National Agency for Food & Drug Administration & Control (NAFDAC)

Food Safety & Applied Nutrition (FSAN) Directorate

UNCONTROLLED COPY

CURRENT GOOD MANUFACTURING PRACTICE GUIDELINES FOR FOOD AND FOOD PRODUCTS (REVISED)

INTRODUCTION 5
1.0 SCOPE 5
2.0 APPLICATION OF GOOD MANUFACTURING PRACTICES 5
3.0 ORGANIZATION AND PERSONNEL 6
3.1 Organization, Qualification, and Responsibilities 6
4.0 TRAINING 7
5.0 BUILDINGS AND FACILITIES 7
6.0 PREMISES 8
6.1 General Requirements for Premises 8
6.2 Grounds 9
7.0 CONSTRUCTION AND DESIGN OF PREMISES 10
7.1 Internal structures and fittings 11
8.0 SANITATION AND HYGIENE 15
8.1 Personnel 15
8.2 Disease Control. 15
8.3 Monitoring of personnel 16
9.0 HYGIENIC PRACTICES (CLEANLINESS) 16
10.0 EDUCATION AND TRAINING 19
10.1 Knowledge and responsibilities 19
10.2 Training programs 19
10.3 Refresher training 18
10.4 Practical advice on training 19
11.0 SUPERVISION 21
12.0 MAINTENANCE AND SANITATION 21
12.1 Hygienic Operations 21
13.0 GENERAL MAINTENANCE 22
14.0 SUBSTANCES USED IN CLEANING AND SANITIZING; STORAGE OF 23

UNCONTROLLED COPY

TOXIC MATERIALS. 23
14.1 Procedures for the proper use of cleaning agents shall include: 23
14.3 Cleaning and disinfection program 24
15.0 PEST CONTROL 25
15.1 Pest control program 25
16.0 SANITATION OF FOOD-CONTACT SURFACES 26
17.0 SANITARY FACILITIES AND CONTROLS 27
17.1 Water Supply – 27
18.0 VENTILATION 32
19.0 LIGHTING. 32
20.0 EQUIPMENT 33
21.0 STANDARD OPERATING PROCEDURE 35
21.1 Standard Sanitation Operating Procedures (SSOPs) and Monitoring 35
22.0 PRODUCTION AND PROCESS CONTROLS 36
22.1 Production Processes and Controls 36
23.0 RAW MATERIALS AND OTHER INGREDIENTS 37
24.0 MANUFACTURING OPERATIONS 38
25.0 WAREHOUSING AND DISTRIBUTION 40
26.0 TRANSPORTATION 41
27.0 STORAGE. 43
28.0 DEFECT ACTION 44
29.0 QUALITY ASSURANCE 44
30.0 QUALITY CONTROL 45
30.1 Quality management 45
30.2 Testing of Reprocessed Products 46
30.3. Testing of Returned Goods 46
31.0 CONTROL OF HAZARDS (HACCP) 47
32.0 PRODUCT RECALL 49

UNCONTROLLED COPY

32.1 Recall procedures 49
33.0 DOCUMENTATION AND RECORDS 54
34.0 MATERIAL RECORDS 56
35.0 MASTER PRODUCTION AND CONTROL RECORDS 56
36.0 BATCH PRODUCTION AND CONTROL RECORDS 57
37.0 PRODUCTION RECORD REVIEW 54
38.0 LABORATORY RECORDS 54
Laboratory records shall include complete data derived from all tests necessary to ensure compliance with established specifications and standards, including examinations and assays, as follows: 54
39.0 DISTRIBUTION RECORD 55
Distribution records shall contain the following: 55
40.0 COMPLAINTS 55
41.0 PRODUCT INFORMATION AND CONSUMER AWARENESS 56
42.0 PACKAGING MATERIALS 57
43.0 FOREIGN MATERIAL CONTROL 58
44.0 LABORATORY SUPPORT (The Laboratory Capabilities Prerequisite System) 60
45.0 RETENTION OF SAMPLES 61
46.0 SUB-CONTRACTING OF MANUFACTURE 61
DEFINITION OF TERMS 62

UNCONTROLLED COPY

INTRODUCTION

Current Good Manufacturing Practice (cGMP) is a key factor for manufacturers/ industries to produce good quality, safe and affordable products. cGMP guidelines are a set of technical principles and recommendations used in processing food products in order to guarantee that they are safe and suitable for consumption, and to prevent contamination or adulteration. They are also sometimes called "good processing practices" or "good fabrication practices".

cGMP guidelines are established to satisfy regulatory requirements as well as maintain the high quality standards of products.
This guideline has been developed to highlight good manufacturing practices that should be followed by manufacturers, operators and employees to maximally assure the production of safe and sanitary products at all times. The guideline offers suggestions for measures and precautions that should be taken regarding employee health, food handling practices, appearance, personal hygiene, plant procedures, plant and equipment design, maintenance, and sanitation. The document also offers some examples of GMP documentation, which has been identified as one of the main shortcomings in implementing food safety and food quality management systems.

It is important that every employee is made knowledgeable and aware of the necessity of adhering to these guidelines at all times. The guidelines need to be re-emphasized by the manufacturer on a regular basis and that regular assessment and review of how well the guidelines are being followed should be conducted by management.

1.0 SCOPE

This guideline applies to food manufacturers/industries and covers all activities undertaken from the point where raw materials are received, through processing, storage and distribution of final products."

2.0 APPLICATION OF GOOD MANUFACTURING PRACTICES

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

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

UNCONTROLLED COPY

also need to perform a hazard analysis for each product or type of process, and for each new product, even though they are not implementing the HACCP. Good Manufacturing Practices and the HACCP system are interrelated and interdependent: application of GMP requires familiarity with the principles of the HACCP system to ensure a comprehensive approach to food safety.

3.0 ORGANIZATION AND PERSONNEL

There shall be an adequate number of personnel, as determined by the company, at all levels having appropriate education, knowledge, training, experience, skill and capabilities or a combination thereof relevant to their assigned functions, in good mental and physical health to be able to execute their duties.

3.1 Organization, Qualification, and Responsibilities

a. The organizational structure of the company should be such that the production and the quality assurance/quality control functions are headed by different managers/heads, neither of whom shall be reporting to the other. Each shall be given full authority and facilities necessary to execute their duties effectively.

b. The production manager/head shall be adequately trained and*/or* shall possess good practical experience in the field of food manufacture or any other related field, and managerial skill, which will enable him/her to perform the function effectively. The production manager shall have full authority and responsibility to manage production of food products. Additionally, the production manager shall have other responsibilities, which he shall share with the quality assurance/quality control manager and the person responsible for engineering.

c. The quality assurance/quality control manager/head shall have adequate training and practical experience, which will enable him perform his function effectively. The quality assurance/quality control manager/head shall have full authority and responsibility in all quality assurance and quality control duties such as establishment, verification and implementation of all quality control procedures.

d. The quality assurance/quality control unit shall be entrusted with the responsibilities and authority to:

   i. Approve/reject all components – raw and packaging materials, labelling materials, as well as bulk and finished products.
   ii. Approve/reject product manufactured or packed or, held under control by a third party manufacturer.
   iii. Approve/reject procedures, which have impact on the product quality or product specifications.
   iv. Review production records and quality control records.

UNCONTROLLED COPY

v. Support monitoring and controlling the manufacturing environment, plant cleanliness, production validation, calibration, training of personnel, approve supply of materials and contract parties, protect products and materials against spoilage and deterioration and the maintenance of records.

e. The quality assurance/quality control manager/head shall share responsibility with the production manager/head for establishing and authorizing written procedures.
f. The production manager/head shall have full authority and responsibility to manage the production of products covering all aspects of personnel, area, equipment and records.
g. The production manager/head shall share with the quality assurance/quality control manager/head the responsibility of product quality and authority in the aspects specified in sections 3.1d (i) to (v).
h. The duties of every employee shall be clearly defined, communicated and well understood, and shall be within an employee's capacity to perform.

4.0 TRAINING

a. All employees who are directly engaged in the manufacturing, processing, packaging and holding of food and food products shall be trained in the particular operations they perform in accordance with the principles of current Good Manufacturing Practice.
b. Training shall be conducted by qualified personnel.
c. Training in Good Manufacturing Practices shall be on a continuing basis and with adequate frequency to assure that employees remain familiar with the Good Manufacturing Practice requirements relevant to their functions.
d. Training in Good Manufacturing Practices shall be in accordance with written programs approved by the production and quality control managers/heads.
e. Records of personnel training in Good Manufacturing Practices shall be maintained.
f. After training, the consequential employees' performance shall be appraised to determine their further training needs.

5.0 BUILDINGS AND FACILITIES

5.1 Buildings

Buildings should be located, designed, constructed, adapted and maintained to suit the operations carried out in them and to facilitate the protection of materials and products from contamination or deterioration. Equipment should be designed, constructed, adapted, located and maintained to suit the processes and products for which it is used and to facilitate protection of the materials handled from contamination or deterioration.

UNCONTROLLED COPY

5.2 **Location**

a. The first thing to consider is where to locate a food processing establishment. The surroundings must be taken into consideration to ensure that they do not have an adverse effect on the food processed. Facilities should not be located near areas considered adverse or harmful, for example, sanitary landfills, areas subject to flooding, industrial activities that pose a threat of contaminating food, or other sources of contamination.
Generally, a minimum distance of 30 meters from potential sources of contamination is recommended.

b. Establishments should be adequately fenced round with blocks to prevent external interference and shall be located away from:

i. Environmentally polluted areas and industrial activities, which pose serious threat of contaminating food;
ii. Areas with excessive dust, foul odours, smoke, airborne microbial and chemical contaminants, such as quarry sites, abattoirs, sewage treatment or oxidation lagoons, animal habitats, dusty roads, soak-away pits, cemetery etc.
iii. Areas subject to flooding unless sufficient safeguards are provided such as channels, drainages etc.
iv. Areas prone to infestation of pests;
v. Areas where wastes, either solid or liquid cannot be removed effectively.

6.0 PREMISES

6.1 General Requirements for Premises

Premises should:

a. provide sufficient space to suit the operations to be carried out;
b. allow an efficient flow of work;
c. provide suitable internal storage areas;
d. facilitate effective communication and supervision;
e. be sited with due regard for the provision of services needed and to avoid contamination from adjacent activities. In existing premises, effective measures should be taken to avoid such contamination;
f. Be maintained in a good state of repair. The condition of buildings should be reviewed regularly, and repairs effected where necessary. Special care should be exercised to ensure that building materials of construction, repair or maintenance operations are not allowed to affect adversely product quality or integrity;
g. Be constructed and maintained with the object of protecting against the entrance and harbouring of vermin, birds, insects, other pests and pets. There should be either

UNCONTROLLED COPY

trained personnel to oversee infestation control or a professional infestation control company should be employed for regular inspection, advice and treatment if required;

h. Be maintained in a clean and tidy condition (including processing areas, laboratories, stores, passageways and external surroundings).
i. Manufacturing areas should not be used as a general right of way for personnel or materials, or for storage (except of materials in process).
j. Access to fire exits must not be blocked or restricted at any time.
k. Premises must be designed to allow cleaning and maintenance to be carried out to a high level.
l. Facilities that must be provided in the premises include but not limited to the following:
    i. availability of washbasins, lavatories;
    ii. adequate supply of potable water;
    iii. ventilation;
    iv. lighting;
    v. drainage facilities;
    vi. changing facilities for staff.

6.2 Grounds

a. Grounds shall be constructed and maintained to protect against weather, flood, ground seepage, and the access and harbouring of vermin, rodents, birds, insects or other animals.
b. If the plant grounds are bordered by grounds not under the operator's control, care shall be exercised by conducting inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination
c. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for
d. adequate maintenance of grounds shall include, but are not limited to:
    i. Good housekeeping. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place or harborage for pest.
    ii. Providing and properly operating systems for waste treatment and disposal designed and constructed in an appropriate manner so that they do not constitute a source of contamination of areas where food is exposed.

UNCONTROLLED COPY

7.0 CONSTRUCTION AND DESIGN OF PREMISES

a. Plant, buildings, and structures shall be of suitable size, design, and construction to facilitate maintenance and sanitary operations for food manufacturing purposes. The individual working areas shall be adequate so that any risk of confusion and cross-contamination that will affect the safety of food manufactured will be avoided.

b. There should be a "Master Plan" diagram that show:
   i. building outline with production areas, service areas and surroundings
   ii. access for personnel and traffic ways – for incoming and outgoing raw material
   iii. rivers, canals and other water catchment areas – e.g. swamps/marshes
   iv. any approximate potential origins of problems – e.g. housing, industries, etc.
   v. waste collection areas
   vi. prevailing wind direction
   vii. definition of main areas – in terms of hygiene zones and functions
   viii. planned cleaning practices – by area
   ix. circulation of people and vehicles – and flow of goods including raw materials, packaging, intermediate products
   x. waste utilities – including the waste water treatment plant

The "Master Plan" diagram is critical in studies to predict where routes could lead to cross contamination, where new barriers maybe necessary and generally to minimize all circulations – with an aim to reduce carriage of dirt and potential contaminants around the factory.

c. Minimum design and construction requirements of plant and facilities shall include:

   i. Sufficient space for placement and operations of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
   ii. Adequate food safety controls through effective design and construction including the separation of operations in which food contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

d. The internal layout of the facilities should permit good hygiene practices, including measures to prevent cross-contamination among raw materials and processed products during the manufacturing process.

UNCONTROLLED COPY

7.1 Internal structures and fittings

Structures within the facilities should be soundly built of durable materials; they should be easy to maintain, clean and, where appropriate, able to be disinfected. In particular the following specific conditions should be met to protect food safety and suitability:

The plant shall be constructed in such a manner that:

7.1.1 Floors

a. Floors in manufacturing areas should be made of impervious materials, laid to an even surface and free from cracks and open joints in areas where product is exposed. They should be of adequate construction and material for the wear and tear and conditions of manufacture encountered.
b. Drains should be of adequate size, and should have trapped gullies and proper ventilation. Any open channels should be shallow to facilitate cleaning.
c. Materials for flooring shall be durable, impermeable, easy to wash and disinfect, resistant to hot liquids, impact damage, abrasion, slip-resistant, and have adequate slope in order to allow natural flow of water towards the drainage system.
d. Floor covering such as carpeting or similar material shall not be installed as floor covering.
e. Floor junctures shall be coved and closed to no larger than 1mm.
f. The floors in food production in which water flush cleaning methods are used shall be provided with drains and be graded to drain and the floor and wall junctures shall be covered and sealed.

Examples of flooring materials are:

1. Vinyl safety flooring
2. Vinyl tiles
3. Quarry tiles with water-proof grouting
4. Terrazzo
5. Epoxy resin

7.1.2 Walls

a. Walls should be sound and finished with a smooth impervious and easily cleaned surface.
b. Walls should have a smooth surface up to a height appropriate to the operation; 1.8 meters (6 feet) from the floor is usually adequate.

UNCONTROLLED COPY

c. Walls where appropriate, shall be of waterproof, non-absorbent and washable materials sealed and free of insects and shall be light colour
d. Angles between walls, between walls and floors, and between walls and ceiling in food handling areas shall be sealed and coved to facilitate cleaning.
e. Materials for walls shall be heat, steam, and shock resistant and shall also be smooth, light coloured, easy to wash and disinfect and made from non-toxic materials.

Examples of materials are:

1. Sheet cladding of stainless steel or polypropylene
2. Ceramic tiles with water-proof grouting
3. Washable painted plaster

7.1.3 Windows

a. Windows should be of toughened glass or plastic, adequately screened and secured, and with ledges sloped away from the glass at an angle to prevent items being left on them. Materials should be chosen so as to avoid tainting or otherwise contaminating food materials.
b. Windows should be easy to clean, designed to minimize dirt build up, and fitted with removable and cleanable insect-proof screens; cornices should not be right angled. These measures will improve lighting and ventilation and keep out pests.

7.1.4 Doors

Doors should have smooth and non-absorbent surfaces in order that they are easy to clean and when necessary, disinfect, tight fitting to prevent entry of pests and where appropriate, be self-closing and close fitting.

Examples of materials are:

i. Aluminum doors
ii. Stainless steel doors

7.1.5 Ceilings

a. Ceilings should be so designed, constructed and finished so as to prevent the accumulation of dirt and minimize condensation, mould development and flaking and shall be easy to clean.
b. Suspended ceilings should not permit the accumulation of dirt and should be installed as to reduce condensation, the formation of mould and the release of loose particles.
c. The coving of junctions between walls, floors and ceilings in critical areas is recommended.

UNCONTROLLED COPY

d. Materials for ceiling shall be heat, steam and fire resistant and also smooth, and light coloured.

Examples are:

i. Washable painted plaster
ii. Suspended ceiling panels

7.1.6 Drains

Drains should be of adequate size, and should have trapped gullies and proper ventilation. Any open channels should be shallow to facilitate cleaning.

7.1.7 Working surfaces

a. Working surfaces that come into direct food contact should be in sound condition, durable and easy to clean, maintain and disinfect; they should be made of smooth, non-absorbent materials, and be inert to the food, detergents, and disinfectants under normal operating conditions.
b. The use of wood should be avoided, but is acceptable as part of structure, framing for shelves, etc., provided it is in sound condition, free of surface imperfections and sealed with varnish or paint so as to be fully washable. Use as tabletops and chopping boards is not suitable; wood handled knives, spoons and paddles should be replaced when excessively worn or split. Such utensils should be phased out
c. Woodwork used in construction should be pre-treated with ant-resistant chemical
d. There should be effective protection to prevent the access and sheltering of insects, rodents and other pests.

Examples are:
i. plastic laminates
ii. Stainless steel
iii. Food grade plastics
iv. Ceramics and toughened glass

7.1.8 Stairs lift cages and auxiliary structures

Stairs lift cages and auxiliary structures such as platforms, ladders, chutes, shall be so situated and constructed as not to cause contamination to food. Chutes shall be constructed with inspection and cleaning hatches.

UNCONTROLLED COPY

7.1.9 Utility Lines

Utility service lines and pipes shall not be exposed. Surface utility lines may be covered with suitable materials such as trunking pipes for electrical wires.

7.1.10 **Lighting**

Adequate natural or artificial lighting shall be provided throughout the establishment. Shatter proof light bulbs, fixtures, skylights, or other glass suspended over exposed food shall be provided or otherwise, there shall be protection against food contamination in case of glass breakage.

7.1.11 **Ventilation**

a. Adequate ventilation shall be provided to prevent excessive buildup of heat, dust, odors and vapors (including steam and noxious fumes) in areas where they may contaminate food.

b. Fans and other air-blowing equipment shall be located in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces, i.e. the direction of the air flow within the plant shall never be from a dirty area to a clean area.

c. Ventilation openings shall be provided with a screen or other protecting enclosure of non-corrodible material. Screens shall be easily removable for cleaning.

7.1.12 Adequate screening or other protection against pests shall be provided.

7.2 The processing of materials for food products shall be separated from the production of non-food products.

7.3 There shall be a separate space for:
a. Cleaning mobile equipment
b. Storage of cleaning materials

7.3 Locker/gowning room shall be directly connected to but separated from processing areas.

7.4 Toilets shall not be opened directly to production areas and shall have adequate supply of water and ventilation.

7.5 There shall be defined areas for the following operations:
a. gowning/change rooms for all personnel
b. receiving of starting materials
c. incoming goods quarantine
d. sampling room for sampling of deliveries of starting materials

UNCONTROLLED COPY

e. storage for approved materials (chemical & packaging)
f. storage of reject materials
g. Quality Control facilities
h. Preparation of materials
i. Processing operations
j. Equipment washing
k. Storage of cleaned, idle/non-functional equipment
l. Major repair and maintenance activities
m. Storage of cleaning tools and supplies
n. Staging/storage of bulk products
o. Packaging/labelling operations
p. Quarantine storage for finished products
q. Storage/warehouse for approved finished products
r. Canteen

8.0 SANITATION AND HYGIENE

8.1 Personnel

The plant management shall define its policy and document its procedures on sanitation and personnel hygiene and take all reasonable measures and precautions to ensure the Following:

8.2 Disease Control.

a. Persons directly involved in the manufacturing, food processing or packing should be fit and capable of discharging their duties effectively.

b. Food Handlers test/ medical fitness certificate for production staff should include the following:
1.Typhoid Vaccination Certificate (valid for 3 years from last vaccination date).
2. Hepatitis A Vaccination Certificate
3. Laboratory Investigation
i. Stool microscopy, culture and sensitivity
ii. Hepatitis A Antigen

Note:

See Appendix I for Medical Examination for Food Handlers along the Food Supply Chain as contained in the National Guidelines for Food Handlers' Medical Test 2024

UNCONTROLLED COPY

8.3 Monitoring of personnel

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

i. Keeping track of employees' health through health files for each employee where all health-related events are recorded.
ii. Requiring all persons or visitors who enter processing rooms to first fill out a form on their health status so as to prevent food contamination.
iii. Excusing food handlers with diarrhoea or other type of digestive illnesses from work because, even if they are not in contact with food, their use of toilet facilities among others may lead to contamination of other employees.
iv. Use of liquid soap in toilet facilities to prevent cross-contamination that can occur when bar soap is used.
v. Equipping toilet and hand-washing facilities with paper towels, individual towels, or hot-air dryers.
vi. Having foot-operated or sensor-operated toilets and faucets to avoid handling plumbing accessories in toilet facilities.
vii. Not allowing people with illnesses that can be food-borne in areas where food is handled. Employees should learn to inform their supervisors if they have a contagious disease that can be transmitted through food.
viii. Not allowing employees with open injuries to handle food or remain in areas with food contact surfaces unless the wound is protected securely with bandages and covered by waterproof material, for example, rubber gloves.
ix. Requiring persons who enter a food handling area to wash their hands. Employees should submerge their hands in a disinfectant solution or use a disinfectant solution to clean their hands. This procedure should be verified.

9.0 HYGIENIC PRACTICES (CLEANLINESS)

All personnel working in direct contact with food, food contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food.

There shall be established/ documented procedures and work instructions made known to all appropriate personnel for maintaining cleanliness to include, but are not limited to:

a. Wearing outer garments including working shoes suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

UNCONTROLLED COPY

b. Maintaining adequate personal cleanliness.

c. Washing hands thoroughly at frequent intervals, preferably in 'warm' water, using a non-perfumed bactericidal soap. (and sanitizing if necessary to protect against contamination with undesirable microorganisms) 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.

d. Hands should be thoroughly dried, nails kept short, well-manicured and cleaned by using a nailbrush. Where appropriate, non-perfumed barrier creams or alcohol based skin sanitizers should be provided.

Hands must be washed:-

i. Immediately before putting on protective clothing, particularly n important in the case of high risk personnel.
ii. Immediately before commencing work, or entering production areas.
iii. After handling debris, refuse or food waste.
iv. If they become soiled or visibly contaminated.
v. after visiting the toilet.
vi. After blowing the nose or touching the mouth

e. Removing all unsecured jewellery and other objects that might fall into food, equipment, or containers, and removing hand jewellery that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewellery cannot be removed, it shall be covered by material which can be maintained in an intact, clean and sanitary condition and which effectively protects against food contamination by these objects.

f. Employees working in production areas must not wear false fingernails, fingernail polish, rings, except for plain wedding rings, exposed body piercings, or watches, etc.

g. Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

h. Fine mesh net hair restraints for head and facial hair must be required in all production, processing and warehouse areas by all employees. If moustaches, without hair restraint, are allowed by the plant, they must be well groomed and not extend below the corners of the mouth.

i. Storing clothing or other personal belongings in areas, other than where food is exposed or, where equipment or utensils are washed.

UNCONTROLLED COPY

j. If dedicated aprons, lab coats, smocks, etc. are utilized, the plant must provide and the employees must use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities. Coat hooks should be made available for employees to hang their outer garments outside the toilet facilities.

k. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

l. People engaged in food handling activities should refrain from conduct that could result in food contamination, for example:
   - smoking,
   - spitting,
   - chewing gum or eating,
   - sneezing or coughing over unprotected food,
   - touching their hair or face, or using their hands to wipe away
   - perspiration while at work,
   - wearing their uniform in areas where they can be exposed to contamination,
   - using jewellery, pins, or other objects that can pose a threat to food safety and suitability,
   - keeping their clothes and other personal effects in areas where food is exposed or where equipment and utensils are washed.

m. Pens, combs, pencils, thermometers, etc., should not be carried above the waist at any time while in food handling/processing areas.

n. Where the risk exists, the carrying of loose items (including mobile phones) in the production areas should be restricted or prohibited.

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

p. Strong perfumes are not allowed because of the possibility of taint food.

q. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with micro-organisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, money and medicines applied to the skin.

UNCONTROLLED COPY

10.0 EDUCATION AND TRAINING

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

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

c. A training program shall be established and maintained to define appropriate training necessary for food manufacturers and supervisors on proper food handling techniques and food-protection principles.

d. Training shall be regularly instituted and validated to ensure compliance of personnel to established procedures and work instructions.

e. Training is fundamentally important in the Good manufacturing practice manufacturing system.

10.1 Knowledge and responsibilities

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

10.2 Training programs

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

a. the nature of the product and the risks of contamination,
b. process operations (incoming raw materials, supplier oversight, storage practices, control of key operations, monitoring and measurement of control parameters, cleaning procedures, labeling, transportation, distribution),
c. record management, and the different quality procedures, programs and manuals.

UNCONTROLLED COPY

10.3 Refresher training

Training programs should be periodically reviewed and updated, preferably once a year or when processing conditions change (for example, if new requirements have been added, if changes are made in the process, if new equipment is introduced).
Food producers/processors should remain aware of all the procedures necessary to maintain the safety and suitability of food.

10.4 Practical advice on training

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

b. Staff training needs should be evaluated annually, based on the results of the previous year and the assessment of training program effectiveness.

c. Training should be appropriate to the complexity of the process and the tasks assigned:
   i. All personnel, including suppliers, should receive GMP training.

   ii. Employees involved in processing should also receive specific training on key operations as well as control and measurement activities. Primarily, they should understand the hygiene program, the pest control program, and the proper care and handling of water.

   iii. Warehouse personnel should receive training in good storage and pest control practices.

   iv. Persons responsible for equipment should receive training in preventive maintenance, instrument calibration, and general maintenance.

   v. Persons responsible for purchases should receive training in the use of specification sheets for all products and in the monitoring of suppliers.

   vi. Office personnel should receive training for monitoring carrier services and vehicle conditions.

   vii. All personnel should receive training in record management, program compliance, preventive measures and corrective actions.

UNCONTROLLED COPY

viii. Supervisory staff should receive training in plant inspection, assessment and interpretation of hygiene profiles, hygiene program verification, personnel monitoring, and analysis of end products, as well as in the management of preventive measures and corrective actions.

ix. Senior managers should be fully versed in food law, hygiene principles, and the importance of hygiene control systems, all of which should be reflected in the business' safety management policy.

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

xi. Periodic assessments should be performed of the effectiveness of training and instruction programs.

11.0 SUPERVISION

a. Authority and responsibility for assuring compliance to established procedures and work instructions and identifying sanitation failures or food contamination by all personnel shall be clearly assigned to competent supervisory personnel (Shift Hygiene and Sanitation Officer or any other title).
b. Overall sanitation of the plant shall be under the supervision of one or more competent individuals given the responsibility for this function.
c. Personnel responsible for identifying sanitation failures or food contamination problems should have an educational background or experience, or a combination thereof, with a level of competency necessary for production of clean and safe food.
d. Also, routine supervision and checks should be carried out to ensure that procedures are being performed effectively.

12.0 MAINTENANCE AND SANITATION

12.1 Hygienic Operations

12.1.0 Cleaning Procedures and Methods

a. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.
b. Cleaning procedures will involve, where appropriate:

UNCONTROLLED COPY

i. Removing gross debris from surfaces;
ii. Applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
iii. Rinsing with water to remove loosened soil and residues of detergent;
iv. Dry cleaning or other appropriate methods for removing and collection residues and debris; and
v. Where necessary, disinfections with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing are not required.

12.1.1 Cleaning Programs

a. Cleaning and disinfections programs should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of equipment.

b. Cleaning and disinfections programs should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

- Where written cleaning programs are used, they should specify:
  - Areas, items of equipment and utensils to be cleaned;
  - Responsibility for particular tasks;
  - Method and frequency of cleaning; and
  - Monitoring arrangements.

b. Where appropriate, programs should be drawn up in consultation with relevant specialist expert advisors.

13.0 GENERAL MAINTENANCE

a. There shall be procedures for general maintenance of the plant and its premises. The procedures shall include the following:

b. Establishments and equipment should be kept in an appropriate state of repair and condition to:
i. Facilitate all sanitation procedures;
ii. Function as intended, particularly at critical steps
iii Prevent contamination, e.g. from metal, flaking plasters, debris and chemicals.

c. Buildings, fixtures and other physical facilities of the plant shall be kept in good repair and shall be regularly cleaned and maintained in a sanitary condition. Cleaning operations shall be done properly to avoid the danger of contamination of food and food-contact surfaces.

UNCONTROLLED COPY

14.0 SUBSTANCES USED IN CLEANING AND SANITIZING; STORAGE OF TOXIC MATERIALS.

a. Cleaning should 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. Disinfections may be necessary after cleaning.

b. Detergents, sanitizers and other supplies employed in cleaning and sanitizing procedures should 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 a manner and under conditions that ensures their safe use.

14.1 Procedures for the proper use of cleaning agents shall include:

i. Cleaning chemicals, detergents, sanitizers should be handled and used carefully and in accordance with manufacturer's instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.
ii. Food and equipment should be protected during maintenance.
iii. Where there is a risk of food contact, food grade materials for maintenance must be used.
iv. Maintenance personnel must be trained on specific maintenance procedures on quality and hygiene before allowing them to work during Plant Maintenance.

14.2 Cleaning procedures and methods

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

i. removing gross debris from surfaces; this removes dirt and dust, and the mechanical action reduces environmental bacteria suspended in those particles;
ii. applying a detergent solution to loosen soil and bacterial film: this eliminates dirt and grease adhered to surfaces, and the mechanical action reduces the bacteria in the film;
iii. rinsing with water to remove loosened soil and detergent residues: dust, grease and bacteria are eliminated by the detergent and the scrubbing;
iv. where necessary, disinfection; the main objective of disinfection is to eliminate or reduce bacteria and fungus.
v. When water-free methods are indicated, dry cleaning procedures should be used and waste eliminated by vacuuming or by applying moistened sanitized towels. This type of

UNCONTROLLED COPY

cleaning should be followed by disinfection, depending on the nature of the product and the processes.

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

14.3 Cleaning and disinfection program

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

b. Cleaning and disinfection programs should specify:

i. what surfaces, equipment and utensils are to be cleaned, along with the name of the responsible person;

ii. what method and procedures are to be used (detergents, disinfectants, concentration), as well as frequency of cleaning and disinfection; and

iii. monitoring arrangements (levels of action).

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

14.4 Monitoring effectiveness

Cleaning and disinfection procedures for equipment, food contact surfaces, and critical environments should be verified. Verification consists of collecting objective proof that cleaning and disinfection objectives have been met; in other words, verification is performed to confirm the effectiveness of procedures that will subsequently be maintained and monitored.

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

Monitoring of a cleaning program takes place at two levels:

i) periodic inspection, through visual observation; and

ii) monitoring of surfaces (swabbing or rubbing), environmental controls (sedimentation plates), employees' hands (swabbing or fingertip sampling), among others.

14.5 Some thoughts on disinfectants

b. Although there are many disinfectants that can be used in a food processing plant, it is important to be well aware of the biohazards related to the product and the

UNCONTROLLED COPY

manufacturing process, and to take this into account to select the most suitable disinfectant.

c. It is important to know the following about a disinfectant:
   i. the active ingredient and the concentration needed to eliminate or reduce identified hazards,
   ii. at what pH level it acts,
   iii. how it performs in the presence of organic matter or water hardness levels,
   iv. the temperature at which it should be used,
   v. how long it takes to act,
   vi. the purity of its active ingredient.

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

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

15.0 PEST CONTROL

Pests pose a major threat to the safety of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests. Good sanitation of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

15.1 Pest control program

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

i. **Preventing access**

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

Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

UNCONTROLLED COPY

ii Harborage and infestation

a. The availability of food and water encourages pest harborage and infestation. Potential food sources should be stored in pest proof containers and/or stacked above the ground away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest proof containers.

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

iii. **Monitoring and detection**

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

iv. **Eradication**

Eradication should be done immediately, using means that do not adversely affect food safety or suitability of products. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety and suitability of food

iv. A pest control program should include the name of the person responsible for the program, the name of the company or individual hired to carry out the pest control program, the list of chemical products used, their concentration, where they are applied, and the method and frequency of application.

v. It is necessary to keep a map showing where rodent traps have been set, and control points outside the establishment. Monitoring of these traps will help map rodent incidence and identify where the establishment is most vulnerable to incoming pests. The pest control program should specify the type and frequency of inspection.

vi. Rodenticides may only be used outside the facilities.

16.0 SANITATION OF FOOD-CONTACT SURFACES

a. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

b. Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

c. In wet processing, when cleaning is necessary to protect against the introduction of micro-organisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food contact surfaces may have become contaminated.

d. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

UNCONTROLLED COPY

e. Non-food contact surfaces of equipment used in the operation of food factories shall be cleaned as frequently as necessary to protect against contamination of food.
f. Single-service articles shall be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
g. Sanitizing agents shall be adequate and safe under prescribed conditions of use.
h. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

17.0 SANITARY FACILITIES AND CONTROLS

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

17.1 Water Supply –

a. Water shall be of the quality necessary for the product, process or use. The plant should demonstrate that the water supply is potable and that portability is maintained at all times.
b. The premises shall have continuous supply of running potable water that meets the Nigerian Industrial Standard (NIS) for Drinking Water.
c. Water supply must only be from an approved source, such as:
   i. A public water system
   ii. A private water system that is constructed, maintained, and operated to meet health requirements, i.e. Nigerian Industrial Standard (NIS) for drinking water.
   iii. Enclosed vehicular water tankers certified for lifting potable water and stored using suitable holding tanks and internal delivery.
   iv. A properly constructed, maintained and operated water distribution system.
d. A certified laboratory should document potability testing at least annually. Potability certificates available from private water suppliers are acceptable. If the facility is using water from a private water system, there should be a credible potability test at least every 6 months.
e. Plant water should be chlorinated or otherwise treated to assure potability.
f. Plants using their own private system should be able to demonstrate water potability on a continuing basis. If chlorination is applied, the system should have automated controls that prevent inadvertent use of the water or an alarming mechanism to immediately notify facility management if the chlorination system fails.
g. Plant should have an identification system for potable and non-potable water lines and current schematics. Dead ends on potable water lines should be eliminated. Hose drops should not be submerged.

UNCONTROLLED COPY

17.1.1 Potable water – Water can be used as a product ingredient, for cooling and heating, and in this case, it shall be of potable quality. An ample supply of water under adequate pressure and suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution. There shall be adequate protection against contamination of stored water.

17.1.2 Non-potable water – Non-potable water in the plant, e.g., for fire control, refrigeration and other similar purposes, not used in food manufacture shall be in identified circuits separated from potable water.

17.2 Plumbing

Plumbing shall be of adequate size and design and adequately installed and maintained to:

a. Supply enough water to areas in the plant where it is needed;
b. Carry sufficient quantities of water to required locations throughout the plant.
c. Properly convey sewage and liquid disposable waste from the plant.
d. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
e. 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.
f. Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

17.3 Effluent and Waste Disposal

The facility shall have an efficient effluent and waste disposal system and facilities for storage of waste and inedible material, which should at all times be maintained in good order and repair and in conformance with the competent authority. All effluent lines (including sewer systems) should be large enough to carry peak loads and shall be so constructed as to avoid contamination of potable water supplies.

17.4 **Toilets**

a. Adequate number of toilets shall be provided in all establishments. Separate male and female toilets must be provided which are adequate for the number of employees on site.
b. Toilets shall be designed and constructed so as to ensure hygienic removal of waste matter. Hand-washing facilities with sufficient supply of potable water, hand cleaning preparation and with suitable hygienic means of drying hands, shall be provided adjacent to toilets and located in a passageway towards the processing area. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near a washing facility. Taps of a non-hand operable type are desirable.

UNCONTROLLED COPY

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

d. **Toilet rooms for staff should:**
- Be completely enclosed and provided with tight-fitting and self-closing door, with the exception of those washrooms which are designed for use by handicapped persons (in all cases doors must be closed at all times);
- Have hand washing notices prominently displayed;
- Be conveniently located and accessible to workers during all hours of operation
- Provide hooks outside the facility to hang aprons, white coats, etc.;
- Have at least one service link or one curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.
- Containers and materials (plastic bowls, towels, napkins, cups, buckets, kettles) which are used in toilet areas shall be adequately marked and restricted to food manufacturing areas.

e. **Toilet rooms for the public should:**
- Be completely enclosed and provided with a tight- fitting and self-closing door, with the exception of those washrooms which are designed for use by handicapped persons (in all cases doors must be closed at all times);
- Be equipped with a hand wash station; including a liquid soap and paper towel dispenser;
- Have hand washing notices prominently displayed;
- Be conveniently located and accessible to patrons during all hours of operation
- Be easily cleanable, well ventilated, and well lit;

17.5 Hand Washing Facilities

The hands, frequently in direct contact with foodstuffs, need to be considered as the first operational tool. For this reason, detailed attention must be given to their cleanliness (just as with any equipment placed at the operator's disposal) and to their washing regime. It should be noted that the hands, if not subjected to strict hygiene rules, constitute the first vector of contamination of food stuffs, by germs (pathogens) passed on from the operator. The implementation of training to demonstrate the proper technique for hand washing and drying is recommended.

UNCONTROLLED COPY

17.5.2 Hand Washing Facilities in Processing Areas

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

b. Adequate and conveniently located facilities for hand washing and drying shall be provided where appropriate. Where appropriate, facilities for hand disinfection should also be provided. Potable water and a suitable hand cleaning preparation shall be provided.

c. There should be suitable hygienic means of drying hands. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility.

d. Taps of a non-hand operable type are desirable. The facilities shall be furnished with properly trapped wastewater pipes leading to drains.

e. In areas where product is exposed or handled by employees, handwash and/or sanitizing stations should be convenient to the employee workstations. Sanitizing stations are not a replacement for handwashing.

f. Hand wash requirement signs, in appropriate languages and/or graphics, Should be clearly posted at the locations and contain instructions as provided below.
   i. Signs at locker room and toilet facility exits should instruct employees to wash their hands prior to returning to work. Note: Washing hands prior to exiting the locker room and toilet facilities does not substitute for washing hands just prior to or immediately upon entrance to food handling and food processing areas.
   ii. Signs at entrances to food handling and food processing areas should instruct employees to wash and sanitize their hands prior to returning to work.
   iii. Signs at hand wash stations should instruct employees on the proper procedures for washing their hands.

17.5.3 Hand Wash sinks

Hand wash sinks shall conform to the following principles:

- Water flow shall not be operated by hand, but by foot or knee or by an automatic presence detector.
- Liquid (or foam) soap shall be bactericidal but not a skin irritant (thereby excluding toilet soaps without bactericidal effect).
- Soap dispensers shall be placed in a position adjacent to the wash sinks.

UNCONTROLLED COPY

- A second dispenser reserved for a disinfecting solution (e.g. of alcohol solution) can be associated with the liquid soap dispenser.
- The device devoted to hand drying must be of single use (paper towels being practically the only possible solution).
- Nailbrushes complete the wash-stand equipment. They should be made entirely from synthetic matter (handle and bristles) and need to be kept in a dilute clean disinfectant solution, renewed for each work period.

17.6 Facilities for Storage of Waste and Inedible Material

Facilities shall be provided for the storage of waste and inedible material prior to removal from the processing plant. These facilities should be designed to prevent access by pests and possible contamination of food, food contact surfaces, potable water, equipment, building or roadways on the premises.

17.7 **Disinfection Facilities**

Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be constructed of corrosion resistant materials, capable of being easily cleaned, and shall be fitted with suitable means of supplying potable water in sufficient quantities.

17.8 **Eating Facilities**

a. Consumption of food in processing areas, warehouses and offices inside the production areas and in laboratories shall be strictly forbidden, as such eating facilities shall be provided.

b. All food for consumption by personnel should stay in the eating facilities. Hygienic conditions and practices shall be maintained in the eating facilities.

c. Cafeterias and break areas must be adequately sized, well lit, clean and effectively ventilated. Adequate storage for employee food items, in easily cleanable areas, must be available. Food preparation areas must meet restaurant standards for sanitation and cleanliness. Vending machines should be maintained in a sanitary condition with easy access for cleaning underneath and behind.

17.9 Changing Facilities

a. Adequate, suitable and conveniently located changing facilities shall be provided.

b. Adequate lockers must be provided for all personnel for the safe storage of personnel effects such as outdoor clothing, bags, etc. This will eliminate the risk of them being brought into

UNCONTROLLED COPY

production areas. Lockers should be easily cleaned and, if possible, designed with a sloping top to prevent dust harbourage and use as a shelf.

c. Changing facilities must not be used for eating, drinking or smoking.

17.10 RUBBISH AND OFFAL DISPOSAL

b. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odour, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces

c. Refuse receptacles shall be constructed and maintained in a manner that protects against contamination of food.

18.0 VENTILATION

a. Buildings should be effectively lit and ventilated, with appropriate air control facilities (including temperature, humidity and filtration where necessary) suitable both to the operations undertaken within them and to the external environment. Air supply and extraction trunking should be designed so that contaminants are not introduced into Products.
b. Ventilation is important for preventing condensation and controlling humidity thus, adequate means of natural or mechanical ventilation should be available in order to minimize food contamination, and to control ambient temperatures and humidity.

19.0 LIGHTING.

a. Adequate natural or artificial lighting should be provided to enable the operations to proceed in a hygienic and efficient manner.
b. The intensity should be adequate to the nature of the operation, such as inspection and the reading of controls, among other things.
c. Lighting should not be such that the resulting color is misleading as this can lead to erroneous decisions, for example in inspections or when heat applied to products causes a change in color (for example, cooking or toasting), as these are important indicators.
d. Plant lighting should be of such design and construction to provide adequate illumination in production, support, and storage areas. The light fixtures should provide adequate protection from breakage and possible contamination.
e. All glass lights should be completely enclosed in shatter-resistant protective shields or manufactured with shatter-resistant materials to prevent glass contamination of product. This includes all operating areas, warehouses, packaging areas, receiving and shipping docks, storage areas, maintenance, toilet areas, break rooms, and welfare areas.

UNCONTROLLED COPY

f. All lights should be protected, including but not limited to, emergency lights, forklift lights, and adjustable trailer lights on the dock.
g. Light fixtures should be maintained clean and free of cracks, dust or other materials that could cause contamination. Protective covers in processing areas should be kept free of any evidence of moisture accumulation inside the covers.
h. A periodic assessment of this program should be undertaken to ensure the glass and brittle plastic program is current and up to date.

20.0 EQUIPMENT

a. Equipment can be a source of food contamination, including:
    i. Metal splinters, from the wearing of edges or other materials
    ii. Lubricants, when equipment is lubricated or if nearby equipment needs
    iii. lubrication
    iv. Remains of detergents and disinfectants, if equipment is not carefully rinsed
    v. Microbial contamination, if equipment traps food residues along the edges, in difficult to clean corners, or around irregular welding

Since equipment is fundamental in food preparation, the manufacturer should have a written preventive maintenance program to ensure that equipment is kept in good working order.
This program should include:

- A list of equipment requiring regular maintenance,
- The procedures and frequency of maintenance (for example, equipment inspection, adjustment and replacement of parts, screws and nuts), based on the equipment manufacturer's manual or equivalent, or on operating conditions that can affect the conditions of the equipment.

b. When the equipment is second-hand or one-of-a-kind, the processor should examine the design carefully and formulate a preventive maintenance program for it, taking into account the aforementioned considerations.
c. The preventive maintenance program for equipment should ensure there are no potential physical or chemical hazards, for example, inappropriate repairs, flaking paint and rust, excessive lubrication.
d. Equipment and utensils directly utilized for food manufacture shall be designed and constructed using material that is easily and adequately cleanable and maintained.
e. All food contact surfaces shall be corrosion resistant. Food contact surfaces shall be made of non-toxic materials and designed to withstand the environment of intended use. Seams of food contact surfaces should be smoothly bonded and maintained to minimize accumulation of food particles. Equipment should be designed to preclude or divert condensate away from product and product contact surfaces
f. Equipment shall be suitably installed and located to eliminate cross contamination and facilitate the cleaning of equipment and of adjacent spaces. All equipment shall be located and installed at least 1 meter apart.

UNCONTROLLED COPY

g. Holding, conveying and manufacturing systems, including gravimetric, pneumatic, closed and automated systems, shall be of a design and construction that enables them to be maintained in appropriate sanitary condition. Other equipment in the processing area that does not come in contact with food shall likewise be constructed in a manner that facilitates their cleaning and maintenance.
h. Freezer and other cold storage equipment, incubators and other controlled environment equipment shall be fitted with proper measuring devices for regulating the control parameters such as temperature. These regulating instruments shall be calibrated and maintained in good operating condition. Records of calibration shall be provided and maintained.
i. Clean and sanitized portable equipment and utensils with product-contact surfaces shall be stored in a manner that product-contact surfaces are protected from splash, dust and other contamination.
j. Equipment should not have glass parts, unless the same is shatter proof. Equipment parts should not be lacquered nor painted. Equipment should not have any hollow bodies where there is a chance of product contact.
k. All equipment must allow for sampling and measuring of product quality.
l. The use of wood in open food production areas must be avoided. The use of wooden pallets is only allowed for fully enclosed products protected by outer packaging in peripheral assembly or storage areas.
m. Conveyor belts for product contact shall be of impervious, non-absorbent material. Fiber- backed or sandwiched belts shall not be used for product contact conveyors. Belts shall be maintained in good condition with no holes, cuts, frayed edges or damage that renders the belt difficult to clean or present a foreign material hazard. Product contact surfaces, such as conveyor belts shall not be closer than 18” to the floor or shall be effectively protected from contamination during operations.
n. Equipment shall be free of cracks and non-continuous or rough welds where product may become embedded and make cleaning difficult.
o. Equipment with sides or shields or scrapers or other items that are attached to product contact areas shall have sufficient clearance between the pieces to permit cleaning and prevent product accumulation (approximately ¼” is generally sufficient).
p. Equipment shall be free of oil leaks and excessive grease build-up on bearings and motor housings where they may contaminate product. Bearings and motors near and above product areas shall have catch pans to protect product below. The pans shall be drained in a sanitary manner.
q. Equipment shall be constructed in such a manner to preclude metal-to-metal contact between moving parts.
r. Hollow drums or rollers shall not be used for food processing equipment. Open rollers that can be effectively cleaned or solid rollers or drums are required. If hollow drums/rollers are used, they shall be completely sealed and the maintenance department shall have a record of inspection and corrective actions instituted.

UNCONTROLLED COPY

s. Appropriate covers/lids shall be provided to protect product from contamination. Tanks or vessels containing food products shall be covered when they are not actually being filled, used or undergoing other activities requiring access.
t. Equipment shall be free of flaking paint, rust or other contaminants that could become detached.
u. Product and clean product containers should be adequately protected to preclude contamination. Gasket material should be non-toxic, non-absorbent and in good condition.
v. Small support utensils and equipment should have specific, convenient and sanitary storage hangers or shelves.
w. Tanks, vats and product lines that are Clean-in-Place (CIP) cleaned should be self-draining.
x. Refrigeration unit drip pans shall be adequately sized to be effective and properly drained to prevent accumulation of standing water. Refrigeration drip pan discharge should not flow onto the floor. Drain lines into sewer or vent lines should be "trapped" (e.g., P-trap), or if drained into floor drains, Should have an "air gap". Refrigeration unit drip pans should contain anti-microbial chemicals (sanitizer blocks) to minimize microbial concerns.

21.0 STANDARD OPERATING PROCEDURE

a. There shall be standard operating procedures for all operations and controls for manufacturing, processing, packaging, holding, distributing, recalling, cleaning, and maintenance control designed to ensure that the food or food products are safe, wholesome and are of the quality they purport to possess. These standard operating procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality assurance unit.

Standard operating procedures for production and process control procedures shall be followed and documented at the time of performance.

21.1 Standard Sanitation Operating Procedures (SSOPs) and Monitoring

a. The plant should have documented Standard Sanitation Operation Procedures (SSOP) for operational areas, individual pieces of food processing equipment, and facility areas and structures which specifies and defines:
    i. Standard cleaning methods, including the level of disassembly required for cleaning, and assigned responsibility for each task.
    ii. Frequency of cleaning.
    iii. Unless purchased as ready-to-use, there should be specific preparation procedures regarding dilution factors for the specific chemicals or sanitizers used and, where appropriate, verification testing and documentation.

UNCONTROLLED COPY

iv. Water temperature requirements for washing (>140°F for cleaning unless otherwise recommended in writing by chemical supplier).

b. Plant should have detailed SSOP Monitoring Procedures with records of monitoring activity. Records should clearly show equipment condition and list all deficiencies found. When deficiencies are found there should be a clear explanation of the activities performed to bring the equipment into a sanitary condition and a detailed corrective action plan to prevent a recurrence.
Note: Performed activities (fixes) and corrective actions are not the same.

c. If machine operators are responsible for general maintenance and equipment cleaning, procedures should be available describing steps for cleaning and sanitizing and the cleaning should be documented in the Master Sanitation Program or on the Master Sanitation Schedule, as appropriate.

d. Written procedures should be available for cleaning and sanitizing equipment (and water/steam lines, if applicable) after maintenance is performed and prior to returning equipment into service. Records of such maintenance and documentation of sanitation is required.

e. All equipment taken out of service for maintenance should be properly cleaned and sanitized before being put back into service. These activities should be appropriately documented.

22.0 PRODUCTION AND PROCESS CONTROLS

22.1 Production Processes and Controls

a. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food should be conducted in accordance with adequate sanitation principles.

b. There shall be appropriate quality control operations procedures to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

c. All reasonable precautions should be taken to ensure that production processes do not contribute contamination from any source. All food that has become contaminated to the extent that it is adulterated shall be rejected, or if permissible, treated or reprocessed to eliminate the contamination.

d. To prevent problems, which could affect consumer safety or satisfaction, each line must be under control. Hazard and root cause analyses must be used to specify control measures: Critical Control Points (CCPs) for food safety and Control Points (CPs) for consistency.

UNCONTROLLED COPY

23.0 RAW MATERIALS AND OTHER INGREDIENTS

There shall be procedures and work instructions for the sanitary handling of raw materials and other ingredients.

a. Raw materials and other ingredients shall be inspected and either segregated or otherwise properly handled to ascertain that they are clean and suitable for processing into food.

a. Raw materials shall be stored under conditions that will protect against contamination and minimize deterioration. Containers and carriers of raw materials shall be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

b. No raw materials or ingredients shall be accepted by a food establishment if they are known to be, or might reasonably be expected to be, so contaminated with parasites, pathogenic micro-organisms, or toxic, decomposed or foreign substances, that after normal sorting and/or preparatory or processing procedures hygienically applied by food establishments, would still be adulterated or unfit for human consumption.

c. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labelled and stored in separate and secure containers.

d. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Potable water shall be used for washing, rinsing, or conveying. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.

e. Raw materials and other ingredients susceptible to contamination with aflatoxins or other natural toxins shall comply with regulations and guidelines of the Agency, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

f. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable micro-organisms, or other extraneous matter shall comply with applicable regulations of the Agency, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

g. Raw materials and other ingredients shall either not contain levels of micro-organisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of these guidelines. Compliance with this requirement shall be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

UNCONTROLLED COPY

h. Rework items shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held in a manner that will prevent the food from becoming contaminated. Material scheduled for reprocessing shall be identified as such.

i. Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents their becoming contaminated.

24.0 MANUFACTURING OPERATIONS

Procedures and work instructions shall be established for the sanitary handling and maintenance of equipment and utensils for manufacturing operations.

a. Equipment and utensils and finished food containers shall be maintained in a sanitary condition through appropriate cleaning and sanitizing. Where appropriate, equipment shall be taken apart for thorough cleaning.
b. Physical factors such as time, temperature, humidity, water activity (aw), pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration shall be monitored to ensure that mechanical breakdowns, time delays, temperature fluctuations, and uncontrolled events do not contribute to the decomposition or contamination of food.
c. Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be handled in a specified manner that prevents the food from becoming contaminated.
d. Work-in-process shall be handled in a manner that protects against contamination.
e. Finished food should not be handled together with raw materials, other ingredients, or refuse in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination.
f. Sieves, traps, magnets, electronic metal detectors, and other suitable means should be used to protect against the inclusion of metal or other extraneous material in food.
g. Glass, foreign matter should likewise be prevented from contaminating food by exclusion of the use of breakable glass as processing equipment, sampling containers, laboratory glassware, etc. in production areas. If use of breakable glass in production areas cannot be avoided, as in the case where packaging material is glass, there should be a procedure on how to deal with broken glass in food.
h. Food, raw materials, and other ingredients that are adulterated/ contaminated shall be disposed of in a manner that protects against the contamination of other food. Adulterated/Contaminated food opted to be reconditioned shall be reprocessed using a

UNCONTROLLED COPY

method proven to be effective and shall be tested as non-adulterated or non-contaminated before being incorporated into other food.

i. Food such as but not limited to, dry mixes, nuts, intermediate moisture food and dehydrated food, that relies on the control of a for preventing control of undesirable microorganisms shall be processed and maintained at safe moisture level at all times.
j. Processes such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being contaminated.
k. Physical protection of food from contaminants that may drip, drain, or be drawn into the food during operations like washing, peeling, trimming, etc. shall be done properly to protect food against contamination. Protection may be provided also by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.
l. Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.
m. Batters, breading, sauces, gravies, dressings, and other similar preparations shall be protected against contamination by any effective means.
n. Filling, assembling, packaging, repacking and other operations shall be performed in a manner that protects food against contamination by any effective means.
o. Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below.
p. Ice used in contact with food shall be made from potable water and shall be manufactured, stored and handled in accordance with good manufacturing practice.
q. Steam used in contact with food must be of food grade quality. Make-up water shall be potable. Steam pipe insulation should be sealed, in such a manner that it does not become a hiding place for insects.
r. Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture non-human food grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.
s. All food manufacturing establishments using one or several critical allergens as ingredients shall take all reasonable precautions to avoid cross contact of products that do not normally contain these allergens and that do not normally carry a specific mention in the ingredient statement.

UNCONTROLLED COPY

25.0 WAREHOUSING AND DISTRIBUTION

a. There shall be appropriate procedures for sanitary handling of food on storage and distribution. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

b. Warehouses should be kept free from rodents, insects, birds and other pests. All product spills should be cleaned up immediately, as this is an important preventive measures against pests.
c. No pesticides, disinfectants, toxic chemicals or other contaminating materials must be stored in close proximity to finished products or incoming products.
d. In plants, storage must be organized to ensure that potentially contaminated incoming materials are not stored next to finished products.
e. Defective stock, market returns or complaint goods must be stored in a separate area preferably locked.
f. Storage facilities must be secure enough to prevent theft, tampering, etc.
g. First in-first out system must operate and a stock control system must be in place.
h. All storage premises must be kept clean and tidy-not only inside but also in the surrounding areas.
i. Warehouse conditions should be maintained and controlled in a manner to assure product integrity.
j. Finished product, packaging materials, equipment or ingredients should not be stored in close proximity to any chemical, cleaning product, pesticide or other nonfood materials. Such nonfood items should be stored in separate areas that can be closed and secured, away from any food materials or ingredients.
k. Only properly packaged product in undamaged containers may be stored in and shipped from the finished warehouse. Product not "cleared" for shipment, or held for any other purpose, should be clearly identified and not stored in a location in the warehouse where it is likely that it may be shipped in error.
l. Damaged, leaking or unsound product should be immediately isolated and placed on hold for evaluation by designated personnel. Product disposition should be timely.
m. Partially used or previously opened ingredient containers should not be stored with finished product. Such product may be stored in a designated separate storage area, if it is properly identified and sealed to prevent contamination.
n. Allergen containing ingredients should be stored separately from non-allergen containing ingredients and different allergen containing ingredients. Separation should take place both horizontally and vertically in storage locations.

UNCONTROLLED COPY

26.0 TRANSPORTATION

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

The following are some important points to bear in mind:

i. Food must be adequately protected during transport. The type of conveyance or container required will depend on the nature of the food and conditions under which it needs to be transported.

j. The conveyance or container should be designed and constructed to prevent food from contamination from dust, exhaust, fuel, the loading of other food, among other things.

k. Conveyances and containers used to transport food and food warehouses should be kept clean and in good repair. Where the same conveyance or container is used for transporting different foods or non-foods, effective cleaning and, where necessary, disinfection should take place between loads. When the same means of transportation is used for different types of products, that is, when the conveyance or container is not used exclusively for food, it should be checked and monitored periodically and only accepted if there is certainty that there is no serious risk of contamination.

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

m. The impact of transportation on food safety can be illustrated with a case of contamination by salmonella. “In this particular case, pasteurized milk was transported in a milk tanker that had previously carried unpasteurized eggs.

   As the tanker that carried that high-risk product was not properly cleaned or disinfected after use, when the pasteurized milk was loaded it became contaminated with salmonella. Although one might think that the carrier was fully responsible for this event, in fact it was the responsibility of the pasteurized milk producer to monitor the shipment. In this case, the producer most likely did not evaluate the carrier or request information on the previous cargo or the cleaning and disinfection treatment used”. This is a true case and can happen to anyone who does not adequately monitor the transportation process.

n. Food manufacturers should ensure that the conveyance or container they use is suitable for transporting food. Following are some important recommendations in this regard:

   i. Inspect the conveyance or container before and during loading to ensure that it is not contaminated and that it is suitable for transporting food.

   ii. Establish a program to check that carriers have been effectively cleaned, for example, by drawing up a written guide on cleaning and sanitation procedures for bulk transport vehicles.

   iii. When vehicles are used for different purposes, it is important to have procedures in place to restrict the type of cargo they are allowed to carry. Keep records on vehicle cleaning and on the materials previously transported. All vehicles should be inspected before food is loaded.

UNCONTROLLED COPY

iv. Carriers should be loaded, arranged and unloaded in a manner that protects the cargo and does not damage or contaminate the food being transported.
v. Bulk tanks for the transport of food should be designed and built to permit complete drainage and prevent contamination.
vi. Where appropriate, transportation vehicles should be constructed of materials that are suitable for food contact.

o. Design a general training program to raise the awareness of food transporters of the hazards associated with food transportation and distribution (including storage).
p. Define the requirements or specifications for handling and distributing ingredients or food; communicate this information to the carriers and distributors.
q. Require companies that transport and store food to adopt the necessary hygienic actions to protect food, and to maintain and keep records that demonstrate that these requirements have been met.
r. Transport ingredients or products that require refrigeration without breaking the cold chain. To this end, it is important to carefully monitor transportation and to record the temperatures when loading, during transportation, and when unloading. Frozen products and raw materials should not be allowed to thaw during transport.
s. Food should be transported under conditions that prevent contamination by microbiological, physical, or chemical hazards.

26.1Prevention of Microbiological hazards:

In order to prevent contamination by microbiological hazards

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

UNCONTROLLED COPY

26.2 Prevention of Chemical hazards:

To prevent contamination with chemical hazards:

a. Do not transport food products or ingredients along with containers of fuel or chemical products that can transfer odors or contaminate the product by contact.
b. Never transport food in vehicles or other types of conveyances that are also used to transport chemical products.
c. Exercise great care when products are transported in rented bulk tanks. Should bulk tanks be necessary, require the supplier to set aside certain trucks exclusively for food transportation. Keep a record of the trucks used and, for every shipment, the vehicle's inspection and identification data.

26.3 Prevention of Physical hazards

To prevent physical contamination:

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

27.0 STORAGE.

a. Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.
   Where necessary, adequate facilities should be provided for the storage of food (raw materials, intermediate products, ingredients and non-food chemicals (e.g., cleaning materials, lubricants, fuels).

b. Storage areas should be designed or adapted to ensure good storage conditions. They should be clean, dry and well maintained. Where special storage conditions are required (temperature and humidity) these should be provided, checked and monitored.
c. Receiving and dispatch bays should protect materials and products from weather.
d. Reception areas should be designed and equipped to allow incoming materials to be cleaned if necessary before storage.
e. Storage areas for quarantine should be clearly demarcated.
f. Wherever possible sampling area for starting materials should be provided to prevent contamination.
g. Hazardous materials should be safely and securely stored.
h. Storage facilities should be designed and constructed to permit adequate maintenance and cleaning, prevent pest access and harbourage, effectively protect food from contamination

UNCONTROLLED COPY

during storage and, where necessary, provide special conditions to minimize food spoilage (e.g., controlled atmosphere).

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

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

28.0 DEFECT ACTION

a. Defect action levels shall apply to natural or unavoidable defects in food for human use that present no health hazard.
b. All foods shall comply with maximum defect action levels established from time to time by the Agency.
c. Foods produced based on new and advanced technologies, formulations, or based on the availability of new information that comply with maximum defect action levels shall not be hazardous to health.
d. The manufacturer, distributor and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
e. The mixing of a food containing defects above the current defect action level with another lot of food shall not be permitted and shall render the final food adulterated
f. Compliance with defect action levels shall not excuse violation of the requirement.

29.0 QUALITY ASSURANCE

1. Quality Assurance is the part of quality management focusing on increasing the ability to fulfil quality requirements, according to current ISO standards.
   The objectives of Quality Assurance are achieved when processes have been defined which, when followed, will yield a product that complies with its specification and the quality expected, and when the finished product:
   a. contains the correct ingredients in the correct proportions;
   b. has been correctly processed, according to the defined procedures;
   c. is of the purity required;
   d. is enclosed in its proper container, which;
   e. bears the correct label (or is otherwise suitably marked or identified);
   f. is stored, distributed and recommendations given for its subsequent handling in accordance with the recommended storage conditions, so that its quality is maintained throughout its designated or expected life.

UNCONTROLLED COPY

2. Quality Assurance normally covers the following points:
    a. Procedures are written in instructional form, in clear and unambiguous language, and are specifically applicable to the facilities provided;

    b. records are made during manufacture (including packaging), which demonstrate that all the steps required by the defined procedures were in fact taken, and that the quantity and quality produced were those expected;

    c. records of manufacture and distribution, which enable the complete history of a lot to be traced, are retained in a legible and accessible form;

    d. a system is available to withdraw or recall from sale or supply any lot or product, should that become necessary;

    e. the quality assurance procedures of the suppliers of raw and packaging materials should be monitored, preferably with regular audits. A Supplier Quality Assurance procedure should be developed to define the criteria for selection, approval, review and ongoing approval to ensure that purchased products and services meet the organisation's requirements;

    f. there needs to be rapid feedback of information in the form of summaries of quality performance data (accompanied, where appropriate, by advice) to manufacturing personnel, enabling prompt adjustment or corrective action to be taken when necessary; and to the purchasing function in respect of raw material lots;

    g. customer/consumer complaint samples should be examined, the causes of defects investigated where possible, and appropriate measures advised for corrective action to prevent recurrence.

    h. due heed should be taken of new developments especially those requiring changes in compositional standards and labelling requirements which may necessitate changes to specifications for raw materials or finished products.

    i. A continual review of the Quality Assurance systems should be undertaken to ensure that they remain effective. This should be done by self-inspections.

30.0 QUALITY CONTROL

30.1 Quality management

a. A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions following standard procedures to ensure the quality and safety of the product.

UNCONTROLLED COPY

b. The quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk and finished products. It also includes where applicable, review of batch documentation, sample retention program, stability studies, product complaints, product recalls, and maintaining correct specifications of materials and products.

30.2 Testing of Reprocessed Products

a. The methods of reprocessing should be evaluated to ensure that they do not affect the quality of the product.
b. Additional testing of any finished product, which has been reprocessed, should be performed.

30.3. Testing of Returned Goods

a. Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.
b. All returned products should be tested if necessary, in addition to physical evaluation before being released for distribution.
c. Any returned products that do not comply with the original specification should be rejected.
d. Rejected products should be disposed according to appropriate procedures.
e. Records of returned products must be maintained.

30.4 Effective Quality control

To achieve effective control of quality:

a. The authority and responsibilities of the Production Management and the Quality Control Management functions respectively should be clearly defined so that there is no misunderstanding. Where possible, the Quality Control Management should be on a separate reporting structure from the Production Management and be empowered to make independent decisions on the product quality;

b. adequate facilities and staff should be available for sampling, inspecting and testing starting materials, packaging materials, intermediate, bulk and finished products, and where appropriate, for determining environmental quality;

c. samples of starting materials, packaging materials, intermediate products, bulk products and finished products should only be taken by personnel and using methods approved by the person responsible for Quality Control;

UNCONTROLLED COPY

d. results of the inspection and testing of materials, and of intermediate, bulk or finished products, should be formally assessed against specification by the person responsible for Quality Control (or a person designated by him) before products are released for sale or supply;

e. product assessment should include a review and evaluation of relevant manufacturing (including packaging) documentation;

f. sufficient reference samples of starting materials and finished products should be retained (the latter in the final pack for the finished product) to permit future examination if necessary.

30.5 Quality Audits

A quality audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. A quality audit may be conducted by outside or independent specialists or an internal audit team designated by the management for this purpose. Such audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each quality audit.

31.0 CONTROL OF HAZARDS (HACCP)

A manufacturer of food or food products shall control food hazards through the use of systems such as Hazard Analysis and Critical Control Points (**HACCP).** The HACCP system recommends that food business operators:

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

a. The HACCP system is science based and provides a systematic approach to identify specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess potential hazards and establish control systems that focus on prevention rather than relying on finished product testing.
b. A HACCP system should be developed by each food establishment and tailored to its individual products, processes, and distribution conditions. The HACCP plan should analyze and identify control measures for the potential biological, chemical and physical hazards from procurement, receipt, and storage of raw materials through the production, handling, manufacturing, storage, distribution and consumption of the finished product. It is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan.

UNCONTROLLED COPY

c. Approval of the HACCP plan should be documented with a written signature from top management. The plan should be kept current with regular performance reviews by the HACCP management team. Experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP plan.

Note: If the product is amenable to a mandatory HACCP plan requirement, then the plan should be in compliance with the regulatory requirements. If a mandatory HACCP plan is not required, the facility should still comply with prerequisite programs (found in subsequent Sections of this document) and all HACCP requirements through the determination and documentation of whether any hazards and CCPs exist. If it is determined that CCPs do exist, a complete HACCP program is required whether mandated or not.
In all cases, a formal assessment and sign-off of the program by the HACCP team, including top management, is required at least annually. The assessment is to document performance and/or to determine if any changes are needed in the plan. If at any time a process, formula, ingredient or equipment change is made, the team Should immediately and formally evaluate the change to determine if the HACCP plan is impacted, making all necessary changes to the plan documents.

1) Preliminary HACCP Tasks

There are five preliminary tasks that should be accomplished before the application of the HACCP principles.

a. A HACCP team should be assembled with individuals having the appropriate product, process, and sanitation specific knowledge and expertise necessary for the development of an effective HACCP plan. Where such expertise is not available on site, expert advice should be obtained from other sources.

    i. Team members and their responsibilities Should be clearly identified as part of the HACCP plan. The entire team should be involved in the development, final approval, and subsequent reviews of the plan.

    ii. Documented team meetings should occur at least annually to assess HACCP records and issues. The team should assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness.

b. The intended use of the product should be determined and should be based on the expected uses of the product by the end user or consumer.

c. The HACCP Team should construct a clear and easy to understand process flow diagram for each HACCP plan.

    i. The process flow diagram should outline each step involved in the process that is directly under the control of the establishment. The diagram Should indicate the ingredient and material categories used in all preparation steps, all equipment used, blending steps, processing steps, rework and returned products, packaging materials, packaging equipment and the steps preceding and following the

UNCONTROLLED COPY

process. The same flow diagram may be used for a number of products that are manufactured using similar processing steps.

ii. The process flow diagram should remain current.

iii. Once CCPs (Critical Control Points) have been determined, they should be clearly identified on the flow diagram and numbered to correspond with the Hazard Analysis and CCP records and documentation.

d. The HACCP team should perform and document an on-site review of the operation to verify the accuracy and completeness of the process flow diagram during all stages and hours of operation. Modifications should be documented on the flow diagram, as necessary.

e. Additional Best Practices Opportunities are as follows:

- Documented team meetings should occur at least quarterly to assess HACCP records and issues.
- Product Description - A full description of the product should be developed, including relevant safety information such as: composition, physical and chemical attributes, processing, packaging, durability and storage conditions, and method and conditions of distribution. Products with similar characteristics or processing steps may be grouped together for the purpose of development of the HACCP plan.
- The flow diagram should be signed annually by knowledgeable operations management and dated to verify its completeness and accuracy.

The process flow diagram should be created and published with CAD-CAM software.

2) Hazard Analysis (HACCP Principle 1)

There should be a detailed Hazard Analysis document for each type of product or product line. Failure to have a complete, accurate hazard analysis should be rated as a Major Nonconformance.

h. The HACCP team should prepare a list of all of the hazards (chemical, physical, biological or other) that may be reasonably expected to occur at each step, from raw material receipt, processing, manufacture, storage, and distribution until the point of consumption. Evaluation should include all ingredients, equipment, processing steps, and packaging materials.

i. The HACCP team should conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. The hazard analysis Should include:

i. The likely occurrence of hazards and severity of their adverse health effects.

ii. The qualitative and/or quantitative evaluation of the presence of hazards.

iii. Survival or multiplication of microorganisms of concern.

iv. Production or persistence in foods of hazardous toxins, chemicals or physical agents.

v. Conditions leading to the above.

UNCONTROLLED COPY

Note: Consideration should be given to what identified, prerequisite control measures, if any exist, 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 specific control measure.

j. **Additional Best Practices Opportunities here is as follows**

- The scope of the HACCP plan should be identified and should describe which segment of the food chain is involved and the general classes of hazards to be addressed.
- A "Severity of Hazard Consequences" and "Likelihood of Hazard Occurrence" scoring matrix should be developed to assist with the determination of needed control measures.

3) Critical Control Points (HACCP Principle 2)

a. A logical, reasoned, documented approach should be used to determine Critical Control Points (CCPs) for potential hazards. If a formal hazard analysis is not used to determine the need for CCP's, there should be a documented risk assessment for that purpose.
b. Documentation for determining whether a step or process is a CCP or not Should be clear and thoroughly explained, defining the hazard and the specific controls that eliminate or reduce the hazard.

Note*:* If it has been determined that there are no hazards or CCPs, no further HACCP plan development is necessary. However, the HACCP Team Should continue to conduct regular meetings to review any changes in the process or procedures that could affect the hazard or CCP determination. The requirements of sub-sections "Verification and Validation" (HACCP Principle 6) and "Documentation and Record Keeping" (HACCP Principle 7) below should also be satisfied to verify the HACCP conclusions and to document all HACCP decisions and conclusions.

c. **Additional Best Practices Opportunities**

- The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), “Decision Tree” or the CODEX decision tree should be used to determine CCP's.
- Appropriate personnel should be trained in the application of a decision tree or risk assessment.

4) Critical Limits (HACCP Principle 3)

Once a control measure has been established for a CCP, operating and critical limits should also be established.

UNCONTROLLED COPY

a. Critical limits should be specified and validated for each CCP. Failure to demonstrate that CCP critical limits are scientifically and/or technologically sound for controlling each hazard should be rated as a Major Nonconformance.
b. Critical limits should be measurable. Variable or attribute measures are acceptable.
c. There should be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. (Validation) Proprietary data may be acceptable, providing there are sufficient data approved by an appropriate, qualified process authority.
d. Documented process capability studies or CCP monitoring records should be available to demonstrate that established CCP limits are compatible with the plant process and capable of being met.

5) CCP Monitoring (HACCP Principle 4)

Monitoring procedures should be able to detect loss of control at the CCP.

a. If monitoring is not continuous, then the type and frequency of monitoring should be sufficient to guarantee the CCP is in control.
b. Monitoring data should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.
c. Documentation of the measured attribute should be on clearly identified HACCP records. Records should have CCPs identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required in the event that a measurement is not in compliance.
d. A deviation log should be maintained and available for review.
e. All records and documents associated with monitoring CCPs Should be signed by the person(s) doing the monitoring.
f. **Additional Best Practices Opportunities**
    - Monitoring should predict a loss of process control in time to make adjustments to prevent violating the critical limits.
    - Electronic monitoring methods should be used to record and evaluate CCP critical limit performance.

6) Corrective Actions (HACCP Principle 5)

Specific corrective actions should be developed for each CCP in the HACCP system to deal with deviations when they occur.

a. Corrective actions should include instructions of necessary actions to take to secure and manage affected product.
b. Corrective actions should ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation.

UNCONTROLLED COPY

c. Documented product disposition procedures that would become effective if a deviation were to occur should be developed.

7) Verification and Validation (HACCP Principle 6)

a. Verification documentation is required, confirming that the products are achieving the level of safety required and that the HACCP plan is operating effectively.
b. Examples of verification activities include:
   i. Review of the HACCP system and Plan and its records.
   ii. Review of deviations and product dispositions.
   iii. Confirmation that CCPs are properly monitored and kept under control.
c. Validation of the HACCP plan should be available through documentation or supporting data that confirms the Plan is scientifically and technically sound, that all hazards have been identified, that CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.
d. Subsequent validation of the Plan should be performed and documented on an ongoing basis as needed based on corrective and preventive actions and should be performed at least annually.
e. **Additional Best Practices Opportunities**
f. Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions.

8) Documentation and Record Keeping (HACCP Principle 7)

HACCP procedures should be documented.

a. Documentation and record keeping should 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.
   Examples of documentation include: hazard analysis, CCP determination, risk analysis, and critical limit determination.
      i. Examples of record keeping include: CCP monitoring activities, deviations and associated corrective actions, verification procedures performed, modifications to the HACCP plan.
      ii. Records may be electronic, but if so, Should be effectively access-controlled. (See Section A.6)
b. Deviations from the HACCP plan should be thoroughly documented with detailed corrective actions and product dispositions.
c. The documents and their data should be self-explanatory and complete. The records should be in ink (not pencil) and signed by the operator. There should be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation should be provided.

UNCONTROLLED COPY

d. All records and documents associated with HACCP plan monitoring should be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.
Note: Signatures of the operator, supervisor and designated record reviewer are required in some regulated situations.
e. Records should be easily retrievable and secured in a safe storage area.

32.0 PRODUCT RECALL

a. All quality-related complaints, whether received orally or in writing, shall be recorded and investigated according to a written procedure. Documented records of complaint should be retained to evaluate trends, product-related frequencies and severity with a view to taking additional and if appropriate, immediate corrective action.
b. There shall be a written procedure that defines the circumstances under which a recall should be considered. The recall procedure should designate who should be involved in evaluating the information, how a recall should be initiated, who should be informed about the recall, and how the recalled material should be treated.
c. In the event of a serious or potentially life-threatening situation, all concerned local and national authorities shall be informed and their advice sought. If it is necessary to get in touch with concerned international authorities, communication should come from the Agency and not from the local companies.
d. It is important to have a record of the traceability of raw materials, packaging materials, processing data and laboratory results which could be relevant to analyze the effectiveness of the implementation of procedure for product recall.

32.1 Recall procedures

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

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

UNCONTROLLED COPY

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

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

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

33.0 DOCUMENTATION AND RECORDS

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

b. All documents related to the manufacture and operations from raw materials, packaging materials, master production and control, batch production, laboratory control and batch production record review should be prepared, reviewed, approved and distributed according to written procedures.

c. The issuance, revision, superseding and withdrawal of all documents, should be controlled by maintaining revision histories.

d. A procedure should be established for retaining all appropriate documents (e.g. development history reports, scale-up reports, technical transfer reports, process validation reports, training records, production records, control records, and distribution records). The retention period for these documents should be specified.

e. Records of major equipment use, cleaning, sanitation, and/or sterilization and maintenance shall show the date, time (if appropriate), product, and batch number of each batch processed in the equipment and the person who performed the cleaning and maintenance.

f. Specifications shall be established and documented for raw materials, labeling and packaging materials. Acceptance criteria should be established and documented for in-process controls.

UNCONTROLLED COPY

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

h. Every entry on a record should be made by the person responsible at the time the event occurred. Once complete, the record should be signed and dated by the supervisor or the person in charge

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

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

Classes of documents
The following lists are not exhaustive but do give an indication of the types of documents which are advisable:

a) Specifications, Instructions and Procedures:
- Ingredient specifications;
- Packaging materials specifications;
- Copy of order and/or terms of conditions of purchase;
- Master manufacturing instructions (including standard recipes);
- Intermediate specifications;
- Bulk product specification;
-Finished product specifications;
- Quality control (including analytical and microbiological) procedures and methods;
- Standard procedure for product recall;
- Plant operating instructions;
- Cleaning instructions, good housekeeping and pest control schedules;
- Plant maintenance schedules;
- HACCP plans.

b) Records and reports
- Records of receipt, examination, approval and issue for use of raw materials and food packaging materials as required by law;
- Records of the testing and release of intermediates, bulk products and finished products;
- Records of process control tests;

UNCONTROLLED COPY

- In-process recording instruments charts;
- Weight or volume control charts;
- Lot manufacturing records;
- Customer complaint records;
- Quality control summaries and surveys;
- Quality audit reports and records;
- HACCP review reports;
- Training records;
- Superseded documents.

c) Programmes
- Production programmes;
- Training programmes;
- Quality audits.

34.0 MATERIAL RECORDS

These records shall include the following:

a. Identity and quantity of each shipment of each lot of materials.
b. Name and location of the prime manufacturer, where different from the supplier.
c. Results of any test or examination performed (including those performed as required and the conclusions derived therefrom).
d. Individual inventory record of each material and record of reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of food or food product associated with the use of each component, food or food product container, and closure.
e. Documentation of the examination and review of labels and labeling for conformity with established specifications shall be as prescribed by the Agency.
f. The disposition of rejected materials.

35.0 MASTER PRODUCTION AND CONTROL RECORDS

f. To ensure uniformity from batch to batch, master production and control records for each food or food product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a standard operating procedure which shall be followed.
    b. Master production and control records shall include:
        i. The name, ingredient list and a description of the food product;

UNCONTROLLED COPY

ii. The unit of weight or measure of the food or food product, and a statement of the net weight or measure;
iii. A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic;
iv. An accurate statement of the weight or measure of each component, using the same weight system. A statement concerning any calculated excess of component;
v. A statement of theoretical weight or measure at appropriate phases of processing;
vi. A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation is required.
vii. A description of the food or food product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;
viii. Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

36.0 BATCH PRODUCTION AND CONTROL RECORDS

Batch production and control records shall be prepared for each batch of food or food product produced and shall include complete information relating to the production and control of each batch.

These records shall include:

a. An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;
b. Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:
    i. Date and time;
    ii. Identity of individual major equipment and lines used;
    iii. Checks that the equipment and work station are clear of previous products, documents or materials not required for the planned process, and that equipment is clean and suitable for use;
    iv. Specific identification of each batch of component or in-process material used;
    v. Weights and measures of components used in the course of processing;
    vi. In-process and laboratory control results;
    vii. Inspection of the packaging and labeling area before and after use;
    viii. A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;
    ix. Complete labeling control records, including specimens or copies of all labeling used;
    x. Description of food or food product containers and closures;
    xi. Any sampling performed;

UNCONTROLLED COPY

xii. Identification of the persons performing and directly supervising or checking each significant step in the operation;
xiii. Any investigation made
xiv. Results of examinations made.

37.0 PRODUCTION RECORD REVIEW

a. All food or food product production and control records, including those for packaging and labelling, shall be reviewed and approved by the quality control unit to determine compliance with all established and approved standard operating procedures before a batch is released or distributed.
b. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same food or food product and other food or food products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and follow-up.

38.0 LABORATORY RECORDS

Laboratory records shall include complete data derived from all tests necessary to ensure compliance with established specifications and standards, including examinations and assays, as follows:

i. A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, batch number or other distinctive code, date sample was taken, and date sample was received for testing.
ii. A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. The suitability of all testing methods used shall be verified under actual conditions of use.
iii. A statement of the weight or measure of sample used for each test, where appropriate.
iv. A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, food or food product container, closure, in-process material, or food or food product and batch tested.

UNCONTROLLED COPY

v. A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors.
vi. A statement of the results of tests and how the results compare with established standards of identity and quality of food or food product container, closure, in-process material, or food or food product tested.
vii. The initials or signature of the person who performs each test and the date(s) the tests were performed.
viii. The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

b. Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are accurate and reliable for the material being tested as the established method.
c. Complete records shall be maintained of all out-of-specification investigations carried out.
d. Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions.
e. Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices.
f. Complete records shall be maintained of all shelf life studies performed.

39.0 DISTRIBUTION RECORD

Distribution records shall contain the following:

a. Name and pack size of the product
b. Description of the food or food product,
c. Name and address of the consignee,
d. Date and quantity shipped,
e. Batch or control number of the food or food product.
f. Date of manufacture and best before date.

40.0 COMPLAINTS

a. A person responsible for handling complaints and deciding the measures to be taken should be designated. If this person is different from the authorized person, the latter should be made aware of any complaint, investigation or recall.

b. There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.

UNCONTROLLED COPY

c. Complaints involving product defects should be recorded with all the original details and investigated.

d. If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.

e. Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.

f. All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

g. Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and might justify the recall of marketed products.

h. The competent authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety issues.

41.0 PRODUCT INFORMATION AND CONSUMER AWARENESS

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

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

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

UNCONTROLLED COPY

c) Labelling

Pre-packaged food should be labeled with clear instructions to enable the next person in the food chain to handle, display, store, and use the product safely. NAFDAC Pre-packaged Food Labelling Regulations 2005 and the prevailing labeling standards should apply.

d) Consumer information

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

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

iii. Practical advice include the following:

1. Comply with NAFDAC labelling regulations.
2. When products are for export markets, comply with the applicable regulations of the destination market.
3. Include the following information on the label:
    - Name of the food,
    - List of ingredients and food additives used in preparing the product,
    - Net contents and drained weight,
    - Country of origin,
    - Lot identification,
    - Production date,
    - Expiration date,
    - Instructions for conservation,
    - Instructions for use,
    - Manufacturer's name,
    - Manufacturer's address,
    - Name, business name of the importer, distributor, Packer, Vendor (this can go on a separate label),
    - NAFDAC Registration Number

42.0 PACKAGING MATERIALS

Each packaging material should have and comply with its specification (including any legal requirements), which should be such as to ensure that:

UNCONTROLLED COPY

i. the product is adequately protected during its expected life under normal conditions of storage and use (with a safety margin for adverse storage);
ii. in the instance of packaging coming into immediate contact with the product, there is no significant adverse interaction between product and packaging material
iii. where the packaged product undergoes subsequent treatment, whether by the manufacturer, caterer or consumer, the packaging adequately stands up to the processing conditions and no adverse packaging/product interaction occurs;
iv. the packaging is capable of providing the necessary characteristics and integrity where the preservation of the product depends on the pack;
v. the packaging provides adequate protection to ensure the chemical and physical stability of the product during the declared shelf life, with an adequate safety margin for adverse storage;
vi. the finished pack will carry the statutory and other specified information in the required form and location. In the case of products containing known food allergens these should be clearly stated on the label in terms easily understood by the consumer.
vii. Where packaging material carries information required by law (e.g. labels, printed packages, lithographed cans), Quality Control should ensure that the specification is updated as required to comply with new legal provisions, and that stocks of packaging materials that no longer comply are quarantined for modification (if possible and desired) or destruction.

When a new pack or label design is introduced for a product the obsolete packaging or labels should be destroyed and this disposal recorded.
Each label should contain a code which will cross-reference it to the formulation to ensure that changes in formulation are reflected in the label copy.

Each delivery or lot of packaging should be given a reference code to identify it in storage and processing, and the documentation should be such that, if necessary, any lot of finished product can be correlated with the deliveries of the respective packaging materials used in its manufacture and with the corresponding laboratory records. Deliveries should be stored and marked in such a way that their identities do not become lost

Packaging materials should be assigned a shelf life where appropriate. Deliveries of packaging material should be quarantined upon receipt and released for use only when the necessary quality assessment has been made. Operators should be trained and encouraged to report immediately anything unusual about the appearance, odour or behaviour of packaging materials issued. Temporarily quarantined packaging material should be located and/or marked in such a way as to avoid risk of its being accidentally used before release. Material found totally unfit for use in packaging operations should be suitably marked and physically segregated pending appropriate disposal.

UNCONTROLLED COPY

All packaging materials should be stored in hygienic conditions, and as indicated in their respective specifications. Stocks of packaging materials in store should be inspected regularly to ensure that they remain in acceptable condition.
In issuing packaging material from store for production use, stock rotation should normally be observed, unless otherwise authorised or specified by Quality Control.

Authorised procedure and documentation should be established and followed for the issue of packaging materials from store, and for the return of part-used lots of packaging to store. The returns procedure should consider the need to re-seal part used boxes of packaging to prevent foreign body contamination.
All printed packaging components should be issued from and returned to a secure area with controlled personnel access

There should be a procedure for the reconciliation of all printed packaging component stock from quantity issued, quantity used, wastage and that returned to store.

43.0 FOREIGN MATERIAL CONTROL

All finished product should be inspected for potential metal contamination. The highly preferred method is for all finished packaged product to be scanned through an electronic instrument calibrated to identify and separate contaminated product. Typical systems include metal detectors or x-ray units. If electronic devices are not used, other measures designed to prevent physical contamination should be employed. Examples of such measures would include liquids that pass through a fine mesh screen, free-flowing items that pass over, under, or through rare earth magnets or food items that are secured in the final package with metal fasteners, but pass through metal detection devices in the filling process. These “other measures” Should also be calibrated, monitored and documented. The plant should have a documented procedure for monitoring their process and finished product for the presence of foreign material.

a) Electronic Foreign Material Detectors, if used: There should be a written procedure describing the maintenance, set-up and verification tests of detector systems. The procedure should describe the initial set-up procedures and frequency of verification checks with actual product at start-up, during the shift and at the end of production. Test units to check equipment performance should be used and appropriate for the nature of the product and the size of the package. Detectors should be set-up at the beginning by qualified personnel and calibrated for the particular product being run. Documentation of calibration and set-up should be part of daily production records along with initial, operational and final verification checks.

i. Detectors should have calibration and set-up verified by placing the test units or cards containing them along with the first product or package through the detector. Calibration should include the use of ferrous, non-ferrous and stainless steel test samples. Customer

UNCONTROLLED COPY

specifications should be used, if available. At the start of the production run, the first product through should be tested to verify performance and ability to detect and reject the specified test units. Test units should be placed along with the product in a sanitary manner so as to avoid product contamination. Special care should be given to make sure that test units are promptly recovered from the test packages.

ii. A successful verification check should detect and reject three successive challenges for each test unit. For those situations where three successive challenges may be difficult to accomplish, one challenge for each test unit is acceptable during the production run; however, three successive challenges are still required at start up and at finish. An example of this might be a system where detection is conducted just prior to packaging of a bulk ground meat product that is conveyed in line and insertion of the test unit is quite complicated.

iii. If product used in the verification checks is not discarded, it should be re-run through the detector after the test units have been removed from the package.

iv. Frequency of verification checks during production and test metal samples used should be sufficient to assure continued accurate performance. Some customers may require specified verification frequencies and test metal samples used.

v. A verification check of the detector performance should be made on the last product run during the shift or lot. This will provide documentation that the detector was functioning properly from beginning to the end of production.

vi. Rejected units from the detector should be retested and pass 3 successive times before accepted as a false positive. The detector should be properly calibrated at the time the rejected product is retested. Reject units should be opened promptly and examined to determine the source of the problem.

vii. A record of detector rejects and the cause for rejection Must be recorded on the verification/test log.

viii. In the event the detector fails a verification check, all product produced since the last documented successful verification check Must successfully pass through a properly functioning detector device.

b. When magnets are used for the detection and removal of potential metal contaminants, the method of calibration should be the manufacturer's recommended pull strength test.

c. A program should be in place to minimize foreign material contamination from the outside of bagged ingredients when being added in open mixing units.

d. There should be an accountability program in place for knives and similar hand tools.

44.0 LABORATORY SUPPORT (The Laboratory Capabilities Prerequisite System)

When conditions warrant, laboratory support functions provide very valuable information to assure process control for food safety and product quality.

UNCONTROLLED COPY

1) Laboratory Facility and Staffing

The plant laboratory for chemical and physical analytical testing and microbiological evaluation of ingredients, in-process components and finished product should be adequately equipped and staffed to provide the essential technical support to the plant.

a. Laboratory staff should have documented qualifications by way of specific training, certification or other forms of credentialing.
b. Laboratory should be clean, orderly and well lit. It should have at least the appropriate equipment and instruments to provide effective evaluation for food safety and specification compliance of the ingredients and finished product.
c. The laboratory should be isolated from the production area and control procedures should be implemented to ensure that it does not contribute to potential contamination. Laboratory drains should be directed to the sanitary sewer system and not to production area drainage systems.
d. Pathogen analyses should not be performed at a plant laboratory unless there is competent professional supervision and there is an effective program to secure pathogen organisms from misuse. The pathogen testing laboratory should comply with BSL2 requirements as well as the Good Laboratory Practices (GLP) requirements set forth.
e. All toxic supplies should be securely stored and properly labeled.

2) Laboratory Procedures and Documentation

Laboratory procedures should be documented with proper authorization and dates.

a. Testing procedures should be based on recognized and approved procedures.
b. Documentation of all testing Should be available, including records of COAs where in-house testing is not performed.

3) Laboratory Equipment Calibration

It is essential that every laboratory have a detailed and documented calibration and verification programs for instruments and measuring devices.

a. Balances and laboratory test equipment should be calibrated (certified) by a demonstrably competent company or individual at a prescribed frequency as defined by the manufacturer. Records of this certification should be maintained. Certification of reference standards, weights, and thermometers should be available.
b. There should be an in-house policy for periodic verification of test equipment at appropriate frequencies. This should include at least start of production checks of scales, balances and thermometers with appropriate test weights and calibrated thermometers. Documentation may be on routine data sheets.

4) Analytical Accuracy Verification

There should be documented evidence that the results of the laboratory are accurate and reliable.

UNCONTROLLED COPY

a. Quality manual test procedures, work instructions, training records and record keeping Should be established to verify that monitoring is occurring and that the results meet specifications and finished product requirements.
b. Plant should have documented detailed procedures for all microbiological, analytical, physical and chemical tests performed.
c. Microbiological test procedures should meet accepted standards (BAM, USDA or recognized authority).
d. Chemical test procedures should meet accepted standards (AOAC or recognized authority).

45.0 RETENTION OF SAMPLES

Retention samples of a batch product provide a useful tool for the investigation of a product complaint.

1. An appropriate and adequate number of samples of the finished batch product shall be withdrawn from the production/packaging line to serve as reserve or retention samples.

The number shall be such that it will be adequate for a complete testing, if and when necessary to do so.

2. Retention samples shall be stored in an area compatible with storage condition prevailing in the market.

46.0 SUB-CONTRACTING OF MANUFACTURE

The conditions of contract manufacturing should be defined, agreed, and controlled so as to avoid misunderstandings, which could result in a product or work of unacceptable quality. All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards. There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities.

UNCONTROLLED COPY

DEFINITION OF TERMS

For the purpose of these guidelines the following terms shall mean:

1. **Accuracy** – An indicator of how near an obtained value is, during measurement or analysis, to a true value.
2. **Acid foods or acidified foods** - Food that have an equilibrium pH of 4.6 or below.
3. **Adequate** –That which is needed to accomplish the intended purpose in keeping with good public health practice.
4. **Adulteration** – To make impure by mixing in a foreign or inferior substance.
5. **Batch** - A quantity of manufactured food produced in a given cycle of manufacture that is uniform in character and quality.
6. **Batter** - A semi fluid substance, usually composed of flour and other ingredients, into which principal ingredients of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
7. **Calibration** - Combination of checking an instrument and adjusting it to bring it within its limit for accuracy according to recognized standards.
8. **Clean Area** - An area with defined environmental control of particulate and microbial contamination constructed and used in such a way as to minimize the introduction, generation and retention of contaminants within the area.
9. **Component** - Any ingredient intended for use in the manufacture of a product, which include raw and packaging materials, including those that may not appear in the finished product.
10. **Contaminants** - Any biological or chemical agent, foreign matter, or other substances that are not intentionally added to food, which may compromise food safety or suitability.
11. **Controlled Area** - An area constructed and operated to control the introduction of potential contaminants.
12. **Critical Control Point** - A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to acceptable level.
13. **Cross Contamination** - Contamination of raw materials, in-process and finished products brought about by other ingredients that may compromise food safety and suitability.
14. **Disinfection** - The reduction by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability.
15. **Documentation** - All written procedures, instructions and records involved in the manufacture and quality control of products.
16. **Facilities** - Refers to the building, premises and equipment necessary for the manufacture, packing, repacking and holding of food.
17. **Food** - Any substance, whether processed, semi processed or raw which is intended for human consumption and including beverages, chewing gum and any substance which has been used as an ingredient on the manufacture, preparation or treatment of "food"
18. **Food Allergens** - usually proteins or protein fragments that trigger well defined adverse reaction involving the immune system, most often mediated by immunoglobulin E. Examples of critical food allergens are: *eggs*, peanuts, tree nuts, milk, soya, fish, crustacean,

UNCONTROLLED COPY

wheat and other gluten containing cereals.
19. **Food Handling** - Any operation in the preparation, processing, packaging, repacking, storage, transport, distribution and sale of food product.
20. **Food Hygiene** - All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.
21. **Good Manufacturing Practice** - A quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to a quality appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedures.
22. **Holding** - An indication that something is to be reserved or stored.
23. **Ingredient** - Any substance including food additive, used as a component in the manufacture or preparation of a food and present in the final product in its original or modified form.
24. **Lot** - food produced during a period of time and under more or less the same manufacturing condition indicated by a specific code.
25. **Manufacture or Manufacturing** - The complete set of activities to produce a product that comprise production and quality control from acquisition of all materials through processing and subsequent packaging to the release for distribution of the finished product.
26. **Microorganisms** - Refers to yeasts, molds, bacteria and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.
27. **Packaging** - The process of packing that is part of the production cycle applied to a bulk product to obtain the finished product. Any material, including printed material, employed in the packaging of a product, including any outer packaging used for transportation of shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
28. **Pest** - Any objectionable animals or insects including, but not limited to birds, rodents, flies, and larvae.
29. **Plant** - the building or the facilities or parts thereof, used for or in connection to the manufacturing, packing, labeling or holding of food products.
30. **Premises** - Plant and grounds within the bounds of the industrial establishment.

31. **Procedures** - Description of the operations to be executed, the precautions to be implemented directly or indirectly related to the manufacture and the repacking of food products.
32. **Processing** - The part of production cycle starting from weighing of raw materials to the obtaining of a bulk product.
33. **Production** - All operations involved in the preparation of a product, starting from acquisition of starting materials through processing and packaging, to its completion as a finished product.
34. **Quality Assurance** - The activity of providing the evidence needed to establish confidence that the quality function is being performed adequately.

UNCONTROLLED COPY

35. **Quality Control Operation** - A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated and thereby achieve its quality and safety.
36. **Raw Material** - All substances whether active or excipients that are employed in the processing of a finished product.
37. **Repacking** - Process of packaging or changing of container, wrapper (that may include or not a changing of label) in furtherance of distribution of food.
38. **Representative Sample** - A sample representing a lot, a batch, or the total amount of materials based on a sampling plan.
39. **Reprocessing** - The reworking of all or part of a batch of product of an unacceptable quality from a defined step of production in order that its quality aspect may be rendered acceptable by one or more additional operations.
40. **Rework** - Clean, unadulterated food that has been removed from processing for reasons other than being unsanitary or unsafe and that has been successfully reconditioned by reprocessing and rendered suitable for use as food.
41. **Sanitize** - To adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, an in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or the safety of the consumer.
42. **Shall** - A term used to state specific minimum mandatory requirements.
43. **Should** - A term used to state recommended or advisory procedures or identify recommended equipment.
44. **Water Activity (aw)** - A measure of the free moisture in food. It is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

UNCONTROLLED COPY

APPENDIX I: MEDICAL EXAMINATION FOR FOOD HANDLERS ALONG THE FOOD SUPPLY CHAIN

Name:			
State of Domicile			
Nationality:		**Hospital No:**	
Address:	**Home:**	**Work Place:**	
Contact No:			

A. Declaration Form (to be completed by food handler)	**Yes**	**No**
1. Are you now, or have you over the last seven days, suffered from diarrhoea/vomiting?		
2. Have you suffered from a fever since more than one week ago?		
3. At present, are you suffering from:		
a. Skin trouble affecting hands, arms or face		
b. Boils, styes or sepsis on your fingers or hands		
c. Discharge from eye, ear, nose or gums/mouth		
4. Do you suffer from:		
a. Recurring skin or ear infection		
b. A recurring bowel disorder		
5. In the last 5 days, have you been in contact with anyone who may have been suffering from cholera?		
6. In the last 7 days, have you been in contact with anyone with diarrhoea or vomiting?		
7. In the last 21 days have you been in contact with anyone who may have been suffering from typhoid or paratyphoid or jaundice person?		
8. Have you ever had, or are you now known to be a carrier of typhoid or paratyphoid?		
9. Have you ever had, or are you now known to have typhoid fever?		

B. Physical Examination (To be completed by a doctor)	**Yes**	**No**

UNCONTROLLED COPY

1. Fever		
2. Jaundice		
3. Skin infection on hands, arms, face		
4. Boils, styes or sepsis on finger		
5. Discharge from eye, ear, nose or gums/mouth		

C. Food Handlers Vaccination Record

Name of Recipient:
Date of Birth:
Gender:
Address of Recipient: Name of Employer:

Stamped picture

Vaccine	**Date of vaccination**	**Brand name of Vaccine**	**Batch Number**	**Signature**	**Next visit** (Where applicable)	**Comments**
Typhoid Fever						
Hepatitis A						

Name of Vaccinator:
Hospital name/address:

D. Laboratory Test

1. Stool culture (if required)
   a. Typhoid
   b. Cholera
2. Other tests (if required)

Result

Positive	**Negative**

Case Summary

UNCONTROLLED COPY

I hereby confirm that Mr/Ms/Mrs …… Hospital no.
……..…. registration/referral no..... had undergone medical examination and found to be:

- Healthy and fit to work as food handlers
- Not fit to work as a food handler
- Can return to work on _____

I declare that all the above statements are true and complete to the best of my knowledge.

Signature: ……. Date: ……..……

Official Stamp

Name……..

Name of Hospital or Place of Practice: ……..

UNCONTROLLED COPY