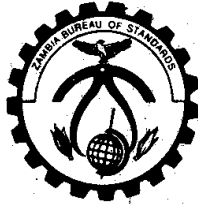


Zambia Bureau of Standards



STANDARDS ACT, 1994

Standards (Compulsory Standards) (Declaration) Order, 2003

Standards (Compulsory Standards) (Declaration) Order, 2006

PERMIT CONDITIONS
FOOD AND BEVERAGES

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1. Preamble

1.1 Compulsory Standards are mandatory requirements declared by the minister, when satisfied upon recommendation by the Director of the Bureau, that it is necessary or expedient for the promotion of public safety or otherwise in the public interest.

1.2 The Bureau shall give written authority for supply to any establishment that manufactures a product to which a compulsory standard applies. This written authority is called a Permit-to-Supply and shall be given under the conditions determined by the Bureau as contained herein.

2. Scope

2.1 These conditions stipulate the responsibilities, obligations and procedures to be followed by establishments producing food and beverage products to which a compulsory standard applies in order to obtain written authorization to supply the products.

2.2 The conditions further stipulate the regulatory actions that will be effected in the case of non-compliance.

3. Objectives

3.1 These conditions stipulate food hygiene practices applicable to establishment operations in order to achieve the goal of ensuring that food is safe and suitable for human consumption.

3.2 These conditions also stipulate administrative requirements to be fulfilled in order to acquire and maintain a permit to supply food and beverage products to which a compulsory standard.

4. Interpretation

For the purpose of these conditions, the following terms have the meaning stated:

Appeal - Request by the Applicant/Permittee to the Bureau for reconsideration of a decision it has made relating to a permit to supply.

Applicant - This is an individual or body corporate that has applied for but has not yet been granted a permit to supply.

Bureau – The Zambia Bureau of Standards

Certificate – A document issued in accordance with these conditions certifying compliance with the compulsory standard and these conditions

Certification - Third-party activity of authorizing and issuing a statement that fulfilment of specified requirements related to products, processes, systems or persons has been demonstrated

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

Complaint - Expression of dissatisfaction, other than appeal, by any person or organization to the Bureau, relating to its certification by the Bureau, where a response is expected.

Compliance – fulfillment of specified regulatory requirements

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

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

Corrective Action - Action to eliminate the cause of a detected non-compliance and prevent recurrence.

Note

Correction relates to containment whereas corrective action relates to the root cause.

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

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

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

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

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

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

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

Inspection - Examination of a product design, product, process or installation and determination of its compliance with specific requirements or, on the basis of professional judgment, with general requirements

Inspector – Any person or employee of the Bureau who is authorised to perform inspection functions under the Standards Act

Permit to Supply – Certificate authorizing the marketing of a product to which a compulsory standard applies in accordance with these conditions.

Permittee - The authorized holder of a permit authorizing the marketing of a product to which a compulsory standard applies.

Revenue - the total amount of money received by the establishment for the sale of food and beverage products to which a compulsory standard applies during a certain time period.

Sampling - Activity related to obtaining a representative sample of the material, product, process, installation or system, according to a procedure.

Surveillance - Systematic iteration of inspection and/or testing activities as a basis for maintaining the validity of the permit to supply.

Suspension - Temporary invalidation of the permit to supply.

Testing - Determination of one or more characteristics of a material, product, process, installation or system, according to a procedure.

Withdrawal - Cancellation of the permit to supply.

5. Powers and Authorities

5.1 Authority to Determine Conditions for Permission to Supply – Standards Act, Section 12(4)

The Bureau may give written authority to supply a product to which a compulsory standard applies on such terms and conditions as it considers necessary to ensure continued compliance with a compulsory standard.

5.2 Authority to Enter – Standards Act, Section 29 (1)

An inspector may enter, at all reasonable times, enter any premises in or upon which he has reason to believe that a product to which a compulsory standard applies is produced manufactured, processed, treated, finished or stored.

5.3 Authority to Inspect – Standards Act, Section 29 (1)

An inspector may:

- (a) inspect or take samples of product to which a compulsory standard applies;
- (b) inspect or take samples of any material or substance which he has reason to believe is used or is intended to be used in the production, manufacture, processing, treatment or finishing of a product to which a compulsory standard applies;
- (c) open any package or container which he has reason to believe contains any product to which a compulsory standard applies or any material or substance used or is intended to be used in the production, manufacture, processing, treatment or finishing of the product;
- (d) inspect any process or operation which is carried on in connection to with the production, manufacture, processing, treatment or finishing of any such commodity;
- (e) examine and make copies of or take extracts from any book, notice, record, list or document which relates to any such commodity;
- (f) require any person to explain any entry in any such book, notice, record, list or document;
- (g) carry out any other investigations in connection with any such commodity; and
- (h) exercise such other powers as are more connected with or incidental to his powers under this section.

5.4 Provision of Facilities by the Establishment – Standards Act, Section 29 (2)

The person in charge of the premises shall provide such facilities as are reasonably necessary for the performance by the inspector of his functions.

5.5 Use of Equipment– Standards Act, Section 29 (3)

The inspector when entering the premises may take such equipment as may appear to him to be necessary for the exercise of his powers

5.6 Hindrance of Inspectors– Standards Act, Section 29 (4)

Any person who hinders or obstructs an inspector in the course of his duty or who willfully fails to comply with any requirement lawfully made under this section shall be guilty of an offence and shall be liable upon conviction

6. Establishment Authorizations

6.1 The permit to supply authorizes the establishment to manufacture and place on the market food and beverage product brands as stipulated in the schedule attached to the permit.

6.2 Compliance with conditions of the permit does not relieve the permittee of the obligation to comply with all other applicable regulations or laws.

7. Fees

7.1 Fee Structure

7.1.1 Application Fee

The first step when seeking a permit to supply is to submit a completed application form and the application fee so that the Bureau can begin consideration of the applicant's readiness for a permit.

7.1.2 Inspection Work

Inspection work is that required for the grant of a permit to supply under a standard separate from any currently held, surveillance inspection work that is required for maintenance of a permit to supply and re-inspection work required for the renewal of a permit to supply. This will be priced at the current fee rates as per fee schedule below.

For all other work, including the clearance of any non-compliance identified as a result of an inspection, whether this involves extra visits or not, we will give an individual invoice based on the amount of work required.

7.1.3 Test Work

Test work is that required for determining the characteristics of a product will be charged at cost.

7.1.4 Extension to Scope

Establishments wishing to extend their permit to include another grade or brand within a standard they must complete an application for a permit to supply and submit the required application fee.

7.1.5 Units of Time

Rates for our services are calculated in days and half-days. An Inspector Unit is one inspector for one day and is K550, 000.00. Individual invoices are made to establishments based on the number of days and inspectors required, which in turn are dependent on the number of products in the scope of the permit and the size of the establishment.

7.1.6 Annual Permit Fees

Apart from the fees for audit work above, there is a charge for maintaining a permit-to-supply against each compulsory standard and relevant product or product group conditions. This charge is called the Annual Permit Fee.

7.1.7 Inspector Supplement

Where an establishment's specialty or other circumstances require us to use specialist inspectors or experts, we reserve the right to pass on to the establishment any excess charges we incur.

7.1.8 Expenses

We will bill to customers any travel and accommodation expenses at cost.

8. Establishment Operations

8.1 Buildings, Facilities and Equipment

8.1.1 Location

8.1.1.1 Establishments shall be located away from environmentally polluted areas and industrial activities which pose a serious threat of contaminating food.

8.1.1.2 Establishments shall be located away from areas subject to flooding unless sufficient safeguards are provided.

8.1.1.3 Establishments shall be located away from areas where wastes, either solid or liquid, cannot be removed effectively.

8.1.2 Premises and Rooms

8.1.2.1 The internal design and layout of Product establishments shall permit good food hygiene practices, including protection against cross-contamination between and during operations.

8.1.2.2 Structures within product establishments shall be soundly built of durable materials and shall be easy to maintain, clean and where appropriate, able to be disinfected. The following requirements shall be implemented where necessary to protect the safety and suitability of product:

- a) The surfaces of walls, partitions and floors shall be made of impervious materials with no toxic effect in intended use;
- b) walls and partitions shall have a smooth surface up to a height appropriate to the operation;
- c) floors shall be constructed to allow adequate drainage and cleaning;
- d) ceilings and overhead fixtures shall be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles;
- e) windows shall be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows shall be fixed;
- f) doors shall have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;
- g) working surfaces that come into direct contact with product shall be in sound condition, durable and easy to clean, maintain and disinfect. They shall be made of smooth, non-absorbent materials, and inert to the Product, to detergents and disinfectants under normal operating conditions.

8.1.3 Equipment

8.1.3.1 The permittee shall have available to it suitable and adequate equipment to permit all activities associated with the manufacture of the product to be carried out.

8.1.3.2 The permittee shall have clear rules for the access to and the use of specified equipment.

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

8.1.3.4 Equipment and containers shall be made of materials with no toxic effect in intended use. Equipment shall be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and to facilitate inspection for

8.1.3.5 Equipment used to cook, heat treat, cool, store or freeze product shall be designed to achieve the required product temperatures as rapidly as necessary in the interests of product safety and suitability, and maintain them effectively.

8.1.3.6 Equipment shall have effective means of controlling and monitoring temperature, humidity, material flow, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of product.

8.1.3.7 Containers for waste, by-products and inedible or dangerous substances, shall be specifically and clearly labelled, suitably constructed and, where appropriate, made of impervious material.

8.1.3.8 Containers used to hold dangerous substances shall be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of Product.

8.1.4 Facilities

8.1.4.1 An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, shall be available whenever necessary including at cleaning facilities to ensure the safety and suitability of product.

8.1.4.2 Potable water shall be periodically tested by a recognized laboratory for quality.

8.1.4.3 Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate Product), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

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

8.1.4.5 Adequate facilities, suitably designated, shall be provided for cleaning the product, utensils and equipment.

8.1.4.6 Adequate means of hygienically washing and drying hands, including wash basins and a supply of water shall be available.

8.1.4.7 Adequate lavatories of appropriate hygienic design shall be available

8.1.4.8 Adequate changing facilities for personnel shall be available

8.1.4.9 Depending on the nature of the product operations undertaken, adequate facilities shall be available for heating, cooling, cooking, refrigerating and freezing Product, for storing refrigerated or frozen Products, monitoring Product temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of Product

8.1.4.10 Adequate means of natural or mechanical ventilation designed and constructed so that air does not flow from contaminated areas to clean areas shall be provided

8.1.4.11 Adequate natural or artificial lighting shall be provided to enable the undertaking to operate in a hygienic manner. Lighting fixtures shall, where appropriate, be protected to ensure that Product is not contaminated by breakages

8.1.4.12 Where necessary, adequate facilities for the storage of product, ingredients and chemicals shall be provided. The storage facilities shall be designed and constructed to: permit adequate maintenance and cleaning; avoid pest access and harbourage; enable product to be effectively protected from contamination during storage; and where necessary, provide an environment which minimizes the deterioration of product

8.1.4.13 Separate and secure storage facilities for cleaning materials and hazardous substances shall be provided.

8.2 Personnel

8.2.1 Competency and Availability

8.2.1.1 The permittee shall have a sufficient number of permanent personnel with qualifications, training, experience and a satisfactory knowledge of the technology and procedures for manufacturing the product.

8.2.1.2 The permittee shall ensure that personnel have relevant knowledge, qualifications, training and experience for the evaluation of product at various stages of manufacture, and of the defects which may occur during manufacture. They shall understand the significance of deviations found with regard to the normal use of the products.

8.2.2 Training

8.2.2.1 The permittee shall establish a documented training system to ensure that the training of its personnel in the technical and administrative aspects of the work in which they will be involved is kept up-to-date. The training required shall depend upon the ability, qualifications and experience of persons involved.

8.2.2.2 The permittee shall establish the necessary stages of training for each of its personnel. These may include:

- a) an induction period;
- b) a supervised working period with experienced personnel; and
- c) Continuation training, throughout employment, to keep pace with developing technology.

8.2.2.3 The permittee shall ensure by way of refresher training that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

8.2.2.4 Records of academic or other qualifications, training and experience of each member of its personnel shall be maintained by the permittee.

8.2.3 Management and Supervision

8.2.3.1 Managers and supervisors shall have adequate knowledge of food hygiene principles and practices to be able to judge potential risks, and take appropriate preventive and corrective action,

8.2.3.2 Managers and supervisors shall carry out routine supervision and checks to ensure that procedures are being carried out effectively.

8.3 Control of Operations

8.3.1 Ingredient, Material and Product Control

8.3.1.1 The permittee shall ensure that raw materials and ingredients shall not be accepted if they contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which cannot be reduced to an acceptable level by normal sorting and/or processing.

8.3.1.2 The permittee shall ensure that specifications for raw materials and ingredients are identified, documented and applied.

8.3.1.3 The permittee shall ensure that raw materials and ingredients are inspected and sorted before processing. Where necessary, laboratory tests shall be made to establish fitness for use or the materials shall be accompanied by test certificates, test report, written guarantees or other certifications. Only sound, suitable raw materials or ingredients shall be used.

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

8.3.1.5 The permittee shall ensure that ingredients, materials or product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

8.3.1.6 The permittee shall deal with nonconforming ingredients, materials or product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application.

8.3.1.7 When nonconforming ingredients, materials or product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

8.3.1.8 When nonconforming ingredients, materials or product is detected after delivery or use has started, the permittee shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.3.1.9 Where appropriate, the permittee shall identify the ingredients, materials and product by suitable means throughout production.

8.3.1.10 The permittee shall have a system for batch or lot traceability. It is the responsibility of the permittee to determine what constitutes a batch or lot.

8.3.1.11 Records of the nature of nonconformities, non-conforming products, inspection and verification of stocks, and any subsequent actions taken, including concessions obtained, shall be maintained.

8.3.2 Process Control

8.3.2.1 The permittee shall describe the production process in the form of a block diagram. The block diagram shall at least contain the following information:

- a) route and direction of the ingoing and outgoing material and energy flows;
- b) denomination and flow rates of ingoing and outgoing materials;
- c) characteristic operating conditions.
- d) process measurements and controls at essential points;

8.3.2.2 The permittee shall identify critical production processes and arrange operators with appropriate qualifications, knowledge and experience at the processes.

8.3.2.3 Where special environmental conditions are required, the establishment shall meet the requirements.

8.3.2.4 The permittee shall monitor and control appropriate process parameters and product characteristics, as applicable.

8.3.2.5 Production shall be inspected at appropriate stages of manufacture to ensure that ingredients, materials, and products are in accordance with specifications.

8.3.2.6 The permittee shall identify the product status with respect to inspection and testing requirements.

8.3.2.7 Inspection and test records shall be maintained. The records shall include sufficient information to permit satisfactory evaluation of the inspection and/or test.

8.3.3 Packing, Handling, Storage and Delivery

8.3.3.1 Ingredients, materials or products shall be packaged, stored and handled in such a way as to ensure that they will continue to comply with the applicable specifications and/or standards.

8.3.3.2 Packaging design and materials or gases where used must be non-toxic and shall provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling.

8.3.3.3 Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfected.

8.6.3.4 Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition.

8.6.3.5 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.

8.3.4 Documentation and Records

8.3.4.1 Where product quality and safety cannot be guaranteed when there is no operating document, appropriate operating instructions shall be prepared to ensure production processes are under control.

8.3.4.2 Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product.

8.4 Maintenance, Cleaning and Sanitation

8.4.1 Maintenance Programmes

8.4.1.1 The permittee shall ensure that buildings, surroundings, plant and equipment are properly maintained and in a state of good repair, in accordance with written maintenance schedules.

8.4.1.2 The permittee shall establish clear identification systems for equipment.

8.4.1.3 The permittee shall ensure that, where appropriate, measurement equipment is calibrated before being put into service and thereafter according to an established programme. The overall programme of calibration of measurement equipment shall be designed and operated so as to ensure that wherever applicable, measurements made by the permittee are traceable to national and International Standards of measurement where available. Where traceability to national or International Standards of measurement is not applicable, the permittee shall provide satisfactory evidence of correlation or accuracy of inspection and test results.

8.4.1.4 Defective equipment shall be removed from service by segregation, prominent labelling or marking.

8.4.1.5 Relevant information on the equipment shall be recorded. This will normally include identification, calibration where applicable and maintenance.

8.4.2 Cleaning and Sanitation Programmes

8.4.2.1 The permittee shall establish and document cleaning and disinfection programmes that ensure that all parts of the establishment are appropriately clean, and shall include the cleaning of surfaces, equipment and utensils.

8.4.2.2 The permittee shall ensure that cleaning and disinfection programmes specify:

- a) areas, items of equipment and utensils to be cleaned;
- b) responsibility for particular tasks;
- c) method and frequency of cleaning; and
- d) monitoring arrangements.

8.4.2.3 The permittee shall ensure that appropriate cleaning shall 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:

- a) removing gross debris from surfaces;
- b) applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
- c) rinsing with water which complies with section 4, to remove loosened soil and residues of detergent;
- d) dry cleaning or other appropriate methods for removing and collecting residues and debris; and
- e) where necessary, disinfection with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing is not required.

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

8.4.2.5 Records of cleaning done, chemicals used and materials safety data sheets shall be maintained

8.4.3 Pest Control Systems

8.4.3.1 The permit shall develop and document a pest control program

8.4.3.2 Buildings shall be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, open windows, doors, ventilators drains and other places where pests are likely to gain access shall be kept sealed or fitted with wire mesh screens. Animals shall be excluded from the grounds of factories and food processing plants.

8.4.3.3 The permittee shall ensure that potential food sources are stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises shall be kept clean and the establishment and surrounding areas shall be regularly examined for evidence of infestation.

8.4.3.4 The permittee shall ensure that treatment with chemical, physical or biological agents shall be carried out without posing a threat to the safety or suitability of food.

8.4.3.5 Records of monitoring pests, use of chemicals and materials safety data sheets shall be maintained

8.4.4 Waste Management

8.4.4.1 The permittee shall ensure that there are suitable provisions for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business. Waste stores shall be kept appropriately clean.

8.5 Personal Hygiene

8.5.1 Health Status, Illness and Injuries

8.5.1.1 The permittee shall ensure that people known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, are not be allowed to enter any food handling area . Any person so affected should immediately report illness or symptoms of illness to the management or supervisor.

8.5.1.2 The permittee shall ensure that food handlers are medically examined every six months. Records of personnel medical examination shall be maintained

8.5.1.3 The permittee shall ensure that the following conditions which shall be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered:

- a) diarrhoea;
- b) vomiting;
- c) fever;
- d) sore throat with fever;
- e) visibly infected skin lesions (boils, cuts, etc.);
- f) discharges from the ear, eye or nose.

8.5.1.4 Cuts and wounds, where personnel are permitted to continue working, shall be covered by suitable waterproof dressings.

8.5.2 Personal Cleanliness and Behaviour

8.5.2.1 Food handlers shall maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Personnel shall avoid handling ready-to-eat food, where appropriate.

8.5.2.2 Personnel shall always wash their hands when personal cleanliness may affect food safety, for example:

- a) at the start of food handling activities;
- b) immediately after using the toilet; and
- c) after handling raw food or any contaminated material, where this could result in contamination of other food items;

8.5.2.3 Personnel engaged in food handling activities shall refrain from behaviour which could result in Contamination of food, for example:

- a) smoking;
- b) spitting;
- c) chewing or eating;
- d) sneezing or coughing over unprotected food.

8.5.2.4 Personal effects such as jewellery, watches, pins or other items shall not be worn or brought into food handling areas.

8.5.5 Visitors

8.5.5.1 The permittee shall ensure that visitors to food manufacturing, processing or handling areas shall wear protective clothing and adhere to other personal hygiene requirements in these conditions.

8.6 End-Product

8.6.1 Compliance to Compulsory Standard

8.6.1.1 The permittee shall ensure that the end-product complies with the declared compulsory standard.

8.6.2 Product Information

8.6.2.1 All food products shall be accompanied by or bear adequate and accurate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly. Where indicated, nutritional information must be supported by adequate test records that verify the nutritional claims periodically.

9. Permit Acquisition

9.1 Application

9.1.1 The applicant shall formally apply for a permit to supply, using the appropriate application forms, and shall complete all sections.

9.1.2 Each establishment shall require a separate application form.

9.1.3 Each product for which a different compulsory standard applies shall require a separate application form. However, the application form shall contain all the brands of that product.

9.1.4 The application form shall be completed and signed by an authorized representative who shall hold executive authority within the corporate structure.

9.1.5 On acceptance of a completed application form and receipt of the application fee, the Bureau shall provide the applicant with an estimate of the time and cost required to conduct of the initial inspection.

9.1.6 Incomplete applications shall result in a delay in processing; the applicant shall ensure that all the required information is complete before returning the application form to the Bureau.

False or misleading information shall result in the rejection of the application.

9.2 Inspection, Sampling and Testing

9.2.1 Initial Establishment Inspection

9.2.1.1 The initial establishment inspection shall be to determine its ability to consistently meet specified operational requirements these conditions and the standards for the product(s). This shall be carried out on a date notified to the applicant, after processing the application.

9.2.1.2 The establishment inspection shall be a careful, critical, official examination of an establishment to determine its compliance with the laws and requirements administered by the Bureau.

9.2.1.3 The Establishment Inspections shall obtain evidence to support legal action when violations are found, and to obtain specific information on good manufacturing practices.

9.2.1.4 Sampling of product will be carried out before or during the establishment inspection.

9.2.1.5 Testing of product shall normally be carried out during establishment inspection, or after the establishment inspection.

9.2.1.6 The duration of the establishment inspection shall be calculated based on: the number of products applied for; the complexity of the product and manufacturing process; and the scale or size of the establishment, normally 1-4 man-days for each establishment.

9.2.1.7 The Initial establishment inspection shall be Comprehensive (directs coverage to everything in the establishment subject to the Bureaus jurisdiction to determine the establishments compliance status)

9.2.1.8 Surveillance inspections shall be Directed Inspection (directs coverage to specific areas of the inspection plan).

9.2.2 Sampling of Product

9.2.2.1 The sampling for tests and examination is based on the specified requirements for sampling in the applicable standard or otherwise any applicable international standards. In the case of no suitable sampling standards, the Bureau shall at its discretion decide on the appropriate quantity of product units.

9.2.2.2 Samples shall be representative of the entire line or group of products to be inspected, and shall be: made using materials, components and sub-assemblies identical to those used in production; made from production tools; and assembled using methods established from the production run.

9.2.3 Testing

9.2.3.1 The Bureau may, at its discretion, use its own laboratories, client facilities and/or subcontracted facilities to conduct testing.

9.2.3.2 The Bureau decides if the sample shall be retained or returned to the applicant at the applicant's expense.

9.2.3.3 The Bureau shall retain the test/evaluation records and is entitled to make them accessible to authorities (e.g. regulatory Agencies), together with the sample, if necessary. Individual agreements to the contrary are ineffective.

9.2.3.4 The Bureau shall not be liable for the loss of or damage to samples arising from testing, evaluation, theft, water, storms, floods, fire, war, or other such events.

9.2.4 Reports and Recommendations

9.2.4.1 Inspection findings will be brought to the attention of the guides and area managers during the inspection, and Non-compliance Reports are then raised by the Inspector(s).

9.2.5 Follow-up and Close-out of Corrective actions

9.2.5.1 The inspection finding is called a non-compliance. The applicant shall be notified about the results of the inspection and where non-compliances have been identified, a corrective action plan shall be submitted within a period determined by the Inspector specifying the actions to be taken to implement the corrective actions.

9.2.5.2 A Corrective Action Plan shall define the maximum time frame an establishment shall take to be in compliance. The urgency of corrective actions shall be measured by the degree of seriousness related to health, safety and quality issues as shown in Table 9.2.5.2

Table 9.2.5.2

Plan Submission and Corrective Actions

Category	Action plan Submission	Corrective action
Critical	Immediate	Immediate
Major	Two weeks	One month, three months , six months or one year
Minor	Two weeks	One month, three months , six months or one year

In *Table 9.2.5.2*, the **Category** rating classifies a non-compliance according to seriousness and provides a basis for risk management. The **Action Plan Submission** column defines the maximum time frame for the establishment to submit their written correction plan. The **Corrective Action** column defines the maximum time frame an establishment should take to be in compliance

9.2.5.3 written report identifying how each non-compliance has been corrected shall be submitted by the applicant within a time period agreed by the inspector.

9.2.5.4 An inspector(s) shall follow-up non-compliances to verify the implementation, effectiveness and sustainability of the corrective action. The applicant shall demonstrate ability to prevent recurrence of such non-compliances

9.2.5.5 Follow-ups shall be by submission of required documentation or by a follow-up visit.

9.3 Award of Permit-to-Supply

9.3.1 The decision as to whether or not to issue a permit to supply shall be taken by the Bureau on the basis of the information gathered during the evaluation/inspection process and any other relevant information.

9.3.2 The Bureau shall notify the establishment of the decision to award a permit to supply.

9.3.3 The Bureau shall issue a permit that is non transferable and shall remain the property of the Bureau.

9.3.4 The establishment acquiring this permit to supply shall accept the laid down permit conditions and shall adhere to the requirements set forth by the Bureau.

10. Maintenance of Permit

10.1 Surveillance

10.1.1 The Bureau shall exercise surveillance of the products on the basis of the requirements of the relevant compulsory standard and these conditions to ensure that mandatory specifications are complied with. To implement this, inspectors shall conduct:-

- periodic visits to establishment
- open market surveillances
- random spot checks: and
- investigations routinely and where need arises

10.1.2 Elements of the production process shall be examined or a full inspection of the Establishment may be conducted during the surveillance depending on the reasons for the activity. The frequency of surveillance inspections shall normally be every 4 months. A favourable compliance history may lead to an extension of the interval between surveillance inspections.

10.1.3 The Bureau may accept existing inspection and test results for inspection and/or tests carried out by the permittee's own laboratory facilities or subcontracted facilities.

10.1.4 The Bureau shall check samples at random from the permittee's premises or any sales outlet and from the open market.

10.2 Corrective Actions

See 9.2.5

10.3 Renewal of Permit-to-Supply

10.3.1 The permittee is required to notify The Bureau of their wish to have their Permit renewed at least 60 days before the date of expiry of the Permit.

10.3.2 If the re inspection has not been completed by the expiry Date the Permit shall lapse, and the permittee shall no longer be permitted to supply the product on the market.

11. Enforcement and Compliance Actions

11.1 General

11.1.1 The following factors, along with other applicable information, shall be considered when deciding upon the most appropriate action:

- a) The offender's history of compliance with the legislation or these permit conditions;
- b) Willingness to achieve compliance;
- c) Evidence of corrective action taken;
- d) The seriousness of harm or potential harm.

11.1.2 The inspector shall institute one or more of the following actions as appropriate

- a) Non-Compliance Report
- b) Warning
- c) Product Confiscation
- b) Suspension or withdrawal of permit
- c) Prosecution Action

Instances of non-compliance shall be re-evaluated prior to proceeding with enforcement action

11.2 Non-Compliance Report

11.2.1 Where Bureau inspectors shall have reasonable grounds to believe there has been a contravention of the Standards Act or applicable legislation or these permit conditions, they shall conduct investigations to determine the facts of the alleged infraction(s). The inspector shall gather and preserve evidence. Once non-compliance has been verified, the inspector shall complete a Non-Compliance Report.

11.2.2 The non-compliance report shall be used in instances where the non-compliance is due to carelessness, easily corrected, the establishment demonstrates due diligence in its operations and conduct.

11.3 Warning

A written warning letter shall be used in instances of non compliance where the establishment has not made reasonable efforts to correct or mitigate the violations reported in the non-compliance report or makes repeat violations.

11.4 Prosecution Action

11.4.1 Prosecutions shall be considered for offences under the Standards Act, regulations and permit conditions enforced by the Bureau except where it shall have been determined that:

- a) Warning under these permit conditions shall be the most effective means of achieving compliance; or
- b) Permit suspension or cancellation shall be the most effective means of achieving compliance.

11.4.2 Prosecution shall always be pursued when the offence involves:

- a) death of, or injury to, a person and the evidence indicates that the death or injury was directly attributed to failure to comply with any of the provisions of the Standards Act or regulations or permit conditions administered and/or enforced by the Bureau;
- b) Serious harm or risk to the environment;
- c) Risk to the health and safety of humans, animals;
- d) The prohibited sale of a product subject to a compulsory standard;
- e) The unsafe manufacturing of food and beverages;
- f) Forging, altering or tampering with an inspection report, certificate or permit;
- g) Knowingly providing false or misleading information, or making a false or misleading statement to an inspector;
- h) Obstructing or interfering with an inspector exercising his/her powers or carrying out his/her duties and functions;
- i) Removing, altering or interfering with any thing seized and detained or the movement of which is restricted or prohibited;
- k) Producing records, documents or electronic data that knowingly contains false or misleading information;
- l) Refusal to comply with the directions of an inspector, a detention order or a recall order; or

- m) A conviction for a previous similar offence, a repeated offence or a continuing offence.

11.5 Product Confiscation

11.5.1 An inspector shall file an application for institution of court proceedings as provided for by the Standards Act, Section 35 (1) to confiscate and dispose of non-compliant products. The detention of products or other things shall be generally appropriate when a violation is suspected and when:

- a) The violation poses a health and safety risk;
- b) The person demonstrates an unwillingness to comply by failing to remove the product from the market or failing to take corrective action to bring the product into compliance.
- c) The product is not in compliance with a compulsory standard.

11.5.2 Confiscation of product shall be considered to be one of the most expeditious and effective tools to promote compliance.

11.6 Suspension or Withdrawal of Permit

11.6.1 Suspension

11.6.1.1 A permit may be suspended if:

- a) Inspection or surveillance of the product and/or establishment shows non-compliance with the specified requirements in the standard or these permit conditions of such nature that immediate cancellation is not necessary.
- b) The permittee fails to comply with the due settlement of financial obligations;
- c) The permittee stops production for a period of 6 consecutive months.

11.6.1.2 The holder of a permit that is suspended shall be officially notified of the suspension by the Bureau in a registered letter.

11.6.1.3 The Bureau shall indicate to the permittee under which conditions the suspension will be removed, such as for example corrective action taken.

11.6.1.4 At the end of the suspension period, the Bureau shall investigate whether the indicated conditions for re-instituting the Permit have been fulfilled. On fulfilment of these conditions, the suspension shall be removed by notifying the permittee.

11.6.1.5 During the period of suspension, the permittee shall not be allowed to supply the product onto the market.

11.6.2 Withdrawal

11.6.2.1 The Bureau may withdraw any permit:

- a) If surveillance of the product shows non-compliance with the specified requirements in the applicable compulsory standard of such a serious nature that immediate withdrawal is necessary.
- b) If the permittee fails to comply with the due settlement of financial obligations;
- c) If inadequate measures are taken by the permittee in the case of suspension.
- d) If the permittee commits any other serious breach of or ceases to comply with the laid down conditions of the permit;
- f) If the permittee, being a company, is dissolved or enters into compulsory or voluntary liquidation except for the purposes of amalgamation or reconstruction;
- g) If the permittee has a receiver or administrator appointed of his business;
- h) If at any time The Bureau forms the opinion that the product does not comply with the Standard;
- g) If the Product does not comply with any amended or new edition of the standard or conditions of the permit within the period of time allowed to the permittee by The Bureau.

11.6.2.2 A permittee may surrender a permit by giving 90 days notice to the Bureau.

11.6.2.3 On withdrawal of a permit, The Bureau shall immediately give notice of such cancellation to the permittee. The cancellation shall be effective from the day following the dispatch of such notice.

11.6.2.4 On withdrawal of a Permit, the Bureau may publish the withdrawal.

11.6.2.5 On withdrawal of a permit, all outstanding fees payable will continue to be due for payment by the Applicant.

12. Appeals and Complaints

12.1 Where an applicant or licensee considers that he has been refused a permit or that his permit has been suspended or withdrawn unreasonably then the following procedures are available to him to make an appeal within fourteen days after having been officially informed of such refusal or cancellation:

- a) To the Director: The applicant or permittee may present his grievance in writing to the Director who shall consider the grievances within 14 days of their being made.
- b) To the Standards Council: If the Applicant or permittee does not accept the ruling of the Director following consideration of his grievance he may formally appeal to the Standards Council who shall hear the appeal and whose decision shall be final.

12.2 Where an applicant or permittee considers that the results of an inspection by a Bureau inspector are not accurate or fair he may formally express his dissatisfaction by contacting the Inspections Manager at the Bureau head office during normal business hours