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A REGIONAL GUIDANCE ON CRITERIA FOR GOOD MANUFACTURING PRACTICES/HAZARD ANALYSIS AND CRITICAL CONTROL POINT [GMP/HACCP] FOR ASIAN COUNTRIES



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ON
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GOOD MANUFACTURING PRACTICES/
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CONTROL POINT (GMP/ HACCP)
FOR ASIAN COUNTRIES**

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**FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC
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FOREWORD

Foodborne disease and food contamination continue to be significant public health issues in both the developed and developing countries of Asia. Unsafe food causes many acute and lifelong diseases, ranging from diarrhoeal diseases to various forms of cancer, with more than 200 diseases being spread through contaminated food.

To ensure the safety and quality of food, it is necessary to implement a preventive approach based on risk that focuses on building quality and safety throughout the food chain. In the preventive approach, the focus is on ensuring that hazards are prevented from entering the food chain or reduced to acceptable levels or eliminated through the implementation of Good Practices and HACCP systems. The food business operators need to implement such an approach for processes under their purview or control to ensure that the hazards are prevented from entering the food chain or are reduced to acceptable levels. Likewise it is important for governments to incorporate such an approach into their legislation and enforcement systems whereby they focus on checking the controls being maintained by the food business operators and assessing whether these are appropriate to ensure food safety.

FAO has recognized the importance of the GMP/HACCP system for ensuring the safety and quality of food and the prevention of foodborne diseases for over 30 years and the Codex Alimentarius Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1) have been developed which lay a firm foundation for ensuring food hygiene and recommend a Hazard Analysis and Critical Control Point (HACCP) approach wherever possible to enhance food safety. To support Member States across Asia to fully integrate this approach in national food control systems and incorporate GHP/HACCP into their regulations, this guidance document has been developed which adapts the Codex text from advisory into standards or criteria which are more directive and specific and therefore enforceable. It also includes additional requirements based on the experiences of participants and also discussions at the "Scientific colloquium of experts on HACCP – The road ahead" held from 3 to 6 June in Finland. The requirements or criteria developed in this document can, directly or with adaptations, be included by governments in their legislation to provide a basis for compliance of GMP/HACCP based food safety management systems, which could be applied either on a mandatory or a voluntary basis.

The guidance document has been developed on the basis of the discussions held during the regional consultation workshop "Implementation of GMP/HACCP in Asia – A status review" held from 23 to 25 June 2014 in Bangkok, Thailand in which 56 persons from 20 countries of Asia and resource persons participated. In addition, guidance has also been taken from various regional guidelines/codes.

I wish to acknowledge the contributions made by all participants, resource persons and especially to the Federal Food Safety and Veterinary Office of Switzerland for their generous funding support for organising the Regional Consultation workshop. I sincerely hope that this guidance document on Criteria for GMP/HACCP for Asian countries will be useful to governments and FBOs in managing food safety across the food value chain and will lead to greater safety in food moving in domestic, regional and international markets.



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I. BACKGROUND

Foodborne diseases and food contamination have been significantly increasing as public health issues in both the developed and developing countries of Asia. Unsafe food causes a great number of acute and lifelong diseases ranging from diarrhoeal diseases to various forms of cancer, with more than 200 diseases spread through contaminated food. Such foodborne illnesses lead to not only health related issues but have adverse effects on trade and tourism, earnings and productivity, employment and litigation.

To ensure the safety and quality of foods, it is essential to implement a preventive approach based on risks that focuses on building quality and safety throughout the food chain. Good Hygienic Practices (GHP) and Good Manufacturing Practices (GMP) together with Hazard Analysis and Critical Control Point (HACCP) systems have been recognized globally as important for ensuring the safety and quality of food and for preventing foodborne diseases. In this preventive approach, the focus is on building safety into products by identifying hazards and either preventing them from entering the food chain, by eliminating them, or reducing them to acceptable levels. Although such a preventive approach needs to be implemented by food businesses, it also needs to be incorporated by governments into national legislation.

The Codex Alimentarius Commission has developed the Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1), since 1969, but the same is not being fully implemented as many Member States across Asia have yet to fully integrate the preventive approach in national food control systems. The Codex texts are advisory in nature and the use of terminology such as “adequate”, “acceptable” and “should” does not qualify compliance. To be enforceable requirements need to be more directive and specific. Countries have been requesting FAO’s support in adopting/ adapting GHP/HACCP in their regulations.

This document develops/adapts the Codex texts into requirements or criteria which can be included by governments in their legislation to provide a basis for compliance with GMP/HACCP based food safety management systems, which could be applied either on a mandatory or a voluntary basis. The document is in two parts – Criteria for GMP/GHP and Criteria for HACCP. Governments may incorporate both or one into their requirements depending on the situation of their businesses.

The document is not a substitute for food regulations and licensing requirements. It may however be used to support the legislation by incorporating the requirements into country regulations with modifications as needed. It is the responsibility of the food operators to ensure compliance with the applicable national regulations.

This document may also be used for the purpose of internal and/or external inspection or evaluation of compliance with these requirements by governments or any others.

The document closely follows the numbering system given in CAC/RCP 1 Recommended International Code of Practice General Principles of Food Hygiene.

II. CRITERIA FOR GOOD MANUFACTURING/ HYGIENIC PRACTICES

SECTION 1 – INTRODUCTION

This part of the document is based on the Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1 – 1969 as amended). The objective of this part is to define Good Hygienic Practice /Good Manufacturing Practice (GHP/ GMP) requirements that any food industry needs to implement for the production of safe and suitable food.

SECTION 2 – SCOPE AND USE

This part of the document specifies the basic GHP/GMP for the production of safe and suitable food. The requirements as given in this part apply to the entire food processing industry. The document has specified requirements where compliance with the criteria is essential and obligatory and in such cases the word “shall” is used. In addition, certain recommended good practices for which different means of implementation could be adopted and practices where recorded evidence of compliance may not always be required but may be preferred have also been identified and in such cases the word “should” is used.

This part of the document is applicable to all food sectors including the manufacturing, processing and food services sectors. It may also be applied to the feed industry where it may have an impact on food safety and protection of consumer health (see note below). For the retail sector a separate guidance titled “Guidance on hygiene and safety in the food retail sector” published by FAO (RAP Publication 2014/06) is applicable.

Note: Countries may consider the application of these criteria for the feed industry according to specific country situations.

SECTION 3 – DEFINITIONS

For the purpose of this document, the following expressions have the meaning stated:

Cleaning – the removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant – any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination – the introduction or occurrence of a contaminant in food or the food environment.

Disinfection – the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

Establishment – any building or area in which food is handled and the surroundings are under the control of the same management.

Food hygiene – all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

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

Note: Some examples of “conditions of food” may include those causing choking hazards because of the texture of such foods such as certain sticky foods, grapes (for consumption by infants).

HACCP – a system which identifies, evaluates, and controls hazards which are significant for food safety.

Food handler – any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

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

Food suitability – assurance that food is acceptable for human consumption according to its intended use.

Primary production – those steps in the food chain up to and including, for example, harvesting, slaughtering, milking, fishing.

Traceability – ability to follow the movement of the food through specified stage/s of production, processing and distribution.

GHP and GMP – these are prerequisite programmes that provide basic environmental and operating conditions for production of safe and suitable food and are a prerequisite to a successful implementation of HACCP.

Note:

GHP stands for Good Hygienic Practice and covers the system/ measures for maintaining hygiene and sanitation and includes personal hygiene and employee health conditions, maintenance of plant and equipment hygiene including food contact surfaces, pest control, waste disposal, water quality, toilet and hand washing facilities and prevention of cross-contamination.

GMP stands for Good Manufacturing Practice and includes manufacture and process controls and covers supplier control, specifications, calibration of equipment, traceability and recall, equipment designs where conditions for food safety can be achieved, maintained and monitored, lighting and ventilation systems, storage conditions and control of operations.

There are some overlapping areas in both the terms, and in the context of this document both terms are used interchangeably.

SECTION 4 – ESTABLISHMENT DESIGN AND FACILITIES

4.1 Location

4.1.1 Establishments

Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food.

Establishments shall be located away from:

- environmentally polluted areas and industrial activities that pose a serious threat of contaminating food;
- areas subject to flooding or stagnating waters unless sufficient safeguards are provided;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

Where buildings are surrounded by grassed or planted areas, a clear space should be provided between grassed planted areas and the main building. Such grassed/ planted areas shall be regularly tended and well-maintained.

External pathways and roads surrounding the establishment shall be suitably surfaced and maintained in good repair to avoid contamination of the product.

4.2 Premises and rooms

4.2.1 Design and layout

4.2.1.1 External design

The external design, layout and construction shall be such that it does not compromise food safety requirements (e.g. bird nesting, sealing gaps around pipes, ingress of water and other contaminants).

4.2.1.2 Internal design

The internal design and layout of food establishments shall be such as to permit good food hygiene and manufacturing practices, including protection against cross-contamination between and during operations by foodstuffs. In particular the following conditions shall be satisfied:

- Basic infrastructure appropriate to the operations shall be in place. Flow shall be so designed that there is no criss-cross movement of men and material. Entry and exit points for material and personnel shall as far as possible be separate. Food flow shall be in one direction, as far as possible. When designing, it shall be ensured that storage areas are clearly demarcated so that passage ways and processing areas are not used for regular storage purposes.
- Adequate space should be provided for various activities such as raw material receipt and storage, processing, final product storage, changing facilities for personnel, foot bath facilities as appropriate to the industry, separate eating area that is located away from the process area, toilets/ washrooms and do not open directly into the processing/ packing/ storage areas.
- There shall be adequate separation between storage areas (raw material, packaging material and finished goods), processing area, packing area, utility area etc.
- There should be provision of appropriate loading and unloading points that facilitate movement of material and the same, where provided for, shall be suitably covered to provide adequate protection from pests, rain, etc.
- All requisite "No Objection Certificates (NOC)" or similar permits/ certificates from various authorities as required, shall be obtained during the design stage.

4.2.2 Internal structures and fittings

Structures within food establishments shall be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors shall be made of impervious materials with no toxic effect in intended use and easy to clean;
- walls and partitions shall have a smooth surface (with no crevices or damage) up to a height appropriate to the operation, wall paint shall not be flaking off and there shall be no crevices to harbour pests;
- floors shall be constructed to allow adequate drainage and cleaning and the junctions with walls shall be such that they are cleanable , e.g. coved (without sharp angles);
- ceilings including false ceiling and overhead fixtures shall be constructed and finished to minimize the build-up of dirt and condensation, and the shedding of particles, they shall be constructed so as to be gap free and water resistant and it is recommended to avoid asbestos for ceilings;

- windows and ventilators shall be easy to clean, be constructed to minimize the build-up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens/louvers; mesh on windows (ventilator) shall not be cut/ damaged to avoid pest entry and, where necessary, windows should be fixed; window glasses shall be protected to ensure that food is not contaminated by breakages;
- doors shall have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect; entry/exit points should be suitably fitted with measures such as strip PVC /air curtains/ wire mesh doors / doors with self-closing devices etc. to ensure dust, insects, birds and animals are kept out;
- drains should be designed and constructed in a way to protect the entry of pests, rodents, etc; and
- working surfaces that come into direct contact with food shall be in sound condition (free from cracks, crevices, open seams, etc.), durable and easy to clean, maintain and disinfect; they shall be made of smooth (such as free from sharp internal angles or corners, protruding rivets, nuts and bolts, etc.) non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions; the material of the contact surface shall not release hazards making food unsafe.

4.2.3 Temporary/mobile premises and vending machines

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, and temporary premises in which food is handled such as tents and marquees. All requirements of design, operations and hygiene as applicable to other facilities shall apply to such premises and structures with a view to ensuring safety and suitability of food. In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities shall be adequately controlled to ensure the safety and suitability of food.

4.3 Equipment

4.3.1 Location

Equipment shall be located so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates good hygienic practices, including monitoring, if required.

4.3.2 General requirements

Equipment and containers (other than once-only use containers and packaging) coming into contact with food shall be designed and constructed to ensure that they can be adequately cleaned, disinfected where necessary, and maintained to avoid the contamination of food.

Equipment and containers should be made of materials that are impervious, non-reactive and with no toxic effect in intended use and do not pass on colours, odours or taste to food.

Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

Non-food contact surfaces of the equipment should be free from unnecessary projections and crevices and designed and constructed to allow easy cleaning and maintenance.

4.3.3 Specific requirements

4.3.3.1 Food control and monitoring equipment – equipment used to cook, heat treat, cool, store or freeze food shall be designed to achieve the required food temperatures as rapidly as necessary for food safety and suitability, and maintain them effectively. Such equipment shall also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP-based plans can be monitored; and
- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

4.3.3.2 Calibration of equipment – the monitoring and measuring devices (including inspection and testing equipment) shall be periodically calibrated and records maintained. The frequency of calibration should be based on the type of equipment, criticality of the measurement, location and extent of usage.

4.3.4 Containers for waste and inedible substances

Containers for waste, by-products and inedible or dangerous substances, shall be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances shall be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food. Access shall be restricted to authorized personnel.

4.4 Facilities

4.4.1 Water supply

An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature or any other controls, shall be available whenever necessary to ensure the safety and suitability of food. In case water is stored in tanks, these shall be such that they prevent contamination of water. They shall be suitably covered to prevent access by animals, birds, pests and other extraneous matters. The water pipes shall be made of material that is nontoxic, corrosion resistant, free from cracks, impervious and shall be sealed.

Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

4.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities shall be provided. They shall be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

The disposal of sewage and effluents shall be in conformity with the requirements of the pollution control authority of the country (including effluent treatment plant (ETP), rendering plant, etc. as applicable).

No manhole shall be situated inside any food processing area. Rainwater pipes, if inside, shall be constructed of impervious rust-proofing materials. These shall not open in the food processing area.

Drains, if any, in the processing area shall be made of impervious rust proofing material and shall be covered. These shall have adequate trapping devices to avoid the entry of pests. Drains shall allow for effective cleaning as relevant (such as fat trap, pressure cleaning). They shall not allow any stagnation or backflow of water.

4.4.3 Cleaning

Adequate facilities, suitably designated, shall be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

4.4.4 Personnel hygiene facilities and toilets

Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

- adequate means of hygienically washing and drying hands, including wash basins and a supply of adequate (hot/ cold or suitably temperature controlled) water of potable quality; taps should be non-hand operated, and the hand wash basins/ sanitizers should be situated at the entrance to process areas and /or where required;
- lavatories of appropriate hygienic design at suitable locations with adequate natural or mechanical ventilation and natural or artificial lighting; and
- adequate changing facilities for personnel, as appropriate to the operations.

Hygienic design and cleanliness shall be monitored and the results of the monitoring shall be maintained.

Such facilities shall be suitably located and designated.

4.4.5 Temperature control

Depending on the nature of the food operations undertaken, adequate facilities shall be available for heating, cooling, chilling, 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.

4.4.6 Air quality and ventilation

Adequate natural or mechanical ventilation shall be provided, in particular to:

- minimize airborne contamination of food, for example, from aerosols and condensation droplets;
- control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity, where necessary, to ensure the safety and suitability of food.

Ventilation systems shall ensure that air does not flow from contaminated areas to clean areas and, where necessary, that they can be adequately maintained and cleaned.

Food processing areas where operations result in release of fumes, smoke, steam or any vapour shall be equipped with an exhaust system or ventilation that can efficiently and effectively remove these.

4.4.7 Power supply and lighting

4.4.7.1 Power supply

Adequate power supply shall be provided. Suitable power backup facilities e.g. generators, invertors should be provided to ensure uninterrupted supply as necessary for the production of safe food. An emergency plan for sudden power outages shall be developed, validated and routine training on the same given.

4.4.7.2 Lighting

Adequate natural or artificial lighting should be provided to enable the food premises to operate in a hygienic manner both for various operations and other activities within the facility (e.g. sanitary conveniences). Where necessary, lighting should not be such that the resulting colour is misleading. The intensity shall be adequate to the nature of the operations (e.g. sorting, cleaning, grading, inspection and testing require greater intensity of light). Lighting fixtures shall, especially where food or food contact surface is exposed, be shatter proof or be protected with shatter-proof covers to ensure that food is not contaminated by breakages. The fixtures shall be designed to avoid accumulation of dirt and be easy to clean.

4.4.8 Storage

Where necessary, adequate facilities for the storage of food, ingredients, packaging material, non-conforming materials and non-food chemicals (e.g. cleaning materials, lubricants, fuels) shall be provided and segregated appropriately.

Where appropriate, food storage facilities shall be designed and constructed to:

- permit adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination during storage; and
- where necessary, provide an environment that minimizes the deterioration of food (e.g. by temperature, ventilation and humidity control).

The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided. Whenever required, cold storage facilities shall be provided for raw, processed/packed food according to the type and requirement.

SECTION 5 – CONTROL OF OPERATIONS

The food business operator shall develop a system to reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at appropriate stages in the operations.

5.1 Control of food hazards

Food business operators should control food hazards through the use of systems such as HACCP. Details given in Section II.

5.2 Process control

5.2.1 Time and temperature control

Where time and temperature are critical to the safety and suitability of a food, the time and temperature combinations of heating, cooking, cooling, processing and storage shall be defined and

systems shall be in place to ensure that temperature is controlled effectively. These controls shall eliminate food safety hazards or reduce those that may be present in the food to an acceptable level.

Temperature control systems shall, as applicable, take into account:

- the nature of the food, e.g. its water activity, pH, and likely initial level and types of micro-organisms;
- the intended shelf-life of the product;
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/ processing or ready-to-eat.

Such systems shall also specify tolerable limits for time and temperature variations.

Temperature recording devices shall be calibrated and checked at regular intervals and tested for accuracy.

5.2.2 Specific process steps

The food business operator shall have a system in place to establish controls over other steps that contribute to food safety. The process steps may include chilling, thermal processing, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging.

5.2.3 Specifications

The food business operator shall define specifications for incoming raw materials, packaging materials and finished products. Where microbiological, chemical or physical specifications are used in any food control system, such specifications shall be based on sound scientific principles and monitoring procedures, analytical methods and action limits shall be documented and records maintained. Where appropriate, specifications for raw materials should be identified and applied, including regulatory requirements. All the finished products shall meet the defined specifications or shall conform to the applicable legislation.

5.2.4 Microbiological cross-contamination

When processing food, adequate steps shall be taken to prevent the food from microbiological cross-contamination. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and, where appropriate, with disinfection.

Access to processing areas shall be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility or other similar means. Personnel shall be required to put on clean protective clothing including footwear and wash their hands before entering. Food business operators shall demonstrate that alternative measures, equivalent to the best practices, are capable of preventing food safety hazards/ effectively controlling the hazards.

Surfaces, utensils, equipment, fixtures and fittings shall be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed so as to prevent contamination.

5.2.5 Physical contamination

Systems shall be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, plastics, and dust. In manufacturing and processing, suitable detection or screening devices (such as filters, sieves, magnets, metal detectors and metal separators) should be used where necessary. If needed, a glass/ foreign body control policy should be defined and adopted to assist in achieving safe food.

5.2.6 Chemical contamination

Systems shall be in place to prevent contamination of foods from chemical contaminants such as harmful fumes, antibiotics, pesticide residues, cleaning agents. Supplier declaration, laboratory test results, etc should be used as methods of verification, where necessary.

5.2.7 Allergen contamination

Systems shall be in place to prevent contamination of foods from allergens, if required as per the applicable legislation of countries. Labelling and segregation of allergens during receipt, storage and processing should be in place.

5.3 Incoming material requirements

No raw material (including packing material) or ingredient shall be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs, radioactive substances or toxic, decomposed or extraneous substances that would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied, including any regulatory requirements.

Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests (in-house or externally conducted) should be made to establish fitness for use. Only sound, suitable incoming material such as raw materials, ingredients or semi-processed products shall be used. This may be ensured through supplier control, certificates of conformity, incoming inspection and testing etc. Imported foods/ raw materials, if used, shall be as per the applicable regulations.

Stocks of raw materials and ingredients should be subject to effective stock rotation.

Linking to primary production - the processor should, as far as feasible, ensure implementation of suitable production processes in activities such as harvesting, slaughtering, milking, fishing, etc.

Records of inspections of raw materials shall be maintained.

5.4 Packaging materials

Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. The materials should be appropriate for the food to be packed and sufficiently durable to withstand the conditions of processing, handling, storage and transportation. Packaging materials or gases, where used, shall be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Use of staple pins, strings, rubber bands, should be avoided. Glue, if used, should not come in contact with the food product, and in case it comes in contact it shall be food grade. Reusable packaging, if used, shall be suitably durable, easy to clean and, where necessary, disinfect. It shall not have been used for packaging non-food products. Packaging materials shall be stored and handled under hygienic conditions away from raw materials and finished products.

Records of inspection of packaging materials shall be maintained.

5.5 Water

5.5.1 In contact with food

Only potable water, shall be used in food handling and processing, with the following exceptions:

- for steam production, fire control and other similar purposes not connected with food;
- and

- in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water).

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water which 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.

5.5.2 As an ingredient

Potable water shall be used wherever necessary to avoid food contamination.

5.5.3 Ice and steam

Ice shall be made from potable water. Ice and steam shall be produced, handled and stored to protect them from contamination.

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

5.6 Management and supervision

5.6.1 The food business operator shall monitor and supervise all operations appropriately. 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 hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision take place.

5.6.2 Management commitment

The management shall demonstrate they are fully committed to the implementation of the requirements of the GMP/GHP.

5.6.3 Self evaluation and review

The food business operator shall conduct a self-evaluation process to verify the effectiveness of the implemented system at periodic intervals, but at least once in a year. Necessary corrective actions based on self evaluation results shall be taken.

The food business operator shall undertake a complete review of the system including self-evaluation results, customer feedback, complaints, new technologies and regulatory updates at periodic intervals, but at least once in a year, for continual improvement.

Records of self evaluation, corrective actions and review shall be maintained.

5.7 Documentation and records

The food business operator shall maintain an effective system of documentation (including procedures) of key processes and activities.

Appropriate records of processing, production and distribution shall be legible, retained in good condition and retrievable for a period that exceeds the shelf-life of the product. It is recommended that records be maintained for at least the following:

- incoming material checks – raw materials, ingredients, packaging materials, etc;
- inspection and testing;
- temperature and time;

- product recall and traceability;
- storage;
- cleaning and sanitation, as appropriate;
- pest control;
- medical examination and health status;
- training;
- calibration;
- complaint and customer feedback;
- corrective and preventive action;
- self evaluation results; and
- review records.

5.8 Recall procedures

Effective recall procedures where applicable, including a description of the responsibilities and actions to be taken, shall be in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot/batch of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions and which may present a similar hazard to public health should be evaluated for safety and may need to be withdrawn. The need for public warnings shall be considered.

For recall to be performed, traceability/ product tracing is a useful tool (CAC GL 60-2006).

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

Records of recalled products shall be maintained. Records should demonstrate effective identification, traceability/ product tracing, recall, subsequent handling and disposal of recalled food.

5.9 Storage procedures

Food products shall be stored under conditions that prevent spoilage, protect against contamination and minimize damage. Food shall be stored in clean areas and stacked in a manner that facilitates ease of movement. Food shall be stored away from the wall and not directly on the floor. Food shall be stored preferably either on pallets/ racks or any other manner to facilitate cleanliness, avoid ingress of moisture, etc. For foods that requires specific storage conditions e.g. temperature (such as hot, chilled and frozen) and humidity, air circulation etc, the same shall be maintained.

All products in storage shall be clearly identified. Stocks of raw materials (including packing material) and ingredients shall be subject to effective stock rotation (see also 5.3).

Cleaning materials and hazardous chemical substances shall be clearly identified, stored at demarcated places away from raw materials, ingredients, packaging materials and shall have restricted access and only to authorized personnel.

Records of storage shall be maintained.

5.10 Outsourced processes or services

The food business operator shall ensure effective controls are in place for outsourced processes and services. If any processes are outsourced they shall be described and the requirements of this document as applicable, shall apply.

The outsourced processes or services shall be documented and monitored.

5.11 Quality control

The food business operator shall have a quality control programme in place to include inspection and testing of incoming, in-process and finished products (for specifications, see section 5.2.3.). Adequate infrastructure shall be available for carrying out testing. In case adequate in-house test facilities are not available, a system shall be in place for testing this in external government approved or accredited laboratories.

Records of testing shall be maintained.

SECTION 6 – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 Maintenance and cleaning

General

Cleaning programmes shall be in place to implement and ensure that good hygienic practices are maintained. Establishments and equipment shall be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures;
- function as intended, particularly at critical steps; and
- prevent contamination of food, e.g. from metal shards, flaking plaster, debris and chemicals.

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

Cleaning chemicals shall be handled and used carefully and in accordance with manufacturer's instructions and stored, where necessary, separately from food, in clearly identified containers to avoid the risk of contaminating food.

6.2 Procedures, methods and programmes

6.2.1 Cleaning procedures, methods and programmes

Cleaning and disinfection programmes shall be in place to ensure that all parts of the establishment including temporary/mobile premises and vending machines are appropriately clean, and should include the cleaning of cleaning equipment.

Cleaning and disinfection programmes shall be continually and effectively monitored for their suitability and effectiveness and where necessary documented.

Where written cleaning procedures are defined, they should specify:

- areas, items of equipment and utensils to be cleaned;
- responsibility for particular tasks;
- method and frequency of cleaning; cleaning chemicals and concentrations;
- equipment and cleaning and sanitizing aids; and
- monitoring arrangements.

It shall be ensured that cleaning and sanitizing chemicals do not contaminate food.

6.2.2 Maintenance procedures, methods and programmes

Maintenance programmes shall be in place to prevent contamination and reduce any potential breakdown of equipment. These shall cover maintenance schedule, responsibilities, methods, tools and gadgets etc., and appropriate records shall be maintained. Consumables like lubricants that come in contact with food shall be food grade and spares shall be non-toxic non-reactive and impervious.

6.3 Pest control systems

6.3.1 General

Good hygiene practices shall be employed to avoid creating an environment conducive to pests.

Suitable and effective pest control programmes shall be in place to minimize pest access, infestation and harbourage. It shall be ensured that there are no signs of pest infestation including flies, cockroaches, lizards, rats. The pest control programme shall identify the pests to be controlled, the area / locations where control is to be applied, the method of control e.g. physical, chemical, the dosage if chemicals are used, control schedule, responsibilities, etc. These shall include use of insectocutors, traps and baits as appropriate, maintaining cleanliness, covering exposed foods and wastes, blocking drain pipes.

6.3.2 Preventing access

Buildings shall be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access shall be kept sealed. All open windows, ventilators and doors, shall have appropriate measures such as strip curtains, air curtains, fly proof mesh, etc. to prevent pest access. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

6.3.3 Harbourage and infestation

Potential food sources shall be stored in pest-proof containers and/or stacked above the ground and away from walls.

Areas both inside and outside food premises shall be kept clean. Refuse or waste shall be stored in covered pest-proof containers.

6.3.4 Monitoring and detection

Establishments and surrounding areas shall be regularly examined for evidence of infestation.

6.3.5 Eradication

Pest infestations shall be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

The pest control activities shall be performed by trained personnel. These shall be continuously monitored for their effectiveness. It shall be ensured that pest control chemicals do not contaminate food.

The measures shall be documented and records maintained.

6.4 Waste management

Suitable provision shall be made for the removal and storage of waste. Waste shall not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment.

Waste bins and storage areas shall be in designated places. These shall be identified, covered and kept appropriately clean.

6.5 Monitoring effectiveness

Sanitation systems shall be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances. The results of monitoring shall be documented and records maintained.

SECTION 7 – ESTABLISHMENT: PERSONAL HYGIENE

7.1 Health status

People known or suspected to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, shall not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected shall immediately report illness or symptoms of illness to the management.

Medical examination of a food handler by a qualified/registered medical practitioner or as defined in applicable national legislation shall be carried out at least once a year and if clinically or epidemiologically indicated. Records of the same shall be maintained.

7.2 Illness and injuries

Personnel working in processing areas shall not have illnesses, injuries or conditions such as:

- jaundice
- diarrhoea
- tuberculosis
- vomiting
- fever
- sore throat with fever
- visibly infected skin lesions (boils, cuts, etc.)
- discharges from the ear, eye or nose.

In cases of such illnesses, injuries or conditions, these shall be reported to the management so that any need for medical examination and/or possible exclusion from food handling is considered.

7.3 Personal cleanliness

Food handlers while working in food processing areas shall maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, shall be covered by suitable waterproof dressings. Nails shall be trimmed, kept clean and without nail polish. Street shoes shall not be permitted. Appropriate measures such as passing through a foot bath, using shoe covers, changing to separate foot wear for internal use shall be used as relevant to food operations.

Personnel shall always wash their hands with soap/ disinfectant when personal cleanliness may affect food safety, specifically:

- at the start of food handling activities;
- immediately after using the toilet; and

- after handling any contaminated materials (such as raw food, money, files, unclean product / food contact surface / body parts).

7.4 Personal behaviour

People engaged in food handling activities shall refrain from behaviour which could result in contamination of food, such as smoking, spitting, chewing or eating and sneezing or coughing over unprotected food.

Personal effects (such as jewellery, watches, pins, mobile phones, or any other potential source of physical hazards, etc.) which can cause a threat to food safety and suitability shall not be worn or brought into food handling areas. The movements of personnel from low to high risk or low hygienic to high hygienic zones shall be restricted.

7.5 Visitors

Visitors to food manufacturing, processing or handling areas shall follow the same norms for protective clothing and adhere to the other personal hygiene provisions as those working in the unit.

SECTION 8 – TRANSPORTATION

8.1 General

Food shall be adequately protected during transport to prevent contamination, deterioration and ensure food safety.

8.2 Requirements

Conveyances and bulk containers shall be designed and constructed so that they:

- do not contaminate foods (including ingredients) or packaging;
- can be effectively cleaned and, where necessary, disinfected;
- permit effective separation of different foods or foods from non-food items where necessary during transport;
- provide effective protection from contamination, including dust and fumes;
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and
- allow any necessary temperature, humidity and other conditions to be checked.

8.3 Use and maintenance

Conveyances and containers for transporting food shall be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, these shall be suitably segregated during transportation and effective cleaning and, where necessary, disinfection shall take place between loads.

The temperature, humidity, atmosphere and other necessary conditions, as appropriate to the product shall be maintained.

Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

SECTION 9 – PRODUCT INFORMATION, CONSUMER AWARENESS AND COMPLAINTS

9.1 Lot identification

All incoming, in-process and finished products shall be suitably identified for product identification, stage of processing, inspection and test status, etc. so as to avoid their inadvertent use. Lot identification shall be done to facilitate traceability, product recall, effective stock rotation, etc.

9.2 Product information

All food products shall be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

9.3 Labelling

Pre-packaged foods shall be labelled with clear instructions to enable the next person in the food chain to handle, transport, display, store and use the product safely. Any special requirements for transporting, handling, storage, processing, use by customer, etc. shall be clearly indicated on labels. All finished products shall have a unique identification number. All legal/ statutory requirements shall be given clearly on the label of the final product as per applicable legislation.

9.4 Consumer education

Consumer education programmes shall cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular, consumers should be informed of the relationship between time/ temperature control and foodborne illness.

9.4 Complaints

All complaints shall be recorded, analyzed and addressed for any improvements with regard to food safety and suitability. Necessary corrective actions including with regard to review of GMP/HACCP shall be taken to prevent the recurrence of complaints.

SECTION 10 – TRAINING

10.1 Awareness and responsibilities

All personnel shall be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers shall have the necessary knowledge and skills to enable them to handle food hygienically.

Those who handle strong cleaning chemicals or other potentially hazardous chemicals shall be trained in safe handling procedures and techniques.

10.2 Training programmes

Suitable training shall be given to all personnel handling food to enable them to have the required knowledge and skills in GHP and GMP for the specific tasks. Adequate training programme shall be in place (preferably approved by the government). Trainings shall be held at appropriate frequencies. The training shall be delivered by qualified/trained personnel. Records of training shall be kept.

Factors to be taken into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected shelf life.

10.3 Instruction and supervision

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being implemented correctly and effectively by all personnel.

Managers and supervisors of food processes shall have the necessary knowledge and skills in food hygiene (GHP and GMP) principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

10.4 Refresher training

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

III. CRITERIA FOR HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

1. INTRODUCTION

This part of the document is based on the Annex of the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1 – 1969 as amended), namely Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application. The objective of this part is to define the requirements of Hazard Analysis and Critical Control Point (HACCP) that a food industry needs to implement for production of safe food.

2. SCOPE AND USE

This part of the document specifies the HACCP system requirements for the production of safe food. The requirements as given in this part apply to food industries throughout the food chain (production, processing, handling, storage, transportation and distribution). The document has specified requirements where compliance with the criteria is essential and obligatory and in such cases the word “shall” is used. In addition, certain recommended good practices for which different means of implementation could be adopted and practices where recorded evidence of compliance may not always be required but may be preferred have also been identified and in such cases the word “should” is used.

This part of the document is applicable to all food sectors including the manufacturing, processing and food services sectors. It may also be applied to the feed industry where it may have an impact on food safety and protection of consumer health (see note below). For the retail sector a separate guidance titled “Guidance on Hygiene and safety in the food retail sector” published by FAO (RAP Publication 2014/06) is applicable.

Note: Countries may consider the application of these criteria for the feed industry according to specific country situations.

3. DEFINITIONS

Control (verb) – to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun) – the state wherein correct procedures are being followed and criteria are being met.

Control measure – any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action – any action to be taken when the results of monitoring at the CCP indicate a loss of control. This also addresses measures taken to prevent the recurrence of the cause of the nonconformity.

Contaminant – any substance not intentionally added to food that is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

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

Critical limit – a criterion that separates acceptability from unacceptability.

Deviation – failure to meet a requirement including critical limits.

Flow diagram – a systematic representation of the sequence and interactions of steps or operations used in the production or manufacture of a particular food item.

Food chain – the sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption.

Note 1 This includes the production of feed for food-producing animals and for animals intended for food production.

Note 2 The food chain also includes the production of materials intended to come into contact with food or raw materials.

Food chain approach – recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain, i.e. by all involved with the production, processing, trade and consumption of food. This approach encompasses the whole food chain from primary production to final consumption. Stakeholders include farmers, fishermen, slaughterhouse operators, food processors, transport operators, distributors (wholesale and retail) and consumers, as well as governments obliged to protect public health.

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

HACCP – a system that identifies, evaluates, and controls hazards that are significant for food safety.

HACCP plan – a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

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

Hazard analysis – the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Note: In the context of food safety, the terms “hazard” and “risk” are often treated as synonymous, thus leading to the use of the incorrect expression “risk analysis” instead of the correct expression “hazard analysis”.

Monitor – the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Non-conformity (NC) – a deficiency (or deficiencies) observed with respect to the requirements of the standard.

Prerequisite programme (PRP) – basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe food for human consumption.

Note: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

Step – a point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation – obtaining evidence that the elements of the HACCP plan are effective or
or

obtaining evidence that a control measure or combination of control measures if properly implemented is capable of controlling the hazard to a specified outcome.

Verification – the application of methods, procedures, tests and other evaluations in addition to monitoring to determine compliance with the HACCP plan

or

the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

4. PRINCIPLES OF THE HACCP SYSTEM

It shall be ensured that the following seven principles of the HACCP system are followed:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

5. APPLICATION OF THE HACCP SYSTEM

Prior to application of HACCP, food businesses shall have in place prerequisite programmes such as good hygienic practices and appropriate food safety requirements. These prerequisite programmes, including training, shall be well established, documented as appropriate, fully operational and verified.

Management awareness and commitment is necessary for the implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills. (See also requirements under “Training” and “Management Commitment” at the end of this section).

Redesign of the operation should be considered if a hazard that must be controlled is identified but no CCPs are found.

The food business operator shall apply the HACCP principles consisting of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

5.1 Assemble HACCP team

The food operation shall ensure that the appropriate product specific knowledge and expertise is available for the development and implementation of an effective HACCP plan. A multidisciplinary team shall be assembled either in-house or if such expertise is not available on-site, expert advice shall be obtained from other sources, such as trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). The scope of the HACCP plan shall be identified and shall describe which segment of the food chain is involved and the general classes of hazards to be addressed (all or selected classes).

5.2 Describe product

A full description of the product shall be drawn up, including relevant safety information such as composition (including raw materials, ingredients, allergens), origin, physical/chemical properties that impact food safety (including A_w , pH, etc), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc), packaging, labelling, durability and storage conditions and method of distribution. Within businesses with multiple products for example, catering operations with similar characteristics or processing steps may be grouped for the purpose of development of the HACCP plan.

5.3 Identify intended use

The intended use of the product shall be defined based on the expected uses of the product by the end user or consumer. The suitability of the product for vulnerable groups of the population such as pregnant women, infants, elderly should be considered, as necessary.

5.4 Construct flow diagram

The flow diagram shall be prepared to cover all steps in the operation for each specific product or product category. When applying HACCP to a given operation, consideration shall be given to steps preceding and following the specified operation.

5.5 On-site confirmation of flow diagram

Steps shall be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a competent person or persons. On-site verification activities shall be carried out whenever there are any changes in the process.

5.6 List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (SEE PRINCIPLE 1)

The HACCP team should list all potential hazards (physical, chemical, biological) that may be reasonably expected to occur at each step according to the scope. It should then conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food.

In conducting the hazard analysis, the following should be included as appropriate:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and
- conditions leading to the above.

For selection of control measures, consideration shall be given to what control measures, if any, can be applied to each hazard.

More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.

5.7 Determine Critical Control Points (SEE PRINCIPLE 2)

For each hazard that requires control, control measures shall be identified. The control measures shall be reviewed to identify those that need to be addressed through the HACCP plan and for which CCPs shall be identified. There may be more than one CCP at which control is applied to address the same hazard or there may be cases where there is no CCP identified. The CCP in the HACCP system shall be determined and this may be facilitated by a logic reasoning approach such as the application of a decision tree (see Diagram 2). The application of a decision tree should be flexible. This example of a decision tree may not be applicable to all situations and alternative approaches may be used.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

5.8 Establish critical limits for each CCP (SEE PRINCIPLE 3)

Critical limits shall be specified and validated for each CCP. In some cases more than one critical limit may be elaborated at a particular step.

These critical limits shall be measurable. Critical limits based on subjective data (such as visual inspection of product, process, handling) shall be supported by instructions or specifications and/or education and training.

5.9 Establish a monitoring system for each CCP (SEE PRINCIPLE 4)

A monitoring system shall be established for each CCP to demonstrate that the CCP is under control. The monitoring shall be able to detect loss of control at the CCP and in time to make adjustments to regain control of the process and prevent violation of the critical limits. Where possible, process adjustments should be made when the results of monitoring indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs.

Data derived from monitoring shall be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring shall be sufficient to ensure that the CCP is under control. The monitoring system shall cover the following:

- a) measurements or observations that provide results within an adequate time frame;
- b) monitoring devices used;
- c) applicable calibration methods;
- d) monitoring frequency;
- e) responsibility and authority related to monitoring and evaluation of monitoring results; and
- f) records.

All records and documents associated with monitoring CCPs shall be signed by the person(s) doing the monitoring and by the responsible reviewing official(s) of the company.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

5.10 Establish corrective actions (SEE PRINCIPLE 5)

Specific planned corrective actions shall be developed for each CCP in the HACCP system in order to deal with deviations when they occur and to prevent their recurrence. This may require identification of the causes of deviation.

The actions shall ensure that the CCP has been brought under control. Actions taken shall also include proper disposition of the affected product. Deviation and product disposition procedures shall be documented. Records of deviations and disposition shall be maintained.

5.11 Establish verification procedures (SEE PRINCIPLE 6)

The verification procedures consist of two activities, verification activities and validation activities.

The food business operator shall have in place a system to verify the HACCP plan at a set frequency. Procedures for verification shall be established. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in-house, verification should be performed on behalf of the business by external experts or qualified third parties.

The HACCP system, including the HACCP plan, shall be reviewed (at least once in a year) and necessary changes made when any modification is made in the product, process, or any step.

Verification activities shall include:

- self evaluation;

- review of the HACCP system and plan and its records;
- review of deviations and product dispositions; and
- confirmation that CCPs are kept under control.

The results of verification shall be maintained and communicated to the HACCP team / relevant staff.

The food business operator shall periodically validate the HACCP plan and necessarily before its implementation and after any changes are made. The objective of the validation process is to ensure that identified hazards are complete, correct and effectively controlled under the HACCP plan. Validation activities should include actions to confirm the efficacy of the HACCP system. Records of validation shall be maintained. An annual review of the complete HACCP system shall be carried out.

Verification and validation activities are also important for maintenance of the system as well as continual improvements.

5.12 Establish documentation and record keeping (SEE PRINCIPLE 7)

HACCP procedures shall be documented. Documentation and record keeping shall be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Documentation shall include (as a minimum) the following:

- HACCP team composition;
- product description;
- intended use;
- flow chart;
- hazard analysis;
- CCP determination;
- critical limit determination;
- validation process; and
- HACCP plan.

The HACCP plan shall include the following information for each identified CCP:

- food safety hazard(s) to be controlled at the CCP ;
- control measure(s);
- critical limit(s) ;
- monitoring procedure(s) ;
- corrections and corrective action(s) to be taken if critical limits are exceeded;
- responsibilities and authorities for monitoring, corrective action and verification;
- verification procedure; and
- record(s) of monitoring.

Records to include:

- CCP monitoring activities;
- deviations and associated corrective actions;
- disposition of non-conforming products;
- verification procedures performed;
- modifications to the HACCP plan;
- validation record;
- product release records; and
- testing records.

An example of an HACCP worksheet for the development of an HACCP plan is attached as Diagram 3.

6. TRAINING

The food business operator shall train personnel in HACCP principles and applications for the effective implementation of HACCP. Work instructions and procedures should be developed for the tasks of the operating personnel to be stationed at each CCP.

Training should also be imparted to consumers to increase their awareness of HACCP and food safety.

7. MANAGEMENT COMMITMENT

The successful implementation of HACCP requires the full commitment and involvement of the management and workforce. The management shall be able to demonstrate they are fully committed to the implementation of the requirements of the HACCP.

DIAGRAM 1

LOGIC SEQUENCE FOR APPLICATION OF HACCP

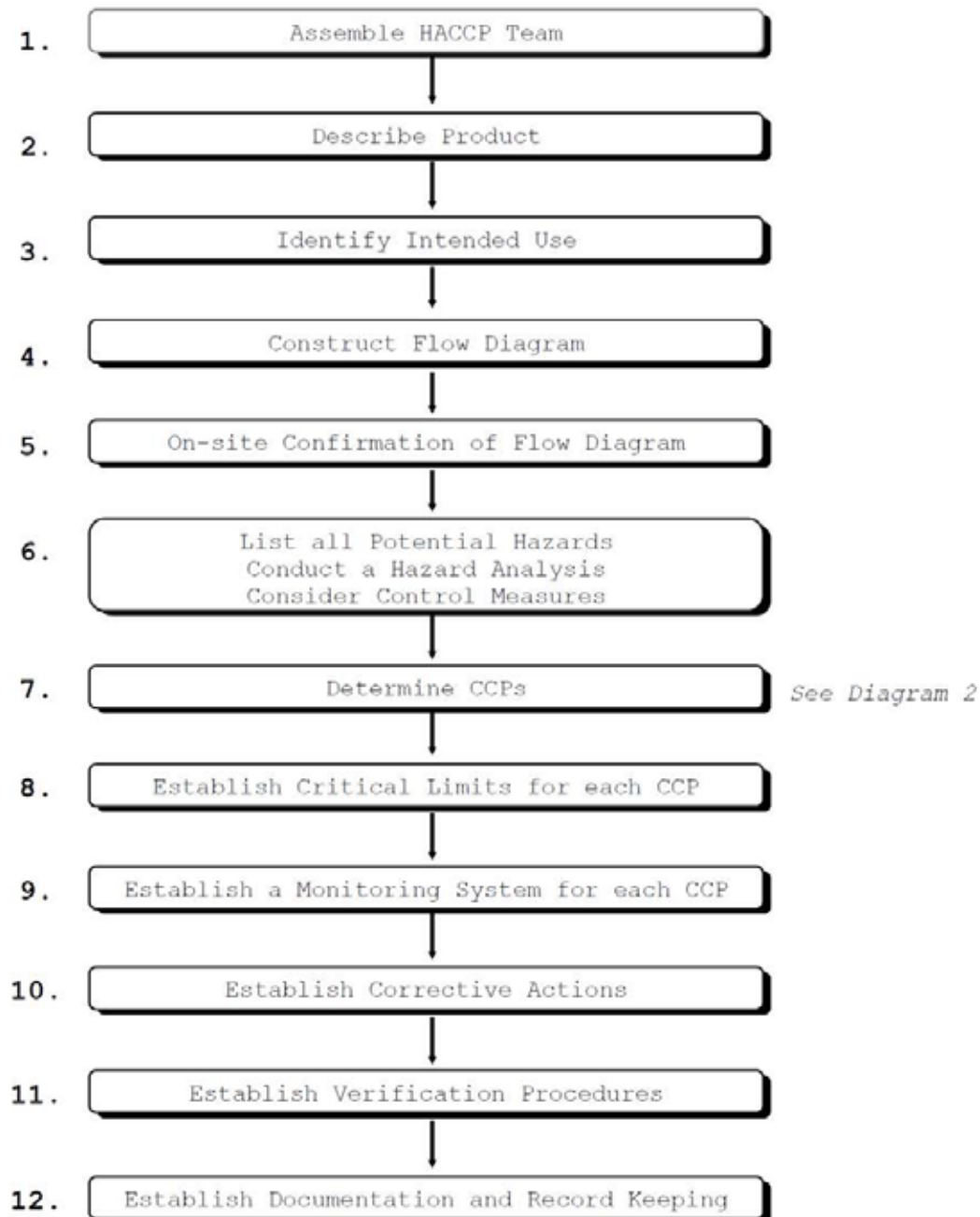
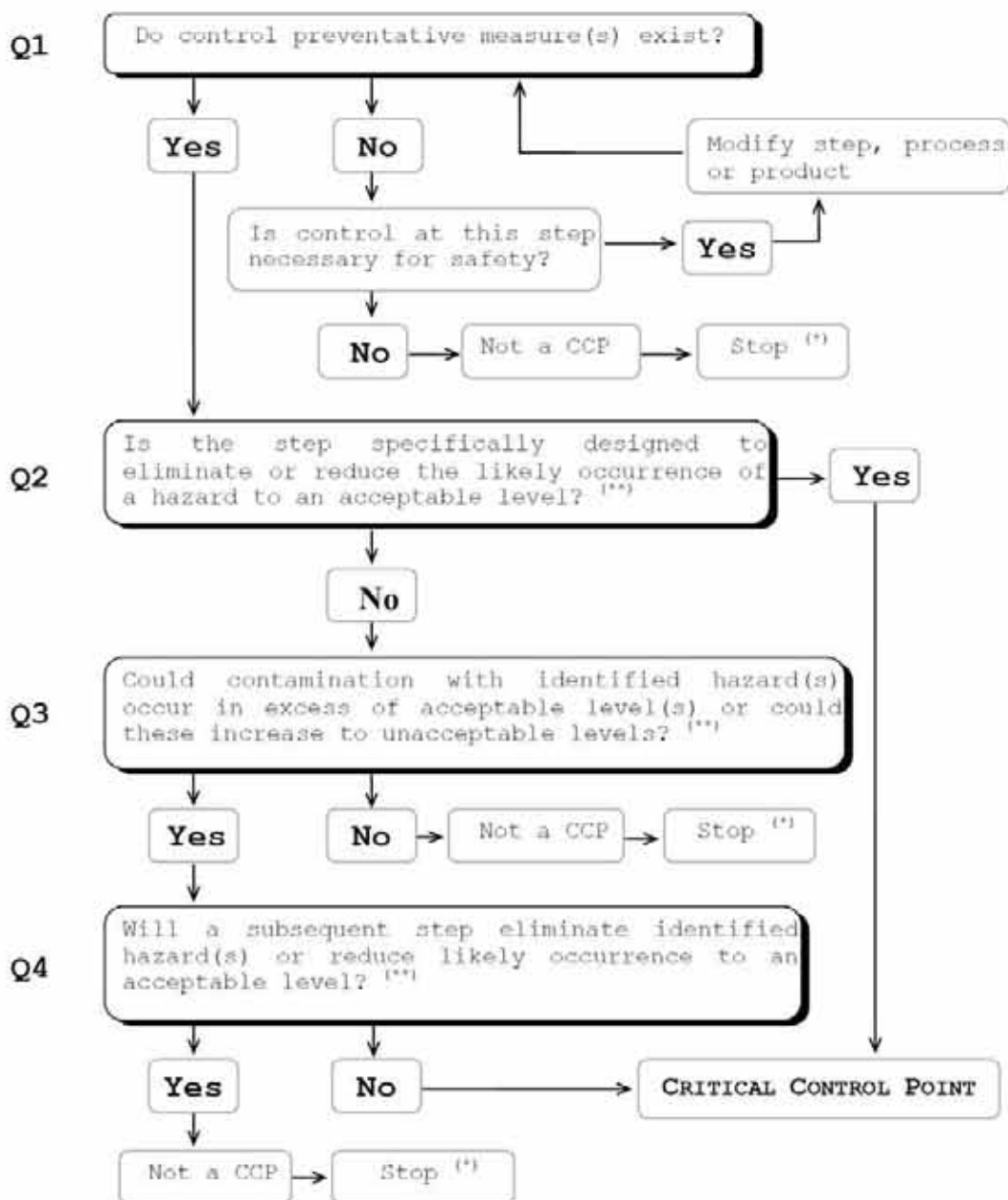


DIAGRAM 2

EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

(answer questions in sequence)



(*) Proceed to the next identified hazard in the described process.

(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

DIAGRAM 3

EXAMPLE OF A HACCP WORKSHEET

1. Describe Product

2. Diagram Process Flow

3.

LIST							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. Verification

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