Dominica National

STANDARD

Good Manufacturing Practices (GMP) - Food Processors & Manufacturers - Requirements

D-DNS 20 202x

ICS 67.020

Month 202x

Price Group

DOMINICA BUREAU OF STANDARDS

Draft No. 1

ISSUED FOR COMMENT ONLY

DRAFT

DOMINICA NATIONAL STANDARD

GOOD MANUFACTURING PRACTICES (GMP) – FOOD PROCESSORS AND MANUFACTURERS – REQUIREMENTS

D-DNS 20: 202x

This is a draft and should not be regarded or used as a Dominica National Standard

Last date for comments ……..

DOMINICA BUREAU OF STANDARDS
National Centre of Testing Excellence
Stockfarm
P.O. Box 1015
Roseau
COMMONWEALTH OF DOMINICA
Email: *info@dominicastandards.org*

GENERAL STATEMENT

The Dominica Bureau of Standards was established under the Standards Act (#4) of 1999 and started operations in April 2000. A broad-based 15-member Standards Council governs the affairs of the Bureau.

The Standards Act gives the Bureau the responsibility to facilitate the development and promotion of Standards and Codes of Practice for products and services for the protection of the health and safety of consumers and the environment as well as for industrial development in order to promote the enhancement of the economy of Dominica.

The Bureau develops Standards through consultations with relevant interest groups. In accordance with the provisions of the Standards Act, public comment is invited on all draft Standards before they are declared as Dominica National Standards (DNS).

The Bureau is a correspondent member body of the International Organization for Standardization (ISO), an affiliate member of the International Electro-technical Commission (IEC), and a member of the Caribbean Regional Organization for Standards and Quality (CROSQ). The Bureau is the local agent for foreign Standard Body, the American Standards for Testing and Measurement (ASTM). The Bureau also serves as the enquiry point for the World Trade Organization (WTO) on matters pertaining to the Technical Barriers to Trade (TBT) Agreement and is the Contact Point for Codex Alimentarius.

In accordance with good practice for the adoption and application of Standards, Dominica National Standards are subject to periodic review every five years.

Amendments

Amendment No.	Date of Issue	Text (s) Affected

DOMINICA NATIONAL STANDARD
GOOD MANUFACTURING PRACTICES (GMP) – FOOD PROCESSORS AND MANUFACTURERS – REQUIREMENTS
D-DNS 20: 202x

TECHNICAL COMMITTEE – NATIONAL FOOD & AGRICULTURE (NFA)

ORGANIZATION	REPRESENTIVE (S) *(Alternate)*
Dominica Manufacturers Association (DMA)	Lana Athanaze *Lucia Sandy* *Alleyna Robin (Chairperson)*
Caribbean Agriculture Research Institute (CARDI)	Dorian Etienne
DBOS Certification Unit	Heinrich Anselm
Dominica Association of Industry and Commerce (DAIC)	Kerwin Jno. Baptiste *Valerie Alexander*
Dominica Export Import Agency (DEXIA)	Lloyd Pascal *Bristol Lawrence*
Dominica Hucksters Association	Mandy Benjamin *Eric Frampton*
Dominica State College	Valda Joseph *Sharon Allicock-Joseph*
Environmental Health Department	Calma Louis *Ray Robinson*
Farmer	Culmore Shillingford
Farmer Association	Michael Warrington *Darnelle Paul*
Inter-American Institute for Cooperation on Agriculture (IICA)	Anthony Cyrille
Ministry with responsibility for Agriculture (Division of Agriculture)	Anna Mary Seraphine-Alexander *Trevorne Douglas*
Ministry with responsibility for Trade	Miranda Ackie *Cleve St. Jean*

TECHNICAL SECRETARY

Naomi Bannis-Sampson
Technical Officer – DBOS

TABLE OF CONTENTS

0.0 FOREWORD

0.1. This Dominica National Standard was adopted by the Bureau of Standards (the Bureau) of the Commonwealth of Dominica on _____ after the draft was finalized by the National Food & Agriculture (NFA) Technical Committee and has been approved by the Minister responsible for the Bureau.

0.2. This Standard became effective as a Voluntary Standard on the date notified by the Minister with responsibility for the Bureau of Standards in a Notice published in the Commonwealth of Dominica Official Gazette on _____.

0.3. In preparing this standard, assistance has been derived from:

(a) Basic Good Manufacturing Practices Program Canada 2012: Guidebook Version 1.0

(b) Food and Drug Administration 2015: 21 CFR Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

(c) SQF Food Safety Code 2020: Food Manufacturing, Edition 9

1.0 SCOPE

1.1. This Dominica National Standard specifies the general principles for Good Manufacturing Practices (GMP) for Food Processors and Manufacturers.

2.0 TERMS AND DEFINITIONS

For the purpose(s) of this standard, the following definitions and/or abbreviations shall apply:

2.1. **Acid foods or acidified foods -** foods that have an equilibrium pH of 4.6 or below.

2.2. **Adulterated -** food that has been manufactured under such conditions that it is unfit for consumption; or that has been prepared, packed, or held under unsanitary conditions, whereby it may have become contaminated.

2.3. **Adequate -** that which is needed to accomplish the intended purpose in keeping with good public health practice.

2.4. **Allergen** - An allergen is an otherwise harmless substance that triggers an allergic reaction in sensitive individuals by stimulating an immune response.

2.5. **Allergen cross-contact -** the unintentional incorporation of a food allergen into a food.

2.6. **Audit -** the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

2.7. **Blanching -** except for tree nuts and peanuts, is a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

2.8. **Corrective action** – the measures taken to fix a problem, control a hazard, dispose of tainted/damaged products and prevent the problem from happening again.

2.9. **Defect action level -** a level of a non-hazardous, naturally occurring, unavoidable defect which may regard a food product as “adulterated”.

2.10. **Food allergen -** Proteins in foods or derivatives of them that cause abnormal immune responses.

2.11. **Food-contact surfaces -** are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

2.12. **Hazard -** any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

2.13. **Holding -** storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

2.14. **Lot -** the food produced during a period of time and identified by an establishment's specific code.

2.15. **Manufacturing/processing -** making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

2.16. **Microorganisms -** yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

2.17. **Monitor -** to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

2.18. **Packing -** placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food.

2.19. **Pathogen -** a microorganism of public health significance.

2.20. **Pest -** refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

2.21. **Quality Control** - process-focused set of operational techniques and activities—such as inspection, testing, and auditing—used to ensure products or services meet specific quality requirements and standards.

2.22. **Plant -** the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

2.23. **Rework -** clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

2.24. **Sanitize -** to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

2.25. **Supplier -** the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

2.26. **Water activity** (a_w) **-** is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

3.0 GENERAL REQUIREMENTS

3.1. Management Commitment

3.1.1. Management Responsibility

3.1.1.1. Management shall prepare and implement a policy statement that outlines at a minimum the commitment of management to:

(a) Supply safe food;
(b) Establish and maintain a food safety culture within the site;
(c) Establish and continually improve the site's food safety management system; and
(d) Comply with customer and regulatory requirements to supply safe food.

3.1.1.2. The policy statement shall be:

(a) Signed by the manager and displayed in prominent positions; and
(b) Effectively communicated to all site personnel in the language(s) understood by all site personnel

3.1.1.3. Management shall lead and support a food safety culture within the site that ensures at a minimum:

(a) Adequate resources are available to meet food safety objectives;
(b) Employees are informed and held accountable for their food safety and regulatory responsibilities;
(c) Employees are positively encouraged and required to notify management about actual or potential food safety issues; and
(d) Employees are empowered to act to resolve food safety issues within their scope of work.

3.1.1.4. Management shall ensure that the facility is registered or permitted as a food handling establishment as required by national regulations.

3.1.1.5. Management shall ensure that the facility has procedures for conducting self-audits to verify compliance with established internal policies and procedures.

4.0 INTERNAL AUDITS

4.1. The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the Food Safety System shall be documented and implemented.

4.2. Staff conducting internal audits shall be trained and competent in internal audit procedures.

4.3. Internal audits shall be conducted at least annually. The methods applied shall ensure:

(a) Correction and corrective action of deficiencies identified during the internal audits are undertaken; and

(b) Records of internal audits and any corrections and corrective action taken as a result of internal audits shall be maintained.

4.4. Management shall ensure that self-inspection of the entire facility and outside grounds are conducted at least monthly.

5.0 CUSTOMER COMPLAINTS

5.1. The facility shall have a customer complaint program.

5.2. The methods and responsibilities for handling and investigating the cause and resolution (corrective actions) of complaints from customers and authorities shall be documented and implemented.

5.3. Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.

5.4. Records of customer complaints and their investigations shall be maintained.

6.0. PRODUCT TRACEABILITY, WITHDRAWAL AND RECALL

6.1. There shall be written product traceability, withdrawal and recall program /procedures.

6.2. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs shall be recorded and maintained.

6.3. A product identification system shall be implemented to ensure that product is clearly identified during all stages of receipt, processing, handling, storage and dispatch.

6.4. Finished product shall be labelled to customer specification and/or regulatory requirements.

6.5. Lot identification shall be labelled on all finished product cases and be clearly legible.

6.6. A product traceability system shall be implemented to ensure finished product is traceable to the immediate next recipient (one up) and to the immediate previous supplier (one back).

6.7. Traceability records shall be readily available.

6.8. The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually.

6.9. Records shall be maintained of withdrawal and recall tests.

7.0. SPECIFIC REQUIREMENTS

7.1. Personnel

7.1.1. Qualification and Training

7.1.1.1. The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties.

7.1.1.2. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

(a) Meet the minimum national requirements for food handling;

(b) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties; and

(c) Be a qualified individual that has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.

7.1.1.3. Supervisory personnel shall have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

7.1.1.4. Records that document training of qualified individuals shall be established and maintained.

7.1.2. Disease control

7.1.2.1. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.

7.1.2.2. Personnel shall be instructed to report such health conditions to their supervisors.

7.1.3. Cleanliness

7.1.3.1. All persons 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 allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(a) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials;

(b) Maintaining adequate personal cleanliness;

(c) Washing hands thoroughly (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 workstation, and at any other time when the hands may have become soiled or contaminated;

(d) Removing all jewelry and other objects that might fall into food, equipment, or containers.

(e) Maintaining gloves in an intact, clean, and sanitary condition;

(f) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints;

(g) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed;

(h) 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; and

(i) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances.

NOTE: Microorganisms and foreign substances include perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

7.2. Facility & Grounds

7.2.1. Grounds

7.2.1.1. 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 adequate maintenance of grounds shall include:

(a) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(b) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed;

(c) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests;

(d) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed; and

(e) If the plant grounds are bordered by grounds not under the operator's control, and they are not maintained in a sanitary manner, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

7.2.2. **Plant construction and design.**

7.2.2.1. The plant shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes, that is manufacturing, processing, packing, and holding. The plant shall:

(a) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food; and

(b) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

7.2.1.2. Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(a) Using protective coverings;

(b) Controlling areas over and around the vessels to eliminate harborages for pests;

(c) Checking on a regular basis for pests and pest infestation; and

(d) Skimming fermentation vessels, as necessary.

7.2.1.3. Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair;

7.2.1.4. Drip or condensate from fixtures, ducts and pipes do not contaminate food, food-contact surfaces, or food-packaging materials;

7.2.1.5. Aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

7.2.1.6. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms

7.2.1.7. Provide adequate lighting in areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned

7.2.1.8. Provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

7.2.1.9. Provide adequate ventilation or control equipment to minimize dust, odors and vapors in areas where they may cause allergen cross-contact or contaminate food.

NOTE: Odors and vapors include steam and noxious fumes.

7.2.1.10. Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

7.2.1.11. Provide adequate screening or other protection against pests.

7.3. **Sanitary Operations**

7.3.1. **General maintenance**

7.3.1.2. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a clean and sanitary condition and shall be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against allergen, cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

7.3.2. **Substances used in cleaning and sanitizing; storage of toxic materials**

7.3.2.2. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement shall be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(a) Those required to maintain clean and sanitary conditions;

(b) Those necessary for use in laboratory testing procedures;

(c) Those necessary for plant and equipment maintenance and operation and;

(d) Those necessary for use in the plant's operations.

7.3.2.2. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

7.3.3. **Pest control**

7.3.3.2. Effective measures shall be taken regularly to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

7.3.3.3. Monitoring of effective pest control measures shall be conducted at least quarterly.

7.3.4. **Sanitation of food-contact surfaces.**

7.3.4.2. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned before and after use or as necessary to protect against allergen cross-contact and against contamination of food.

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

7.3.4.4. In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms 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. 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.

7.3.4.5. Single-service articles shall be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

NOTE: Single service articles such as utensils intended for one-time use, paper cups, and paper towels

7.3.5. **Sanitation of non-food-contact surfaces.**

7.3.5.1. Non-food-contact surfaces of equipment used in the operation of a food plant shall be cleaned as frequently as necessary and, in a manner, to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

7.3.6. **Storage and handling of cleaned portable equipment and utensils**

7.3.6.1. Cleaned and sanitized portable equipment with food-contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

7.4. **Sanitary facilities and controls**

7.4.5. Each plant shall be equipped with adequate sanitary facilities and accommodations including:

7.5. **Water supply**

7.5.5. The water supply shall be adequate for the operations intended and shall be derived from an adequate and potable source. Any water that contacts food, food-contact surfaces, or food-packaging materials shall be safe and of adequate sanitary quality.

7.5.6. Potable water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

7.6. **Plumbing**

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

(a) Carry adequate quantities of water to required locations throughout the plant;

(b) Properly convey sewage and liquid disposable waste from the plant;

(c) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition;

(d) 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; and

(e) Provided 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.

7.7. **Sewage disposal**

7.7.1. Sewage shall be disposed of into an approved sewerage system or disposed of through other adequate means.

7.8. **Toilet facilities**

7.8.1. Each plant shall provide employees with adequate, readily accessible toilet facilities. Toilet facilities shall be kept clean and shall not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

7.8.2. The location of the toilet facilities shall not pose a risk to food safety.

7.9. **Hand-washing facilities**

7.9.1. Each plant shall provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish potable water.

7.10. **Rubbish and offal disposal**

7.10.1. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, 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, food-packaging materials, water supplies, and ground surfaces.

7.11. **Equipment and utensils**

7.11.1. All plant equipment and utensils used in manufacturing, processing, packing, storage or holding of food shall be so designed and of such material and workmanship to be adequately cleanable and maintained to protect against allergen cross-contact and contamination.

7.11.2. Equipment and utensils shall be designed, constructed, used appropriately and maintained to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

7.11.3. Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

7.11.4. Food-contact surfaces shall be corrosion-resistant.

7.11.5. Food-contact surfaces shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

7.11.6. Food-contact surfaces shall be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

7.11.7. Food-contact surfaces shall be smooth and continuous and maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

7.11.8. Any equipment that does not come into contact with food and is used in areas where food is manufactured, processed, packed, or held shall be easily cleaned and kept in a sanitary condition.

7.11.9. 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 an appropriate clean and sanitary condition.

7.11.10. Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device to show the temperature accurately within the compartment.

7.11.11. Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate, precise, maintained, and adequate in number for their designated uses.

7.11.12. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

7.12. Processes and Controls

7.12.1. General

7.12.1.1. All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) shall be conducted in accordance with adequate sanitation principles (Section 7.3).

7.12.1.2. Appropriate quality control management systems shall be implemented to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

7.12.1.3. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned to this function.

7.12.1.4. Adequate precautions shall be taken to ensure that production procedures do not contribute to allergen cross-contact or contamination from any source.

7.12.1.5. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

7.12.1.6. All food that has become contaminated to the extent that it is adulterated shall be rejected, or if appropriate, treated or processed to eliminate the contamination.

7.12.2. **Raw materials and other ingredients.**

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

7.12.2.2. Raw materials and other ingredients shall be stored under conditions that will protect against allergen cross-contact, from contamination and to minimize deterioration.

7.12.2.3. Raw materials and other ingredients shall be washed or cleaned as necessary to remove soil or other contaminants.

7.12.2.4. Water used for washing, rinsing, or conveying food shall be potable. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

7.12.2.5. Raw materials and other ingredients shall either not contain levels of microorganisms that may render the food injurious to the health of 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.

7.12.2.6. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with internationally recognized food regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

7.12.2.7. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable internationally recognized food regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

7.12.2.8. Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework shall be identified as such.

7.12.2.9. 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 the raw materials and other ingredients from becoming adulterated.

7.12.2.10. Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against allergen cross-contact and against contamination.

7.12.2.11. Raw materials and other ingredients that are food allergens, and rework that contains food allergens, shall be identified and held in a manner that prevents allergen cross-contact.

7.12.3. **Manufacturing operations**

7.12.3.1. Equipment, utensils and food containers shall be maintained in an adequate condition through appropriate cleaning and sanitizing as necessary. Wherever necessary, equipment shall be taken apart for thorough cleaning.

7.12.3.2. All food manufacturing, processing, packing, and holding shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

7.12.3.3. Food that can support the rapid growth of undesirable microorganisms shall be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

7.12.3.4. Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity (a_w) that are taken to destroy or prevent the growth of undesirable microorganisms shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

7.12.3.5. Work-in-process and rework shall be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

7.12.3.6. Effective measures shall be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse.

7.12.3.7. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor shall be protected against allergen cross-contact and against contamination as necessary.

7.12.3.8. Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food shall be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

7.12.3.9. Adequate measures shall be taken to protect against physical hazards in food.

EXAMPLE:
glass, metal, plastic, wood, stones, bone

7.12.3.10. Food, raw materials, and other ingredients that are adulterated:

(a) Shall be disposed of in a manner that prevents contamination of other food; or

(b) If the adulterated food is capable of being reconditioned, it shall be:

(1) Reconditioned using a method that has been proven to be effective; or

(2) Reexamined and declared 'free of adulteration' before being incorporated into other food.

7.12.3.10. Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against allergen cross-contact and from contamination. Food shall be protected from contaminants that may enter the food.

7.12.3.11. In the preparation of food capable of supporting microbial growth, heat blanching should be applied when necessary.

7.12.3.12. Growth and contamination by thermophilic microorganisms in blanchers shall be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

7.12.3.13. Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time shall be treated or stored in such a manner that they are protected against allergen cross-contact and from contamination, and minimizing the potential for the growth of undesirable microorganisms.

7.12.3.14. Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

7.12.3.15. Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of water activity (a_w) for preventing the growth of undesirable microorganisms, shall be processed and maintained at a safe moisture level.

7.12.3.16. Food, such as 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.

7.12.3.17. When ice is used in contact with food, it shall be made from water that is potable and shall be used only if it has been manufactured in accordance with current good manufacturing practice.

7.12.4. Warehousing and distribution.

7.12.4.10. Storage and transportation of food shall be under conditions that will protect against allergen cross-contact and from biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

7.12.5. Holding and distribution of human food by-products for use as animal food.

7.12.5.10. Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, shall be held under conditions that will protect against contamination, including the following:

(a) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution shall be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(b) Human food by-products for use as animal food held for distribution shall be held in a way to protect against contamination from sources such as trash; and

(c) During holding, human food by-products for use as animal food shall be accurately identified.

7.12.5.2. Labeling that identifies the by-product by the common or usual name shall be affixed to or accompany human food by-products for use as animal food when distributed.

7.12.5.3. Shipping containers and bulk vehicles used to distribute human food by-products for use as animal food shall be examined prior to use to protect against contamination.

NOTE: shipping containers include totes, drums, tubs etc.

7.12.6. Defect action levels

7.12.6.1. The manufacturer, processor, packer, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

7.12.6.2. The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

7.12.7. General requirements applying to records

7.12.7.1. Records shall:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) Information adequate to identify the plant or facility (*e.g.*, the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code or batch number, if any.

7.12.8. Requirements for record retention

7.12.8.1. All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

7.12.8.2. Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

7.12.8.3. Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, shall be retained by the facility for at least 2 years after their use is discontinued.

EXAMPLE

previous versions of a food safety plan

7.12.8.4. Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

7.12.8.5. The food safety plan shall remain onsite.

NOTE: Electronic records are considered to be onsite if they are accessible from an onsite location.

7.12.8.6 . If the plant or facility is closed for a prolonged period, the food safety plan should be transferred to some other reasonably accessible location but shall be returned to the plant or facility within 24 hours for official review upon request.

Dominica Bureau of Standards

Dominica Bureau of Standards is a statutory body established under the Standards Act No. 4 of 1999 to establish, promote and maintain Standards for:

a. Improving goods and services produced or used in Dominica;
b. Processes and practices for ensuring industrial efficiency and development;
c. Public and industrial welfare, health and safety;
d. Safeguarding the environment.

The National Standard Council

The National Standard Council (NSC), a fourteen (14) member Council representing various interest groups, is appointed by the Minister responsible for the Dominica Bureau of Standards yearly, to guide the policy decision matters of the Bureau and oversee its financial management. The Council is also responsible for the general administrative affairs of the Dominica Bureau of Standards.

-- END OF DOCUMENT --

Dominica Bureau of Standards
National Centre of Testing and Excellence
P.O. Box 1015, Stockfarm, Roseau
Commonwealth of Dominica, W.I.
Tel.: 767-235-1592
Email: info@dominicastandards.org

ICS 67.020