

AGRIBUSINESS SERIES

Export Handbooks

GOOD MANUFACTURING PRACTICES

A GUIDE FOR SMALL AND MEDIUM-SCALE
AGRIBUSINESS OPERATORS

Alejandra Diaz
Rosario Uría

Inter-American Program for the Promotion of Trade,
Agribusiness and Food Safety

© Inter–American Institute for Cooperation on Agriculture (IICA). 2009

The Institute encourages the fair use of this document. Proper citation is requested.

This publication is also available in electronic format (PDF) on the institution's Website: <http://www.iica.int>.

This document was prepared by Alejandra Díaz Rodríguez, Regional Specialist in Agricultural Health and Food Safety for the Central Region for Inter-American Program for the Promotion of Trade, Agribusiness and Food Safety. The program is based in Miami and comes under IICA's Agribusiness Competitiveness Directorate. Mr. Marcos Sánchez, Food Safety Specialist of the Inter-American Program for the Promotion of Trade, Agribusiness and Food Safety assisted in editing the English version.

Editorial coordination: Daniel Rodríguez Sáenz

Translator: Susana Raine

Layout: Karla Cruz

Cover: Zona Creativa

Printed: IICA Headquarters

Díaz, Alejandra

Good manufacturing practices: guide for small- and medium sized agribusiness operators / Alejandra Díaz, Rosario Uría – San José, C.R.: IICA, 2009.

69 p.; 15 x 23 cm. (Agribusiness series: Exports handbooks / IICA, ISSN 1819-9208 ; no.12)

ISBN13: 978-92-9248-074-5

1. Food security 2. Public health 3. Food hygiene 4. Codex alimentarius 5. Small enterprises 6. Enterprises I. Uría, Rosario II. IICA III. Title

AGRIS
Q03

DEWEY
664.024

San Jose, Costa Rica
2009

One of the objectives of the Agribusiness Competitiveness Directorate of the Inter-American Institute for Cooperation on Agriculture (IICA) is to assist the countries in identifying and tapping market opportunities, and to support the efforts of public and private institutions that work to strengthen competitive agribusiness development.

In January 2004, IICA created the *Inter-American Program for the Promotion of Trade, Agribusiness and Food Safety*, with offices in Miami, Florida, U.S. Its mandate is to increase technical cooperation to small- and medium-sized agribusinesses in IICA's member countries with a view to upgrading their business capabilities, identifying trade opportunities, and making information available to facilitate decision-making that promotes trade.

To date, the program's activities have helped identify a set of priority needs or issues that are shared by small- and medium-sized agribusinesses throughout the Americas. These priority issues are the subject of analysis in the publications of IICA's *Agribusiness Series*, which aim specifically to help small- and medium-sized agribusiness operators in the hemisphere increase their competitiveness. The *Export Handbooks* are a subgroup of that series, which address concepts and ideas to facilitate decision-making for those interested in successfully integrating their agribusinesses in international markets.

This publication was prepared with the intention of providing general guidelines on "Good manufacturing practices" (GMP), and is based on the "General Principles of Food Hygiene" of the Codex Alimentarius. We would like to express our appreciation to Alejandra Díaz, IICA's regional agricultural health and food safety specialist for the Central Region, for writing this valuable guide; we also thank Rosario Uría for providing her support and expertise in preparing this document. We trust that small- and medium-scale agribusiness operators will find it useful as a permanent reference tool, as we continue to strive to strengthen their competitiveness and improve their living conditions.

Miguel García Winder
Director of Agribusiness Competitiveness
Inter-American Program for the Promotion of Trade, Agribusiness and Food Safety
IICA Office in Miami

CONTENTS

INTRODUCTION	7
I. HOW TO USE THIS GUIDE	11
II. GENERAL FRAMEWORK	11
2.1 CODEX ALIMENTARIUS	11
2.2 GOOD MANUFACTURING PRACTICES: A CONCEPTUAL OVERVIEW	12
2.3 GENERAL PRINCIPLES OF FOOD HYGIENE OF THE CODEX ALIMENTARIUS	12
2.4 SANITATION STANDARD OPERATING PROCEDURES (SSOP) AND GOOD MANUFACTURING PRACTICES	13
2.5 GOOD MANUFACTURING PRACTICES AND THE HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEM	14
2.6 TOWARD A FOOD SAFETY MANAGEMENT SYSTEM	15
III. GOOD MANUFACTURING PRACTICES	16
3.1 APPLICATION OF GOOD MANUFACTURING PRACTICES	
3.2. PRIMARY PRODUCTION.	16
3.3 INSTALLATIONS: DESIGN AND CONSTRUCTION.	17
3.3.1 GENERAL CONSIDERATIONS.	17
3.3.2 PRINCIPAL CONSTRAINTS	22
3.3.3 PRACTICAL ADVICE	23
3.4 CONTROL OF OPERATIONS	28
3.4.1 GENERAL CONSIDERATIONS.	28
3.4.2 PRINCIPAL CONSTRAINTS	33
3.4.3 PRACTICAL ADVICE	34
3.5 INSTALLATIONS: MAINTENANCE AND SANITATION.	37
3.5.1 GENERAL CONSIDERATIONS.	37
3.5.2 PRINCIPAL CONSTRAINTS	41
3.5.3 PRACTICAL ADVICE	42
3.6 INSTALLATIONS: PERSONAL HYGIENE.	46
3.6.1 GENERAL CONSIDERATIONS	46
3.6.2 PRINCIPAL CONSTRAINTS	48
3.6.3 PRACTICAL ADVICE	48
3.7 TRANSPORTATION.	51
3.7.1 GENERAL CONSIDERATIONS.	51

3.7.2	PRINCIPAL CONSTRAINTS	52
3.7.3	PRACTICAL ADVICE	53
3.8	PRODUCT INFORMATION AND CONSUMER AWARENESS.	55
3.8.1	GENERAL CONSIDERATIONS.	55
3.8.2	PRINCIPAL CONSTRAINTS	56
3.8.3	PRACTICAL ADVICE	56
3.9	TRAINING	57
3.9.1	GENERAL CONSIDERATIONS.	57
3.9.2	PRINCIPAL CONSTRAINTS	58
3.9.3	PRACTICAL ADVICE	58
3.10	DOCUMENTATION	60
3.10.1	GENERAL CONSIDERATIONS	60
3.10.2	PRINCIPAL CONSTRAINTS	60
3.10.3	PRACTICAL ADVICE	60

APPENDIX	63
-----------------	-----------

EXAMPLES OF DOCUMENTATION	63
SUGGESTED FORMAT FOR A MASTER LIST	63
STRUCTURE FOR A PROCEDURE	64
STRUCTURE FOR INSTRUCTIONS	64
STRUCTURE FOR TECHNICAL SPECIFICATIONS.	65
EXAMPLE OF PROGRAM RECORD	66

BIBLIOGRAPHY	69
---------------------	-----------

New trends in world food consumption are driven by the demand for products that must meet increasingly stringent health, safety, and quality standards. This is a result of a trade environment that has become more exacting and competitive through globalization and economic interdependence.

The food crises of the last decade –including microbial contamination of fresh fruits and vegetables, bovine spongiform encephalopathy (“mad cow” disease), and avian influenza– in addition to concern over pesticide residues and genetically modified foods, have increased consumers’ sensitivity to the conditions under which food is produced and sold. As a result, consumers are demanding the highest guarantees to ensure that the food they consume is hazard free.

In response, many countries have established guidelines, standards, regulations, and systems to ensure that food is safe and suitable for consumption. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO) underscores the countries’ right to adopt and enforce food safety measures they consider necessary and justified, provided they are in accord with the SPS Agreement and are based on Codex Alimentarius standards and related documents.

In addition to the official regulations that govern market access, agribusiness operators should also be aware that there is a large body of private regulations and standards that are often even more demanding than official regulations. Although in principle private regulations are not binding, in practice they tend to be, which poses a challenge to businesses, particularly small agribusinesses, because of the costs of implementation, certification, maintenance, and other related costs.

In light of this, IICA decided to produce this guide for small and medium-scale agribusiness operators in the hemisphere in order to provide general guidelines on Good Manufacturing Practices (GMP), based on the General

Principles of Food Hygiene of the Codex Alimentarius. It is envisaged as a starting point for moving forward steadily toward more complex systems. Private certification can lead to market recognition which, in turn, can strengthen competitiveness in trade development strategies that promote superior products with seals that denote value.

To safeguard consumers' health and gain their trust, small and medium-sized agribusinesses must tackle many challenges if they are to implement good practices and increasingly comprehensive and complex food safety management systems. Regardless of whether their products target local or international markets, small and medium-sized businesses have the same responsibilities as any large food company.

The challenges are even greater for small businesses in rural areas due to adverse infrastructure, sanitation, and transportation conditions, as well as an unskilled labor force. Typically, in small businesses in rural areas, all responsibility falls to a single person who must handle everything from production and marketing to complying with food safety and food quality requirements.

As noted earlier, safety is of key importance in the food trade and although food safety today does not offer a significant competitive advantage, no business can produce food without following good manufacturing practices. If products are unable to access markets because they fail to meet requirements, the advantages afforded under a free trade agreement are neutralized. This is why IICA considers it of such importance to provide the sector with practical guidelines for meeting the hygiene requirements needed to achieve food safety. These guidelines are entirely in consonance with existing regulations and offer creative solutions for meeting hygiene criteria.

The guide answers questions about good manufacturing practices (GMP) that are frequently posed by the business sector. For example: what comes first, GMP or HACCP¹? What is the relationship of GMP to other international requirements and standards? These questions are addressed in the first section. The guide also shares some practical advice to facilitate implementation of GMP.

1 HACCP: Hazard analysis and critical control points system

Each section of the document includes an explanation of the pursued objectives with the good practices and suggestions for how to implement them.

The document also offers some examples of GMP documentation, which has been identified as one of the main shortcomings in implementing food safety and food quality management systems. It is our hope that they will serve as a point of reference for a task that needs to be tailored to the requirements of each business.

I. HOW TO USE THIS GUIDE

This guide was written for small and medium-scale agribusiness operators to facilitate the effective implementation of food safety management standards and systems, regardless of business size and product destination (domestic or export).

Each section addresses a different aspect of food safety management and begins with general guidelines on the given practice, followed by the principal constraints that must be addressed to achieve the objective. Each section concludes with practical advice for facilitating implementation of the GMP.

Recommendations should be understood and implemented with a good measure of flexibility. How recommendations are implemented in practice will depend on the nature of the food product and the production technologies of each given establishment. The information in this booklet should be supplemented with that from specific guidelines on the particular product. In addition, an assessment should be made to decide if a hazard analysis should be conducted before introducing recommendations.

The suggestions contained in this guide have been made by the authors for the sole purpose of sharing the experience they have gained and the lessons they have learned in the field of food safety. Their intention is to support small- and medium-scale agribusiness operators implement GMPs within a comprehensive framework of food safety management.

II. GENERAL FRAMEWORK

2.1 *Codex Alimentarius*

The Codex Alimentarius Commission was created in 1963 by the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) for the purpose of developing food standards under the Joint FAO/WHO Food Standards Program. The principal objectives of the program are to protect the health of consumers, to ensure fair trade practices in the food trade, and to promote coordination of all food standards work undertaken by international governmental and nongovernmental organizations.

Codex Alimentarius, which in Latin means food code or food law, is a collection of food standards, codes of practice, and other recommendations that aim to ensure that foodstuffs are safe and suitable for consumption. The WTO/SPS agreement recognizes Codex Alimentarius as an international reference agency in the area of food safety.

2.2 Good Manufacturing Practices: a conceptual overview

Good manufacturing practices are a set of technical principles and recommendations used in processing food products in order to guarantee that they are safe and suitable for consumption, and to prevent contamination or adulteration. They are also sometimes called “good processing practices” or “good fabrication practices”.

Originally, good manufacturing practices were developed in response to serious events caused by the lack of safety, purity, and effectiveness in foods and drugs.

The development of good manufacturing practices dates back to 1906 when the Federal Food and Drugs Act (FDA) was created in the United States. Later, in 1938, the Federal Food, Drug, and Cosmetics Act was enacted, introducing the concept of safety. The decisive event occurred, however, on 4 July 1962 when the side effects of a certain medication came to light. This gave rise to the Kefauver-Harris amendment and to the first guide to good manufacturing practices, which was subsequently amended and revised several times before arriving at the current United States regulations on good manufacturing practices for food (Title 21 of the Code of Federal Regulations (CFR), Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding of Human Food).

Then, in light of the need for a harmonized foundation to guarantee food hygiene throughout the food chain, in 1969 Codex Alimentarius adopted the *Recommended International Code of Practice - General Principles of Food Hygiene*, which brings together inputs from the entire international community.

2.3 General Principles of Food Hygiene of the Codex Alimentarius

The Codex Alimentarius' *Recommended International Code of Practice - General Principles of Food Hygiene* lays the foundation for guaranteeing food hygiene

throughout the food chain, from primary production to final consumption. The code was adopted by the Codex Alimentarius Commission at its Seventh Session (1969) and has been reviewed several times since then.

The General Principles of Food Hygiene offers guidelines on different controls that should be introduced throughout the food chain to guarantee food hygiene. These controls are implemented by applying good manufacturing practices and, insofar as possible, the Hazard Analysis and Critical Control Points (HACCP) system. HACCP is used to optimize food safety, as described in the *Codex Guidelines for the Application of Hazard Analysis and Critical Control Points (HACCP)*, approved by Codex in 1993 and included as an annex in the *Code of Practice - General Principles of Food Hygiene* in 1997. This code was reviewed for the fourth time in 2003 (CAC/RCP 1-1969, Rev. 4-2003).

*Good Manufacturing Practices are part of the
General Principles of Food Hygiene*

It is recognized internationally that the recommendations contained in the General Principles of Food Hygiene are essential for ensuring that food is safe and suitable for consumption. This guide is based on those principles.

2.4 Sanitation Standard Operating Procedures (SSOP) and good manufacturing practices

Hygiene involves a series of procedures that should be envisaged as an integral part of food preparation and processing activities, the objective of which is to ensure food safety. These procedures are more effective when they have been duly verified and are carried out regularly in standardized fashion pursuant to the guidelines that govern food processing and preparation processes.

A safe and efficient way of doing this is to implement Sanitation Standard Operating Procedures (SSOP).

SSOPs cover sanitation procedures that should be carried out before, during and after the preparation process.

*SSOPs supplement Good Manufacturing Practices are
part of the General Principles of Food Hygiene.*

2.5 Good manufacturing practices and the Hazard Analysis and Critical Control Points system

The General Principles of Food Hygiene are an important foundation for the application of more complex and more comprehensive food safety and food quality management systems.

Therefore, before implementing an HACCP system, it is important to have satisfactorily implemented good manufacturing practices (GMP) and sanitation standard operating procedures (SSOP). Prior establishment of an HACCP system can result in the identification of critical control points that should be addressed with GMP, and that do not need to be monitored and overseen by the HACCP system. This can also occur if GMPs are not effectively implemented.

Even though GMP and SSOP are considered prior steps for efficient implementation of an HACCP system, business operators should be familiar with the principles of the HACCP system in order to have a comprehensive vision of food safety.

For example, for building the internal structure of a food processing plant, GMP will recommend that doors have a smooth and non-absorbent surface, are easy to clean and, if necessary, to disinfect. A risk assessment should be conducted to determine whether doors made of a material that is resistant to disinfectants are actually needed. This can be excessive, especially if the nature of the product and the operations only call for a door that physically separates contiguous operations in order to prevent cross-contamination.

The application of Good Manufacturing Practices also requires reassessing the potential risk of each food hazard in food processing. While less severe hazards or hazards not very likely to occur will probably not need to be analyzed in an HACCP plan, they must be addressed within the framework of GMP.

Thus, to apply good manufacturing practices, business operators will also need to perform a hazard analysis for each product or type of process, and for each new product, even though they are not implementing the HACCP.

Good Manufacturing Practices and the HACCP system are interrelated and interdependent: application of GMP requires familiarity with the principles of the HACCP system to ensure a comprehensive approach to food safety.

2.6 *Toward a food safety management system*

Today, food safety requires an analytical and systematic approach to determine what hazards are present and how to control them. It is based on a comprehensive vision of the food chain, “from the farm to the table”; all stakeholders in the chain share responsibility.

The current approach to food safety gives producers more responsibility and autonomy in managing safety, as well as greater flexibility in responding to different and changing market requirements. It also recognizes consumers’ responsibility to store, handle, and prepare food properly.

The interdependent nature of food production requires a multidisciplinary and collaborative effort among all stakeholders in the food chain, both public sector and private sector, in order to identify and control hazards to consumer health. It also requires wide intersectoral coordination among agriculture, health, trade, environment, and economy, and other sectors.

This means that, to safeguard human health, every link in the food chain should be equally sound and this can only be constructed step by step, by adopting good practices and good management systems, in a process of continuous improvement.

The lack of food safety causes many problems related to health, reduced shelf-life, commercial value losses, budget overruns due to reprocessing costs, economic impact, and national image effects. It also gives rise to trade-related problems such as restrictions, retentions and penalties. The cost of these problems is such that it can undermine a business’ solvency and force it to close down.

For reasons of public health, competitiveness, market access, well-being, and overall progress, it is of strategic importance for all countries to address the subject of food safety with firm resolution.

III. Good Manufacturing Practices

3.1 *Application of Good Manufacturing Practices*

Good manufacturing practices should be applied with sanitary criteria in mind. As there will always be situations where specific requirements do not apply, **the key is to assess whether a recommendation is “necessary” from the standpoint of food safety and suitability.**

To decide whether a requirement is necessary or appropriate, the General Principles of Food Hygiene recommend conducting a risk assessment, preferably within the framework of the HACCP approach.

Risk assessments are performed to determine if a requirement is appropriate or not, based on the hazards identified, the quantitative or qualitative assessment, possible concentration in a given food, and impact on consumers. Depending on the nature of the given product, certain hazards may be very unlikely or may occur at such low levels that they will not impact on consumers' health. Should this be the case, it may be unnecessary to adopt stringent control measures. This decision, however, can only be made if the risk assessment reveals insignificant likelihood of risk.

3.2 *Primary production*

Food safety hazards should be controlled throughout the food chain (from the primary production to the final consumer) to ensure that food is safe and suitable for human consumption.

Primary production is undoubtedly a key focus of concern since the most serious food crises of recent years were produced by in-field contamination. At this stage, it is important to reduce food hazards that can impact on consumers' health, especially when later stages of the chain or processing will not be able to reduce the hazard or render food suitable for human consumption.

The quality of raw materials received by a food processing plant depends directly on the controls in place in the field. Primary production has many hazards stemming from the use of agrochemicals such as pesticides and veterinary products. If not controlled, this type of contamination cannot be corrected at the processing plant. In order to effectively control incoming raw

materials, the processing plant must exercise effective oversight of suppliers. Manufacturers should reject raw materials that do not meet established safety and quality standards.

All food-producing businesses should be aware of the conditions under which their raw materials are produced.

Some people mistakenly believe that businesses that do not own their own farms or do not directly supervise farming operations are not responsible for the quality of their raw materials. Regardless of how small the operation may be, however, every business can exercise some control over its raw materials, such as when they purchase the products (for further detail, see section 4.4).

Codex Alimentarius has specific codes with important recommendations on primary production for different commodities. Agribusiness operators are urged to refer to these codes.

Small and medium-scale agribusiness operators can also find specific recommendations for fresh fruits and vegetables in the IICA publication "Good Agricultural Practices," published in its Agribusiness Handbooks series.

3.3 *Installations: design and construction*

3.3.1 *General considerations*

This section deals with the site, construction and design of buildings, equipment and facilities of a food processing room, from a sanitary standpoint. The aim is to reduce incoming contamination, facilitate cleaning and disinfection, and keep out pests.

a) Location

- The first thing to consider is where to locate a food processing establishment. The surroundings must be taken into consideration to ensure that they do not have an adverse effect on the food processed.

Facilities should not be located near areas considered adverse or harmful, for example, sanitary landfills, areas subject to flooding,

industrial activities that pose a threat of contaminating food, or other sources of contamination.

b) Construction and layout of the facilities

- Building design and materials have a bearing on hygiene and safety conditions. These, in turn, affect the conditions under which food is processed. Infrastructure should reduce the possibility of contamination, especially dust, airborne contamination, and pests, from entering the building.
- The internal layout of the facilities should permit good hygiene practices, including measures to prevent cross-contamination among raw materials and processed products during the manufacturing process.

c) Internal structures and fittings

- Structures within the facilities should be soundly built of durable materials; they should be easy to maintain, clean and, where appropriate, able to be disinfected. In particular the following specific conditions should be met to protect food safety and suitability:
 - **The surfaces of walls, partitions and floors** should be made of impervious material; they should be smooth and inert to the food.
 - **Walls** should have a smooth surface up to a height appropriate to the operation; 1.8 meters (6 feet) from the floor is usually adequate.
 - **Floors** should be constructed to allow for adequate drainage and cleaning; if water is used in processing, a 2% floor incline is recommended. Gutters and drains should have an incline that provides good drainage; they should be fitted with screens that allow water to flow out but prevent pests from coming in.
 - **Ceilings and overhead fixtures** should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles; water (from condensation) should not be allowed to drip from overhead fixtures, ducts, and pipes onto food, food contact surfaces, or packing materials.

- **Corridors and work areas** should be open, free of obstructions, and wide enough to enable employees to work comfortably.
- **Windows** should be easy to clean, designed to minimize dirt build-up, and fitted with removable and cleanable insect-proof screens; cornices should not be right angled. These measures will improve lighting and ventilation and keep out pests.
- **Doors** should have smooth, non-absorbent surfaces, be easy to clean and, if necessary, to disinfect.
- **Working surfaces** that come into direct food contact should be in sound condition, durable and easy to clean, maintain and disinfect; they should be made of smooth, non-absorbent materials, and be inert to the food, detergents, and disinfectants under normal operating conditions.
- **Natural or artificial lighting** should be adequate to enable manufacturing to proceed in a hygienic manner and to facilitate inspection. Lighting fixtures should be protected by screens or plastic covers to ensure that food is not contaminated by breakages.
- **Natural or mechanical ventilation** should be designed and constructed so that air does not flow from contaminated areas to clean areas, or from humid areas to dry areas.

d) Temporary/mobile premises and vending machines

- Temporary or mobile premises include mobile sales, market stalls, street vending vehicles, as well as temporary premises in which food is handled, such as tents and marquees.
- Such premises should be sited, designed and constructed to avoid, insofar as possible, cross-contaminating food and harboring insects.
- In the selling and handling of food, adequate control should be exercised to ensure that food does not come into direct contact with dirt, dirty water, pests, rodents, dirty hands or dirty surfaces. Order, cleanliness, and disinfection of utensils and surfaces should be paramount to ensure the safety and suitability of food.

e) Equipment

- Equipment, containers and utensils that come into contact with food should be designed and constructed to ensure that they can be adequately cleaned, disinfected and maintained to avoid food contamination. They should be inert and incapable of transmitting foreign or toxic substances to the food. They should be durable and movable or capable of being easily disassembled to facilitate cleaning and inspection.
- The equipment used to apply temperature-related treatments (heating, cooling, etc.) should be able to attain and effectively maintain the temperatures required to safeguard food safety and suitability. Such equipment should also be equipped with the devices necessary to monitor and control temperature. Where necessary, such equipment should have effective means to control and monitor humidity, airflow and any other parameter that may have a detrimental effect on the safety or suitability of food. Temperature measurement devices should be reliable and accurate.
- Containers for waste, by-products, and inedible or dangerous substances should be specifically identifiable, suitably constructed and made of impervious material. Containers used to hold dangerous substances should also be duly identified and be lockable to prevent malicious or accidental contamination of food.

f) Services

- **Water supply.** An adequate and sufficient supply of potable water with appropriate facilities for its storage, such as in covered tanks and reservoirs, should be available at all times to ensure the safety and suitability of food.
- **Potable water** should be as it is specified in national regulations or the latest edition of WHO Guidelines for Potable Water Quality, or be water of a higher standard when possible.
- **Non-potable water** (i.e., for use in fire control, steam production, refrigeration and other purposes where it will not contaminate food) must be clearly identified and must have its own, separate system that should not be connected to or allow reflux into the potable water system.

- Adequate **drainage and waste disposal** should be provided, designed and constructed to prevent the risk of contaminating food or the potable water supply.
- **Cleaning.** Adequate facilities should be provided for cleaning food, utensils, and equipment. They should be located in areas that will not cause cross-contamination with processed foods, and should have an adequate supply of potable water (hot and cold), where appropriate.
- **Personnel hygiene facilities and toilets.** There should be sufficient facilities to ensure that personal hygiene can be maintained and to avoid contaminating food. They should include adequate means for washing and drying hands and a supply of hot and cold water, lavatories of appropriate sanitary design, preferably not hand-operated, and adequate staff changing facilities. When appropriate, hand-washing facilities should be available at the entry to the processing room where hands can be washed and dried hygienically and, if necessary, disinfected.
- **Temperature control.** Depending on the nature of the operations at the processing plant, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures and, when necessary, controlling ambient temperatures to ensure the safety and suitability of food.
- **Ventilation** is important for preventing condensation and controlling humidity. Thus, adequate means of natural or mechanical ventilation should be available in order to minimize food contamination, and to control ambient temperatures and humidity.
- **Lighting.** Adequate natural or artificial lighting should be provided to enable the operations to proceed in a hygienic and efficient manner. The intensity should be adequate to the nature of the operation, such as inspection and the reading of controls, among other things. Lighting should not be such that the resulting color is misleading as this can lead to erroneous decisions, for example in inspections or when heat applied to products causes a change in color (for example, cooking or toasting), as these are important indicators.

- Storage. Where necessary, adequate facilities should be provided for the storage of food (raw materials, intermediate products, finished products), ingredients and non-food chemicals (e.g., cleaning materials, lubricants, fuels). Where appropriate, there should be separate storage facilities for raw materials, inputs, packaging materials, and the final product. Storage facilities should be designed and constructed to permit adequate maintenance and cleaning, prevent pest access and harborage, effectively protect food from contamination during storage and, where necessary, provide special conditions to minimize food spoilage (e.g., controlled atmosphere).

Cleaning materials and hazardous substances should be stored in separate, secure facilities with restricted access, which should be duly identified and labeled.

Storage and transportation of the final product should be such that the food is protected from physical, chemical and microbial contamination. This applies not only to the food products themselves but also to the containers or packaging.

3.3.2 Principal constraints

Small business operators usually begin operations in their own kitchens, carpools or in a small, affordable establishment. Such facilities are unlikely to comply with GMP recommendations, which can become a key obstacle to achieving food safety. Business operators should therefore learn the minimum requirements so they can gradually introduce improvements and achieve safety objectives, even with limited resources.

An essential factor often overlooked is the measurement of temperatures and other variables that are necessary for ensuring a healthful and safe product. Many processes are carried out on the basis of experience and empirical knowledge; although valuable, this must be supplemented with actions that can effectively demonstrate that GMP's are being used.

Every manufacturing process involves measurement, and calibration is an important aspect of measurement. Measuring instruments (such as

thermometers and scales) must be calibrated to ensure that their readings are accurate.

3.3.3 Practical advice

a) Location and construction of the establishment

- With regard to the location of the establishment, if it is not possible to avoid an adverse environment, measures should be taken to isolate the establishment from that environment. For example:
 - i) Locate windows so that air does not flow from the outside into the premises.
 - ii) Make every effort to prevent the entry of pests, using insect-proof screens on windows and drains, and ensuring that the space between doors and the floor is less than 5 mm (0.2 inches).
 - iii) Rodent traps should be placed outside the facilities and a plan established to check them weekly in order to determine incidence. Ceilings should not accumulate dust, be cracked or show signs of leakage. They should preferably be white, painted with white enamel paint and treated under the same conditions as required for walls.
- If the surroundings are not asphalted, the establishment can be surrounded by concrete or rocks to reduce dust. Nearby shrubs should be pruned periodically to prevent them from becoming a shelter for pests.

b) Internal structures and fittings

- The internal layout of the premises should be designed and constructed after the sequence of activities has been clearly identified. Operations should flow from initial operations (arrival of raw materials, dirty area, wet area) to final operations (finished products, clean area, dry area).
- Operations should not be allowed to cross over each other, nor should final operations return full circle to the area of initial operations as this could result in cross-contamination.

- Waste should not be removed while products are being handled.
- If the premises are too small to accommodate different areas for the different operations, the same premises may be used for different procedures provided the operations are clearly separated by time, and adequately cleaned and disinfected between each stage or shift.
- Wall surfaces should be of a washable sanitary material, such as ceramic with or previously treated with antifungal epoxy. If this is not possible, a smooth wall covered with washable white enamel paint, previously treated with antifungal epoxy, is recommended.
- To facilitate cleaning and prevent dust build up, the floor-wall juncture should be concave (also known as a sanitary base). If this requirement cannot be met, it is important to clean and disinfect the floor-wall angle more frequently and with special care.
- Floors should be smooth and have no cracks or irregularities where dust and humidity can accumulate. A polished concrete floor can meet the required hygiene conditions. Wood floors are not recommended.
- With regard to materials that come into direct contact with food, the most recommended is stainless steel. If possible, choose designs without right angles because they are prone to food residue build up (rounded edges are recommended). Work tables should be smooth, preferably of stainless steel and with polished edges to prevent cuts.
- The bases of all equipment and table legs should be sealed to prevent dirt and moisture build-up otherwise they can become sources of contamination. The seals or junctures of surfaces that come into contact with food should be welded and polished to minimize build up of food particles, dirt, or other organic material where microorganisms can grow.

c) Equipment

- Ideally, equipment should not be located at ground or floor level, and should be arranged in a way that facilitates cleaning. It is recommended that they be sited 40 cm (16 inches) above floor level.

- Avoid designs that create inaccessible and difficult to clean spaces as dirt will be more likely to accumulate there. Some examples are stainless steel tables with sharp corners, equipment with unsealed legs, unused pipes with exposed cores.
- Equipment can be a source of food contamination, including:
 - i) Metal splinters, from the wearing of edges or other materials
 - ii) Lubricants, when equipment is lubricated or if nearby equipment needs lubrication
 - iii) Remains of detergents and disinfectants, if equipment is not carefully rinsed
 - iv) Microbial contamination, if equipment traps food residues along the edges, in difficult to clean corners, or around irregular welding
- Since equipment is fundamental in food preparation, the manufacturer should have a written preventive maintenance program to ensure that equipment is kept in good working order. This program should include:
 - i) A list of equipment requiring regular maintenance,
 - ii) The procedures and frequency of maintenance (for example, equipment inspection, adjustment and replacement of parts, screws and nuts), based on the equipment manufacturer’s manual or equivalent, or on operating conditions that can affect the conditions of the equipment.
- When the equipment is second-hand or one-of-a-kind, the processor should examine the design carefully and formulate a preventive maintenance program for it, taking into account the aforementioned considerations.
- The preventive maintenance program for equipment should ensure there are no potential physical or chemical hazards, for example, inappropriate repairs, flaking paint and rust, excessive lubrication.

d) Services

- If recirculated water (potable water not discarded after first use, but recycled and reused in the process) is used at food processing plants to wash containers (for example, jars or cans), or for any activity that has to do with processing operations, it should be treated, monitored and maintained as appropriate to the intended purpose. Recirculated water should have a separate, clearly identified distribution system.
- Ice used as an ingredient or that comes into direct contact with food should be made from potable water and protected from contamination.
- Equipment and utensils for cleaning and sanitizing and their facilities should be adequately separated from food storage, processing and packaging areas to prevent contamination.
- Lighting is very important in inspection areas. Natural lighting is preferable, but if it is not enough, it should be supplemented with artificial lighting, which should be sufficiently intense to allow effective inspection. Avoid lighting that causes workers to cast a shadow on the work table; lighting should not alter the color of food.
- Lighting should be no less than the following:
 - 540 lux (50 foot-candles) in inspection areas or where detailed examinations are made
 - 220 lux (20 foot-candles) in production areas
 - 110 lux (10 foot-candles) in other areas
- Inspection areas are defined as any point in the different stages of the production process where the food product or container is visually inspected (i.e., where empty containers are checked, where products are checked, where raw materials are checked and sorted, or where measuring instruments, such as thermometers, are monitored).
- Thermometers and other measuring instruments used to control and monitor the parameters (humidity, pH level, water activity, others) of processes to prevent, reduce, or eliminate the growth of non-desirable microorganisms, must be accurate and properly maintained. If measuring instruments are required for the

manufacturing operation, they must be calibrated periodically to ensure accuracy. A written log should be kept for each one, with information on calibration status and date of next calibration; this is especially important for control and monitoring equipment that can have an impact on food safety.

- Cold storage areas where food is stored for preservation purposes should be equipped with a thermometer placed where it is easily accessible and visible. It is important to monitor and keep a daily record of temperature. If possible, the cold storage room should have an automatic thermostat that regulates the temperature or an automatic alarm system that signals when the temperature has fallen significantly below the acceptable limit.
- To store raw materials, supplies, and materials, take into account that:
 - i) Ingredients and other raw materials requiring refrigeration should be stored at 4°C (40°F) or less and should be appropriately monitored. Frozen ingredients should be stored at -18°C (0°F).
 - ii) Food containers (cans, bottles, jars, other) should be handled and stored with care to prevent damage or contamination. They should be kept in dust-proof packaging.
 - iii) Use of ingredients should follow the “first-in, first-out” (FIFO) rotation principle to ensure that expired ingredients or inputs are not used in the process.
 - iv) Humidity-sensitive inputs should be stored appropriately to prevent deterioration.
 - v) Non-food chemical products should be received and stored in a dry, well-ventilated and duly identified area to prevent contamination of food or food contact surfaces.
 - vi) Where required for ongoing use in food handling areas, chemical products should be carefully packaged and clearly labeled to facilitate recognition and prevent cross-contamination.

- vii) Chemical products should be handled and distributed only by authorized and appropriately trained personnel.
- viii) Returned defective or suspect products should be clearly identified and isolated in a designated area for appropriate disposition.
- Finished products should be stored and handled in such a way that damage is prevented. For this purpose, the following recommendations apply:

Stacking heights need to be controlled and forklift damage avoided. Place non-perishable food products on pallets at a distance of no less than 15 cm (6 inches) off the floor and 60 cm (24 inches) or more from the ceiling. Products should not be stacked against the wall; leave 50 cm (20 inches) of space to facilitate inspection.

Perishable products should be stacked in refrigerated areas, ensuring that stored materials do not block the flow of cold air. Materials should be stacked 10 cm (4 inches) off the floor, 50 cm (20 inches) from the ceiling and 15 cm (6 inches) from the walls of the refrigerated area.

3.4 Control of operations

3.4.1 General considerations

This section contains recommendations for food preparation and discusses the importance of effective implementation of control systems to ensure the safety and suitability of food for human consumption. All operations, from receiving inputs to transportation and distribution, should be subject to control and adhere to the Codex General Principles of Food Hygiene.

a) Control of food hazards

According to the Codex General Principles of Food Hygiene, food business operators should control food hazards throughout the food chain, using systems such as HACCP. The HACCP system, which is appended to the Codex General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003), is widely recognized as model for achieving food safety.

The HACCP system recommends that food business operators:

- identify any steps in their operations that are critical to the safety of food.
- implement effective control measures at those steps.
- monitor control procedures to ensure their continuing effectiveness.
- review control procedures periodically and whenever the operations change.

b) Key aspects of hygiene control systems

i. Time and temperature control

All food manufacturing processes, including packaging and storage, should take place under conditions that reduce the possibility of microorganism growth and food contamination to the minimum the possibility of microorganism growth and food contamination. This can be achieved by monitoring certain physical parameters such as time, temperature, humidity, a_w (water activity), pH level, water pressure and flow speed, among others.

The most common of these are control of temperature and time of cooking, cooling, processing and storage to prevent food from becoming a vehicle for transmitting illness and to prevent food deterioration.

Important: it is not enough to control temperature; time must also be controlled. These two parameters should be monitored simultaneously.

Such systems should also specify tolerable limits of time and temperature variations. Temperature and times should be checked at regular intervals and recorded systematically.

Operations that contribute to food safety (i.e., freezing, refrigeration, cooling, thermal processing, acidification, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging) should be monitored carefully. Tolerable limits of time and temperature variations should be established for each, and they should be checked regularly and recorded systematically. Never allow operations to proceed if there are mechanical problems, time delays, fluctuating temperatures, or other negative factors. If these situations are not controlled, they can contribute to food contamination or spoilage.

ii. Microbiological specifications and others

In some manufacturing processes it is necessary to establish microbial, chemical, or physical specifications to ensure food safety and suitability. These should be based on sound scientific principles and indicate, where appropriate, operational limits, monitoring procedures and analytical methods.

iii. Microbiological contamination

Microbiological pathogens are invisible to the naked eye, and can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces (poorly cleaned equipment or work tables) or the air. Steps must therefore be taken to prevent microbial contamination.

For example, raw, unprocessed foods should be separated (either physically or in time) from ready-to-eat foods, with effective intermediate cleaning and, when appropriate, disinfection. Depending on the risk and the nature of the food, access to processing areas may sometimes need to be restricted, either through controls at the point of entry or by having special areas, ante-chambers, or corridors at the entry to processing areas where the personnel can change into clean and exclusive protective clothing, including footwear, and hand-washing and boot-washing stations.

Surfaces, utensils, equipment, fixtures and fittings should be cleaned thoroughly and, where necessary, disinfected after raw food, especially meats, fruits and fresh vegetables, have been handled or processed.

Systems that control time, temperature, acidity, pH and a_w (water activity) are of critical importance to reduce microbial contamination.

iv. Physical and chemical contamination

Control systems should be put in place to prevent contamination of foods by foreign bodies such as glass or metal shards, wood splinters from the equipment or working surfaces, dust, harmful fumes and unwanted chemicals from lubricants, packaging, paints and rust. Suitable controls and detection or screening devices such

as filters or screens, traps, magnets and electronic metal detectors, should be used where necessary.

Mechanical operations such as washing, peeling, cutting, chopping, sorting, pounding, shredding, grinding, draining, cooling, grating, extracting, drying, beating, degreasing, among others, should be performed in such a way as to protect the food from contamination, especially physical and chemical.

v. Requirements related to raw materials

No raw material or ingredient should be accepted by an establishment if it is suspected or known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic agents, decomposed or extraneous substances which would not be eliminated or reduced to an acceptable level during the manufacturing process. To this end, specifications for raw materials and ingredients should be identified and implemented.

Depending on the type of food product, raw materials or ingredients should be checked and sorted before processing. If necessary, laboratory tests should be conducted to confirm suitability.

Stocks of raw materials and ingredients should be subject to the "first-in, first-out" FIFO principle to ensure effective stock rotation.

vi. Packaging

According to the General Principles of Food Hygiene, packaging design and materials should provide adequate protection for products in order to minimize contamination, prevent product damage, and accommodate proper labeling. If gases are used for packaging, they must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Reusable packaging should be durable, easy to clean and, where necessary, easy to disinfect.

vii. Water

In contact with food

Only potable water should be used in food handling and processing, except in the following cases: when the water is used

in operations not connected with food, for example, for steam production, cooling systems, or fire control systems.

Water can be reused, provided it is treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. Recirculated water that has received no further treatment, and water recovered from processing of food by evaporation or drying, may be used provided its use does not constitute a risk to the safety and suitability of food.

As an ingredient

Potable water must be used wherever necessary to prevent food contamination.

Ice and steam

If used in direct contact with food, ice should be made from potable water. Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or with food contact surfaces should not constitute a threat to the safety and suitability of food.

viii. Management and supervision

According to the General Principles of Food Hygiene, the type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge of food safety principles and practices to be able to judge potential risks, take appropriate preventive and corrective actions, and ensure that effective monitoring and supervision takes place.

Hygiene is a reflex of not only management policies but also the knowledge, commitment and conduct of all the people involved in making decisions.

ix. Documentation and records

Appropriate records of processing, production and distribution procedures should be implemented and maintained for a period

stipulated under national law or, in the case of exports, as required in destination markets.

Documentation is important for product traceability and to enhance the credibility of the business' food safety control system. (For more information on documentation, see section 4.10.)

x. Recall procedures

Senior managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated product.

When there are other products that may represent a public health hazard, they should be evaluated for safety and recalled if necessary. Consideration should be given to issuing public warnings for risk communication.

Recalled products should be securely held until they are destroyed, used for purposes other than human or animal consumption, determined to be safe for human or animal consumption, or reprocessed in a manner to ensure their safety.

Lots of safe food may not be mixed with defective lots or lots with an unacceptable level of contaminants; if this occurs, the final product is considered adulterated.

3.4.2 Principal constraints

Some people believe that small factories or home-made product industries cannot apply control processes, monitor suppliers or keep records of activities.

In fact, experience has shown that all types of manufacturing, including home-made and artisanal industries, can implement control processes, select their suppliers, and keep simple records that will provide them with a historical account of the process and enable them to demonstrate that they have met all necessary requirements.

Just as any home kitchen needs equipment and utensils that are in good condition, manufacturing companies must also provide maintenance for their equipment. Perhaps the greatest obstacle for small businesses is to get used to measuring the parameters of the process, especially temperature, and to have access to calibrated thermometers to ensure accurate measurements. These activities, however, are a cornerstone of the control process and must be performed to achieve food safety. With adequate training, they get easy to carry out.

3.4.3 Practical advice

Implementation of the following recommendations will improve control in the manufacturing process:

a) Raw material and inputs

- Product safety depends to a large extent on the control of raw materials and inputs. Inadequate control of raw materials can result in product contamination.
- Product formulations should be kept in writing. Special attention needs to be given to the concentration and weight of food additives, their identity and purity (the supplier of the additive should provide this information). The manufacturer must be able to demonstrate through calculations that food additives are used within the maximum level specified in the food law.
- Manufacturers should ensure that additives and their concentration meet Codex Alimentarius standards and the standards of relevant legislation.

The degree of control exercised over incoming raw materials and inputs should be proportional to the risk.

- Keep control of specification sheets of all raw materials, ingredients, inputs, packing material, and food additives. This includes cleaning and disinfection agents, lubricants and sanitary grease.
- When inputs considered critical because they can introduce hazards into the process are used, the supplier should provide a certificate

stating that each lot meets the requirements of the food law and the corresponding specifications sheet.

In the case of additives, manufacturers should have analytical protocols that specifications have been met, and the degree of purity should be clearly indicated on the container.

- Every now and then, depending on the level of risk, the manufacturer should verify compliance with the specified requirements. The business should have a master list of suppliers, organized by raw material and input, and rate them on their degree of compliance with the requirements stated on the specification sheets.

The manufacturer should regularly audit suppliers in order to confirm their status on the master list.

- When the concentration of ingredients is of key importance in the final product, manufacturers should exercise strict control over formulation to guarantee accurate measurement and adequate blending for homogeneity (especially important for additives, salts, minerals, and vitamins). This control is indispensable in dietary foods, infant formulae, meal replacements, fortified foods, and foods for which nutritional claims have been made (i.e., low-calorie or reduced sodium content), since the characteristic that differentiates them is their nutritional value.
- Manufacturers should have control procedures in place to guarantee that label information accurately reflects the product's composition and nutritional value. Controls should include having specification sheets for the labels that include the model and design of the label, verification for each lot received that all specifications have been met, and verification that the label entering the processing room corresponds to the product being manufactured.

These controls are necessary to prevent the presence of undeclared ingredients or misinformation concerning product composition. Manufacturers should ensure that label information provides the public with accurate information related to net contents, product name, manufacturer's name, packer's name and/or distributor's name, as well as instructions for proper handling and preparation at home. It should also provide information on potential allergens.

b) Water

- Water should comply with established regulations and the manufacturer should submit it to analysis, with due frequency, to check its potability. Well water or water from sources other than that provided by the municipal network should be treated and tested to guarantee potability. Chlorine must be applied and chlorine-free residual should be checked daily. Records must be kept of these controls.
- To ensure there are no pests inside, the condition of water reservoirs should be checked weekly. Semiannual cleaning of wells or cisterns is recommended, although the frequency depends on the water source and quality, frequency of use, and room temperature.

c) Control of operations

- Control should be maximized in operations designed to reduce microbial contamination and preserve food. This requires trained staff, calibrated measuring instruments, and recordkeeping that can demonstrate that operations are being supervised with the due frequency. Some of the most frequent of these operations are:
 - Refrigeration ($< 5^{\circ}\text{C}$).
 - Freezing (-18°C).
 - Thermal treatments ($> 70^{\circ}\text{C}$).
 - Drying.
 - Concentration.
 - Acidification.
 - Chemical preservation.

d) Documentation and records

- Measurement records should be legible and permanent, and should accurately reflect the actual situation. Include any errors that may have occurred and changes made. The idea is to have a “process history” and to be able to determine the causes of deviations. If records are altered and only the final corrected version is kept, information that may be useful in the future for making improvements will have been lost.

For example, if an original measurement needs to be corrected, it should be struck out with a single stroke and initialed near the correction or change. Every entry on a record should be made by the person responsible at the time the event occurred. Once complete, the record should be signed and dated by the supervisor or the person in charge.

- Records should be retained for at least one year after the expiration date on the label or container or, if there is no expiration date, for two years after the date of sale. In any event, the period should comply with relevant legislation.

Records should be kept at the processing plant and be available upon request.

e) Recall procedures

- There should be a written procedure for recalls that includes the name of the person responsible for recalling the product, the methods to be used to identify, control, and store recalled products, a requirement to investigate other products that may be affected by the hazard and that should be included in the recall, and a procedure for monitoring the effectiveness of the recall to the appropriate distribution level. Recall information should also include the amount of product produced, in inventory, and distributed; the name, size, code or lot numbers of food recalled, the area of distribution of the product (i.e., local, national, international), and the reason for the recall.

Distribution records should contain sufficient information to permit the traceability of a certain code or lot number. At the very least, these records should include the following information: product identification and size, code or lot number, quantity, customer's name, address, and telephone numbers to the initial level of product distribution.

3.5 Installations: maintenance and sanitation

3.5.1 General considerations

This section discusses the importance of having effective systems to ensure adequate and appropriate maintenance and cleaning, pest control, waste

management, and of monitoring the effectiveness of maintenance and sanitation procedures.

a) Maintenance and cleaning activities

Establishments and equipment should be kept in an appropriate state of repair and condition to facilitate all sanitation procedures, the well functioning of the equipment, and to prevent food contamination. The condition of equipment and food contact surfaces affects the effectiveness of cleaning procedures.

Cleaning should remove food residues and dirt which may be a source of contamination. The cleaning methods and materials required will depend on the nature of the food business.

If the production process requires a disinfection procedure, this should only be done after thorough cleaning since disinfectants usually lose their effectiveness in the presence of organic matter.

Cleaning chemicals should be handled and used carefully, in accordance with manufacturers' instructions. They should be stored separately from food, in clearly identified containers to avoid the risk of contaminating food.

b) Cleaning procedures and methods

The cleaning and disinfection methods and materials used will depend on the type of process. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces; this removes dirt and dust, and the mechanical action reduces environmental bacteria suspended in those particles;
- applying a detergent solution to loosen soil and bacterial film; this eliminates dirt and grease adhered to surfaces, and the mechanical action reduces the bacteria in the film;

- rinsing with water to remove loosened soil and detergent residues: dust, grease and bacteria are eliminated by the detergent and the scrubbing;
- where necessary, disinfection; the main objective of disinfection is to eliminate or reduce bacteria and fungus.
- When water-free methods are indicated, dry cleaning procedures should be used and waste eliminated by vacuuming or by applying moistened sanitized towels. This type of cleaning should be followed by disinfection, depending on the nature of the product and the processes.

Operations should only begin after cleaning and disinfection procedures have been completed.

c) Cleaning and disinfection program

The purpose of the cleaning and disinfection program is to ensure that all facilities, including floors, processing room walls, refrigerated areas, warehouses, equipment, utensils, toilet facilities, and cleaning equipment, among others, are appropriately clean. Cleaning programs also cover the area where equipment and utensils are cleaned and the waste disposal area.

Cleaning and disinfection programs should specify:

- what surfaces, equipment and utensils are to be cleaned, along with the name of the responsible person;
- what method and procedures are to be used (detergents, disinfectants, concentration), as well as frequency of cleaning and disinfection; and
- monitoring arrangements (levels of action).

If the business does not have specialized staff who can design these programs, they should be drawn up in consultation with specialized expert advisors or may consider the use of certified third party providers.

d) Pest control program

Pest control programs have the purpose of preventing pests from entering the premises and breeding, and include eradication measures, if necessary. The likelihood of infestation can be reduced by thorough cleaning and effective inspection. Waste disposal areas, the principal focus of pest breeding sites, should be the focus of special attention.

i. Preventing access

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. All holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

ii. Harborage and infestation

Eliminate sources of food and other conditions that encourage pest harborage and infestation.

iii. Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of the entry, breeding, and infestation of pests.

iv. Eradication

Eradication should be done immediately, using means that do not adversely affect food safety or suitability of products.

e) Waste management

It must not be allowed to accumulate waste; this is achieved by ensuring prompt removal or storage. Waste areas should be kept clean and, if necessary, disinfected.

f) **Monitoring effectiveness**

Cleaning and disinfection procedures for equipment, food contact surfaces, and critical environments should be verified.

Verification consists of collecting objective proof that cleaning and disinfection objectives have been met; in other words, verification is performed to confirm the effectiveness of procedures that will subsequently be maintained and monitored.

Monitoring should be performed periodically and conscientiously; it should be documented to evaluate the suitability and effectiveness of cleaning and cleaning programs.

Monitoring of a cleaning program takes place at two levels:

- i) periodic inspection, through visual observation; and
- ii) monitoring of surfaces (swabbing or rubbing), environmental controls (sedimentation plates), employees' hands (swabbing or fingertip sampling), among others.

3.5.2 *Principal constraints*

The main constraint associated with effective cleaning programs is when procedures have not been verified and their effectiveness is therefore unknown.

Some people believe that cleaning is enough to combat contamination, perhaps because they think that what looks clean to the naked eye is in fact clean. In food processing, however, contamination occurs at levels invisible to the naked eye. Therefore, when appropriate, disinfection should be applied to guarantee adequate hygiene. Depending on the nature of the product and the associated risks, disinfection may not be necessary and may actually cause quality problems; for example, products may lose their aroma or moisture may be introduced into dry processes.

Many establishments use disinfectants without having first cleaned thoroughly; this affects the effectiveness of sanitation. In addition, and this can be very dangerous, instead of disinfecting, the process may be creating more resistant bacteria.

The principal constraint related to pest control is the level of staff training. Employees should be made aware of the relationship between pests (flies, cockroaches, birds and rodents, among others) and illness. They should also understand pests' capacity for reproduction and their biological cycle, which is usually very short.

If rodents or cockroaches are not eradicated immediately, infestation can occur in a very short period of time. These pests simply cannot be allowed on site.

Businesses should seek the advice of pest control professionals. Pests are a problem that must not be underestimated because they will, with all certainty, cause damage to the food being processed.

3.5.3 *Practical advice*

a) Verification

- The cleaning program should be verified to determine what cleaning and disinfection procedures will be used in the establishment and how they are implemented. Verification helps provide the certainty that the chosen procedures are effective by the use of validation procedures.

Verification will be effective so long as there are no changes in the conditions under which it was originally performed.

A new verification and validation should be performed when changes have occurred in:

- 1) the cleaning and disinfection program,
- 2) cleaning and disinfection methods,
- 3) the active ingredients of cleaning and disinfection products,
- 4) infrastructure, equipment, or the flow of operations.

- Verification is performed by selecting areas of the process including critical areas and controlled or clean areas. Critical areas are defined as areas where food is exposed; where the nature of the operation, the infrastructure, and the equipment hinder cleaning and disinfection activities; where there is high traffic; and where there is a risk of cross-contamination.

If the program proves effective in critical areas, then all points of the process are covered so long as they receive the same treatment as those that were verified.

Recommendations: Steps for verification

1. *Assign one person to be responsible for verification.*
2. *Select which procedures will be verified.*
3. *Make available the resources necessary (staff, time, sampling and testing methods, sampling and testing materials) for conducting the verification.*
4. *Determine which critical areas will be verified and the sampling frequency.*
5. *Apply the cleaning and disinfection procedure under normal work conditions.*
6. *Take the first sample immediately after applying the procedure being verified.*
7. *Proceed to sample with the frequency defined for each selected point (areas, equipment, etc.). Complete the sampling before the end of the given frequency period.*
8. *Analyze all samples or send them out for analysis.*
9. *Assess the findings, comparing them with maximum allowable limits.*
10. *Based on the findings and the assessment, prepare the verification report.*
11. *When appropriate, coordinate with the processing plant to implement corrective measures. Corrective action may consist of, but not be limited to, applying the procedure with the frequency used for a sample that met the requirements. If the first sample produces unsatisfactory results, the procedure is not effective and should be modified.*

b) Cleaning and disinfection procedures

- Cleaning and disinfection procedures for equipment should be very specific in terms of:
 - i) identifying the equipment and utensils that need to be cleaned and disinfected,
 - ii) providing clear instructions on when parts should be disassembled and assembled for cleaning or inspection activities,
 - iii) identifying areas of the equipment requiring special attention,
 - iv) cleaning, rinsing, and disinfection methods.
- The cleaning program should also include cleaning procedures that can be done inside the facilities while processing is going on; for example, taking advantage of breaks to discard waste and defining how frequently waste should be removed from the establishment.

c) Some thoughts on disinfectants

- Although there are many disinfectants that can be used in a food processing plant, it is important to be well aware of the biohazards related to the product and the manufacturing process, and to take this into account to select the most suitable disinfectant.
- It is important to know the following about a disinfectant:
 - i) the active ingredient and the concentration needed to eliminate or reduce identified hazards,
 - ii) at what pH level it acts,
 - iii) how it performs in the presence of organic matter or water hardness levels,
 - iv) the temperature at which it should be used,
 - v) how long it takes to act,
 - vi) the purity of its active ingredient.

Of these factors, the most important are the concentration and action time.

- Use at least two different active ingredients. Rotate disinfectants occasionally to prevent bacteria and fungi from developing resistance. Both of the disinfectants selected should be submitted to verification.
- For all disinfectants, keep a specification sheet with information on factors that influence their action. It is the supplier's responsibility to provide adequate information and all due assistance. The degree of purity of the disinfectant's active ingredient is vital information.

d) Pests control program

- In addition to a cleaning program, all establishments must have a pest control program. Insects, rodents, and birds are the primary pests that need to be controlled. A pest control program should include the name of the person responsible for the program, the name of the company or individual hired to carry out the pest control program, the list of chemical products used, their concentration, where they are applied, and the method and frequency of application.
- Keep a map showing where rodent traps have been set, and control points outside the establishment. Monitoring of these traps will help map rodent incidence and identify where the establishment is most vulnerable to incoming pests. The pest control program should specify the type and frequency of inspection.

Rodenticides may only be used outside the facilities.

e) Waste disposal

- For temporary storage of waste, use clearly identified containers that have been tested for leakage; if appropriate, they should be covered.
- Once waste has been eliminated, containers should be cleaned and disinfected to minimize the possibility of contamination.

3.6 Establishment: personal hygiene

3.6.1 General considerations

This section focuses on the personal hygiene of food handlers. If employees do not receive hygiene training and if no control measures are implemented, employees could become the principal source of food contamination.

Personal hygiene measures are implemented and food-handler hygiene is monitored in order to prevent food contamination and the transmission of illnesses to consumers.

a) Health status

Food businesses must ensure that people who are ill or who are carriers of a disease or illness that can be transmitted through food are not allowed to enter food handling areas.

People with those conditions should immediately report their illness or symptoms to their supervisor.

b) Illnesses and injuries

Illnesses, symptoms and injuries that should be immediately reported by employees to management so they can be examined by a doctor include:

- jaundice (yellowing of skin and eyes),
- diarrhea,
- vomiting,
- fever,
- sore throat with fever,
- visibly infected skin lesions (boils, cuts, etc.),
- discharges from the ear, eye or nose.

c) Personal hygiene

Food handlers should maintain a high degree of personal hygiene and wear appropriate, wear suitable protective clothing, head covering, and footwear. Personnel with cuts or injuries should preferably be assigned to work in areas where they will not have direct contact

with food. If they are allowed to continue working, the injuries must be appropriately bandaged and when possible covered with rubber gloves.

Employees should always wash their hands when personal hygiene may affect food safety, including at the start of food handling activities, immediately after using the toilet, and after handling raw materials or raw foods.

d) Personal conduct

People engaged in food handling activities should refrain from conduct that could result in food contamination, for example:

- smoking,
- spitting,
- chewing gum or eating,
- sneezing or coughing over unprotected food,
- touching their hair or face, or using their hands to wipe away perspiration while at work,
- wearing their uniform in areas where they can be exposed to contamination,
- using jewelry, pins, or other objects that can pose a threat to food safety and suitability,
- keeping their clothes and other personal effects in areas where food is exposed or where equipment and utensils are washed.

e) Visitors

Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and comply with the personal hygiene provisions described in this section, emphasizing on proper practices to avoid cross-contamination.

f) Sanitation facilities for employees

Food businesses should provide employees with access to a sufficient number of hygienic toilet facilities that are working properly.

They should be kept clean and in good condition; doors should not open directly onto food processing areas unless special measures have been taken to prevent contamination, such as double doors or positive airflow systems.

Hand-washing facilities must also be in good repair, easily accessible and have running water at all times. Hand-washing stations in processing rooms should provide for disinfection and be equipped with paper towels or an automatic dryer to limit recontamination of hands upon departure.

3.6.2 *Principal constraints*

The principal constraint in the area of personal hygiene is lack of training, which merits priority attention.

Training must be dynamic and include practical examples; otherwise employees are unlikely to adopt hygiene principles and a multiplier effect will not be achieved.

Establishments must ensure that employees have access to sanitation facilities that are in good working order, uniforms that are appropriate to their type of work, clean toilets and hand-washing stations that also provide for disinfection.

Hygiene practices required of employees should be a matter of company policy.

3.6.3 *Practical advice*

a) Monitoring of personnel

The business should have a set procedure for monitoring the personal health status of employees that includes, among other things:

- Keeping track of employees' health through health files for each employee where all health-related events are recorded.
- Requiring all persons or visitors who enter processing rooms to first fill out a form on their health status so as to prevent food contamination.
- Excusing food handlers with diarrhea or other type of digestive illnesses from work because, even if they are not in contact with food, their use of toilet facilities may lead to contamination of other employees.

- Stocking toilet facilities with liquid soap since it prevents the cross-contamination that can occur when bar soap is used.
- Equipping toilet and hand-washing facilities with paper towels, individual towels, or hot-air dryers.
- Having foot-operated or sensor-operated toilets and faucets to avoid handling plumbing accessories in toilet facilities.
- Not allowing people with illnesses that can be foodborne in areas where food is handled. Employees should learn to inform their supervisors if they have a contagious disease that can be transmitted through food.
- Not allowing employees with open injuries to handle food or remain in areas with food contact surfaces unless the wound is protected securely with bandages and covered by waterproof material, for example, rubber gloves.
- Requiring all people who enter a food handling area to wash their hands. Employees should submerge their hands in a disinfectant solution or use a disinfectant solution to clean their hands. This procedure should be verified.

How to verify a hand-disinfection procedure

You will need three people who do not have injuries on their hands and who have received appropriate training on correct hand washing and disinfection.

- *Have person 1 touch a surface that can be contaminated.*
- *Take a sample from the hands of person 1, by swabbing or with fingertip sampling.*
- *Have person 2 touch the contaminated surface and wash his/her hands with the liquid soap being evaluated.*
- *Take samples from the hands of person 2.*
- *Have person 3 touch the contaminated surface, wash his/her hands, and disinfect them with the disinfectant being evaluated.*
- *Take samples from the hands of person 3.*
- *Compare results: The sample of person 1 should produce bacteria growth; the sample of person 2 should show less bacteria growth; the sample of person 3 should show no significant bacteria growth.*

- Once the procedure has proven to be effective, employees should be given training in the correct procedure. Signs with appropriate messages should be placed on the walls in hand-washing areas. Hand-washing practices should be checked, preferably on a daily basis.

The procedure can be verified with the chosen frequency, which can be monthly or more frequently, depending on the results of product evaluations. If it is suspected that employees are the source of contamination, hand washing should be monitored every day and verifications performed weekly until the problem is brought under control.

- Preferably, employees should wear clean, white clothing exclusively in areas where they work in contact with food. Hair should be covered. Footwear should be appropriate and, if necessary, disinfected upon entering the processing room.
- Earrings, rings, chains, or bracelets should not be worn in food handling areas. If necessary, watches may be used. To prevent physical contamination, personal belongings and clothing should not be stored in food handling areas but rather in a dedicated area; all workers should have a personal locker.
- Employee and visitor access to the food processing plant should be controlled in order to prevent contamination.
- Employee traffic within the facilities should be routed to prevent contamination of the product and separate areas of raw and processed products.
- If necessary, gloves may be used so long as they are intact and clean. Gloves should be waterproof and appropriate for the task at hand.

Even if employees wear gloves, they must still comply with hand-washing requirements.

- The following are sources of contamination: perspiration, hair, cosmetics, nail polish, tobacco, chemical products, and medical products applied on the skin.

- Managers in charge of supervising employees, and monitoring hygiene and food contamination should be well versed and experienced in hygienic practices to ensure hygienic and safe food production. Food handlers and supervisors alike should receive instruction in appropriate food handling techniques and be able to control hazards caused by poor personal hygiene.
- Signs that encourage good hygiene are a practical way to remind employees of the training they have received. Bear in mind, however, that messages by themselves are ineffective: people must first receive training where the message is transmitted with practical examples so that, when they see the sign, they are reminded of its importance.

3.7 *Transportation*

3.7.1 *General considerations*

This section refers to the hygiene measures and care needed to keep food safe during transportation. Regardless of how many precautions are taken earlier in the food chain, if hygiene is neglected during transportation, food runs a very high risk of spoilage or becoming contaminated.

The following are some important points to bear in mind:

- Food must be adequately protected during transport. The type of conveyance or container required will depend on the nature of the food and conditions under which it needs to be transported.
- The conveyance or container should be designed and constructed to prevent food from contamination from dust, exhaust, fuel, the loading of other food, among other things.
- Conveyances and containers used to transport food and food warehouses should be kept clean and in good repair. Where the same conveyance or container is used for transporting different foods or non-foods, effective cleaning and, where necessary, disinfection should take place between loads. When the same means of transportation is used for different types of products, that is, when the conveyance or container is not used exclusively for food, it should be checked and monitored

periodically and only accepted if there is certainty that there is no serious risk of contamination.

- Pallets, recipients and containers used to transport food in bulk should not be used for any other purpose. To control cross-contamination, keep a record of previous shipments.

3.7.2 Principal constraints

Businesses often assume that if processing has been done carefully with the proper controls in place, food will be kept under control during transportation and reach its destination in perfect condition.

This error occurs when businesses design their operations and establish controls in the understanding that transportation and distribution are not part of the production process. This is incorrect under good manufacturing practices (GMP).

In the food chain approach, controls begin in primary production and end at the final destination.

Transportation and distribution are key operations; if they are not appropriately monitored the effort of all previous stages can be lost.

The impact of transportation on food safety can be illustrated with a case of contamination by salmonella. In this particular case, pasteurized milk was transported in a milk tanker that had previously carried unpasteurized eggs. As the tanker that carried that high-risk product was not properly cleaned or disinfected after use, when the pasteurized milk was loaded it became contaminated with salmonella.

Although one might think that the carrier was fully responsible for this event, in fact it was the responsibility of the pasteurized milk producer to monitor the shipment. In this case, the producer most likely did not evaluate the carrier or request information on the previous cargo or the cleaning and disinfection treatment used.

This is a true case and can happen to anyone who does not adequately monitor the transportation process.

3.7.3 *Practical advice*

- Food manufacturers should ensure that the conveyance or container they use is suitable for transporting food. Following are some important recommendations in this regard:
 - Inspect the conveyance or container before and during loading to ensure that it is not contaminated and that it is suitable for transporting food.
 - Establish a program to check that carriers have been effectively cleaned, for example, by drawing up a written guide on cleaning and sanitation procedures for bulk transport vehicles.
 - When vehicles are used for different purposes, it is important to have procedures in place to restrict the type of cargo they are allowed to carry. Keep records on vehicle cleaning and on the materials previously transported. All vehicles should be inspected before food is loaded.
 - Carriers should be loaded, arranged and unloaded in a manner that protects the cargo and does not damage or contaminate the food being transported.
 - Bulk tanks for the transport of food should be designed and built to permit complete drainage and prevent contamination.
 - Where appropriate, transportation vehicles should be constructed of materials that are suitable for food contact.
- Design a general training program to raise the awareness of food transporters of the hazards associated with food transportation and distribution (including storage).
- Define the requirements or specifications for handling and distributing ingredients or food; communicate this information to the carriers and distributors.
- Require companies that transport and store food to adopt the necessary hygienic actions to protect food, and to maintain and keep records that demonstrate that these requirements have been met.
- Transport ingredients or products that require refrigeration without breaking the cold chain. To this end, it is important to carefully monitor

transportation and to record the temperatures when loading, during transportation, and when unloading.

Frozen products and raw materials should not be allowed to thaw during transport.

- Food should be transported under conditions that prevent contamination by microbiological, physical, or chemical hazards.

In order to prevent contamination by microbiological hazards:

- Products should be carefully packed, with the packaging intact.
- The means of conveyance should be clean and disinfected if necessary; there should be no food remains or evidence of pests.
- Perishable foods that will be in transit for a long period of time should be kept at an appropriate temperature.
- Where the same carriers are used for food and non-food loads, food should be kept in protective boxes (including thermal) to conserve the temperature and protect them from external contamination.
- When rented bulk tanks are used to transport food products, it is imperative to find out what it transported previously and to evaluate if the previous load posed a greater risk of contamination than the present product to be transported. Should this be the case, the tank must be cleaned and disinfected before loading, and records be duly kept of these operations.

To prevent contamination with chemical hazards:

- Do not transport food products or ingredients along with containers of fuel or chemical products that can transfer odors or contaminate the product by contact.
- Never transport food in vehicles or other types of conveyances that are also used to transport chemical products.
- Exercise great care when products are transported in rented bulk tanks. Should bulk tanks be necessary, require the supplier to set aside

certain trucks exclusively for food transportation. Keep a record of the trucks used and, for every shipment, the vehicle's inspection and identification data.

To prevent physical contamination:

- Make sure that the vehicle is free of splinters or nails that can damage or tear product packing. This applies particularly to wood pallets or packing boxes that can splinter or whose nails can damage the product or introduce physical hazards.

3.8 Product information and consumer awareness

3.8.1 General considerations

This section is of special importance because label information is intended to ensure that the next person in the food chain has adequate and accessible information for handling, storing, processing, preparing, and displaying the product safely and correctly. It also makes it possible to easily identify and recall the product, if necessary.

Information should be helpful, clear, and truthful.

a) Lot identification

Lot identification is essential for traceability purposes and for facilitating product recall, should this be necessary (making it possible to identify affected lots). Also, lot identification and production dates contribute to effective stock rotation, both in commercial warehouses and in consumers' pantries. Each container of food should be permanently marked to identify the producer, the lot, and the expiration date.

b) Product information

All food products should be accompanied by adequate information to enable the next person in the food chain to handle or use them without affecting product safety.

c) Labeling

Pre-packaged food should be labeled with clear instructions to enable the next person in the food chain to handle, display, store, and use the product safely. Prevailing labeling standards should apply.

d) Consumer information

Consumers should be aware of general food hygiene practices so they can understand the importance of product information, make informed choices and follow the instructions that accompany the products. Manufacturers should take advantage of labels to instruct consumers, and can include a telephone number for consumers to call if they have any questions.

3.8.2 Principal constraints

Without adequate information, consumers may handle food products incorrectly. This can result in serious consequences for people's health, or products becoming unsuitable for consumption, even where good manufacturing practices were diligently followed earlier in the food chain.

3.8.3 Practical advice

- Comply with local labeling regulations.
- When products are for export markets, comply with the labeling regulations of the destination market.
- Include the following information on the label:
 - Name of the food,
 - List of ingredients and food additives used in preparing the product,
 - Net contents and drained weight,
 - Country of origin,
 - Lot identification,
 - Production date,
 - Expiration date, when necessary,
 - Instructions for conservation,
 - Instructions for use,
 - Manufacturer's name,
 - Manufacturer's address,

- Name, business name of the importer (this can go on a separate label),
- Sanitary registration number (pursuant to national regulations; it is a code number granted by the competent health authority).

4.9 Training

4.9.1 General considerations

This section explains how good manufacturing practices are based on appropriate training and/or instruction for all people who come directly or indirectly into contact with food.

Training is fundamentally important in any food safety management system.

a) Knowledge and responsibilities

Among other things:

- All employees should be aware of their role and responsibility in protecting food from contamination and spoilage.
- All employees should know how to handle the product hygienically.
- Employees who handle chemical products should receive instruction in safe handling techniques.
- Process supervisors should have expertise in managing process operations.
- Employees should be familiar with the cleaning and disinfection programs and the pest control program to a level appropriate to their responsibilities.

b) Training programs

Training programs should be appropriate to the complexity of the manufacturing process, taking into account:

- the nature of the product and the risks of contamination,
- process operations (incoming raw materials, supplier oversight, storage practices, control of key operations, monitoring and measurement of control parameters, cleaning procedures, labeling, transportation, distribution),

- record management, and the different quality procedures, programs and manuals.

c) Instruction and supervision

As in other programs, periodic assessments should be performed of the effectiveness of training and instruction programs.

Also, routine supervision and checks should be carried out to ensure that procedures are being performed effectively.

d) Refresher training

Training programs should be periodically reviewed and updated, preferably once a year or when processing conditions change (for example, if new requirements have been added, if changes are made in the process, if new equipment is introduced).

Food handlers should remain aware of all the procedures necessary to maintain the safety and suitability of food.

3.9.2 Principal constraints

A food establishment's capacity to achieve food safety and suitability depends, to a great extent, on staff training (both for workers and for supervisory personnel). Inadequate training in hygienic procedures and the manufacturing process makes every person involved in food-related activities a potential threat to the safety of food products.

Training should be planned and designed with a view to achieving specific objectives; to not do so is to invite serious consequences for product safety and suitability.

3.9.3 Practical advice

- Food processing businesses should have a written training program for their employees which is reviewed periodically and implemented as planned. Records should be kept of the personnel who attend the training activities.

- Staff training needs should be evaluated annually, based on the results of the previous year and the assessment of training program effectiveness.
- Training should be appropriate to the complexity of the process and the tasks assigned:
 - All personnel, including suppliers, should receive GMP training.
 - Employees involved in processing should also receive specific training on key operations as well as control and measurement activities. Primarily, they should understand the hygiene program, the pest control program, and the proper care and handling of water.
 - Warehouse personnel should receive training in good storage and pest control practices.
 - Persons responsible for equipment should receive training in preventive maintenance, instrument calibration, and general maintenance.
 - Persons responsible for purchases should receive training in the use of specification sheets for all products and in the monitoring of suppliers.
 - Office personnel should receive training for monitoring carrier services and vehicle conditions.
 - All personnel should receive training in record management, program compliance, preventive measures and corrective actions.
 - Supervisory staff should receive training in plant inspection, assessment and interpretation of hygiene profiles, hygiene program verification, personnel monitoring, and analysis of end products, as well as in the management of preventive measures and corrective actions.
 - Senior managers should be fully versed in food law, hygiene principles, and the importance of hygiene control systems, all of which should be reflected in the business' safety management policy.

- Additional training should be provided as necessary, for example, to inform personnel of the latest technological advances and when new equipment is introduced into operations.

3.10 Documentation

3.10.1 General considerations

Food-processing establishments need to be able to demonstrate that they are applying good manufacturing practices. This cannot be achieved without adequate documentation and record keeping.

3.10.2 Principal constraints

Establishments are frequently unaccustomed to keeping records of their work, and consider documentation to be a tedious practice that serves no useful purpose. This may be true if records are kept of what is not done.

Sometimes, especially when GMP or safety management systems are being implemented for the first time, more importance is given to documentation than to the activities themselves, as if the manuals or documents constitute good management practices or systems.

Experience has shown that documents are useful if they are well designed and simple, and provided the objective is to help systematize the work and demonstrate that things have been done correctly.

3.10.3 Practical advice

Documentation makes it possible to replicate activities and helps make good practices a living part of workplace culture. Documentation facilitates tasks, making it possible to improve them and creating opportunities for innovation, creativity, and training.

Unless good practices are documented, it will be impossible to know for certain if tasks are being carried out correctly and in the same way. This leads to improvisation and loss of control.

Effective application of a documentation process is a reflection of the maturity of the system; it is not achieved overnight.

Businesses will develop documentation as they identify their needs. Following is a list of documents to be considered.

a) Principal documents to be considered:

Master lists:

- List of all documents, duly identified.
- List of all suppliers.
- List of all inputs.
- List of raw materials.
- List of ingredients.
- List of cleaning and disinfection products.
- List of packing materials (different types and models).
- List of labels (different types and designs).

Programs:

- Hygiene program.
- Maintenance program.
- Calibration program.
- Pest control program.
- Supplier oversight program.

Procedures:

- Supplier oversight and procurements.
- Control of key operations.
- Personal hygiene control.
- Hygiene verification program.
- Pest control.
- Inspections, audits.
- Product recalls.
- Control of unacceptable products.

Instructions:

- Cleaning (Standard Sanitation Operating Procedures, SSOP).
- Disinfection (SSOP).
- Monitoring process control parameters.
- Visitor control.
- Staff movement within the premises.
- Waste management.

Specification sheets:

- For raw materials.
- For inputs and ingredients.
- For end products.
- For labels.
- For packing materials.
- For cleaning products.
- For transport vehicles.

Records:

- Supplier oversight.
- Process operations.
- Personal hygiene control.
- Inspection of plant and warehouses; pest control.

Reports:

- Inspection and audit reports.
- Verification reports.
- Product test reports.
- Calibration reports on calibrated instruments.

Examples of documentation

SUGGESTED FORMAT FOR A MASTER LIST

Document Master List						
Document	Code	Area	Date prepared	Review current	Distribution level	Number of controlled copy
Manuals						
Programs						
Procedures						
Instructions						
Specifications						

STRUCTURE FOR A PROCEDURE

Business name:	PROCEDURE Title	Code Review Date
<ol style="list-style-type: none"> 1. Objective 2. Scope 3. Definitions 4. Documents to be consulted 5. Responsibilities 6. General considerations 7. Procedure 8. Records 		
Prepared by:	Reviewed by:	Approved by:

STRUCTURE FOR INSTRUCTIONS

Business name:	PROCEDURE Title	Code Review Date
<ol style="list-style-type: none"> 1. Objective (brief description) 2. Where applied (specify) 3. Responsibilities 4. Instructions (steps to follow) 5. Records 		
Prepared by:	Reviewed by:	Approved by:

STRUCTURE FOR TECHNICAL SPECIFICATIONS

Business name:	TECHNICAL SPECIFICATIONS FOR PRODUCT Name	Code Review Date																														
<p>1. Description</p> <p>2. Sensory requirements:</p> <ul style="list-style-type: none"> - Flavor - Aroma - Color - Others <p>3. Physical-chemical requirements</p> <table border="1" data-bbox="212 595 1002 734"> <thead> <tr> <th data-bbox="212 595 476 630">Item</th> <th data-bbox="476 595 740 630">Tolerance</th> <th data-bbox="740 595 1002 630">Evaluation method</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>			Item	Tolerance	Evaluation method																											
Item	Tolerance	Evaluation method																														
<p>4. Microbiological requirements</p> <table border="1" data-bbox="212 828 1002 1038"> <thead> <tr> <th data-bbox="212 828 408 862">Requirement</th> <th data-bbox="408 828 523 862">n</th> <th data-bbox="523 828 638 862">m</th> <th data-bbox="638 828 753 862">M</th> <th data-bbox="753 828 867 862">c</th> <th data-bbox="867 828 1002 862">Method</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> <p>n: number of samples, m: minimum value, M: maximum value, c: possible number of samples between m-M</p>			Requirement	n	m	M	c	Method																								
Requirement	n	m	M	c	Method																											
<p>5. Packaging requirements</p> <p>6. Labeling requirements</p> <p>7. Verification of quality:</p> <ul style="list-style-type: none"> - inspection on arrival - tests - certificates from supplier - audits of supplier <p>8. Transportation requirements</p> <p>9. Storage requirements</p>																																
Prepared by:	Reviewed by:	Approved by:																														

EXAMPLE OF PROGRAM RECORD

Business name:													Year:												
ANNUAL PROGRAM OF PREVENTIVE MAINTENANCE FOR EQUIPMENT																									
EQUIPMENT	CODE	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	OBS											
	E-001	X								X															
	E-002		X								X														
	E-003			X								X													
	E-004			X								X													
	E-005				X								X												
	E-006					X							X												
	E-007																								
	E-008		X						X																
	E-009		X				X					X													
	E-010			X						X															
Prepared by:																									

Business name:			Year:		
HYGIENE PROGRAM					
Area/ place	Treatment	Instructions/ record	Frequency	Materials	Person responsible
Floors	Cleaning	IL001	Daily	Detergent	
Walls	Cleaning	IL002	Weekly	Detergent	
Tables	Cleaning and disinfection	II-003 ID-001	Daily	Detergent Disinfectant	

Business name:			Year:		
MASTER PROGRAM FOR DISINFECTANTS					
Area/place	Product/ active ingredient	Purity	Concentration for use	Preparation	Person responsible
Inert surfaces in indirect contact with food (floors, walls, ceilings)	XXXX	%	parts per million (ppm)	XX drops/ xx L of water	Employee 1
Inert surfaces in direct food contact (tables, equipment, utensils)				XX teaspoonfuls/ xx L of water	Employee 2
Food (fruits, meats, vegetables, etc.)				ml/xx L of water	Employee 1
Live surfaces: employees' hands					Employee 2
Potable water					Employee 1
Toilet facilities					Employee 2
Surfaces in waste areas					Employee 1
Others					

BIBLIOGRAPHY

Codex Alimentarius (2003). *Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)*

Codex Alimentarius (2003). *Code of hygiene practice for fresh fruits and vegetables (CAC/RCP53-2003)*.

Codex Alimentarius (1991). *General standard for the Labelling of Prepackaged Foods (Codex Stan 1-1985, Rev1-1991)*.

Díaz, A. (2008). *Buenas prácticas agrícolas. Guía para pequeños y medianos agroempresarios*. Serie de Agronegocios. Cuadernos para la Exportación. Programa Interamericano para la Promoción del Comercio, los Negocios Agrícolas y la Inocuidad de Alimentos, Instituto Interamericano de Cooperación para la Agricultura.

Díaz, A. (1999). *La calidad en el comercio internacional de alimentos*. Comisión para la Promoción de Exportaciones - PROMPEX. European Union Export Agreement - PROMPEX. Lima, Peru.

FDA USA (1999). *Good Manufacturing Practices in the Manufacturing, Packing or Holding of Human Foods (Part 110 -21 CFR 110.1 - 110.110 – Code of Federal Regulations)*

FAO (2002). *Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System*. Rome, Italy.

Ichikawa, T. and Díaz, A. (2002). *Diseño y ensayo de un sistema de medición de los costes de no calidad y su impacto en la viabilidad de las Pymes*. Export Promotion Commission - PROMPEX, CONCYTEC. Lima, Peru.

O'Brien, T. and Díaz, A. (2004). *Mejorando la competitividad y el acceso a los mercados de exportaciones agrícolas por medio del desarrollo y la aplicación de normas de inocuidad y calidad. El ejemplo del espárrago peruano*. IICA.

Servsafe (1995). *Food Service Sanitation*. Certification Coursebook. National Restaurant Association. USA.

Uría R. (2005). *Buenas prácticas de higiene en la manipulación de alimentos. Manual de capacitación*. APEC - OVTA Cooperation Agreement, Ajinomoto del Perú.

Uría R. and Jerí I. (2001). *Buenas prácticas de almacenamiento de alimentos. Manual de capacitación*. Instituto Nacional de Salud - Programa de Complementación Alimentaria PACFO - Peru.

Internet websites

Codex Alimentarius: <http://www.codexalimentarius.net>