chemicals must be approved by the food authority and stored separately from the product.

Solid waste must not be allowed to accumulate inside the premises and must be appropriately contained and regularly disposed of. Liquid waste must be disposed of in accordance with environmental regulations and local ordinances.

Pests and other animals must be prevented from entering the facility. Practices that promote proliferation of pests, for example accumulation of materials or waste inside and around the facility, should be avoided and a pest control programme must be in place and be implemented.

f. Personnel facilities and hygiene

The facility must include toilets, which must be kept clean, and hand washing station(s) that do not open directly to food handling areas. There must be a separate eating area or room for personnel, changing rooms and showers.

The personnel must wear appropriate, clean clothing and protective gear and refrain from eating, drinking or smoking within the facility. Hand washing must be required after using the toilet, touching floors, contaminated surfaces or materials, and upon re-entering the facility.

2) Monitoring and record keeping

Depending on national regulations, records may be required for the following:

- personnel health certificates;
- sources of incoming material;
- raw product received (including monitoring analyses of such contaminants as pesticide residues and microbial contaminants);
- water analyses;
- cleaning and sanitation checks;
- pest control;
- control point monitoring (e.g. temperature charts from cool rooms);
- maintenance reports (including calibration of equipment and instruments);
- finished product records;
- distribution records;
- training records;
- records of any deviation from the establishment's quality and safety management system plan, and the corrective action taken.

3) Training

Training of management, supervisory staff and labourers should be provided on farm or on the premises to ensure that everyone has the knowledge necessary to produce safe products. Initial training should be followed by periodic refresher training to maintain the level of proficiency. The staff must be aware of the importance of complying with the establishment's quality and safety management system and the potential consequences of failure to do so for the well-being of consumers and for the company. They must be willing to conduct themselves in ways that ensure food safety and quality.

Training must include issues of hygiene in addition to technical aspects. A system for measuring the efficacy of training and for reviewing training methods and materials accordingly should also be in place.

4) Production and harvesting practices and raw product transportation

Primary production facilities should require, or at a minimum encourage, suppliers to undergo training in and to apply good agricultural practices (GAPs) and/or good

animal husbandry practices (GAHPs) as applicable. In all cases, action must be required from suppliers with regard to the following:

- irrigation water quality, to ensure that it is free from pathogenic micro-organisms and chemical contaminants;
- keeping animals out of produce fields and orchards;
- providing toilet facilities for field labourers and requiring hand washing;
- exclusion of sick workers from activities that involve contact with food or food contact surfaces;
- applying only approved pesticides and observing recommended preharvest withdrawal periods;
- transporting raw produce in ways that do not result in contamination or damage.

5) *Packaging and labelling*

Packaging at primary production facilities is usually in bulk. Boxes or crates should be new, or sanitized if reused. Cans or bags should be new and/or clean.

Labelling must comply with legal requirements and regulations and client specifications. In all cases, labels must clearly identify the product and must bear the producer's name and address and a code indicating the date of production and lot number (and supplier number for traceability if possible).

6) *Storage and transportation of the finished product*

Finished products should be stored in ways that prevent contamination: avoid excess moisture, contact with floors, dust, and contact with or proximity to raw product. Refrigerated storage may be necessary, in which case temperature control will be essential.

Transportation of the finished product should be performed in ways that prevent recontamination of the product through exposure to insects, dust, fumes or leftover contaminants from such previous cargoes as raw meat or fish. Transport vehicles must be clean and fit to contain and protect the product appropriately, and not be used for transporting refuse, substances that are toxic or animals.

7) *Corrective action and recalls*

The business should have designated corrective actions in the event of a system failure. Records of any such failures and corrective actions subsequently taken must be available.

In addition, there must be a plan for implementing recalls; this emphasizes the importance of appropriate product coding and of keeping distribution records. The recall plan must include procedures for disposing of recalled products.

3.8. Closing meeting

Upon completion of the walk through, the inspector should hold a closing meeting with the management to discuss the positive and negative findings, emphasizing any non-compliance

or violation detected. It is important to explain the associated food safety implications of any non-compliance, as this will improve the managers' understanding of food safety and will also assist in the implementation of the necessary controls.

Some relevant positive findings should be mentioned. Depending on the situation, the inspector can start with the discussion and explanation of the positive findings. Relevant positive aspects should also be included in the written report.

A timeline for correcting non-compliances and violations should be agreed upon (it is up to the food control authority to demand immediate cessation of violations). The inspector should complete and sign the report, have the management sign it and provide the management with a copy of the report.

The closing meeting should also be used to foster the partnership between inspector and inspected by discussing possible improvements to the process if any are possible and feasible. This is where the inspector's training and experience play a central role in improving the establishment's quality and safety management system in particular.

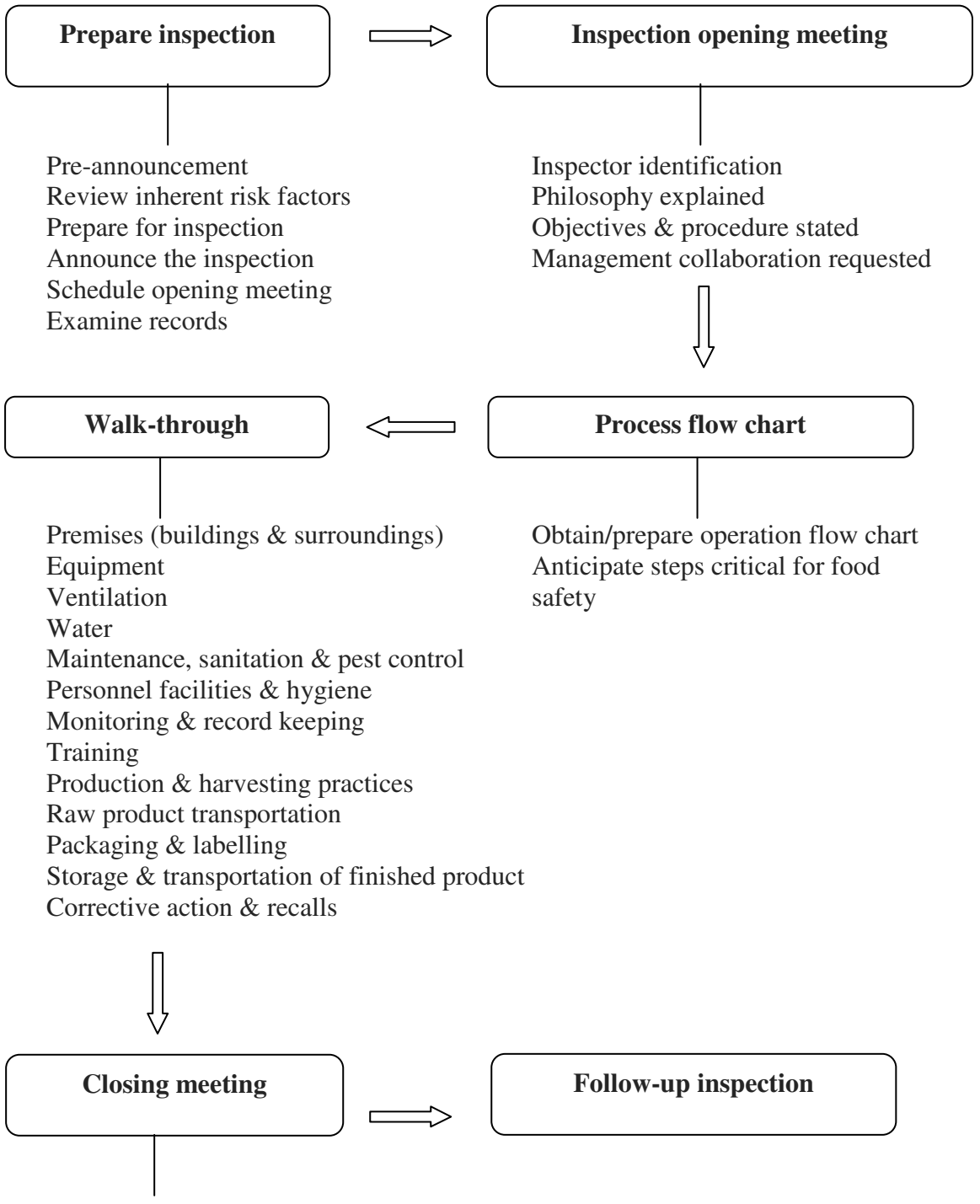
The inspector should file the report upon returning to his/her office. If non-compliances or violations were noted and a timeline for correction was agreed upon, a copy of the report should be kept in the appropriate folder in a "pending" file to facilitate follow-up. A follow-up inspection (unannounced) should then be scheduled for verification of corrections.

Box 3.6. Summary: Closing meeting

- Discuss findings, especially non-compliances and violations.
- Explain the food safety implications of any non-compliances.
- Mention and report some relevant positive findings.
- Establish a timeline for correction of violations.
- Discuss possible improvements to the quality and safety management system.
- Sign the report and give copies to management.
- File the report.
- Schedule follow-up inspection if needed.

Figure 1 presents a schematic summary of the procedures and considerations involved in conducting inspections of primary production facilities.

Figure 1. Inspection of a primary production facility.



4. General inspection approach for food processing facilities

4.1. Introduction

Unlike primary production facilities, food processing plants perform operations that go well beyond mere sorting, cleaning, washing and packaging of fruit or vegetables, or cooling milk. Processing operations consist of physical, chemical or microbiological treatments of foods that effect changes in their characteristics. Some of the processes applied to foods are designed to preserve them, e.g. heating, cooling, drying, pH alterations, water activity modification, whereas others are only cosmetic, e.g. shaping, colouring, or applied with the purpose of changing sensory properties, e.g. texture, appearance, odour or taste.

Of all processes applied to foods, the most critical ones from the standpoint of safety are those meant to result in inactivation (e.g. "kill steps") or growth inhibition of pathogenic micro-organisms. These processes must receive special attention from inspectors because foods thus treated are commonly considered "safe" and ready to eat by even the most food safety-conscious customers.

4.2. Objectives

In accordance with the stated goal of basing food inspections on risk, the objectives of inspecting food processing facilities are the following.

1. To assess the adequacy and effectiveness of the facility's controls for addressing all the food-borne disease risk factors identified for the product or products handled therein.
2. To examine possibilities for improving the systems that are in place and for progression to a HACCP-based process when appropriate.
3. To improve the quality and safety management system continuously.

4.3. Scope of inspection

The inspection of food processing facilities covers the entire process, that is, the set of procedures for active managerial control of food-borne disease risk factors that have been established by the food processor to help ensure the safety of the food products.

4.4. Organization of the inspection

1) Inspection approach

Inspection of food processing facilities should follow the basic approach proposed in this manual: risk-based inspection of identified risk factors for food-borne disease. However, unlike primary production facilities where operations are usually basic and straightforward, food processing plants often perform a number of complex operations on the same product; this makes it harder to identify risk factors and critical steps. In addition, food processing facilities usually handle more than one product or type of product, thus making the inspector's task all the more difficult. The inspector may wish to review, ahead of the inspection, the most common operations conducted by the type of facility to be inspected and the risk factors associated with them and the product(s).

Moreover, the inspector should conduct the inspection in a spirit of partnership to foster continuous improvement of the quality and safety management system.

Box 4.1. Summary: Inspection approach (food processing facilities).

- Review risk factors ahead of inspection.
- Perform risk-based inspection of risk factors.
- Make recommendations for improving the systems that are in place and progression to a HACCP-based process when appropriate.

2) Inspection scheduling

Similar to inspections of primary production facilities, inspection of food processing establishments should be announced and an appointment should be made with the management. The inspector is reminded that the purpose of the inspection is not to surprise the operator, and that failure to schedule the inspection may result in not having the collaboration of the management during the inspection. Lack of collaboration would defeat one of the objectives of the inspection: to develop a partnership with the establishment with the goal of improving the quality and safety management system, and in so doing, to advance food safety.

Scheduling of inspections should be undertaken on the basis of establishment characterization and history of compliance. On that basis, establishments processing high-risk foods or having a history of non-compliance or violations should receive more attention and closer scrutiny than those handling more stable products, and facilities that have been historically compliant. A good history of compliance, therefore, must be seen as a demonstration by an establishment of commitment to food safety and quality.

Box 4.2. Summary: Inspection scheduling (food processing facilities).

- Schedule inspection with the facility.
- Use risk-based categorization of establishments to determine frequency of inspections.

3) *Response to consumer and trade complaints*

If the inspection is being conducted in response to consumer or trade complaints or because the food control authority has become aware of non-compliance by the processing plant, the inspection should be conducted with a sense of urgency and not be pre-announced. Under these circumstances, pre-announcement would make it hard or impossible to verify the veracity of the complaint and that, in turn, could pre-empt fair compensation to customers or third parties. Thus, this approach is based on fairness (the consumer's right to safe food) and assignment of responsibilities (the operator must provide safe food).

Box 4.3. Summary: Response to consumer and trade complaints (food processing facilities).

- If responding to complaints or suspected non-compliance violations, do not announce inspections.

4) General preparation

Preparation for the inspection must include selection of appropriate clothing, protective devices (if needed) such as coat, goggles, gloves and a hard hat, and common tools such as a calibrated thermometer, calibrated pH meter and/or wide-range pH paper, flashlight, sterile tongs, spatulas, tweezers, sterile bags, cooler, ice or dry ice, labels, marker, and sampling devices (if needed). A review of the products manufactured by the facility before the inspection is essential to determine what items should be sampled, and thus to select the right sampling tools and materials to take along, and to prepare a list of additives and packaging materials approved for these products.

It is always useful to have to hand a copy of the applicable regulations in case on-site consultation becomes necessary. The inspector must also have the required form(s) and note-taking materials.

It may also be useful to determine beforehand the exact address of the facility and the optimal route to access it. Sufficient time should be allowed for reaching the facility on time. Punctuality must be observed and sufficient time must be allocated to conduct the inspection properly. The inspector must not allow time limits to be imposed on the performance of his/her task. In keeping with the principle of always setting an example, the inspector must not conduct an inspection while suffering from any contagious disease.

Box 4.4. Summary: General preparation (food processing facilities).

- Allocate sufficient time.
- Dress appropriately.
- Select protective devices, inspection tools and materials.
- Bring copies of regulations and applicable forms.
- Be punctual.

5) Opening meeting

An opening meeting with the manager or supervisor must be scheduled as part of the inspection. At this opening meeting, the inspector should be prepared and willing to answer questions about the laws and regulations empowering him/her, and other relevant questions the management may have. The inspector should be presentable and polite and identify himself/herself and his/her assistant(s), if any, by showing official identification and proof of affiliation whenever they are necessary.

During the opening meeting, the inspector must mention the need to ask questions of employees in the plant and the confidentiality of the inspection and all records and documents involved. The applicable standards and codes or other regulations on which

the inspection will be based should also be mentioned and room for the inspector and his/her assistant(s), if any, to meet and work on the report should be requested.

The objectives of the inspection should be clearly stated. An outline of the scope and procedure of the inspection and the philosophy underlying the inspection should be communicated to the manager in a friendly manner to promote good will, and his/her collaboration should be requested.

Box 4.5. Summary: Opening meeting (food processing facilities).

- Schedule opening meeting.
- Open meeting with introductions and identification.
- Sign establishment register as needed.
- State inspection objectives, scope and outline.
- Assure management of confidentiality.
- Ensure management collaboration in improving the food safety and quality.

6) *Closing meeting*

A closing meeting should be held with the management of the processing plant to discuss the findings, and attendance by all concerned should be encouraged.

Some relevant positive findings should be mentioned. Depending on the situation, the inspector may start with the discussion and explanation of the positive findings. Relevant positive aspects should also be included in the written report.

The closing meeting should emphasize any non-compliance or violations detected and the associated food safety implications. If there is any non-compliance or violation, a corrective action plan must be agreed upon that specifies the correction(s) to be made and an appropriate timeline for completing the correction(s). The corrective action plan must be written into the inspection report.

The closing meeting should also be used to foster the partnership between inspector and inspected by discussing possible improvements to the process. This is where the inspector's training and experience play a central role in improving the safety system. If improvements are agreed upon, they should be included in the inspection report for future reference.

The inspector should then complete the inspection report, including in it the corrective plan if any corrective action is to be taken by the establishment, ask the management to sign the report and provide the management with a copy.

The inspector must file the report upon returning to his/her office. If non-compliances or violations were noted and a corrective action plan with a timeline for correction was agreed upon, a copy of the report should be filed in the appropriate folder in a "pending" file organized by month to facilitate follow up. A follow-up inspection (unannounced) must be scheduled for verification of corrective action.

Box 4.6. Checklist for closing meeting (food processing facilities).

- Hold inspection closing meeting.
- Mention and report some relevant positive findings.
- Discuss non-compliance violations and the associated food safety implications, and agree on a corrective action plan.
- Discuss possible system improvements.
- Sign the report, give copies to management and file with food control authority records.
- Schedule follow-up inspection to verify corrections.

7) Inspection techniques

Inspection of the facility usually entails the application of several techniques, including the following:

a. Observation

The inspector must observe the processes and procedures carried out at the facility, paying particular attention to those that may adversely affect product safety, to ensure that they are done correctly.

b. Inspection

Inspection may require actual handling of product(s) to determine such sensory characteristics of the products as odour (e.g. fresh fish). It may also consist of activities such as checking the cleanliness of equipment and food contact surfaces and taking note of the temperature indicated by thermometers or charts. The inspector must perform these inspections with carefully washed hands (which can be used as a means of reinforcing the message of good personal hygiene) or using disposable gloves, if necessary, and ensuring that he/she does not become a source of contamination. At no time should any cleaning products or chemicals be smelled directly.

c. Measuring

Measuring goes a step further than simple inspection in that the inspector uses an instrument to determine such parameters as temperature (e.g. of cold rooms or the product), pH, weight, time (e.g. the time for which a product is subject to cooking to achieve a predefined internal temperature), or the chlorination strength of wash water. The purpose of measuring during the inspection is to ascertain whether the facility's control instruments are working properly. Note that the inspector's instruments must be periodically calibrated against a traceable standard to serve this purpose.

d. Sampling and testing

The inspector may take samples for testing on site or later testing at a laboratory. Sampling must be done using aseptic techniques and adequate sampling plans. Samples must be handled in ways that ensure that the product is not adversely

affected by time, temperature and the mode of transportation to the laboratory and testing must be performed using standard methods.

e. Questioning

The inspector should feel free to talk to facility operators during the inspection and question them about the procedures they follow when performing their tasks. The inspector should have advised the management during the opening meeting about his/her intention to talk to operators and emphasized that this would be done in the least disruptive manner.

f. Record review

Reviewing the facility's records is a very important part of the overall inspection process. It begins ahead of the actual inspection with the review of previous inspection reports, and continues during the inspection. The inspector must review such records as personnel health certificates and training certificates, laboratory results/certificates covering inputs and products, records of system failures and corrective action taken, distribution records and any other relevant records. A checklist may be used to facilitate the recording process (Annex 2).

Box 4.7. Summary: Inspection techniques (food processing facilities).

- Use inspection techniques as needed: observation, inspection, measuring, testing, questioning.
- Use accepted sampling techniques and testing methods.
- Review all relevant records prior to and during the inspection.

8) Inspection equipment

a. Protective clothing

Depending on the type of facility to be inspected, the inspector must wear protective clothing such as a coat (white is preferable). The inspector must always set an example of cleanliness by wearing clean and well-kept clothing. It might be necessary to wear a hard hat in some types or areas of food processing plants. A hair net should always be worn when inspecting ready-to-eat and other finished product areas. Hard and/or disposable gloves may also be necessary; disposable gloves must always be worn if the inspector handles the product in any way. Note that some establishments require inspectors to wear the protective clothing provided on site.

b. Tools and instruments

The inspector must select, prepare and take to an inspection an appropriate set of tools and instruments. Some useful tools to take along are a flashlight, tongs, spatulas, tweezers, cotton swabs, metal-tipped thermometer, scalpel, scissors, timer, ruler, pH strips (low and high range) and chlorine strips. Tools should be sterilized before the inspection if they are to be used in sampling for microbiological tests, or be adequately washed and sanitized in all other cases.

c. Sampling and sealing equipment

The inspector must bring along all necessary tools and materials for adequately taking and preserving samples, keeping in mind that sample taking is part of product quality and safety for verification of the effectiveness of the inspection procedures. Tools for microbiological sampling, e.g. scalpel, tweezers, tongs, spatulas, syringes, test tubes, pipettes, cotton swabs and gauze, must be sterile. Other sampling tools and materials, such as borers, insertion tubes, sealable bags, sealing tape and an insulated ice box containing ice or dry ice to transport perishable samples, are often necessary. If the samples may be used for potential enforcement action, tamper-proof seals should also be taken. Selection of tools and materials to take along is performed during the inspection planning stage. Having the right tools and materials and using aseptic sampling techniques conveys an image of professionalism and generates additional respect for the inspector.

d. Photographic equipment and techniques

Documenting non-compliance and violations photographically can be very important as proof, as well as being helpful for follow-up inspection to verify that corrective action was taken. Photographs – particularly those taken using digital cameras that allow instant review – can also be useful for discussing potential improvements to the system during the closing meeting. Digital cameras also allow electronic sharing of pictures with the facility's management for use in discussing corrective action, and with the inspector's higher authorities for enforcement purposes.

Box 4.8. Summary: Inspection equipment (food processing facilities).

- Set an example by wearing clean and appropriate clothing, having the right equipment, tools and materials and using proper techniques.
- Document violations or possible system improvement ideas photographically if possible.
- Use proper sampling techniques and preserve samples correctly for transportation to the laboratory.

4.5. General process flow

1) Product list, production lines and flow diagrams

The inspector must request a complete product list. If the processing facility has more than one processing line, the inspector should ask the management to indicate which products correspond to each line prior to the walk-through inspection.

A process flow diagram for each product should be at hand prior to initiating the walk-through inspection. The process flow chart is an integral part of the establishment's quality and safety management system. However, if one is not available, the inspector should prepare one in collaboration with the manager or supervisor during the opening meeting. The process flow diagram consists of a graphic depiction of all major operations that each product undergoes within the facility.

Box 4.9. Summary: Product list, production lines and flow diagrams (food processing facilities).

- Obtain or prepare a process flow chart.
- Use the flow chart to anticipate critical steps in ensuring product safety.

2) Critical control points (CCPs)

A quick glance at the various processing operations should give the inspector guidance concerning specific points that may be critical for product safety (e.g. washing, heating and cooling) and on which his/her attention should focus. Critical control points are those where a control measure can be implemented to prevent, eliminate or reduce to an acceptable level any of the food-borne disease risk factors earlier identified for each particular product. The food processor must be able to describe in detail all the operations performed on his/her products, identify the operations that are critical to ensure product safety and point out the measures that have been taken to control the identified risk factors for food-borne disease.

If the processing facility operates under a HACCP system, the CCPs are an integral part of the plan. If not, the inspector must ascertain that the plant management, supervisory personnel and floor operators are aware of the food-borne illness risk factors inherent to each product and of the critical measure(s) necessary to control them, and that such measure(s) are being implemented.

Examples of CCPs are the time and temperature necessary to pasteurize milk (71.5 °C/15 seconds or equivalent), the concentration of chlorine in wash water needed to inactivate *Salmonella* spp. on the rind of cantaloupe melons (≥200 ppm) or the recommended internal temperature to ensure inactivation of *E. coli* O157:H7 in hamburger patties (71.1 °C or 160 °F).

Box 4.10. Summary: Critical control points (food processing facilities).

- Determine operations critical to product safety.
- Determine whether plant personnel are aware of risk factors inherent to each product and operation.
- Determine that control measures for each risk factor are in place.

3) Critical limit(s) per CCP

To be effective, most measures designed to control food-borne disease risk factors at a CCP must be applied at a predetermined level or value or within a range. For example, the temperature necessary to ensure milk pasteurization is 71.5 °C for a minimum of 15 seconds. Lower temperatures and longer times are also effective, as are higher temperatures and shorter times. These levels or values are the critical limits. For pasteurization, a certain time/temperature relationship is required and therefore both parameters must be controlled. However, the critical limit may be a single value, such as pH <4.8 to control growth of, and enterotoxin A production by, *Staphylococcus aureus* during the manufacture of fermented sausages.

The inspector should determine whether controls implemented at CCPs are working properly and are being correctly applied. For example, if the control involves temperature, the inspector should verify if the specified temperature will control the food safety hazard and check the internal temperature of the product using his/her own, duly calibrated, thermometer. If the critical limits are not being observed, corrective actions should be implemented and the results of the changes verified.

Box 4.11. Summary: Critical limit(s) per CCP (food processing facilities).

- Ascertain that the critical limits being used are appropriate.
- Determine that the critical limits are being observed.
- Determine that corrective actions are in place in case the critical limits are not reached.

4) Process validation

The inspector must review the facility's records of tests conducted to verify that the controls in place are effective. These records must be substantiated by analytical results.

Box 4.12. Summary: Process validation (food processing facilities).

- Verify that controls in CCPs meet the requirements of the quality and safety management system.

5) CCP control records

The inspector must review any records kept for each control measure implemented at each CCP. These could be hand-written records of temperatures taken periodically, for example, or automatically recorded temperature charts. The absence of such records should indicate to the inspector that there might not be adequate monitoring of the control measure.

Box 4.13. Summary: CCP control records (food processing facilities).

- Review CCP control records.

4.6. Counter-flow walk-through inspection

The walk through is a very important part of the inspection and the items to be checked by the inspector are numerous. The walk through should be conducted in a direction opposite to the flow of product so that the inspector will not become a potential source of cross-contamination by moving from raw to finished product areas. Care should be taken by the inspector to avoid being injured by equipment, conveyors, hooks and other hazards. The walk-through inspection should be timed to allow the inspector a complete view of the facility's processes, taking into account that certain operations such as reception of raw materials may take place only at certain times. Before initiating the walk through, the inspector must take any necessary measures to ensure that he/she will not bring contaminants into the processing plant. To that end, he/she should wash his/her hands, put on a laboratory

coat, a hair net and hard hat if necessary, and consider the need to change footwear (e.g. to sanitized rubber boots).

In addition to specific aspects of the facility and processes that the inspector must pay attention to as he/she performs the walk-through inspection, there are various physical characteristics of food processing facilities that the inspector must keep in mind throughout the entire inspection. The state of walls, floors, ceilings and doors and air quality are examples of these factors.

The following is a list of general checkpoints for a walk-through inspection. It is important to note that it is for guidance only and the actual requirements should be appropriate for the risks associated with the specific food items produced.

1) *Facility assessment*

a. Plant surfaces

Walls and floors should be made of impermeable, smooth materials (e.g. polished cement), free of cracks or peeling paint. Walls should taper over the floor creating a concave joint to minimize accumulation of dirt and residues.

b. Plant ceilings

The inspector should ensure that packaging and finished product areas have ceilings that prevent dust fallout on to the product and insect access.

c. Plant doors

Doors should be in good condition, have appropriate width and height for the particular area and use, and have self-closing mechanisms.

d. Plant windows

Windows should have insect screens. Window sills should incline towards the outside to minimize dust and rain water collection and entry.

e. Lighting

Food processing areas must be lit naturally and/or artificially in ways that allow operators of equipment and other employees to see clearly what they are doing without straining their eyesight or being exposed to bodily hazards.

f. Ambient temperature

The temperature inside the processing plant should be regulated naturally or artificially to provide a pleasant working environment and protect the product. Areas for handling perishable products must be air-conditioned.

g. Air quality

Air within the processing facility must be clean and as free of dust and moisture as possible. Air circulation can be natural or mechanical. The inspector must ensure that air from raw material handling areas is not circulated into finished product areas.

h. Water and ice

Processing water and water for cleaning and sanitizing equipment and floors must be potable. The inspector must review laboratory reports of the quality of the facility's water and may want to take samples for verification. The facility should have enough ice producing capacity to fulfil its needs. Because ice is a common source of product contamination, it must be produced using potable water. As with water, the inspector may want to take samples of ice for analysis.

i. Steam

Steam production capacity and pressure should be adequate for the processing and cleaning needs.

j. Drainage and sewage systems

All food processing areas must be adequately drained to prevent stagnation of water on floors, which may be a source of product contamination as well as hazardous to personnel. Drains must be equipped with covers and traps to collect solid materials that could clog them and siphons to prevent gas backup. Drain covers and traps must be cleaned periodically. The inspector must ascertain that sewage disposal complies with national and local environmental regulations and does not contribute to contamination of the facility or its surroundings in ways that may affect product safety.

k. Waste disposal

In-plant waste disposal must be conducted using appropriate containers that can be thoroughly washed and sanitized. These containers must be emptied as often as necessary and must not become a source of cross-contamination within the plant during the emptying and return process. Waste disposal facilities outside the processing plant must be hygienic, not constitute a habitat for or attract animals or insects and not be a source of foul odours. Waste receptacles must be emptied as often as necessary to prevent overflow.

Box 4.14. Summary: Facility assessment (food processing facilities).

- Check walls, floors and other surfaces for cracks and peeling paint.
- Check walls and floors (smooth, no cracks), including coved floor/wall joints.
- Check that ceilings effectively prevent dust fallout and insect entry.
- Check that doors are self closing and windows have screens.
- Check that there are no gaps under doors or holes in walls etc. that could allow the ingress of pests.
- Check that the illumination is appropriate, the temperature is pleasant or sufficiently low if needed and the air is free of moisture and dust.

- Ensure that air is not circulated from raw to finished product areas.
- Ensure that water is potable and ice is made from potable water.
- Check effectiveness of drains and cleanliness of covers and traps.

2) Product assessment

When conducting the walk-through inspection counter to product flow, the inspector will first come upon the finished product area. Some of the aspects to consider at this stage are the following:

a. Product storage (dry storage, refrigerated storage)

The inspector should examine product dry storage areas for evidence of moisture and pests. If the product requires refrigeration or freezing, the inspector should take note of the temperature of cold rooms or freezers indicated by thermometers and/or temperature charts. Always confirm that first-in first-out procedures are routinely followed for product movement.

b. Product loading and transportation

Loading of product into transport vehicles should be done in ways that protect the product from damage due to exposure to sunlight, rain, dust, insects or other adverse factors. Products in need of refrigeration or freezing should not be left out in the open at ambient temperatures for prolonged periods of time, as this can cause a risk to consumers and/or loss of other product quality attributes.

The inspector must examine the conditions of vehicles used for transportation. Food transport vehicles should not be used for purposes such as transport of hazardous substances, live animals or waste materials, or other uses that may contribute to product contamination. Cargo holds should be clean and appropriate to protect the product from contamination during transport, including refrigeration if necessary.

c. Product labelling, code identification and distribution records

The inspector should ascertain that products are labelled according to legal requirements. Labels should adequately and accurately describe the product, the manufacturer, list the ingredients, net weight and expiration date if needed, and provide any storage and use indications that customers may need to ensure the safety of the product.

Distribution records should be available for the inspector to see, to provide proof that a recall would be possible if it became necessary.

d. Package closure and code

The inspector must examine package closures for integrity and product protection against tampering. Packages should contain a code indicating batch or product lot and manufacturing date.

e. Product sampling for testing

Samples may be taken before or during the inspection for on-site or laboratory testing. The inspector should have planned during the inspection preparation phase which items to sample and prepared sampling tools and materials accordingly.

Box 4.15. Summary: Product assessment (food processing facilities).

- Examine dry product storage areas for moisture and pests.
- Check temperatures in refrigerated and frozen storage areas.
- Check that first-in first-out procedures are in place for the product.
- Observe loading procedure and transportation vehicles:
  - loading must not damage or contaminate the product;
  - transportation vehicles must protect the product and not contribute to contamination.
- Check product labelling for compliance with regulations and consumer protection against tampering and fraud.
- Ensure labels enable recalls.
- Examine product distribution records.

3) Manufacturing equipment assessment

a. Design

Equipment must be designed in ways that allow thorough cleaning and sanitizing and installed in such a way that there are no areas where product or other matter can accumulate. Equipment design must also protect moving products from being contaminated by dripping condensation, lubricants, fumes or other extraneous substances.

b. Materials

Equipment should be made of materials that are resistant to scratching and corrosion and allow thorough cleaning and sanitizing. Stainless steel is optimal for food contact surfaces but other materials may also prove adequate. The inspector should discourage the use of breakable plastics, glass or wood on food processing equipment.

c. Maintenance

The equipment should be kept in good state of repair. The inspector should ask about the equipment maintenance programme. Unused or faulty equipment should not remain in the processing area.

d. Calibration

The inspector must ask about the calibration programme for controls that are critical for the safety of the food produced. Particular attention must be paid to thermometers, automatic valves and scales.

e. Product residue

There should be no accumulation of product residue on equipment that may allow microbial growth and contamination of moving products. Spots on the equipment where residues accumulate must be eliminated.

f. Filters

Filters are notorious for residue accumulation. Periodic cleaning of filters during processing may be necessary to ensure proper filtration and reduce clogging with materials that may contribute to product contamination.

g. Lubricants

All lubricants used in and on food processing equipment must be approved for such use. The inspector must check for potential dripping or rubbing of lubricants on the product.

h. Condensation

Dripping of condensation is a major source of product contamination in food processing. There must be no pipes suspended over product conveyors or directly above other product handling areas, particularly if these pipes transport cold water.

i. Splashing

Care must be taken to avoid splashing of liquids, including water and wash water, from sinks or other equipment on to the product. Sinks must be physically separated with splash guards from conveyors or other product handling or moving areas.

j. Hand washing facilities

The inspector must ensure that hand washing facilities are available and appropriately distributed throughout the facility. Location of hand washing stations such that the supervisor can see operators using them upon returning from toilets and after re-entering the processing area from other areas is helpful in ensuring proper hand washing.

Box 4.16. Summary: Manufacturing equipment assessment (food processing facilities).

- Check that equipment design and materials allow proper cleaning and sanitizing.
- Check maintenance and calibration programmes.
- Ensure that lubricants are approved for food processing use and do not contaminate the product.
- Ensure that condensation and splashing are prevented.
- Observe proper location and use of hand washing stations.

4) Employees and staff assessment

a. Health status

The inspector must examine employee and staff health records and certificates during the opening or closing meetings and ask about the facility's policy regarding sick employees. Employees and staff suffering from communicable diseases – particularly enteric diseases – and open sores must not be allowed to report to work where they come in contact with food or food surfaces until free of symptoms[23]. To encourage disclosure of such conditions, management should be encouraged to establish a system of compensation for sick employees.

b. Personal hygiene and sanitation practices

The inspector should ask about the facility's policy regarding personal cleanliness. Employees must be required to wash their hands after using the toilet and upon re-entering the processing area. Soap (in liquid soap dispensers) and drying towels must be provided at hand washing stations. Smoking, eating, drinking and spitting must not be permitted within the processing facility.

c. Working apparel

The inspector should observe the clothing worn by supervisors and floor personnel. Clothing should be clean and as protective as necessary to ensure employee safety and well-being and to protect the product. Anti-skid rubber boots should be worn by employees working in wet areas and hair and beard nets by those handling the product. Employees handling the product must not wear jewellery or any loose accessories.

d. In-plant mobility of employees

The inspector must verify that there is complete physical separation between raw material handling areas and final product areas to minimize the risk of cross-contamination (for the same reason as inspectors are asked to conduct the walk-though inspection counter to product flow). Personnel working in raw material areas, including supervisors, must not be allowed to enter final product areas, and those handling the final product must not circulate around other plant areas. Colour-coded clothing may be useful in enforcing exclusion of personnel from restricted areas.

e. Employee training

The inspector should ask about the facility's sanitation training policy, programme and records for employees. All personnel working in a food processing plant should be aware of the reasons for requiring them to observe good hygiene practices.

[23] See WHO's Food-borne disease outbreaks. Guidelines for investigation and control for further information. (available at: http://www.who.int/foodsafety/publications/foodborne_disease/fdbmanual/en/index.html).

In addition, operators in charge of critical processing steps (CCPs) must be properly trained and actively encouraged to report system failures immediately. Whenever possible, these operators should be given authority to stop the processing line when a system failure occurs, so that no faulty product continues to move forward until repairs and/or the predetermined corrective action is taken.

Box 4.17. Summary: Employee and staff assessment (food processing facilities).

- Examine employees' health records/certificates and sick employee policy at opening or closing meetings.
- Encourage a compensation system for sick employees.
- Observe employee and staff hand washing practices after using the toilet and upon re-entering the processing area; soap and disposable towels must be available.
- Ensure that smoking, eating, drinking and spitting are banned within food processing areas.
- Observe employees' clothing for cleanliness and protection.
- Observe that no jewellery or loose accessories are worn.
- Ascertain that there is complete physical separation of raw material and finished product areas and personnel.
- Review employee hygiene and CCP training programmes and records.

5) Employee facilities assessment

a. Dressing rooms, lockers, showers and toilets

The inspector must check the conditions of dressing rooms and showers. Dressing rooms must be provided for employees so that they do not wear working clothes on the street. Ideally, each employee should have his/her own locker and the changing rooms should have access to clean showers. Employees should be encouraged to shower before starting work.

The inspector must check the conditions and cleanliness of toilets. Toilets must be kept clean and must not open directly onto food processing areas, they must also not be built in the same area in which dressing rooms and showers are located.

b. Hand washing stations

The inspector must pay particular attention to the availability and location of hand washing stations. These should be located next to toilet areas – but not within them – and adjacent to access doors to processing areas. To encourage hand washing after using the toilet or upon entering the processing areas from other areas, washbasins should be visible from the processing floor. Hand washing stations should be equipped with liquid soap dispensers and dry, disposable towels. Sink faucets/taps should be knee, foot or electronically operated.

c. First aid

First aid supplies and equipment should be available and easy accessible to staff and other personnel, and trained first aid staff should also be available as needed.

d. Laboratory

No isolation or enumeration of pathogenic micro-organisms should be conducted by a food processing establishment's on-site laboratory.

Box 4.18. Summary: Employee facilities assessment (food processing facilities).

- Check showers, changing rooms, eating facilities and toilets for cleanliness.
- Observe availability and location of hand washing stations.
- Hand washing stations must include soap and dry, disposable towels.
- Check availability of first aid cabinet and supplies.
- Ensure any analyses involving pathogenic micro-organisms are done only in accredited external laboratories.

6) Raw materials assessment

Because the inspector is performing the walk-through inspection counter to product flow, he/she will inspect the facility's raw materials and handling area at the end of the walk through. This is an important consideration when planning the inspection. Raw material reception may take place first thing in the morning and the inspector might miss the reception process. If reception of raw materials is, in fact, an early operation, the inspector might consider bringing along an assistant to perform an inspection of the receiving area while he/she initiates the inspection opening meeting. Another option for the inspector would be for he/she to perform an inspection of the receiving area, following which he/she must be submitted to all hygiene control procedures (including showering) before continuing his/her work.

a. Specifications, certifications, lot identification

The inspector must review the records of raw material lots received by the facility, their specifications and certification of compliance with the specifications, if available (e.g. laboratory analysis). Lack of appropriate reception records identifying suppliers would render any traceability effort useless. Similarly, lack of evidence of compliance with raw material specifications casts doubt on their quality and safety and may point towards a need for the inspector to take samples.

b. Raw material reception

The inspector should focus on aspects of raw material reception that may affect the safety of products, such as the cleanliness and other uses of transportation vehicles and the temperature of perishable raw materials received. Record keeping at the reception stage should also be observed by the inspector.

c. Raw material handling and sorting

Raw materials should not be placed directly on the ground or loading dock floor but on or in pallets, boxes, tables or tanks, as appropriate. Perishable raw materials should not remain long on the unloading dock, particularly in the sun.

The inspector should take note of handling and sorting procedures for raw materials. Hazardous substances should not be received in the same location as food products, additives and processing aids or food packaging materials.

d. Raw material storage

Raw materials should be stored adequately. Perishable goods should be refrigerated or placed in frozen storage as soon as possible and the inspector should check the accuracy of thermometers in cold rooms and freezers. Dry goods should be kept off the floors. Hazardous substances must be stored separately from materials that will become part of or be in touch with food products.

e. Stock rotation

The inspector should observe and/or ask about the in and out movement of raw materials from storage. First-in first-out should be the rule.

Box 4.19. Summary: Raw materials assessment (food processing facilities).

- Consider bringing along an assistant to inspect raw materials reception.
- Review records of material received, specifications and compliance with specifications.
- Focus on aspects of raw material reception that affect product safety.
- Observe the reception record keeping process.
- Take note of raw material handling, sorting and storage procedures.
- Determine whether stock rotation follows the first-in first-out rule.

4.7. Site assessment

Because an assessment of the food processing plant site entails walking around the facility, it should be done after the walk-through inspection unless the inspector intends to change his/her footwear for the walk through. As mentioned earlier, the inspector must set a good example at all times.

1) External environment, building design and construction

The quality of the surroundings of a food processing plant is an important factor with regard to food safety. Thus, depending on the state of cleanliness and upkeep of the neighbourhood the facility may be exposed to fumes from nearby industries or vehicles, dust from unpaved streets, roads or empty fields or lots, insects and other pests from adjacent waste dumps, agricultural or industrial operations or otherwise unsanitary areas. The inspector must note the quality of the general area in which the facility is located and its particular surroundings as part of the inspection.

Food processing plants should be constructed of materials that prevent accumulation of dust and moisture, which may become breeding grounds for potential microbial contaminants and insects. Buildings should be designed to prevent or minimize adverse external factors that may affect product safety. In addition, a food processing plant should have a means of controlling access to the facility in general, and to food processing areas in particular. The inspector should note the general state of repair of

the buildings. There should be no major areas of dust accumulation, mould growth, cracks on outside walls or openings on the roof that could allow entry of rodents and other vermin. The plant floor must be above ground level.

2) *Zoning and separation*

Buildings should be designed in ways that contribute to smooth and ideally straight product flow, avoid narrow passageways, minimize corners and small hard-to-clean spaces, and keep personnel circulation and crossing points at a minimum. The inspector must ensure that finished product areas are completely separated from those where raw materials and products are handled.

3) *Plant services*

Depending on the type of product, a food processing facility might be required to have its own or a backup electricity generator to ensure the continuity of refrigeration of perishable products in the event of a power failure. A generator may also be necessary to provide continued illumination, air movement and power for running the equipment.

If the facility utilizes water from a well continuously or as a backup the inspector must ensure that there is chlorination or another water purification system (e.g. ultraviolet, ozonation) to render the well water potable. The inspector should review the results of periodic analytical tests of such water. If the water source is the municipal supply, the inspector must review the results of periodic analytical tests verifying that such water is potable.

Box 4.20. Summary: Site assessment (food processing facilities).

- Conduct a site assessment after the walk-through inspection.
- Note the characteristics of the general area and the surroundings of the facility.
- Check the design, materials and upkeep of the buildings.
- Ensure complete physical separation of raw and finished product areas.
- Check the facility's electrical supply stability and backup.
- Ensure the water supply is routinely analysed, regardless of origin.

4.8. Food additives

1) *Approvals*

The inspector must examine the list of food additives being used in each product and ensure that they are approved for that use and level.

2) *Specifications*

The inspector must examine the specifications for food additives used by the facility in product formulation. These specifications should be part of the purchasing orders and agree with any national standards and regulations.

3) Use

During the walk-through inspection, the inspector must observe the way food additives are being used. He/she may also resort to questioning operators about product formulas to check whether levels and additives are being used as indicated in labels.

4) Labelling

The inspector must check that labelling of food additives and ingredients agrees with the product formulation.

Box 4.21. Summary: Food additives (food processing facilities).

- Check that the food additives and levels being used in products are approved.
- Review food additive purchasing orders for specifications.
- Observe the use and levels of additives and compare with the labelling.

4.9. Non-food chemicals

1) Receiving

The inspector must determine how non-food chemicals (e.g. cleaning or sanitizing compounds, lubricants, paint, fuels) are received, handled and stored at the facility to ensure that there is no possibility of contamination of foods with such materials.

2) Storage

Non-food chemicals must be stored separately from food products, food additives and processing aids and packaging materials.

Box 4.22. Summary: Non-food chemicals (food processing facilities).

- Check that non-food chemicals are received, handled and stored separately from food products, food additives and packaging materials.

4.10. Packaging materials

1) Approval

The inspector should examine the list of the packaging materials being used that are in direct contact with food and ensure that these materials are approved for such use.

2) Storage

Packaging materials should be stored in ways that prevent contamination with dust or chemicals, damage, and contamination by insects or other pests.

Box 4.23. Summary: Packaging materials (food processing facilities).

- Examine the list of packaging materials and ensure that such materials are approved for use on foods.
- Check that packaging materials are adequately stored.

4.11. Sanitation and pest control

1) Sanitation protocol and schedule

The inspector should pay particular attention to the facility's sanitation protocol and schedule for equipment and processing areas. Only potable water should be used in washing and sanitizing of equipment and floors. If steam is applied for sanitation, care must be taken to prevent condensation that may later drip on to food processing lines. If high-pressure water is used to clean equipment and floors, the inspector must ensure that this cleaning is done prior to equipment sanitizing and never after it, because aerosols and splashing from floors would re-contaminate sanitized equipment surfaces. The inspector must ascertain that the cleaning compounds and sanitizers being used are approved by the appropriate regulations and used in accordance with the manufacturers' instructions.

2) Pest control protocol and schedule

A pest control protocol and schedule must be available. If the facility applies its own pest control procedures, the operator in charge must be specifically trained, and licensed if required by regulations. Contractors must be licensed for pest control in food processing plants. The inspector should examine the pest control application records.

3) Pest barriers

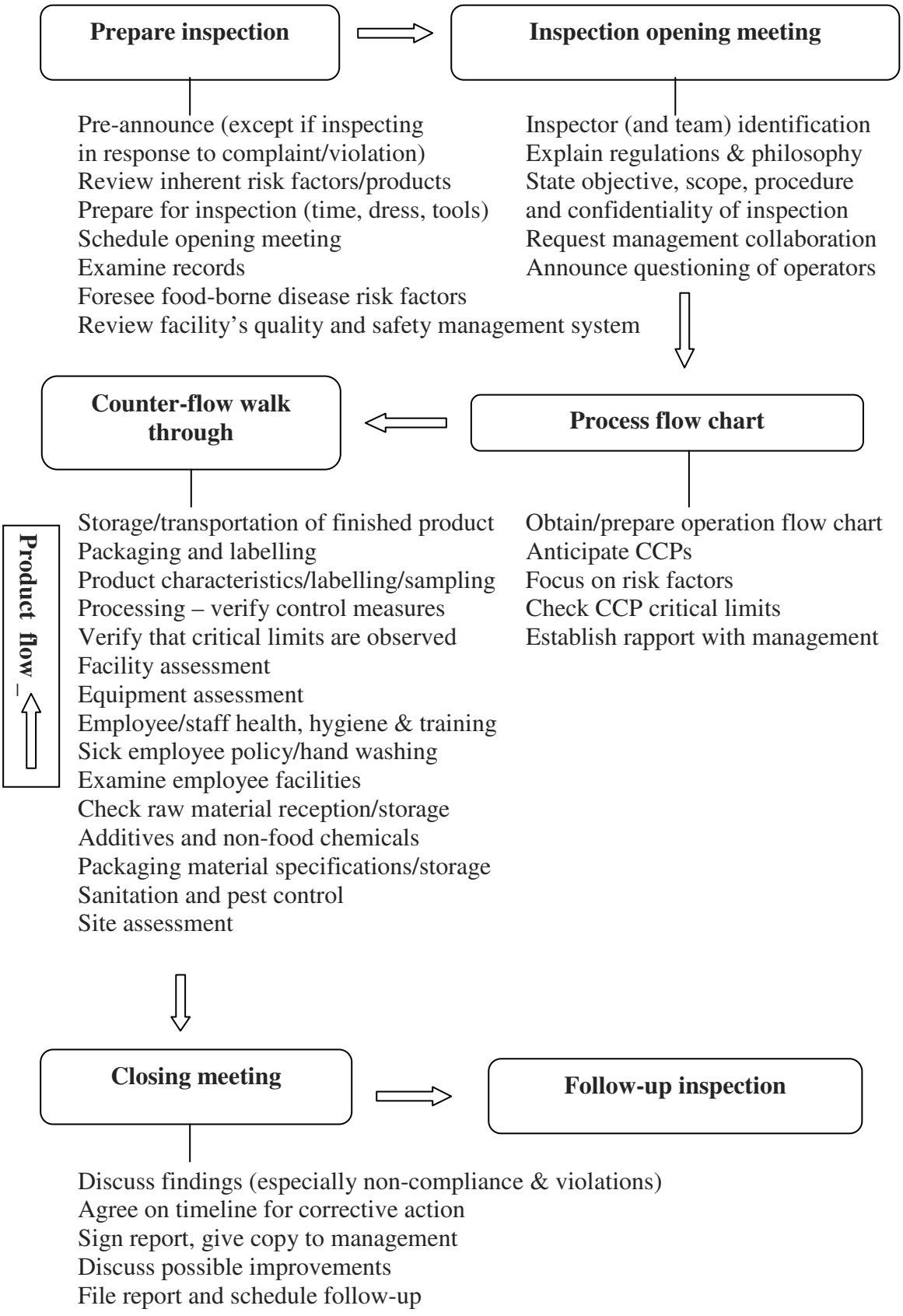
The facility should have pest barriers. Window screens were described earlier, but other pest barriers such as air curtains for entry doors are available. Where walls do not reach the roof and there are no ceilings, barriers should be installed on top of the walls to prevent rodent movement. Rodent barriers should also be installed on hanging wires and pipes.

Box 4.24. Summary: Sanitation and pest control (food processing facilities).

- Examine the sanitation protocol and schedule.
- Ensure that only potable water is used for cleaning and sanitizing.
- Check high-pressure water cleaning is done before equipment sanitization.
- Check that cleaning/sanitizing compounds are approved for use in food plants.
- Examine the pest control protocol, schedule and records.
- Check that the pest control applicator is trained and licensed.
- Check the building's pest barriers on windows, doors and wall tops.

Figure 2 presents a schematic summary of procedures and considerations for conducting inspections of food processing facilities.

Figure 2. Inspection of a food processing facility.



5. Enforcement and compliance

5.1 Regulatory basis for effective quality and safety management systems

1) Applicable food law(s)

The inspector and the inspection process must necessarily be empowered by one or more laws and regulations. The inspector must be thoroughly knowledgeable about these laws and regulations and about the scope of the authority vested in him/her. The inspector should have copies of all pertinent law(s) and regulations for consultation in case of any disagreement.

Because this manual proposes an inspection system that is based on risk and focuses on process rather than product, it is important that national food control authorities give consideration to the need to revise current legislation and/or regulations to adapt them to modern concepts of food safety and quality assurance. FAO and WHO have published guides to facilitate restructuring of national food control systems.[24]

In the absence of laws and regulations to allow an inspector to implement a risk-based approach to food inspection, areas for improvement identified during the inspection can be raised as recommendations instead of non-compliances while legislation is reviewed.

2) Other pertinent regulation(s)

In addition to food law(s) and regulations, the inspector should be aware of other laws and regulations that may have food safety implications, such as environmental laws and regulations addressing such issues as sewage and waste disposal. Food processing, in general, is very water intensive, and this issue and the potential need to treat effluents may be an important consideration in areas where water is scarce.

There are food processing facilities that cater for export markets and therefore must comply with particular national or international food safety and quality regulations. This manual has been developed as an aid for food inspection at the national level only. Nevertheless, many of the issues addressed in the manual may be applicable to other circumstances.

Box 5.1. Summary: Regulatory base for effective quality and safety management systems

- Know the law(s) and regulations that empower you as a food inspector and bring copies along.
- Know other relevant regulations.

5.2 Knowledge and skill requirements for food inspectors

Food processing involves many disciplines because food matrices are extremely complex. In addition to proteins, carbohydrates, fats and minerals, the basic blocks of food, there are innumerable interactions between food components and with multiple external factors that

[24] FAO/WHO. 2003. Assuring food safety and quality: Guidelines for strengthening national food control systems. FAO Food and Nutrition Paper 76 (available at: ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf).

may have an effect on the quality and safety of food. These factors may be microbiological, chemical, physical or sensory. Even human perception plays an important role in food quality. In addition, the ultimate objective of food inspection is consumer protection against food-borne disease and fraud. Consequently, the modern food inspector must be a professional who has a solid background in food science and technology and in public health. Essential areas of knowledge and skill for the food inspector are the following:

1) *Thorough knowledge of food law(s) and pertinent regulations*

   It is essential that the food inspector has a thorough knowledge of the law(s) and regulations governing the operation of food processing facilities and the corresponding inspection procedures. In addition, the inspector must know other pertinent regulations such as those dealing with environmental issues and workplace safety. Also of importance to product quality and safety are regulations affecting agricultural practices, food transportation and food distribution.

2) *Background information on the field of food safety and quality*

   Inspectors must know and understand all elements of a quality and safety management system, the role these play in food safety and the way these elements interact with one another. Central to this understanding is knowledge of food processing operations, food microbiology and food chemistry.

3) *Prerequisite sanitation, hygiene, and pest control practices*

   A thorough understanding of prerequisite programmes requires prior knowledge of the properties of various types of cleaning and sanitizing compounds, and their interactions with food matter, with each other and with other materials, particularly those materials that equipment is made of (e.g. chlorine and steel). Moreover, it is important that the inspector is aware of the characteristics and effects of sanitizing compounds on target bacterial groups and the accepted limits for residues of such compounds in food.

   The inspector must also be knowledgeable about hygiene practices, including personnel hygiene, and must be able to convey this knowledge to management and employees so that the objectives of relevant regulations are easily understood.

   The field of pest control products and practices is another area in which inspectors must be knowledgeable. Most pest control products can be deleterious if they find their way into food. The inspector should be able to communicate this knowledge to food processors.

4) *HACCP principles*

   Although this manual does not specifically cover Hazard Analysis and Critical Control Point (HACCP) systems, the HACCP approach is risk-based and its elements are helpful to use during an inspection. As such, it should be thoroughly understood by the inspector. Furthermore, the inspector should use inspections as an opportunity to promote HACCP to businesses. Ideally, food inspectors will have taken courses and been certified in the application of HACCP.

5) *Inspection techniques*

Food inspection, as approached by this manual, is a review of the food safety and quality aspects of a primary processing operation or a food processing facility. It is expected that the manual will provide the inspector with sufficient insight into inspection techniques to properly fulfil his/her task.

6) *Sampling techniques for product testing*

Knowledge of sampling techniques, particularly aseptic techniques, and of sample handling for transportation to a laboratory are essential to guarantee the integrity of samples taken for verification. In addition, the inspector must have a good knowledge of testing techniques so that he/she can make informed decisions about sampling methods and properly interpret the results of testing.

7) *Compliance verification skills*

Beyond academic and practical knowledge of food regulations, food processing, food microbiology and chemistry, it is essential that inspectors have sufficient professional experience and criteria to be able to focus the inspection on the truly important factors affecting food product safety: the risk factors associated with food-borne disease.

8) *Communication and other skills*

The food inspector must also possess good communication skills to enable him/her to adequately convey technical and regulatory information regarding safe food handling to others. In addition, the inspector must have professionalism and confidence and exhibit dignity and integrity.

9) *Original training certificate and required certificate updates*

The food industry is in constant change. New food processing technologies, new controls, new equipment and new ingredients constantly come onto the market, as do new testing methods. The food inspector needs appropriate training and must have a diploma/certificate attesting to his/her professional standing and must attend certified continuing education courses to stay up to date with new developments. Mentoring of new inspectors by experienced colleagues is highly desirable.

Box 5.2. Summary: Knowledge and skill requirements for food inspectors.

- A food inspector conducting food process inspections based on risk must know about the following:
  - relevant laws and regulations;
  - food safety and quality;
  - food processing operations, food microbiology and food chemistry;
  - prerequisite programmes;
  - properties and use of cleaning and sanitizing compounds;
  - hygiene practices, including personnel hygiene;
  - the HACCP system;

- inspection techniques;
- food sampling techniques and testing methods.

- The inspector must have compliance verification skills, experience and focus
- The inspector must have appropriate training, a certificate/diploma and update certificates.
- The inspector must not be suffering from or carrying any disease that can be transmitted during an inspection.
- The inspector must be a good communicator and exhibit dignity and integrity.

5.3. Compliance and enforcement policy

1) Responsibilities

Food regulations are mandatory and must be complied with by the processor and enforced by the inspector and food control authorities in all cases, because violations constitute offences. Failure by the inspector or other food control authorities to enforce regulations at all times, besides being illegal, defeats the purpose of having a food control system and promotes non-compliance across the industry by example. It would be unfair to demand compliance from one processor and not from others.

The inspector's primary responsibility is to protect the consumer by ensuring compliance with food safety laws and regulations, given that the public's well-being is the ultimate objective of a national food control system. Producers and processors, in contrast, are in business to make a profit and that priority may well impair their perception of accountability to society. Therefore, it is also the inspector's duty to remind producers and processors of their responsibility to produce safe foods. This message can be made more relevant by explaining to food producers and processors that the safety of their products not only fulfils their responsibility towards society – something that may seem idealistic and ethereal – but may also be determinant in developing their business. For example, the adverse effect of bad publicity and the use of favourable publicity as a marketing tool could be described.

Compliance with guidelines and voluntary standards, on the other hand, depends on the good will and disposition of the processor and should be strongly encouraged by the inspector.

2) Principles

The modern food inspector must think of himself/herself as a reviewer of the food safety control measures and a contributor to their improvement. Control measures must individually evolve continuously in response to technological advances and to the establishment's own experience, and as part of what should be an equally evolving national food control system. Such improvements can also be very advantageous to the processor from a marketing standpoint. Product safety and quality are characteristics that can be exploited to gain advantage in the marketplace. The food inspector is in a unique position to convey these messages to food producers and processors. **Creating awareness about food safety and quality among food producers and processors is as important an element of food inspection as verifying compliance with regulations.**

Improvements to a quality and safety management system are almost always possible and attainable if the processor is willing to progress and the inspector is able to assist. A generalized trend in modern food processing safety and quality assurance systems is the concept of statistical process control (SPC), which is based on continuous improvement. Although this manual has dealt with SPC only marginally, when discussing critical limits, **disseminating the concept of continuous improvement of the quality and safety management system and actively contributing to such improvement must be integral parts of food inspections**.

Box 5.3. Summary: Compliance and enforcement policy

- Enforce mandatory food regulations in all cases.
- Consider that ensuring consumers' well-being is your primary responsibility.
- Consider producing safe food to be the producer's and processor's responsibility.
- Convey the message that safe, quality food is a marketing tool.
- Create awareness about food safety among producers and processors.
- Disseminate the notion of and contribute to continuous improvement of quality and safety management systems, towards the development and implementation of a HACCP system.

5.4. Response to non-compliance and violations

1) Corrective action plan

"Non compliance" refers to a failure by a food producer or processor to comply with a regulation, whereas the term "violation" refers to doing something that is against the law or a regulation. The inspector must note non-compliance and violations in the inspection report. Any non-compliance or violation noted during the inspection must be disclosed to and discussed with the management during the closing meeting. It is important that the inspector clearly explains the basis for the particular regulation involved in the non-compliance or violation in terms of its effect on the safety of the food product, and the need to comply with it. The processor, in turn, has the right to explain the reasons for non-compliance and the inspector must pay attention, show understanding and use this information to help solve the problem. Nevertheless, if the non-compliance or violation concerns a mandatory regulation, it must be corrected.

A corrective action plan and a timetable for implementation must be agreed upon between the inspector and the management during the closing meeting. In some cases, straightforward, simple corrective action can be taken immediately; otherwise, the proposed timetable must be reasonable and tailored to the seriousness of the non-compliance or violation in terms of the food-borne disease risk factors involved. In extreme cases, when non-compliance or violations may seriously affect product safety, the inspector might be forced to issue a stop production order until corrections are made, or even recommend a temporary plant closure. Some food laws do not allow violations to proceed beyond the point of detection, in which case finding a violation would require immediate correction. Recall orders may also result from a gross violation or serious non-compliance detected during an inspection. When inspectors' orders are technically and legally justifiable, it is the food control authority's duty to support the decisions taken by inspectors; failure to do so seriously undermines the food control system.

Corrective action plans may also result from unannounced inspections conducted in response to consumer complaints or known violations. The procedure is similar to that resulting from a routine inspection, although in this case a compensation plan for affected consumers and possibly a product recall may also be agreed upon.

The agreed corrective action plan should be entered in the inspection report and the report should be signed by both parties. The inspector must give a copy of the signed report to the management.

Non-compliance with voluntary standards or guidelines should not be overlooked by the inspector. Guidelines exist for the purpose of improving the system. Non-compliance with such guidelines points towards an attitude of disinterest on the part of the producer or processor in adopting a continuous improvement policy. The role of the inspector in this case should be to point out the advantages that the producer or processor could attain through voluntary compliance and to offer collaboration in designing a plan to achieve it. It is also important to note that the inspector has a responsibility to make a clear distinction between what is a legal requirement and what is a recommendation of good practice.

2) *Corrective action follow-up and verification*

Upon return to the office, the inspector must file the inspection report according to the procedure indicated by the food control authority. When the report includes a corrective action plan, a copy should be filed manually or electronically in a way that allows timely follow-up. Simultaneously and in agreement with the agreed timetable for corrections, the inspector should schedule an unannounced visit to the facility to verify implementation of the actions agreed in the corrective action plan.

3) *Corrective action closure*

Once the inspector has verified during an unannounced inspection that corrective actions agreed during the previous inspection have been implemented, the inspection can be closed. The inspector also needs to decide upon and record the time interval before the next programmed inspection of the premises or other intervention. A record of the follow-up inspection should be filed with that of the initial inspection for future reference.

Box 5.4. Summary: Response to non-compliance and violations.

- Take note of non-compliance and violation(s) in the inspection report.
- Discuss non-compliance and violation(s) with management.
- Agree on a corrective action plan and timetable.
- Point out the advantages of complying with voluntary standards or guidelines and offer collaboration to implement them.

5.5. Enforcement actions and appeal process

1) Enforcement policy and approach

The effectiveness of a national food control system depends on having appropriate legislation and regulations and adequate enforcement. Enforcement, in turn, can only be as effective as the national policy permits and as the training and experience of and resources available to inspectors allow.

Ideally, enforcement of food laws and regulations should be a cooperative effort between the private and public sectors. Food laws and regulations not only protect – or should protect – consumers, but also provide a level playing field for competition among producers and processors. Enforcement of laws and regulations, therefore, must be equally fair to all producers and processors.

Enforcement of food legislation and regulations varies extensively from one country to another depending on the scope and strength of the laws, the influence of public opinion and the strength of consumer organizations, policy and the availability of resources. There may be differences in enforcement policy and approach even within the same country, especially when there is no centralized food control authority and the public institutions or agencies in charge of such enforcement are also entrusted with conflicting promotion of the regulated sector, for example ministries of agriculture conducting meat inspection.

However, irrespective of all the above considerations and in keeping with the approach predicated throughout this manual, **enforcement actions should focus on positively promoting compliance with risk-based food safety and quality assurance systems**.

Ideally, the enforcement process should consist of a dialogue between regulator and regulated such that non-compliances with or violations of laws and regulations are corrected at the earliest possible time and in a permanent fashion. The inspector can contribute to this constructive process more than any other component of the food control system could. However, when non-compliance or violations become recurrent, the inspector must be firm and proceed to enforce the law with whatever instruments it allows. Enforcement actions may consist of notices of non-compliance or violation, which usually include a time limit for correction, warnings of impending enforcement action (the last step before physical measures such as police intervention may be taken), fines and other coercive measures that may include jail sentences and/or temporary or definitive closure of establishments. Offending products may be subjected to voluntary or forcible recall, or be seized and/or destroyed.

2) Product recall

Product recall may become necessary when hazardous food products have left the processing facility and have been distributed in the marketplace. A recall programme is an integral part of the quality and safety management system and should be triggered by non-compliances or violations that may seriously endanger consumers.

Because the cost of recalls may be high, the national food control system should have the authority to order recalls at the expense of the processor in the event that a voluntary recall by the producer or processor is not forthcoming.

In the event of recalls, there must be a dialogue between the regulator and the producer or processor to define the ultimate fate of the recalled products. Depending on the identified hazard that originated the recall, some recalled products may be salvaged through reworking or transformation, or they may have to be destroyed. The recall programme should include a predetermined disposal route for products that need to be destroyed.

3) Appeal process

Most legislation rightly allows an appeal process. Food legislation is no exception, although the seriousness of the food-borne disease risk factors involved should override any economic considerations, or the perishable character of the food product involved, in guiding food control authorities with respect to the interim measures to be taken during the appeal process.

Box 5.5. Summary: Enforcement actions and appeal process.

- Approach enforcement as a dialogue and a cooperative effort between regulator and regulated.
- Enforce laws and regulations fairly and equally.
- Focus enforcement actions on positively affecting compliance with risk-based food safety and quality assurance systems at the earliest possible time.
- Be firm and enforce the law with whatever instruments it allows when non-compliance or violations recur.
- Order recalls when non-compliances or violations may endanger consumers.
- Discuss with producers or processors the ultimate fate of recalled products.
- An appeal process is fair; however, the seriousness of the food-borne illness risk factors involved should overcome any other considerations.

6. Annexes

Annex 1: Sample primary production facility inspection checklist

Primary Production Facility Inspection Checklist				
Inspector: **Establishment:** **Address:** **Tel. no.:** **E-mail Address:** **Manager/Supervisor:** **No. of Shifts:** **No. of Employees:** **Establishment Categorization:**				
Objective of Inspection: (Regular, Follow-up or Response to Complaint/Violation)				
Scope: (Full Inspection, Partial, Specific)				
Last Inspected	**Non-Compliances:** **Corrections:**	**Violations:** **Corrections:**		
Product and Categorization	**Food-borne Disease Risk Factors** **Intrinsic**	**Specific**	**Addressed** **YES**	**NO**
1.				
2.				
3.				
4.				
5.				
Critical Steps Identified (from Flow Diagram)				
1.				
2.				
3.				
4.				
5.				
……				
Walk-Through Inspection				
Where to look?	**What to look for?**	**Problem?**		
Buildings (walls, floor, ceiling,	Cracks, drainage, screens			

windows)	gaps, cleanliness	
Equipment	Condition, materials, cleanliness, sanitation	
Ventilation	Ambient temperature, dust	
Water	Analytical records	
Maintenance	Plan, records	
Sanitation	Schedule, protocol, chemical storage	
Pest Control	Plan, schedule, evidence	
Personnel Hygiene	Hand washing practices, signs, cleanliness, apparel	
Personnel Facilities	Cleanliness, soap, disposable towels, signs	
Monitoring of Critical Steps 1. 2. 3. 4. 5.	Training, procedures	
Raw Product Storage	Sanitary practices & handling	
Packaging	Cleanliness, product protection	
Labelling	Compliance, coding	
Final Product Storage	Product protection	
Product Transportation	Dedicated transport, product protection	
Premises	Dirt, dust, weeds, garbage	

.....

Record Keeping	Details	In Order	Problem
Monitoring (critical steps) 1. 2. 3. 4. 5.			
Training			
Production Practices (irrigation water quality, field hygiene, animals)			

Harvesting Practices (pesticide withdrawal periods, field hygiene)			
Product Lot/Batch			
Distribution Records			
Recall Plan			
Corrective Action Taken			

……

Overall Assessment

……

Closing Meeting

Findings	**Corrective Action** (if needed)	**Timeline for Corrections**
1.		
2.		
3.		
4.		
5.		

Improvements

1.
2.
3.
4.
5.

……

Inspector Name: Signature and Date:

Manager/Supervisor Name: Signature and Date:

Primary Production Facility: Follow-up Inspection		
Previous Inspection Date:		
Previous Findings	**Corrections Made** **Satisfactory** **Unsatisfactory – Further Action Recommended:**	
1.		
2.		
3.		
4.		
5.		
Date: Inspector Name: Signature:		
FOR ACTION: (Food Control Authority)		

Annex 2: Sample food processing facility inspection checklist

Food Processing Facility Inspection Checklist					
Inspector: **Establishment:** **Address:** **Tel. No.:** **E-mail Address:** **Manager/Supervisor:** **No. of Shifts:** **No. of Employees:** **Establishment Categorization:**					
Objective of Inspection: (Regular, Follow-up or Response to Complaint/Violation)					
Scope: (Full Inspection, Partial, Specific)					
Last Inspected	**Non-Compliances:** **Corrections:**		**Violations:** **Corrections:**		
Product and Categorization	**Food-borne Disease Risk Factors** **Intrinsic**	**Specific**		**Addressed** **YES**	**NO**
1. Production Line:					
2. Production Line:					
3. Production Line:					
4. Production Line:					
5. Production Line:					
Production Line No.	**Critical Step Identified** (from Flow Diagrams)		**Critical Limits**	**Validated** **YES**	**NO**
……					
Walk-Through Inspection					
Where to look?	**What to look for?**		**Problem?**		

Product Loading & Transportation	Temperature, dedicated vehicles, cleanliness	
Product Storage	Temperature, insects, pets, cross-contamination (raw materials?)	
Product Packaging & Labelling	Materials, closure, compliance, accuracy, codes	
Monitoring of Critical Steps 1. 2. 3. 4. 5.	Training, procedure	
Buildings (walls, floor, ceiling, doors, windows)	Cracks, drainage, product & raw material residues, insect screens	
Wall Tops, Pipes, Beams	Pest barriers	
Plant Services (water source, generator?)	Potable water, emergency power supply (if needed)	
Processing Areas	Complete physical (and air flow?) separation from raw material areas	
Equipment Design & Materials	Ease of cleaning, materials	
Equipment Maintenance	Condition, cleanliness, residues, sanitation	
Cleaning Procedures	Schedule, practices	
Sanitation Procedures	Protocol, materials, schedule, verification	
Filters	Cleanliness, residues	
Lubricants	Approval, product contact	
Overhanging Pipes, Vents & Ceilings	Condensation	
Washing Stations, Faucets	Splashing on product	
Hand Washing Stations	Location, signs, available soap & disposable towels, use	
Illumination	Ease of vision	
Ventilation	Ambient temperature	
Air Quality	Airborne dust	
Water & Ice	Analytical records	
Steam	Availability, volume	
Drainage & Sewage	Good drainage, gas traps, screens, appropriate sewage disposal	
Maintenance	Plan, records	
Sanitation	Schedule, protocol, chemical storage	
Pest Control	Plan, schedule, evidence	

Personnel Hygiene	Hand washing practices, signs, cleanliness, apparel	
Personnel Facilities	Cleanliness, soap, disposable towels, signs, first-aid cabinet contents	
Personnel Mobility	Movement from raw material to final product areas	
Final Product Storage	Product protection	
Product Transportation	Dedicated transport, product protection	
Raw Product Handling	Batch mix, temperature	
Raw Product Storage	Sanitary practices & handling	
Food Additives	Specifications, approvals, use, labelling	
Packaging Materials	Approvals, storage	
Stock Rotation	First-in first-out	
Premises	Dirt, dust, weeds, animals & pests, garbage	

…….

Sample(s) Taken	Analyses

…….

Record Keeping	Details	In Order	Problem
Monitoring (critical steps) 1. 2. 3. 4. 5.			
Critical Step Validation 1. 2. 3. 4. 5.			
Equipment/Instrument Calibration			
Personnel/Staff Training			
Raw Product Specifications			
Raw Product Batch/Lot ID			
Additive Specifications			
Packaging Material Specifications			

Finished Product Lot/Batch			
Distribution Records			
Recall Plan			
Corrective Action(s) Taken			

……

Overall Assessment

……

Closing Meeting

Findings	Corrective Action (if needed)	Timeline for Corrections
1.		
2.		
3.		
4.		
5.		

Improvements

1.
2.
3.
4.
5.

……

Inspector Name: Signature and Date:

Manager/Supervisor Name: Signature and Date:

Food Processing Facility: Follow-up Inspection		
Previous Inspection Date:		
Previous Findings	**Corrections Made** **Satisfactory** **Unsatisfactory – Further Action Recommended:**	
1.		
2.		
3.		
4.		
5.		
Date: Inspector Name: Signature:		
FOR ACTION: (Food Control Authority)		

Annex 3: References and Further Reading

CDC. 1996. Surveillance for food-borne disease outbreaks – United States, 1988–1992. *MMWR* 45(SS5): 1–66. Centers for Disease Control and Prevention (CDC) (available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm).

CFIA. Undated. *Food safety enhancement program*. Canadian Food Inspection Agency. (available at: http://www.inspection.gc.ca/english/fssa/polstrat/haccp/haccpe.shtml).

CFIA. 2006. *Fish inspection program. Facilities inspection manual*. Canadian Food Inspection Agency (available at: http://www.inspection.gc.ca/english/anima/fispoi/manman/fimmii/fiiialle.pdf).

FAO. 1996. *World Food Summit. Rome Declaration on World Food Security*. Rome, Food and Agriculture Organization (available at: http://www.fao.org/docrep/003/w3613e/w3613e00.htm).

FAO. 2005. Perspectives and guidelines on food legislation with a new model food law. *In* J. Vapnek & M. Spreij, eds. *FAO Legislative Study 87* Rome, FAO (available at: http://www.fao.org/legal/legstud/ls87/ls87e.pdf).

FAO. 2006. *Strengthening national food control systems. Guidelines to assess capacity building needs. Module 3 Food inspection*. Rome, FAO (available at: ftp://ftp.fao.org/docrep/fao/009/a0601e/a0601e00.pdf).

FAO/WHO. 1969. *Recommended international code of practice. General principles of food hygiene*. Codex Alimentarius Commission CAC/RCP 1-1969, Rev. 4-2003. Annex on Hazard Analysis and Critical Control Point (HACCP) System and guidelines for its application. Rome, Codex Alimentarius Commission (available at: http://www.codexalimentarius.net/web/standard_list.do?lang=en).

FAO/WHO. 1995. *Principles for food import and export certification*. Rome, Codex Alimentarius Commission CAC/GL 20-1995 (available at: http://www.fao.org/DOCREP/005/X4489E/x4489e02.htm#bm2).

FAO/WHO. 1997. *Guidelines for the design, operation, assessment and accreditation of food import and export inspection systems*. Rome, Codex Alimentarius Commission CAC/GL 26-1997 (available at: http://www.fao.org/DOCREP/005/X4489E/x4489e03.htm#bm3).

FAO/WHO. 1997. *Risk management and food safety*. Report of a Joint FAO/WHO Consultation. Rome, Italy, 27 to 31 January 1997. FAO Food and Nutrition Paper 65 (available at: http://www.fao.org/docrep/W4982E/W4982E00.htm).

FAO/WHO. 1998. *Food quality and safety systems. A training manual on food hygiene and the Hazard Analysis and Critical Control Point (HACCP) system*. Rome, FAO (available at: http://www.fao.org/docrep/W8088E/W8088E00.htm).

FAO/WHO. 2001. *Codex Alimentarius – Food hygiene – basic texts*, 2nd edition. Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Rome, FAO (available at: http://www.fao.org/docrep/005/Y1579E/Y1579E00.HTM).

FAO/WHO. 2003. *Assuring food safety and quality: Guidelines for strengthening national food control systems*. FAO Food and Nutrition Paper 76. Rome, FAO (available at: ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf).

FAO/WHO. 2006. *FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses*. Food and Nutrition Paper No. 86. Rome, FAO (available at: ftp://ftp.fao.org/docrep/fao/009/a0799e/a0799e00.pdf).

FDA. Undated. *Hazard Analysis and Critical Control Point*. Washington, DC, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN) (available at: http://www.cfsan.fda.gov/~lrd/haccp.html).

FDA. 2006. *FDA statement on food-borne* E. coli *O157:H7 outbreak in spinach*. FDA News. September 21, 2006. United States Food and Drug Administration (available at: http://www.fda.gov/bbs/topics/NEWS/2006/NEW01460.html).

FDA. 2006. *Managing food safety: A regulator's manual for applying HACCP principles to risk-based retail and food service inspections and evaluating voluntary food safety management systems*. Washington, DC, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN) (available at: http://www.cfsan.fda.gov/~dms/hret3-1.html).

WHA. 2000. Agenda item 12.3. *Resolution on food safety adopted by the 53rd World Health Assembly*. May 2000 Geneva, World Health Organization (available at: http://www.who.int/foodsafety/publications/biotech/WHA53.15.pdf).

WHO. 2006. *Five keys to safer food manual*. Geneva, WHO (available at: http://www.who.int/foodsafety/publications/consumer/manual_keys.pdf).

WHO. 2007. *Food-borne disease outbreaks: guidelines for investigation and control*. Geneva, WHO (available at: http://www.who.int/foodsafety/publications/foodborne_disease/fdbmanual/en/index.html)

WHO. *Food safety inspection guidelines*. Manila, Philippines, WHO Regional Office for the Western Pacific (WPRO).

FAO TECHNICAL PAPERS

FAO FOOD AND NUTRITION PAPERS

1/1	Review of food consumption surveys 1977 – Vol. 1. Europe, North America, Oceania, 1977 (E)
1/2	Review of food consumption surveys 1977 – Vol. 2. Africa, Latin America, Near East, Far East, 1979 (E)
2	Report of the joint FAO/WHO/UNEP conference on mycotoxins, 1977 (E F S)
3	Report of a joint FAO/WHO expert consultation on dietary fats and oils in human nutrition, 1977 (E F S)
4	JECFA specifications for identity and purity of thickening agents, anticaking agents, antimicrobials, antioxidants and emulsifiers, 1978 (E)
5	JECFA – guide to specifications, 1978 (E F)
5 Rev. 1	JECFA – guide to specifications, 1983 (E F)
5 Rev. 2	JECFA – guide to specifications, 1991 (E)
6	The feeding of workers in developing countries, 1976 (E S)
7	JECFA specifications for identity and purity of food colours, enzyme preparations and other food additives, 1978 (E F)
8	Women in food production, food handling and nutrition, 1979 (E F S)
9	Arsenic and tin in foods: reviews of commonly used methods of analysis, 1979 (E)
10	Prevention of mycotoxins, 1979 (E F S)
11	The economic value of breast-feeding, 1979 (E F)
12	JECFA specifications for identity and purity of food colours, flavouring agents and other food additives, 1979 (E F)
13	Perspective on mycotoxins, 1979 (E F S)
14	*Manuals of food quality control:*
14/1	Food control laboratory, 1979 (Ar E)
14/1 Rev.1	The food control laboratory, 1986 (E)
14/2	Additives, contaminants, techniques, 1980 (E)
14/3	Commodities, 1979 (E)
14/4	Microbiological analysis, 1979 (E F S)
14/5	Food inspection, 1981 (Ar E) (Rev. 1984, E S)
14/6	Food for export, 1979 (E S)
14/6 Rev.1	Food for export, 1990 (E S)
14/7	Food analysis: general techniques, additives, contaminants and composition, 1986 (C E)
14/8	Food analysis: quality, adulteration and tests of identity, 1986 (E)
14/9	Introduction to food sampling, 1988 (Ar C E F S)
14/10	Training in mycotoxins analysis, 1990 (E S)
14/11	Management of food control programmes, 1991 (E)
14/12	Quality assurance in the food control microbiological laboratory, 1992 (E F S)
14/13	Pesticide residue analysis in the food control laboratory, 1993 (E F)
14/14	Quality assurance in the food control chemical laboratory, 1993 (E)
14/15	Imported food inspection, 1993 (E F)
14/16	Radionuclides in food, 1994 (E)
14/17	Unacceptable visible can defects – a pictorial manual, 1998 (E F S)
15	Carbohydrates in human nutrition, 1980 (E F S)
16	Analysis of food consumption survey data for developing countries, 1980 (E F S)
17	JECFA specifications for identity and purity of sweetening agents, emulsifying agents, flavouring agents and other food additives, 1980 (E F)
18	Bibliography of food consumption surveys, 1981 (E)
18 Rev. 1	Bibliography of food consumption surveys, 1984 (E)
18 Rev. 2	Bibliography of food consumption surveys, 1987 (E)
18 Rev. 3	Bibliography of food consumption surveys, 1990 (E)
19	JECFA specifications for identity and purity of carrier solvents, emulsifiers and stabilizers, enzyme preparations, flavouring agents, food colours, sweetening agents and other food additives, 1981 (E F)
20	Legumes in human nutrition, 1982 (E F S)
21	Mycotoxin surveillance – a guideline, 1982 (E)
22	Guidelines for agricultural training curricula in Africa, 1982 (E F)
23	Management of group feeding programmes, 1982 (E F P S)
23 Rev. 1	Food and nutrition in the management of group feeding programmes, 1993 (E F S)
24	Evaluation of nutrition interventions, 1982 (E)
25	JECFA specifications for identity and purity of buffering agents, salts; emulsifiers, thickening agents, stabilizers; flavouring agents, food colours, sweetening agents and miscellaneous food additives, 1982 (E F)
26	Food composition tables for the Near East, 1983 (E)
27	Review of food consumption surveys 1981, 1983 (E)
28	JECFA specifications for identity and purity of buffering agents, salts, emulsifiers, stabilizers, thickening agents, extraction solvents, flavouring agents, sweetening agents and miscellaneous food additives, 1983 (E F)
29	Post-harvest losses in quality of food grains, 1983 (E F)
30	FAO/WHO food additives data system, 1984 (E)
30 Rev. 1	FAO/WHO food additives data system, 1985 (E)
31/1	JECFA specifications for identity and purity of food colours, 1984 (E F)
31/2	JECFA specifications for identity and purity of food additives, 1984 (E F)
32	Residues of veterinary drugs in foods, 1985 (E/F/S)
33	Nutritional implications of food aid: an annotated bibliography, 1985 (E)
34	JECFA specifications for identity and purity of certain food additives, 1986 (E F)
35	Review of food consumption surveys 1985, 1986 (E)
36	Guidelines for can manufacturers and food canners, 1986 (E)
37	JECFA specifications for identity and purity of certain food additives, 1986 (E F)

38 JECFA specifications for identity and purity of certain food additives, 1988 (E)
39 Quality control in fruit and vegetable processing, 1988 (E F S)
40 Directory of food and nutrition institutions in the Near East, 1987 (E)
41 Residues of some veterinary drugs in animals and foods, 1988 (E)
41/2 Residues of some veterinary drugs in animals and foods. Thirty-fourth meeting of the joint FAO/WHO Expert Committee on Food Additives, 1990 (E)
41/3 Residues of some veterinary drugs in animals and foods. Thirty-sixth meeting of the joint FAO/WHO Expert Committee on Food Additives, 1991 (E)
41/4 Residues of some veterinary drugs in animals and foods. Thirty-eighth meeting of the joint FAO/WHO Expert Committee on Food Additives, 1991 (E)
41/5 Residues of some veterinary drugs in animals and foods. Fortieth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1993 (E)
41/6 Residues of some veterinary drugs in animals and foods. Forty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1994 (E)
41/7 Residues of some veterinary drugs in animals and foods. Forty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1994 (E)
41/8 Residues of some veterinary drugs in animals and foods. Forty-fifth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1996 (E)
41/9 Residues of some veterinary drugs in animals and foods. Forty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1997 (E)
41/10 Residues of some veterinary drugs in animals and foods. Forty-eighth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1998 (E)
41/11 Residues of some veterinary drugs in animals and foods. Fiftieth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 1999 (E)
41/12 Residues of some veterinary drugs in animals and foods. Fifty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives, 2000 (E)
41/13 Residues of some veterinary drugs in animals and foods. Fifty-forth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 2000 (E)
41/14 Residues of some veterinary drugs in animals and foods. Fifty-eighth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 2002 (E)
41/15 Residues of some veterinary drugs in animals and foods. Sixtieth meeting of the Joint FAO/WHO Expert Committee on Food Additives, 2003 (E)
41/16 Residues of some veterinary drugs in animals and foods. Monographs prepared by the sixty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives, 2004 (E)
42 Traditional food plants, 1988 (E)
42/1 Edible plants of Uganda. The value of wild and cultivated plants as food, 1989 (E)
43 Guidelines for agricultural training curricula in Arab countries, 1988 (Ar)
44 Review of food consumption surveys 1988, 1988 (E)
45 Exposure of infants and children to lead, 1989 (E)
46 Street foods, 1990 (E/F/S)
47/1 Utilization of tropical foods: cereals, 1989 (E F S)
47/2 Utilization of tropical foods: roots and tubers, 1989 (E F S)
47/3 Utilization of tropical foods: trees, 1989 (E F S)
47/4 Utilization of tropical foods: tropical beans, 1989 (E F S)
47/5 Utilization of tropical foods: tropical oil seeds, 1989 (E F S)
47/6 Utilization of tropical foods: sugars, spices and stimulants, 1989 (E F S)
47/7 Utilization of tropical foods: fruits and leaves, 1990 (E F S)
47/8 Utilization of tropical foods: animal products, 1990 (E F S)
48 Number not assigned
49 JECFA specifications for identity and purity of certain food additives, 1990 (E)
50 Traditional foods in the Near East, 1991 (E)
51 Protein quality evaluation. Report of the Joint FAO/WHO Expert Consultation, 1991 (E F)
52/1 Compendium of food additive specifications – Vol. 1, 1993 (E)
52/2 Compendium of food additive specifications – Vol. 2, 1993 (E)
52 Add. 1 Compendium of food additive specifications – Addendum 1, 1992 (E)
52 Add. 2 Compendium of food additive specifications – Addendum 2, 1993 (E)
52 Add. 3 Compendium of food additive specifications – Addendum 3, 1995 (E)
52 Add. 4 Compendium of food additive specifications – Addendum 4, 1996 (E)
52 Add. 5 Compendium of food additive specifications – Addendum 5, 1997 (E)
52 Add. 6 Compendium of food additive specifications – Addendum 6, 1998 (E)
52 Add. 7 Compendium of food additive specifications – Addendum 7, 1999 (E)
52 Add. 8 Compendium of food additive specifications – Addendum 8, 2000 (E)
52 Add. 9 Compendium of food additive specifications – Addendum 9, 2001 (E)
52 Add. 10 Compendium of food additive specifications – Addendum 10, 2002 (E)
52 Add. 11 Compendium of food additive specifications – Addendum 11, 2003 (E)
52 Add. 12 Compendium of food additive specifications – Addendum 12, 2004 (E)
52 Add. 13 Compendium of food additive specifications – Addendum 13, 2005 (E)
53 Meat and meat products in human nutrition in developing countries, 1992 (E)
54 Number not assigned
55 Sampling plans for aflatoxin analysis in peanuts and corn, 1993 (E)
56 Body mass index – A measure of chronic energy deficiency in adults, 1994 (E F S)
57 Fats and oils in human nutrition, 1995 (Ar E F S)
58 The use of hazard analysis critical control point (HACCP) principles in food control, 1995 (E F S)

59 Nutrition education for the public, 1995 (E F S)
60 Food fortification: technology and quality control, 1996 (E)
61 Biotechnology and food safety, 1996 (E)
62 Nutrition education for the public – Discussion papers of the FAO Expert Consultation, 1996 (E)
63 Street foods, 1997 (E/F/S)
64 Worldwide regulations for mycotoxins 1995 – A compendium, 1997 (E)
65 Risk management and food safety, 1997 (E)
66 Carbohydrates in human nutrition, 1998 (E S)
67 Les activités nutritionnelles au niveau communautaire – Expériences dans les pays du Sahel, 1998 (F)
68 Validation of analytical methods for food control, 1998 (E)
69 Animal feeding and food safety, 1998 (E)
70 The application of risk communication to food standards and safety matters, 1999 (Ar C E F S)
71 Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, 2004 (E F S)
72 Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods – Risk characterization of *Salmonella* spp. in eggs and broiler chickens and *Listeria monocytogenes* in ready-to-eat foods, 2001 (E F S)
73 Manual on the application of the HACCP system in mycotoxin prevention and control, 2001 (E F S)
74 Safety evaluation of certain mycotoxins in food, 2001 (E)
75 Risk assessment of *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood, 2003 (E)
76 Assuring food safety and quality – Guidelines for strengthening national food control systems, 2003 (E F S)
77 Food energy – Methods of analysis and conversion factors, 2003 (E)
78 Energy in human nutrition. Report of a Joint FAO/WHO/UNU Expert Consultation, 2003 (E). Issued as No. 1 in the FAO Food and Nutrition Technical Report Series entitled Human energy requirements, Report of a Joint FAO/WHO/UNU Expert Consultation, 2004 (E)
79 Safety assessment of foods derived from genetically modified animals, including fish, 2004 (E)
80 Marine biotoxins, 2004 (E)
81 Worldwide regulations for mycotoxins in food and feed in 2003, 2004 (C E F S)
82 Safety evaluation of certain contaminants in food, 2005 (E)
83 Globalization of food systems in developing countries: impact on food security and nutrition, 2004 (E)
84 The double burden of malnutrition – Case studies from six developing countries, 2006 (E)
85 Probiotics in food – Health and nutritional properties and guidelines for evaluation, 2006 (E S)
86 FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses, 2006 (E F S)
87 Food safety risk analysis – A guide for national food safety authorities, 2006 (E F S)
88 Enhancing developing country participation in FAO/WHO scientific advice activities, 2006 (E F S)
89 Risk-based food inspection manual, 2008 (E)

Availability: April 2008

Ar – Arabic
C – Chinese
E – English
F – French
P – Portuguese
S – Spanish
Multil – Multilingual
* Out of print
** In preparation

The FAO Technical Papers are available through the authorized FAO Sales Agents or directly from Sales and Marketing Group, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy.

89

Risk-based food inspection manual

Food inspection, based on risk analysis, is a vital component of a modern food control system. Food inspection is essential to protect consumers by implementing adequate food controls to ensure domestically produced or imported food is properly handled, stored, manufactured, processed, transported, prepared, served and sold in accordance with the requirements of national laws and regulations. In addition, inspection and verification of food exports promotes confidence in the safety and quality of exports, which is essential for international trade. This manual introduces a risk-based inspection approach and procedures for primary production operations and food processing establishments, and is composed of six parts. The first part, *Concepts and approaches of modern food inspection*, describes the concepts, approaches and frameworks of the modern food inspection process. The second part, *General inspection procedures*, introduces the overall concept of risk-based inspection and describes basic principles and components of food inspection, including organization of an inspection, authorization, rights and responsibilities of an inspector, prerequisite plan, regulatory action plan, traceability and recall plan and the closing, reporting and documentation of an inspection. The third part, *General inspection approach for primary production facilities*, explains the generic inspection procedures covering primary production. The fourth part, *General inspection approach for food processing facilities*, covers the generic inspection procedures for food processing operations. The fifth part, *Enforcement and compliance*, covers general aspects of food inspection, such as the regulatory basis of food safety and quality, the knowledge and skills needed by food inspectors and the compliance, enforcement, appeal and recall processes. Finally, the sixth part comprises the *Annexes*, which include a sample primary production facility inspection checklist, a sample food processing facility inspection checklist and references/further reading.

ISBN 978-92-5-105976-0 ISSN 0254-4725

9 789251 059760

TC/M/I0096E/1/04.08/1150

FAO