

**SCHEME OF SUPERVISION AND CONTROL
RELATING TO
THE USE OF THE HONG KONG Q-MARK**

PART 2. QUALITY SYSTEM REQUIREMENTS (Hygiene related)

2.1. GENERAL

The aim of this part is to ensure a system is in place for the continuous production of products satisfying Part 3 of the Scheme of Supervision and Control. These requirements are in addition to the requirements set out in Part 1 of the Scheme of Supervision and Control.

2.2. DEFINITIONS

The definitions and interpretations used in this document shall be as indicated below:

- (a) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labelling, or holding of human food.
- (c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other micro-organisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

2.3. APPLICABILITY OF PART 1 & PART 3 REQUIREMENTS

All the requirements of Part 1 & 3 shall apply.

2.4. MATERIALS AND COMPONENTS

The licensee shall ensure that all raw materials are supplied in a suitable forms and conditions, which shall be verified comply with appropriate requirements.

The licensee shall establish and maintain procedures for identification, storage, segregation and handling of raw materials to prevent them from contamination or deterioration.

In addition, the licensee shall assess condition of raw materials, which need shelf-life control, in regular basis in order to detect deterioration. They shall bear identification of expiry date, which shall be justified and specified by the licensee. They shall not be used after the expiry date, except for further evaluation with appropriate record maintained (see 2.14)

2.5. DOCUMENT CONTROL

The licensee shall control, but not limited to, following documents which are made available in production floor to provide instructions

- a. Defining the manner, including sequence, step or method, of manufacturing processes of products for workers to comply with;
- b. Defining process control method for workers to comply with (see 2.11 & 2.12);
- c. Defining in-process and final inspection and testing activities for inspectors and/or workers to comply with (see 2.8.2).

Document control includes review and approval of issue and change, revision level, availability of updated revision in location of use and removal of outdated copy from point of use.

2.6. PRODUCTION PROCEDURE

2.6.1. Prior to release for production, raw materials shall be inspected as defined to assure the conformance to specified requirements (see also 2.12.1).

2.6.2. Urgently needed raw materials can be released if positive identification is made to permit necessary recall when the test result is found to be unsatisfactory. However, prior to release of final products for delivery to customer, all planned inspection and testing shall have completed with satisfactory result.

- 2.6.3. The production is proceeded in accordance to specified flow stipulated in company standards, such as production flow.
- 2.6.4. The quality control procedures are proceeded in accordance to specified flow stipulated and documented in company standards (see 2.8.2).
- 2.6.5. Any change to manufacturing flow shall have approval from authorized staff, which shall keep informed of the Council in writing.
- 2.6.6 The licensee shall prepare adequate work instructions (see 2.5.a) to define the manner of production and operation of production machines/equipment and make them available on production line so that workers know how to perform their daily jobs.
- 2.6.7. Final products are to be manufactured to meet the standard as specified in Part 3 of the Scheme of Supervision and Control, and in-house specification.

2.7. PRODUCT IDENTIFICATION

The licensee shall identify product for both identify and its production status throughout factory facility. As traceability is a specified requirement, individual product or batch (lot) shall be uniquely identified, which means shall be recorded (see 2.14).

2.8. INSPECTION AND TESTING

2.8.1. TEST FACILITIES

The licensee shall identify, establish, operate, and maintain adequate test facilities in the production premises. In addition, tests done by external laboratory may be needed in order to ensure raw material, semi-finished, or final product can meet specified requirements.

2.8.2. INSPECTION AND ROUTINE TEST

Inspection and routine test shall be performed according to the corresponding measures and acceptance criteria specified and documented by the company standards.

Before delivery to customer, final product shall be inspected to give evidence that they comply with Part 3 of the Scheme of Supervision and Control, and any other specified requirements.

Inspection and test records (see 2.14) shall be maintained to demonstrate conformance to specified requirements. Inspection and test status, and nonconforming product status shall be properly identified throughout production line.

The licensee shall implement appropriate action, which are justified by designated staff, to prevent recurrence of product non-conformances.

2.8.3. EQUIPMENT CALIBRATION

The licensee shall identify and justify equipment used for inspecting, measuring and testing final product non-conformance to be put under appropriate calibration control.

Those equipment, especially for thermometers and standard weights, shall be calibrated and adjusted at defined intervals. Calibration status and records shall be maintained (see 2.14), which should contain following data:

- Date of calibration or repair;
- Method of calibration with detailed procedure or reference to procedure;
- Acceptance criteria;
- Result of calibration with detailed data.

Calibration shall be conducted against certified equipment, which can be designated as in-house calibration master. This master must be calibrated by external body which can demonstrate calibration traceability to nationally or internationally recognized standard. Where no such standard exists, the basis for calibration shall be documented.

2.8.4 EQUIPMENT VERIFICATION

Where test software or comparative references such as test hardware are used as suitable form of inspection, they shall be checked to prove that they are capable of verifying the acceptability of final product, prior to release for use during production, and shall be rechecked at prescribed intervals. The licensee shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 2.14).

2.9. PRODUCTION EQUIPMENT

All plant equipment and utensils shall be:-

- a. Suitable for their intended use;
- b. So designed and of such raw material and workmanship as to be adequately cleanable; and
- c. Properly maintained.

The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Maintenance record for any preventive and/or breakdown maintenance shall be maintained (see 2.14).

2.10. PERSONNEL

The plant management shall take all reasonable measures and precautions to assure the following :

2.10.1. DISEASE CONTROL

No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wound, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

2.10.2. CLEANLINESS

All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:-

- a. Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.

- b. Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable microorganism) in an adequate hand-washing facility before starting work, after each absence from the work station and at any other time when the hands may have become soiled or contaminated.
- c. Remove all insecure jewelry and during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.
- d. If gloves are used in food handling, they should be maintained in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.
- e. Wear hair nets, headbands, caps, or other effective hair restraints.
- f. Do not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.
- g. Take any other necessary precautions to prevent contamination of foods with micro-organisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicant.

2.10.3. EDUCATION AND TRAINING

Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices. Training records shall be maintained (see 2.14).

2.10.4. SUPERVISION

Responsibility for assuring compliance by all personnel with all requirements of this document shall be clearly assigned to competent supervisory personnel.

2.11. PROCESS CONTROL (GENERAL)

The licensee shall establish and maintain documented procedures which are known to be capable of producing final products that meet the specified requirements. Specifically, the control items, control method, quality characteristics, and testing method shall be established and documented for following appropriate control mechanism.

- a. Initial process approval (pre-setting) before mass production;
- b. Monitoring and control of identified critical process parameters and/or product characteristics;
- c. Compliance with code of practices (see 2.10, 2.12 & 2.13), regulatory or statutory requirements.

Records of implementation of either control mechanism "a" or "b" shall be maintained (see 2.14).

- 2.11.1. Production staff shall follow the defined, authorized and documented procedures for each stage of production process.
- 2.11.2. Any deviation from defined procedures must be reported (see 2.14) and approved. The approval shall be granted by authorized persons from production and/or quality control.
- 2.11.3. Before the start of production, steps shall be taken to ensure that the work area and the environmental conditions are suitable. Equipment used for monitoring environment shall be calibrated in accordance to 2.8.3.
- 2.11.4. Defects and irregularities are reported (see 2.14) and appropriate corrective and preventive action are taken and recorded (see 2.14) to avoid their reoccurrence and occurrence.

2.12. PROCESS CONTROL-SANITATION

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accordance with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable micro-organisms, or any other objectionable material to the processed product:-

- 2.12.1. Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed

or cleaned as required to remove soil or other contamination.

Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

- 2.12.2. Containers and carriers of raw ingredients shall be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.
- 2.12.3. When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.
- 2.12.4. Food-processing areas and equipment used for processing human food should not be used to process nonhuman food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.
- 2.12.5. Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. In so far as necessary, equipment shall be taken apart for thorough cleaning.
- 2.12.6. All food processing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the processed products. Monitoring records of above factors shall be maintained (see 2.14).
- 2.12.7. Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.
- 2.12.8. Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, and shall conform to any applicable public health regulation, and shall provide adequate protection from contamination.
- 2.12.9. Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity shall be utilized

to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records shall be retained for a period or time that exceeds the shelf life of the final product (see 2.14).

- 2.12.10. Storage and transportation of final products shall be under such conditions as will prevent contamination, including development of pathogenic or toxigenic microorganisms, and will protect against undesirable deterioration of the product and the container.

2.13. BUILDINGS AND FACILITIES

2.13.1. PLANTS AND GROUNDS

Grounds. The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including but not limited to the following:

- a. Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harbourage for rodents, insects, and other pests.
- b. Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.
- c. Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or micro-organisms.
- d. If the plant ground is bordered by grounds not under the operations control of the kind described in above paragraphs (a) through (c) of this section, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:-

- a. Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair.

Fixtures, ducts, and pipes shall not be so suspended over working areas that drip or condensate may contaminate foods, raw materials, or food contacting surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food-contact surfaces with clothing or personal contact.

- b. Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable microorganisms, chemicals, filth, or other extraneous materials.
- c. Provide adequate lighting to hand-washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.
- d. Provide adequate ventilation or control equipment to minimize odours and noxious fumes or vapours (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.
- e. Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents).

2.13.2. SANITARY FACILITIES AND CONTROLS

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:-

- a. Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment, utensils, or containers, or employee sanitary facilities require.
- b. Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.
- c. Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to :

- Carry sufficient quantities of water to required locations throughout the plant.
 - Properly convey sewage and liquid disposable waste from the plant.
 - Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an insanitary condition.
 - Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- d. Toilet facilities. Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination. except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.
- e. Hand-washing facilities. Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.
- f. Rubbish and offal disposal. Rubbish and any offal shall be so convened, stored, and disposed of as to minimize the development of odour, prevent waste from becoming an attractant and harbourage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

2.13.3. SANITARY OPERATIONS

- a. General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizer, and other supplies employed in cleaning and sanitizing procedures shall be free of significant

microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

- b. Animal and vermin control. No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to rodents and insects). The use of insecticides or rodenticide is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.
- c. Sanitation of equipment and utensils. All utensils and product contacting surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonproduct contacting surfaces of equipment used in the operation of food plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) shall be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.
- d. Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized with product-contact surfaces shall be stored in such a location and manner that product-contact surfaces are protected from splash, dust, and other contamination.

2.14. QUALITY RECORDS

The licensee shall maintain up-to-date records to demonstrate the achievement of the required quality. The records should also be used to promote quality control method. Besides those quality records identified in above requirements, the licensee shall identify other quality records by their own.

All records shall be legible and identifiable to the product or process involved. They shall be readily retrievable and is available for inspection by the representative of Hong Kong Q-Mark Council. The licensee shall define and document retention time of quality records, which minimum period shall be six months.

2.15. MARKING

Each pack of product manufactured under the licence shall be legibly marked either on the product or packaging with the following information:-

- a. The Hong Kong Q-Mark logo with the designated licence number shall be permanently marked;
- b. The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the product shall be declared;
- c. Name of the product, brand name, or model number;
- d. Date of manufacture, date of best consumption, or lot number which may be in code;
- e. Net content and weight;
- f. List of ingredients shall be declared on the label in descending order of proportion;

2.16. PACKAGING

All products manufactured under the HK Q-Mark licence shall be packed in clean and new container in a appropriate manner suitable for the purpose. The overall package shall give adequate protection against shock and vibration expected during storage and delivery to customer. The licensee shall prepare documented instructions for defining the method of packing of final products in order to prevent them from damage.