

FEDERATED STATES OF MICRONESIA

DEPARTMENT OF HEALTH AND SOCIAL AFFAIRS

REGULATIONS FOR FOOD SAFETY STANDARDS

DHS REGULATION NO. 7- August 2021

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PART 1 GENERAL PROVISIONS

1.1 Authority. These regulations have been promulgated and issued by the Secretary of the Department of Health and Social Affairs pursuant to the authority granted to the Secretary under Section 1025 and 1030 of Title 41 of the Code of the Federated States of Micronesia, as amended by Public Law No. 20-142. Once properly promulgated, these Regulations and any amendments thereto shall have the force and effect of law. Pursuant to Public Law No. 20-142, the Secretary shall give notice of the proposed regulations to the affected industry and shall conduct at least one public hearing no sooner than 10 days after notification. The Secretary of Health and Social Affairs shall also consult with the Secretary of Resources and Development.

1.2 Purpose. The purpose of these Regulations is to protect the health of the public from unsafe food and to protect consumers from deception and food of unacceptable and poor quality, by establishing minimum standards for food products. These Regulations apply to food imported into, or produced and processed in Federated States of Micronesia for export/re-export or domestic consumption.

1.3 Definitions. In addition to the definitions under Section 1003 of the FSM Code (the National Food Safety Act, Public Law 7-116), as amended, the following terms and phrases shall have the following meanings for the purposes of these Regulations unless the context otherwise requires:

“claim” means any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality;

“Codex Alimentarius” means standards, codes of practice, guidelines and other texts developed and maintained by the Codex Alimentarius Commission, a body established in 1963 by the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO);

“Competent Authority” means the official authority charged with the control of these Regulations. The national Competent Authority shall also be taken to mean “the seafood verification unit” under the Act.

“Competent Authority Inspector” means those individuals appointed by the Secretary of Health and Social Affairs to be National Food Inspectors who have been trained and qualified to administer and enforce the provisions of the National Food Safety Act. May also be referred to as “competent authority officers or fish inspectors”

"Consumer" means persons and families purchasing and receiving food in order to meet their personal needs;

“container” means any packaging of food for delivery as a single item, whether by completely or partially enclosing the food and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer;

“date of manufacture” means the date on which the food becomes the product as described;

“date of minimum durability” (“best before”) means the date which signifies the end of the period under any stated storage conditions during which the product will remain fully marketable and will retain any specific qualities for which tacit or express claims have been made, however, beyond the date the food may still be perfectly satisfactory;

“date of packaging” means the date on which the food is placed in the immediate container in which it will be ultimately sold;

"disinfection" means the reduction, without adversely affecting the food, by means of hygienically satisfactory chemical agents or physical methods, of the number of microorganisms to a level that will not lead to harmful contamination of food;

“establishment” means any premises or facilities where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auctions which only display and sale by wholesale take place are not deemed to be an establishment;

"Factory vessel" means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing;

"Freezer vessel" means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging;

"Fresh fishery products" means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling;

“Fishery products” means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals;

“food hygiene” means all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain;

“food safety” means assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use;

“HACCP” means Hazard Analysis and Critical Control Point as defined by the Codex Alimentarius;

“incidental constituent” means any extraneous substance, toxic substance, pesticide, or animal remedy that is contained or present in or on any food; but does not include any preservative, antioxidant, coloring substance, artificial sweetener, flavoring, food conditioner, anticaking agent, gaseous packing agent, propellant, or vitamin, or any mineral other than copper, zinc, selenium, and fluorine;

“industry standards” means a set out the minimum standard to be met by food business operators & the standard to which CA officers should use to audit establishment’s food safety performance.

“lot” means a quantity of food manufactured, processed, prepared and packed under the same conditions during a particular time.;

“national control plan” means a document outlining the organization, legality & process and procedures that define how a National Competent Authority performs their obligated official control duties.

“nutrient content claim” means a claim that describes the level of a nutrient contained in a food such as, but not limited to, "source of calcium"; "high in fibre and low in fat";

“nutrient comparative claim” means a claim that compares the nutrient levels or energy value of two or more foods such as, but not limited to, "reduced"; "less than"; "fewer"; "increased"; "more than";

“nutrient function claim” means a health claim that describes the physiological role of the nutrient in growth, development and normal functions of the body;

“nutrient supplement” means any mineral, vitamin, essential, amino acid or essential fatty acid which, when added either singly or in combination of food, improves or enriches the nutrient content of the food;

“packaged” means packed in a container;

“potable water” means fresh water fit for human consumption. Standards of potability should not be lower than those contained in the latest edition of the "International Standards on Drinking Water" of the World Health Organization (WHO);

“unsanitary condition” means such condition as could cause contamination of a food with dirt or filth, or could render the food injurious or dangerous to health, whether such contamination or injury or danger actually occurs or not.

“re-labelling” means the new labels provided by the supplier in response to the corrective action issued by food inspector after a physical assessment of imported foods and accompanying the food.

“sanitation” means the hygienic disposal or recycling of waste;

“Seafood verification Unit” means the Unit set up under the Act shall act to act as the competent authority for the purpose of implementing the international food safety requirements and related obligations of the Federated States of Micronesia on fish and fishery products.

“Seafood Establishments” means any premise or facility where fishery products are prepared, processed, chilled, frozen, packaged or stored for human consumption. It also includes the harvesting of fish and fishery products from original sources.

“unsanitary condition” means such condition as could cause contamination of a food with dirt or filth, or could render the food injurious or dangerous to health, whether such contamination or injury or danger actually occurs or not.

“use-by date” (recommended last consumption date, expiration date) means the date which signifies the end of the estimated period under any stated storage conditions, after which the product probably will not have the quality attributes normally expected by the consumers after this date, the food shall not be regarded as marketable.

Part 2 AUTHORIZED OFFICERS AND INSPECTORS

2.1 Qualifications of Authorized Officers

(2.1.1) In accordance with the Act that requires the prescription of the minimum qualifications for persons to be authorized officers to administer and enforce the provisions of the Act, the minimum qualifications shall be:

- (a) the Diploma in Public Health inspection or its equivalent and/or any recognized and equivalent food related qualification,
- (b) a degree in food science or technology or its equivalent, and
- (c) satisfactory completion of an in-service/certification training course provided by the Secretary for Health or his/her nominated authorized officer.

(2.1.2) For officers of the Seafood Verification Unit, they will further require to have some basic knowledge on Fish and Fisheries products inspection and competencies that are prescribed under the National Control Plan.

PART 3 GENERAL FOOD STANDARDS

3.1 Application of Codex Standards

(3.1.1) The Codex Alimentarius is adopted and forms part of these regulations together with any future amendments to the Codex Alimentarius made by the Commission.

(3.1.2) The provisions of the Codex Alimentarius adopted under subpart (3.1.1) may be amended or be replaced by a provision in these regulations.

(3.1.3) If there is a conflict between the regulations and the Codex Alimentarius, these regulations prevail.

(3.1.4) Where the provisions of the Codex Alimentarius adopted under subpart (3.1.1) refer to national laws or customs, a standard may be prescribed in regulations made under these regulations to prescribe national requirements.

(3.1.5) Where no Standard has been defined for any product under these regulations, the relevant Codex Standard shall be taken, subject to any variation prescribed under these regulations, to be the relevant Standard which must be met.

(3.1.6) Where no Standard has been defined for any product under these regulations, the relevant Codex Standard shall be taken, subject to any variation prescribed under these regulations, to be the relevant Standard which must be met.

(3.1.7) No food may contain incidental constituents at levels that make the food potentially unsafe for human consumption.

(3.1.8) Despite the generality of subpart (3.1.6), the maximum levels of contaminants in food that shall be permitted in food shall be those limits specified by the Codex Alimentarius unless a different limit is specified by these regulations.

3.2 Relationship with National Control Plan and Industry Standards

(3.2.1) The National Control Plan and the Industry Standard is adopted as legal and official documents that govern the operation of the Federated States of Micronesia Competent Authority/ Seafood Verification Unit.

(3.2.2) The National Control Plan and the Industry Standard shall be reviewed annually to ensure that it is consistent with the changes in the overseas market access requirement

3.3 Food which is unsafe and unfit for consumption

(3.3. 1.) A food is deemed to be unsafe and unfit for consumption if the food:

- (a) might cause death if it is consumed;
- (b) contains material that might endanger human life or cause death if consumed;
- (c) might directly or indirectly result in injury, illness or any other adverse health effect;
- (d) might constitute a cumulative health hazard, in that the health of a person consuming it in ordinary quantities may be severely impaired in the long run;
- (e) bears or contains any toxin, or any poisonous, deleterious substance, or any agent of infection which might render the food injurious or dangerous to health;
- (f) has been prepared, packed, kept or conveyed under unsanitary conditions which might render the food injurious or dangerous to health;
- (g) is wholly or partly damaged, infested, putrid, rotten, decomposed or decayed;
- (h) is wholly or partly the product of a diseased animal, or one which has died naturally and has not been slaughtered when slaughtering is the practice;

(i) contains any matter foreign to the nature of food such as filth, dirt, insect, vermin, excreta or similar matter, which makes it unsafe or unfit for consumption.

3.4 Food which is adulterated

(3.4.1) For the purpose of this Act, a food is deemed to be adulterated if:

- (a) by its labelling or otherwise the food is represented as being a particular type of food but the food contains or is mixed or diluted with any inferior or cheaper substance;
- (b) any constituent of the food has been wholly or partly extracted or removed so that its properties as compared with the food in a whole and pure state are diminished;
- (c) the food is in a package but the contents of the package as originally packed have been wholly or partly removed or replaced by any other component;
- (d) the food bears or contains any substance which is prohibited or not permitted in general or by Codex in relation to that food;
- (e) is more than the maximum amount permitted in relation to that food;
- (f) is known to be harmful, or the amount of which is known to be excessive in relation to that food;
- (g) the food does not comply with the prescribed standards or prescribed specifications in relation to such food; or,
- (g) the food is made to appear better or to have greater value than it really has, unless such processing is specifically permitted in regard to that food.

3.5 Specific Limits on Chemical Contaminants

(3.5.1) Without prejudice to the general regulations on contaminants outlined in Part 3.3, the limits on chemical contaminants specified in Schedule 1 shall be specifically applied on product imported into and produced and processed in Federated States of Micronesia for consumption.

(3.5.2) Any product shall be considered to be non-compliant with these Regulations when any one sample unit contains a chemical contaminant that exceeds the level specified in the Schedule to subpart (2.4.1).

3.6 Pesticide Residues

(3.6.1) The maximum levels of pesticide residues in food that shall be permitted in Federated States of Micronesia shall be those limits specified by the Codex Alimentarius.

(3.6.2) Any product shall be considered to be non-compliant with these Regulations when any one sample unit contains a residue that exceeds the level specified by the Codex Alimentarius.

3.7 Veterinary Drug Residues

(3.7.1) The maximum levels of veterinary drug residues in food that shall be permitted in Federated States of Micronesia shall be those limits specified by the Codex Alimentarius.

(3.7.2) Any product shall be considered to be non-compliant with these Regulations when any one sample unit contains a residue that exceeds the level specified by the Codex Alimentarius.

3.8 Microbiological Criteria

(3.8.1) Food products for sale shall comply, prior to import, at the point of import, and at the point of sale, with the microbiological criteria established in Schedule 2.

(3.8.2) Food importers shall be responsible for ensuring that food imported into Federated States of Micronesia complies with the microbiological criteria established by subpart (3.6.1) prior to importation and, where required by an authorized officer, at the point of import.

3.9 Food Additives

(3.9.1) No food additive may be used in any food imported or sold in Federated States of Micronesia unless permitted by this regulation.

(3.9.2) Unless otherwise prescribed in the Regulations, the additives permitted for use in a given product are those additives permitted for use in the Codex General Standard on Food Additives and the maximum level of each permitted additive in the final product is the maximum level that is permitted for use in that Standard.

(3.9.3) Where no national regulation or Codex Standard exists for additives to be used in a food, the processor or importer shall be required to demonstrate, to the satisfaction of the health authorities, the safety of the additives to be used for a particular product, prior to importation or processing of the product.

(3.9.4) Food business operators, including but not limited to processors and importers shall ensure that the additives present in a given food comply with the requirements of the Codex Alimentarius, unless otherwise prescribed in these Regulations.

3.10 Nutrient Supplements

(3.10.1) No person may import, manufacture, advertise for sale or sell any nutrient supplement other than a permitted nutrient supplement prescribed from time to time, by any standard under these regulations or, where no such standards are prescribed, in the Codex Alimentarius.

(3.10.2) No person shall import; manufacture advertise for sale or sell any food in which is present:

- (a) any nutrient supplement other than a permitted nutrient supplement; or
- (b) any permitted nutrient supplement at a concentration above the maximum permitted by standards established under the Act, from time to time, or, where no such standards are prescribed, then as prescribed by the Codex Alimentarius.

3.11 General Requirements on Labelling

(3.11.1) Pre-packaged food shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

(3.11.2) Pre-packaged food shall not be described or presented on any label or in any labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

(3.11.3) All pre-packaged food produced, processed, packed, distributed, or imported shall be labeled in English with the following information:

- (a) The name of food;
- (b) A list of ingredients;
- (c) The net contents or drained weight;
- (d) The name and address of the manufacturer or packer or distributor;
- (e) Country of origin;
- (f) Lot identification code;
- (g) Date marking and storage instruction; and,
- (h) Instruction for use.

(3.11.4) The name of the food:

- (a) shall indicate the true nature of the food; and
- (b) where a name or names have been established for a food in a Codex Alimentarius Standard, at least one of these names shall be used.

(3.11.5) There shall appear on the label, close to the name of the food, all additional words or phrases necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packing medium, style, and the condition or type of treatment it has undergone; for example: dried, concentrated, reconstituted, smoked.

(3.11.6) In relation to the ingredients in a food:

- (a) except for single ingredient foods, a list of ingredients shall be declared on the label;
- (b) the list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term 'ingredient';
- (c) all ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food;
- (d) cereals containing gluten; crustacean and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of these; milk and milk products (lactose included); tree nuts and nut products; and sulphite in concentrations of 10 mg/Kg or more are known to cause hypersensitivity and shall always be declared and be declared by their specific name;
- (e) added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients;
- (f) water or other volatile ingredients evaporated in the course of manufacture need not be declared;
- (g) dehydrated or condensed foods which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of proportion (m/m) in the reconstituted product provided that a statement such as "ingredients of the product when prepared in accordance with the directions on the label" is included;
- (h) a specific name shall be used for ingredients in the list of ingredients unless a general class name as permitted in the Codex General Standard on the Labeling of Pre-packaged Food would be more informative. In such circumstances, the permitted class names as laid out by the Codex General Standard on the Labeling of Pre-packaged Food, may be used;

- (i) ingredients derived from beef and pork including but not limited to pork fat, lard, and beef fat shall always be declared by their specific names;
- (j) for the identification of food additives, excluding those specified under (d) and (i), it shall be sufficient to list them under their respective classes as specified in the Codex General Standard on the Labeling of Pre-packaged Food together with the specific name or ISN numerical identification;
- (k) the presence of brain, heart, kidney, liver, tongue or tripe in a food, shall be declared either by class name of the offal or by the specific type of offal;
- (l) when a product is labeled as being in “natural oil”, the addition of water, whether declared or not, shall not be permitted such that the consumer is misled by the label as to the packing medium;
- (m) in case of mixed or blended food, words which indicate that the contents are mixed or blended, as the case may be, and such word shall be conjoined with the appropriate designation of the food “mixed” or “blended.....”; and,
- (n) where, the food or its ingredients have been purposefully exposed to ionizing radiation, the statement or declaration indicating that the food or its ingredients has or have been treated with ionizing radiation.

(3.11.7) In relation to the declaration of the net contents:

- (a) the net contents or drained weight shall be declared in metric system (‘System International’ unit) or both in metric and imperial system;
- (b) for solid foods by weight, for liquid foods by volume; and,
- (c) for semi-solid or viscous foods, either by weight or volume.

(3.11.8) In relation to 3.11.3 (d), the name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.

(3.11.9) In relation to the country of origin:

- (a) The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.
- (b) When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

(3.11.10) With respect to lot identification, each container shall be permanently marked to identify the producing factory and the lot.

(3.11.11) In relation to date marking and storage conditions:

- (a) the expiration date shall be declared on all food where the food shall be consumed before a certain date because of health and safety reasons;
- (b) the expiration date shall be declared by the words “use-by ...” or “expiry date ...” or “expiration date...” or “exp ...” and these words shall be accompanied by the date itself in uncoded numerical sequence except that the month may be indicated by letters;
- (c) the date of minimum durability shall be declared on all food where an expiration date is not required unless otherwise exempted by these and subsequent regulations;
- (d) the date of minimum durability shall be declared by the words “best before ...” or a

“use by...” and these words shall be accompanied by the date itself in uncoded numerical sequence except that the month may be indicated by letters;

- (e) the expiration date or the date of minimum durability shall consist at least of the day and the month for products with a minimum durability of not more than three months or the month and the year for products with a minimum durability of more than three months;
- (f) an indication of the date of minimum durability or expiration date shall not be required for fresh fruits and vegetables which have not been peeled, cut or similarly treated;
- (g) in addition to the date of minimum durability or expiration date, any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon;
- (h) an indication of the date of minimum durability or expiration date shall not be required for bread with a shelf life of less than 7 days. Such food shall bear a label with the words “baked-on ...” and these words shall be accompanied by the date itself in uncoded numerical sequence;
- (i) an indication of the date of minimum durability or expiration date shall not be required for packed fresh meat, fish or poultry with a shelf life of less than 7 days. Such food shall bear a label with the words “packed-on ...” and these words shall be accompanied by the date itself in uncoded numerical sequence; and,
- (j) shelf stable food, including but not limited to certain canned food, with a minimum durability of 3 years shall be deemed to have met date marking requirements of these Regulations if it bears the date of manufacture and a statement as to the minimum durability.

(3.11.12) Instructions for use, including reconstitution, where applicable, shall be included on the label, as necessary, to ensure correct utilization of the food.

(3.11.13) For non-retail containers not destined to final consumers, the name of the product, lot identification, net contents and the name and address of the manufacturer, packer, distributor or importer, as well as storage instructions, shall appear on the container, except that for tankers the information may appear exclusively in the accompanying documents.

(3.11.14) Notwithstanding subpart (3.9.12), lot identification, and the name and address of the manufacturer, packer, distributor or importer on non-retail containers may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

3.12 Product Specific Labelling Requirements

(3.12.1) Milk which has been manufactured by recombination or reconstitution shall be labeled as “Recombined milk” or “Reconstituted milk” or another truthful qualifying term if the consumer would be misled by the absence of such labeling;

(3.12.2) It shall be an offense to label a food in such a manner that the consumer could be reasonably misled that the food is “fresh milk” when the product has been prepared by reconstitution, recombination or any other similar process or when it does not comply with the other requirements of the Regulations.

3.13 Presentation of Mandatory Labelling

The following requirements must be met in relation to the labeling of pre-packaged foods: labels in pre-packaged foods shall be applied in such a manner that they will not become separated from the container;

- (A) statements required to appear on the label by virtue of this regulation shall be clear, where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper or not obscured by it;
- (B) the name and net contents of the food shall appear in a prominent position and
- (C) the same field of vision;
- (D) the information on a label shall at least be in the English language and it is an offence for prepackaged foods to be imported with only foreign language.
- (E) in the case of either re-labelling, the information provided shall fully and accurately reflect that in the original label.

3.14 Prohibited Claims

The following claims shall be prohibited:

- (A) claims stating that any given food will provide an adequate source of all essential nutrients, except in the case of well-defined products for which a Codex Standard permits such claims as admissible claims;
- (B) claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients;
- (C) a claim that encourages or condones excessive consumption of any food or contradicts good dietary practice;
- (D) claims which cannot be substantiated;
- (E) nutrition claims and health claims for foods for infants and young children except where specifically provided for in relevant regulations;
- (F) claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition, unless they are in accordance with the provisions of Codex Standards or guidelines and follow the principles set forth in these guidelines;
- (G) claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer; and,
- (H) a claim that a food has obtained an increased or special nutritive value by means of the addition of nutrients, such as vitamins, minerals and amino acids shall be permitted only if such an addition has been made on the basis of nutritional considerations according to the Codex General Principles for the Addition of Essential Nutrients to Foods.

3.15 Use of Nutrient Content Claims, Nutrient Comparative Claims, Nutrition Claims and Health Claims

- (3.15.1) The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, and sodium, and vitamins and minerals for which Nutrient Reference Values have been laid down in the Codex Alimentarius unless otherwise permitted by these Regulations.

(3.15.2) When a nutrient content claim that is listed in Schedule 3 is made, the claim shall be consistent with the Schedule

(3.15.3) Nutrient comparative claims shall be permitted only where:

- (A) the comparison is to the same or similar food; and
- (B) a statement of the amount of difference in the energy value or nutrient content is given.

(3.15.4) Health claims shall be permitted provided that all of the following conditions are met:

- (A) Proof shall be sufficient to substantiate the type of claimed effect as recognized by appropriate scientific review of the data;
- (B) Claims consist of both information on the physiological role of the nutrient or on an accepted diet-health relationship and associated composition information;
- (C) The claimed benefit shall arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet;
- (D) A validated method to quantify the food constituent that forms the basis of the claim is available; and,
- (E) The following information appears on the label or labeling of a food bearing health claims:
 - (i) a nutrient declaration at least complying with the nutrition labeling requirements specified by the Codex Alimentarius;
 - (ii) a statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim;
 - (iii) the target group, if appropriate;
 - (iv) how to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate;
 - (v) if appropriate, advice to vulnerable groups on how to use or to avoid using the food;
 - (vi) maximum safe intake of the food or constituent where necessary;
 - (vii) how the food or food constituent fits within the context of the total diet;
 - (viii) a statement on the importance of maintaining a healthy diet;
 - (ix) claims that relate to dietary guidelines or “healthy diets” shall only be permitted where they are consistent with any national dietary guidelines;

- (x) where the claim is not based on selective consideration of one or more aspects of the food; and,
- (xi) where the food is not described as “healthy” or represented in a manner that implies that a food in and of itself will impart health.

(3.15.5) A claim to the effect that a food is a good source of a vitamin or mineral may be made if the food contains no less than 25% of the recommended daily intake for that vitamin or mineral.

(3.15.6) A claim regarding the food being fortified shall only be permitted where the food has been approved by the health authorities as being suitable for such and shall not include food considered by the health authorities to be high in sugars, fat or salt, with the exception of fortified salt itself.

3.16 Packaging

(3.16.1) Materials and processes used for packaging, including wrapping, shall not be a source of contamination to the food.

(3.16.2) Packaging, including wrapping, shall be stored in such a manner that they are not exposed to a risk of contamination.

(3.16.3) Cartons used to package eggs may not be reused.

(3.16.4) When food business operators retail raw meat and poultry direct to consumers such meat and poultry shall be packaged such that the packaging prevents contamination of the meat and poultry and prevents the meat and poultry from contaminating other food. Such packages shall be labeled in accordance with the mandatory labeling requirements of these Regulations.

(3.16.5) While not limiting the generality of subpart (3.14.4), butcher shops and retailers need not package meat and poultry for display for sale provided such meat and poultry are not potentially subject to consumer handling. Upon selling the meat and poultry direct to consumers butchers shall package the food in packaging that prevents contamination of the meat and poultry and prevents the meat and poultry from contaminating other food.

3.17 Offences

3.17.1 Any food business operator or any person who prepares, processes, manufactures, packs, keeps, conveys, imports or sells any food that:

- (a) is in a manner which is unsafe and unfit for human consumption;
- (b) have been adulterated;
- (c) stores, advertises for sale, displays for sale or sells a food past its-expiration (use-by date);
- (d) advertises for sale, displays for sale or sells a food past its date of minimum durability (best before) or the quality has deteriorated to such an extent that, in the opinion of an authorized officer, a consumer would be misled as to the quality of the food;

- (e) advertises for sale, displays for sale or sells a food past its baked on date or the quality has deteriorated to such an extent that, in the opinion of an authorized officer, a consumer would be misled as to the quality of the food;
- (f) intentionally remove and replace expiration date (use-by date) or date of minimum durability (best before) or bake on dates in order to continue the sales of the food product(s);
- (g) stores or displays for sale a food in a manner contrary to storage requirements prescribed on its label or associated labeling;
- (h) labels on pre-packaged products are all in foreign language;
- (i) importers not in compliance with re-labelling conditions; or,
- (j) contrary to the other requirements prescribed in Part 3 of these Regulations, for which no offence or penalty is prescribed commits an offence and is liable to pay prescribed penalties or serve imprisonments specified in Schedule 13 of this regulation.

3.18 Applying HACCP

(3.18.1) All businesses involved in the handling of food for export to countries requiring HACCP to be in place for such food and in such food operations shall have a documented HACCP system and be applying HACCP as required:

- (a) prior to approval of the production and handling the food for subsequent export,
- (b) as soon as required by the Competent Authority in the country to which the food will be exported, in cases where a transitional period is permitted.

(3.18.2) All food business requiring health certificates for exports including fish and fishery product shall have in place a food safety program based on HACCP principles and is approved by the competent authority empowered under this regulation or their flag state in case of vessels.

(3.18.3) All HACCP plan should be submitted to the Competent Authority office for assessment and approval on an annual basis. License for any establishment shall only be granted on the approval of HACCP.

(3.18.4) All HACCP plan have to follow and or adopt the format and standard prescribed under Codex.

3.19 Other Standards

Specific standards relating to the sourcing, handling, processing, storage, transport and distribution of food may be set by the Secretary for Department of Health and Social Services under the Act and these Regulations.

PART 4 COMMODITY STANDARDS

4.1 Requirements for Different Commodities

Meat and meat products

(4.1.1) Meat and meat products produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall

comply with the requirements prescribed in Schedule 4, unless otherwise required by the importing country's competent authorities for food for export.

Poultry and poultry products

(4.1.2) Poultry, poultry products and eggs produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 5, unless otherwise required by the importing country's competent authorities for food for export.

Fish and fisheries products

(4.1.3) Fish and fisheries products produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 6, unless otherwise required by the importing country's competent authorities for food for export.

Frozen fish and fisheries products

(4.1.4) Fish and fisheries products produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 7, unless otherwise required by the importing country's competent authorities for food for export.

Cereal and cereal products

(4.1.5) Cereal and cereal products produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 8, unless otherwise required by the importing country's competent authorities for food for export.

Salt and spice

(4.1.6) Salt and spice produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 9, unless otherwise required by the importing country's competent authorities for food for export.

Fats and Oil

(4.1.7) Fats and Oil produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 10, unless otherwise required by the importing country's competent authorities for food for export.

Sugars and honey

(4.1.8) Sugars and honey produced, processed, handled, kept, distributed, displayed for sale or sold in FSM or imported into or exported from FSM shall comply with the requirements prescribed under in Schedule 11, unless otherwise required by the importing country's competent authorities for food for export.

Beverage

(4.1.9) Beverage produced, processed, handled, kept, distributed, displayed for sale or sold in or imported into or exported from Federated States of Micronesia shall comply with the requirements prescribed in Schedule 12, unless otherwise required by the importing country's competent authorities for food for export.

4.2 Offences

4.2.1 Any food business operator or any person who produces, processes, handles, keeps, distributes, displays food for sales or sold in or imported into or exported from Federated States of Micronesia contrary in a manner to the requirements prescribed in Part 4 of these Regulations commits an offence and is liable to pay prescribed penalties or serve imprisonment terms specified in Schedule 13 of this regulation.

PART 5. FOOD SAFETY STANDARDS- GENERAL REQUIREMENTS ON GOOD HYGIENE PRACTICES FOR ALL FOOD BUSINESS

5.1 Obligations of Food Business Operators Regarding Good Hygienic Practices

All food business operators shall ensure that good hygienic practices as prescribed in this Part shall be applied at all stages of production, processing, handling, storage and distribution of food under their control.

5.2. General

(5.2.1) Premises shall be located, designed and constructed in a manner that is not likely to contaminate food and that prevents pest and animal access and harborage.

(5.2.2) Premises shall be in good repair and condition.

(5.2.3) Premises, utensils and equipment shall be kept clean.

(5.2.4) Adequate facilities shall be available to maintain personal hygiene.

(5.2.5) An adequate supply of safe water shall be available wherever water or ice is required for food business operations.

(5.2.6) Adequate facilities shall be available to hygienically store and dispose of waste.

(5.2.7) Facilities shall be adequate to ensure proper temperature control of food, where required.

5.3 Location of Premises

(5.3.1) Food business premises shall be located away from:

- (A) environmentally polluted areas and industrial activities which may lead to contamination of food;
- (B) areas subject to flooding unless sufficient safeguards are provided;
- (C) areas prone to infestations of pests; and,
- (D) areas where wastes, either solid or liquid, cannot be removed effectively.

(5.3.2) Where a flood has occurred and food business premises have been affected, no food shall be moved or sold from the premises without permission of authorized officers who shall conduct an inspection to determine the safety or otherwise of such food for salvaging and possible future sale.

5.4 Location of Equipment

Equipment in food premises shall be located so that it:

- a) permits effective maintenance and cleaning; and,
- b) functions properly.

5.5 Design and Layout of Premises

(5.5.1) The internal design and layout of food establishments shall permit good hygienic practices, including protection against cross-contamination from raw or semi-processed food to ready-to-eat food.

(5.5.2) While not limiting the generality of subpart (5.5.1), the internal design and layout of food establishments shall provide adequate working space to allow for the hygienic performance of all operations.

(5.5.3) No room used in food processing, preparation of food, food handling, storage of food, or display of food, shall be used for domestic purposes or located such that it directly opens into a room used for domestic purposes, including but not limited to sleeping.

5.6 Internal Structures and Fittings

(5.6.1) Structures within food establishments shall be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected.

(5.6.2) While not limiting the generality of subpart (5.6.1), the following specific conditions shall be satisfied where necessary to protect the safety of food:

- (a) the surfaces of walls, partitions and floors shall be made of impervious and non-toxic materials;
- (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 buildup of dirt and where necessary, be fitted with removable and cleanable insect-proof screens.
- (f) doors shall have smooth, non-absorbent surfaces, and be easy to clean;
- (g) working surfaces that come into direct contact with food 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 food, to detergents and disinfectants under normal operating conditions; and,

(h) notwithstanding the generality of (5.6.2) (g), cutting boards may be made of wood where necessary for operational reasons provided the wood surface is maintained, and properly cleaned and disinfected after each use.

5.7 Equipment and Containers

Equipment and containers used in food premises shall be designed and constructed of non-toxic materials and shall be in sound condition, durable and easy to clean, maintain and disinfect.

5.8 Cooking Equipment and Associated Exhaust Systems

Cooking equipment and associated exhaust systems shall be designed and operated in such a manner as to:

- a) prevent a buildup of grease and soot in the kitchen; and,
- b) prevent any contamination of food that might arise from the burning of any fuel used for cooking.

5.9 Potable Water

(5.9.1) Unless expressly permitted in these Regulations, water used as an ingredient in the preparation of food or on surfaces on which food is prepared or on surfaces which may otherwise come into contact with food shall be potable water.

(5.9.2) Food businesses shall have adequate potable water available to ensure the safety of food.

(5.9.3) Non-potable water, for uses that will not contaminate food, including but not limited to flushing of toilets, shall have a separate system.

5.10 Ice

(5.10.1) A person shall not sell for human consumption or for use in contact with food for sale, ice produced from water that is not potable or not previously held at boiling temperature for a minimum of 10 minutes, where potable water is not available.

(5.10.2) A person shall not sell for human consumption, ice that has previously been in direct contact with food.

(5.10.3) A person handling ice for human consumption or for use as a coolant in direct contact with food shall not handle it in a manner likely, in the opinion of the health inspector or Food Inspector, to render it unsafe or unsuitable.

5.11 Drainage and Waste Disposal

(5.11.1) Adequate drainage and waste disposal systems and facilities shall be provided. They:

- a) shall be designed and constructed so that the risk of contaminating food or the potable water supply is avoided; and,

b) shall be designed so that they do not pollute the environment.

5.12 Cleaning Facilities

(5.12.1) Adequate facilities shall be provided for cleaning food, utensils and equipment. Such facilities shall have an adequate supply of potable water, including hot water where appropriate.

(5.12.2) Facilities for cleaning of raw meat, fish, poultry or other potentially high risk food shall be separate from any facilities used for washing salad vegetables or other ready-to-eat food, and separate from facilities for washing utensils and equipment.

5.13 Personnel Hygiene Facilities and Toilets

(5.13.1) Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food.

(5.13.2) Where appropriate, including but not limited to restaurants, bakeries, and food processing premises including vessels, suitably located facilities shall include:

- a) adequate means of hygienically washing and drying hands, including wash basins and an appropriate supply of water, including both hot and cold water where possible; and,
- b) toilets of appropriate hygienic design.
- c) hand washing facilities shall be non-hand operated

(5.13.3) In those premises where toilets are present, they shall:

- a. be available in sufficient number to ensure good hygiene is maintained;
- b. have adequate hand washing and drying facilities;
- c. be maintained in a hygienic manner;
- d. not open directly into rooms in which food is being processed, prepared or handled; and,
- e. be connected to an effective drainage system.

(5.13.4) Appropriate changing rooms with adequate facilities including lockers is provided in establishment where it deemed necessary by the competent authority and may include shower.

5.14 Air Quality and Ventilation

(5.14.1) Adequate means of natural or mechanical ventilation shall be provided, in particular to:

- a) minimize air-borne contamination of food and contamination of food from condensation;
- b) control temperatures and humidity; and,
- c) control odors which might affect the suitability of food.

(5.14.2) Ventilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas.

5.15 Lighting

(5.15.1) Adequate natural or artificial lighting shall be provided to enable the business to operate in a hygienic manner.

(5.15.2) All lights in food establishments shall be covered or protected.

5.16 Storage

(5.16.1) Where necessary, adequate facilities for the storage of food, ingredients and non-food items shall be provided.

(5.16.2) Food storage facilities shall be designed and constructed to:

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

(5.16.3) While not limiting the generality of subsection (2), storage facilities in premises of food businesses shall be organized such that:

- a) food is not stored in the same room as fuel or other chemicals, or in any manner that might enable chemicals to contaminate food;
- b) food is stored in an organized manner such that both a food handler and an authorized person can identify which food is closer to its use-by date or which food has been produced or processed most recently;
- c) non-food items are present only as necessary and storage facilities are not also used for storage of personal clothing, personal hygiene items, or other items unless these are stored separately from food and in a manner that doesn't increase the likelihood of food contamination or provide pest harborage; and,
- d) tools and cleaning materials are present only as necessary and are stored separately from food and food handling areas.

(5.16.4) Where non-food items are stored or displayed for sale in a retail or wholesale food business those non-food items shall be stored or displayed in a manner that ensures the food is effectively protected from contamination during storage. Where necessary, this may be taken to mean on separate shelves and in separate locations in the premises.

5.17 General Maintenance of Establishments and Equipment

Food premises and equipment shall be kept in an appropriate state of repair and condition to facilitate all sanitation procedures, to function as intended, and to prevent contamination of food.

5.18 Cleaning and Disinfection

(5.18.1) Food business operators shall implement cleaning and disinfection programs that shall be adequate to ensure that all parts of the establishment, its equipment and facilities are appropriately clean.

(5.18.2) While not limiting the generality of subpart (5.18.1), cleaning shall be adequate to remove food residues and dirt which may be a source of contamination to food.

(5.18.3) While not limiting the generality of subpart (5.18.1), no wall, floor, ceiling, fan, fixture, window, door, material, equipment, or utensil shall be permitted to be contaminated with dirt, dust, grease, or other material indicative of inadequate cleaning.

(5.18.4) When an operator has completed cleaning, including disinfection where necessary, the results of any testing of cleaned surfaces required by or undertaken by authorized officer shall meet any microbiological criteria established by the health authorities, in documented guidance on cleaning and sanitation for food business operators.

(5.18.5) Vehicles, vessels, conveyances and bulk containers for transporting food shall be kept in an appropriate state of cleanliness, repair and condition.

(5.18.6) Where the same vehicle, vessel, conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection shall take place between loads.

(5.18.7) 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 in such a manner as to avoid the risk of contaminating food, and as may be requested by an authorized officer for such purposes.

5.19 Vehicles, Vessels, Conveyances and Bulk Containers

Vehicles, vessels, conveyances and bulk containers for transporting food shall be designed and constructed so that they:

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

5.20 Time and Temperature Control

(5.20.1) Food businesses shall ensure that temperature of food is controlled effectively to protect food from hazards.

(5.20.2) Fresh meat, poultry, seafood and eggs shall be stored under refrigeration during storage and display in all food business operations.

(5.20.3) While not limiting the generality of subpart (5.20.1) and (5.20.2), no food containing meat, seafood, poultry, or milk, other than shelf-stable food, shall be held in a temperature zone of between 5°C and 60°C for more than 4 hours in total, prior to sale.

(5.20.4) The thawing of frozen food shall be undertaken in such a way as to minimize the risk of growth of pathogenic microorganisms or the formation of toxins in the foods.

(5.20.5) While not limiting the generality of subsection (5.20.4), the thawing process shall be carried out under refrigeration, through the use of microwaves, under running potable water, or any other method that the health authorities approves as not likely to result in a risk to health.

(5.20.6) While not limiting the generality of subsection (5.20.4) and (5.20.5), the thawing process for fish and fisheries products including the type of water used shall be approved by the Seafood Verification Unit. Thawing time for Scombroid species prior to pre-cooking shall be taken as first fish out of the cold store to the last fish into the pre-cooker and “steam on”.

(5.20.7) When power shortages are experienced because of supply problems, a food business shall protect the safety of the food by:

- (A) providing power generation facilities that are applied to the running of refrigerators and freezers; or,
- (B) using any other means that both ensures that refrigerators and freezers are able to maintain the temperature of the food at safe temperatures and protects the food from contamination.

(5.20.8) No freezer used to hold food for sale shall have excessive, in the opinion of authorized officers, buildup of ice which may limit the efficiency of the freezer.

(5.20.9) If power to a freezer or freezers is purposely turned off by a food business operator at any time of day or night, and food held in the freezer at the time of the power loss is subsequently offered for sale, the food may be seized and disposed of by authorized officers where there is concern for product quality or safety.

(5.20.10) If power to a freezer or freezers containing food for sale fails at any time of day or night, and food held in the freezer at the time of the power loss is subsequently offered for sale, the food may be seized and disposed of by authorized officers where there is concern for product quality or safety and evidence exists that the food has not been consistently held at least at or below minus 18°C.

(5.20.11) Vehicles or vessels used to transport meat, fish or poultry shall have adequate capacity to ensure frozen product remains frozen throughout the period of transportation and to ensure non-frozen raw meat, fish or poultry are maintained at temperature approaching that of melting ice.

5.21 Microbiological Cross-contamination

(5.21.1) Raw, unprocessed food shall be separated from ready-to-eat foods where to do otherwise could contaminate the ready-to-eat food.

(5.21.2) No surface, including, but not limited to, food handlers' hands, utensils, equipment, cloths, or tables, shall be used in a manner that could transmit microorganisms between raw meat, poultry or fish and ready-to-eat food.

(5.21.3) Surfaces, utensils, and equipment shall be thoroughly cleaned and disinfected after raw meat, poultry or fish has been handled or processed by, on or in them.

(5.21.4) While not limiting the generality of subpart (5.21.1), raw meat, raw fish, raw seafood, and raw poultry shall be stored in covered containers, in a manner that provides adequate protection from microbiological cross-contamination from these foods to other food.

(5.21.5) While not limiting the generality of subpart (5.21.1), no ice for consumption, ice cream or beverages, including but not limited to milk-based drinks and drinking water, shall be stored in the same freezer as any raw meat, raw fish, raw seafood, or raw poultry.

(5.21.6) In those food businesses where rice is cooked for consumption as a meal or component of a meal, to prevent the possible cross contamination between batches of rice, it shall not be permitted to add freshly cooked rice to a previously cooked batch of rice.

(5.21.7) To prevent the growth of microbial contaminants, utensils used to serve food, including but not limited to rice and ice cream, shall not be stored in water, unless that water is held at temperatures that can prevent pathogen growth.

5.22 Re-service of Food Prohibited

A person or business shall not serve, or permit to be served to a person, food that has been served to another person. This regulation does not apply to:

- (a) sugar, salt and condiments that has been put upon a table or counter provided that they are contained and continue to be contained in a protective receptacle; or,
- (b) food that has been completely wrapped or packaged when served and that has remained completely wrapped or packaged without damage to a seal.

5.23 Interference with Food Packages

(5.23.1) A person shall not in, at, or on a premises selling to the consumer, open or otherwise interfere with a package of food intended for sale in that package.

(5.23.2) A food business operator, where packages of food specified in subpart (5.23.1) are exposed for sale, shall display in prominent positions in, at, or on those premises an appropriate notice stating the requirement specified in subpart (5.23.1).

5.24 Restrictions as to Exposure of Food

(5.24.1) A person shall not display or expose for sale food in, at or on any doorway, street, lane, footpath, yard or other open place in a manner that doesn't protect it from contamination.

(5.24.2) While not limiting the generality of subpart (5.24.1), a person shall not display or expose for sale at a lower level than 750 millimeters above ground level, unless otherwise permitted by the appropriate enforcement agency.

(5.24.3) A person shall not deposit or allow or permit to be deposited in, at or on any doorway, street, lane footpath, yard or other open place:

(A) any food;

(B) any tray or like appliance used or intended for use in the conveyance of bread, cakes, pastry, pies or other food that is ordinarily consumed in the same state that in which it is sold.

5.25 Physical Contamination

(5.25.1) Food business operators shall ensure their operations prevent contamination of foods by foreign bodies such as, but not limited to, glass, hard plastic, wood, or metal pieces.

(5.25.2) While not limiting the generality of subpart (5.25.1), no food shall be handled underneath an uncovered light, or underneath a ceiling or overhead fixture in such a manner that might lead to contamination of the food with dust or other foreign matter.

5.26 Health Status of Food Workers

(5.26.1) People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, shall not be allowed to enter any food handling area if there is a likelihood of their contaminating food.

(5.26.2) While not limiting the generality of subpart (5.26.1), conditions which shall be included under subpart (5.26.1) shall include jaundice; diarrhea; vomiting; fever; sore throat with fever; visibly infected skin lesions (boils, cuts, etc.); or discharges from the ear, eye or nose.

(5.26.3) Any person specified in subpart (5.26.1) shall immediately report illness or symptoms of illness to the management of the food business employing them.

5.27 Personal Cleanliness

(5.27.1) Food handlers shall maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear.

(5.27.2) Cuts and wounds, where personnel are permitted to continue working, shall be covered by suitable, dry and clean waterproof dressings.

(5.27.3) Personnel shall always wash their hands when to do otherwise may affect food safety.

(5.27.4) Without limiting the generality of subpart (5.27.3), food handlers shall wash their hands:

- (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.

5.28 Personal Behavior

(5.28.1) People engaged in food handling activities shall refrain from behavior which could result in contamination of food.

(5.28.2) Without limiting the generality of subpart (5.28.1), food handlers, while present on food business premises, shall refrain from:

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

(5.28.3) Personal effects such as jewelry, watches, pins or other items shall not be worn or brought into food handling areas if they pose a threat to the safety of food.

(5.28.4) While not limiting the generality of subpart (5.28.3), no food handler shall wear any jewelry where the jewelry could come in contact with food.

5.29 Food Handler Training

(5.29.1) All newly employed food handlers shall, prior to starting work in a food business, be required to have undergone training.

(5.29.2) All training records shall be made available to the competent authority upon request in any audit and or inspection or verification visits.

5.30 Recall Procedures

(5.30.1) Food business operators shall ensure effective procedures are in place to enable the complete and rapid recall of any implicated lot of food from the market.

(5.30.2) Recalled products shall be held under supervision until they are destroyed, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

5.31 Offences

5.31.1 Any food business operator who does not ensure that good hygienic practices as prescribed in Part 5 of these Regulations and associated Schedules are applied at all stages of production, processing, handling, storage and distribution of food under their control commits an offence and is liable to pay prescribed penalties or serve imprisonment terms specified in Schedule 13 of this regulation.

PART 6. LICENSES

6.1 Premises engaged in food business operations

(6.1.1) All premises where food business operations engaging in the preparation, processing, keeping, packing, manufacturing, conveying, distributing and wholesaling for the purpose of exporting, importing, distributing at interstates for sales shall be licensed with a health license issued by Department of Health and Social Affairs in respect of such premises in accordance with the Act.

(6.1.2) No person shall operate a business if the premises are not licensed or if the license has been suspended or revoked under the Act.

(6.1.3) No person shall for the purpose of the sale or advertisement of the food to which the license applies refer to the license by any such descriptions (other than the special designation authorized by the license) as is likely to suggest that it is tested, approved or graded by any authorized officer.

(6.1.4) The holder of the health license shall:

(a) keep accurate record of the quantities of the raw materials and ingredients and products purchased and products sold and of the names and addresses of the persons from whom the raw materials and ingredients and products were purchased and to whom products were sold, except where the products are directly sold to the consumer;

(b) retain such records as referred to above for a period of six months longer than the expiration date of the product or the expected durability of the product, where an expiration date is not defined;

(6.1.5) Notwithstanding the generality of sub-regulation (6.1.4) food business operators in possession or health licenses for market stalls or mobile or temporary stalls or village retail only outlets shall not be required to maintain written records but shall be able to identify their suppliers to authorized officers upon request.

(6.1.6) Application for the issue or renewal of a health license shall be made in writing on using the prescribe forms.

(6.1.7) Applications under sub-regulation (6.1.6) shall be lodged, along with the fee to respective finance field offices in which the premises are located. Finance field offices are to collect fees and provide applications with a copied receipt to nearby office of the competent authority for inspection.

(6.1.8) Once the application and a copied receipt have been provided, an authorized officers of the food authority in which the premises are located shall cause an inspection to be made to assess compliance and that the food business operations to be conducted, or being conducted, on the premises comply with all requirements of the Act and its Regulations.

(6.1.9) Upon completion of the inspection specified in sub-regulation (6.1.8), authorized officer of the food authority in which the premises are located shall send the recommendations thereon to the Secretary for Health or his/her delegates with the application form and copy of the receipt and any such report as may be necessary.

(6.1.10) A health license shall be in the standard form provided under the logo of the National Government.

(6.1.11) Such further particulars shall be given by the applicant as the Competent Authority may reasonably require.

(6.1.12) The Secretary for Health or his/her delegates may refuse to issue or renew any health license:

(a) in respect of any application or of any premises which does/do not conform with the requirements of the Act and its Regulations; or

(b) of any applicant who during the period of twelve months immediately preceding the date of application for such issue or renewal had been convicted on at least two occasions of offenses against the Act and its Regulations.

(6.1.13) A health license shall, unless revoked or suspended, remain in force until 31 December next following the date on which it is expressed to come into force.

(6.1.14) The Secretary for Health or his/her delegate shall cause to be kept a register of health licenses issued, renewed, suspended, revoked and transferred.

(6.1.15) The Secretary for Health or his/her delegate may, on application in writing of the licensee, transfer the license to another person by endorsing thereon the name of the transferee and such particulars as may be necessary, consequent upon the transfer, provided that the Secretary for Health or his/her delegate may refuse to transfer a license to any person who during the period of twelve months immediately preceding the date of application for such transfer has been convicted on at least two occasions of offenses under the Act and its Regulations.

(6.1.16) If it appears that any premises, licensed by the Competent Authority to carry out any food business operations, are not maintained, kept or constructed in accordance with the provisions of these Regulations or the business operations on the premises do not otherwise comply with the Act and its Regulations, a food authority may order a business to close in accordance with the Act, until the premises and food business operations comply with the Act and its Regulations.

(6.1.17) If it appears that any premises licensed by the Food Authority to carry out any food business operations, are not maintained, kept or constructed in accordance with the provisions of these Regulations or the business operations do not otherwise comply with the Act and its Regulations, the Authority, after giving due notice of its intention to do so, and of the grounds of such intention, to the licensee, and after affording the licensee a reasonable opportunity of remedying any breach of the Regulations specified in such notice, may, on being satisfied that any such breach has not been remedied, revoke the license.

(6.1.18) The Food Authority shall give notice in writing of such revocation and of the date thereof to the licensee.

6.2 Licensing of Sea food establishments

(6.2.1) The Secretary for Health and Social Affairs may license any food business operator or person engages in the harvest, transportation, processing, manufacturing, chilling, freezing and storage of fish and fishery products for export and import purposes. The license issues may be single or multiple depending on the number of seafood establishments and the different type of seafood establishments undertaken by the applicant. The Secretary shall also have power to revoke license.

(6.2.2) Upon the receipt of the application from the Secretary for Health and Social Affairs or his or her delegates, Competent Authority officers shall inspect to verify compliances to Part 7 and other market access requirements prior recommending approval to Secretary.

(6.2.3) Approval to issue license or licenses shall only be granted provided there is no conformities identified by competent authority officers.

(6.2.4) Food business operators shall render all assistances needed to competent authority officers in order to facilitate approval processes.

(6.2.5) The amount of fees charged for Seafood establishments under 6.2.1 by the Secretary for Health and Social Affairs may be in accordance to prescribed license fees prescribed on Schedule 14.

6. 3 Offences

6. 2.1 - Any food business operator or person who operate a business without a valid health license issued by Department of Health and Social Affairs in respect of such premise in accordance with Part 6 of this regulation commits an offence and is liable to pay prescribed penalties or serve imprisonment terms specified in Schedule 13 of this regulation; or

6.2.2- Contravenes any other provision under Part 6 commits an offence and is liable to pay prescribed penalties or serve imprisonments specified in Schedule 13 of this regulation.

PART 7. STANDARD ON SPECIFIC GOOD HYGIENIC PRACTICES FOR FISH AND FISHERIES PRODUCTS

7.1 Scope; Definition

(7.1.1) This Standard applies to all fish and fisheries business operations involved in the catching, harvesting, landing, auctioning, processing, distributing, handling, importing and selling (export) of fish and fisheries products to be imported into Federated States of Micronesia, to be sold in Federated States of Micronesia and to be exported from Federated States of Micronesia.

(7.1.2) In this Standard, unless the context otherwise requires - "Clean sea-water" is sea-water which meets the same microbiological Standards as potable water and is free from objectionable substances.

(7.1.3) Where landing, auction and processing and distribution premises are constructed such that they would not comply with this Standard at the time these Regulations enter into force, food business operators shall be permitted a transitional period of up to 12 months, subject to the agreement of the Competent Authority, to upgrade the premises to achieve compliance, provided all precautions are taken in the transitional period to protect the safety and quality of the fish and fisheries products.

7.2 Environmental Conditions Related to Fish and Fisheries Products

(7.2.1) Authorized officers shall monitor the sanitary soundness of the fish and fisheries products, which means the presence of parasites, toxins, microbes, viruses, accidental and intentional contaminants present in the fish and fisheries products due to:

- (a) their natural presence in the aquatic environment; and,
- (b) the pollution of the aquatic environment and which could endanger human health.

7.3 Fishing and Harvesting Vessels - General Requirements

(7.3.1) Vessels and other facilities shall have a good supply of potable and or clean sea water at adequate pressure.

(7.3.2) All surfaces in handling areas shall be non-toxic, smooth impervious and in sound condition.

(7.3.3) Adequate facilities shall be provided for the handling and washing of fish and shellfish and vessels and other facilities shall have an adequate supply of cold potable water or clean sea water for that purpose.

(7.3.4) Suitable and adequate facilities shall be provided for storage and/or production of ice.

(7.3.5) All plumbing and waste lines shall be capable of coping with peak demand.

(7.3.6) Non-potable water lines shall be clearly identified and separated from potable water to avoid contamination.

(7.3.7) Objectionable substances, which could include bilge water, smoke, fuel oil, grease, drainage and other solid or semi-solid wastes, shall not contaminate the fish and shellfish.

(7.3.8) Where appropriate, containers for offal and waste material shall be clearly identified, suitably constructed with a fitted lid and made of impervious material.

(7.3.9) Adequate hand washing and toilet facilities, isolated from the fish and shellfish handling areas, shall be available where appropriate.

(7.3.10) Vessels and other facilities shall be designed and constructed so as to prevent the entry of birds, insects, or other pests, animals and vermin, where appropriate.

(7.3.11) Vessels shall be designed and constructed to minimize sharp inside corners and projections to avoid dirt traps and minimize damage to product, including but not limited to:

- a) In boxing and shelving storage areas, the design shall preclude excessive pressure being exerted on the fish and shellfish;
- b) Chutes and conveyors shall be designed to prevent physical damage caused by long drops or crushing;
- c) The fishing gear and its usage shall minimize damage and deterioration to the fish and shellfish;
- d) Where used, seines, nets and traps shall be carefully selected to ensure minimum damage during harvesting;
- e) Harvesting areas and all equipment for harvesting, catching, sorting, grading, conveying and transporting of live products shall be designed for their rapid and efficient handling without causing mechanical damage;
- f) Conveying equipment for live and slaughtered products shall be constructed of suitable corrosion resistant material which does not transmit toxic substances and shall not cause mechanical injuries to them;
- g) Where fish is transported live, care shall be taken to avoid overcrowding and to minimize bruising; and,
- h) Where fish are held or transported live, care shall be taken to maintain factors that affect fish health.

(7.3.12) For all vessels seeking competent authority and EU listing and also those that required certification of their products shall comply with additional requirements under the National Control plan and Industry standards.

7.4 Fishing and Harvesting Vessels - Specific Requirements

(7.4.1) Holds or other parts of the vessel where fish and fisheries products are stored shall:

- a) be covered and self-draining;
- b) be well insulated;
- c) have provision for holding an acceptable quantity of ice or have alternative means of refrigeration;
- d) not contain objects or products liable to damage or transmit harmful properties and abnormal characteristics to the food; and,
- e) be designed for ease of cleaning.
- f) Shall be designed nor equipped or used to carry fuel.

(7.4.2) Decks used for fish handling shall be constructed of materials that are easy to clean and disinfect impervious, rust resistant and durable.

(7.4.3) Where fish does not normally come into contact with the deck and the timber is clean, sound and well caulked, timber is allowed on exposed decks.

(7.4.4) The following conditions concerning handling and storage of fish and fisheries products on board vessels shall apply:

- a) as soon as they are taken on board, fish and fisheries products shall be protected from contamination and from the effects of the sun or any other source of heat;

- b) fish and fisheries products shall be handled and stored in such a way as to prevent bruising the use of spiked instruments shall be tolerated for the moving of large fish or fish that might injure the handler, provided the flesh of the products is not damaged,
- c) fish and fisheries products other than those kept alive shall undergo chilling or freezing as soon as possible after landing;
- d) where fish are headed and/or gutted on board, such operation shall be carried out hygienically and products shall be washed immediately and thoroughly with potable water or clean seawater the viscera and parts, which may pose a threat to public health, shall be removed and set apart from products intended for human consumption;
- e) livers and roes intended for human consumption shall be chilled or frozen; and,
- f) staff assigned to handling fish and fisheries products shall maintain a high standard of cleanliness for themselves and all outer clothing.

(7.4.5) The following conditions concerning vessel construction and equipment shall apply:

- a) fishing vessels shall be equipped with holds, tanks or containers for the storage of refrigerated or frozen fish and fisheries products at the temperature laid down by these Regulations including the National Control Plan and the Industry Standard.;
- b) holds shall be separated from the machinery area and the quarters reserved for the crew, by partitions that are sufficiently impervious to prevent any contamination of stored fish and fisheries products;
- c) the inside surface of the holds, tanks or containers shall be water proof and easy to clean and disinfect it shall consist of a smooth material or smooth paint maintained in a good condition, not being capable of transmitting to fish and fisheries products substances harmful to human health;
- d) containers used for the storage of products shall ensure their preservation under satisfactory conditions of hygiene and, in particular, allow drainage of water when used they shall be completely clean;
- e) in refrigerated holds, refrigeration capacity shall be sufficient to rapidly cool fish from ambient temperature to the temperature of melting ice and hold it at this temperature;
- f) water proof and separate storage room shall be provided for the storage of cartons, ship to shore containers and the like;
- g) hydraulic circuits shall be protected in such a way as to ensure no oil leakage can contaminate products;
- h) artificial lighting shall be provided where necessary and where handling, processing and inspection takes place at night and below deck and in enclosed processing areas. The intensity of illumination shall be a minimum of:
 - i. 220 lux in the processing area;
 - ii. 540 lux where the product is being inspected;
- i) sanitary facilities including toilet and shower facilities shall be sufficient in number for the normal complement of crew; and

- j) any toilet shall be equipped with non-hand operated wash basins located in the toilet room or immediately outside the door, wherever possible, and when not possible, the vessel operator shall be required to satisfy an authorized officer that personal hygiene can be met by alternative means.

(7.4.6) The following conditions concerning handling and storage of fish and fisheries products on board shall apply:

- a) ice for chilling of fish and fisheries products shall be used in such away and in such quantities, so that fish and fisheries products will attain the temperature of melting ice as quickly as possible;
- b) the water inlet for vessels, having an intake system for seawater shall be located in front of the outlet for waste and sewerage water;
- c) fishing vessels that use seawater to wash up and process shall do so in uncontaminated waters and whilst the vessel is moving in open waters;
- d) fishing vessels that use seawater and anchor at secure harbourages to wash and process shall ensure that:
 - i. waters are uncontaminated and meet the requirements of clean seawater;
 - ii. toilet facilities are not used unless they are self-contained; and
 - iii. the vessel is far enough from the shore and in deep water.

(7.4.7) If fish and fisheries products are frozen on board, this operation shall be carried out in accordance with following conditions:

- a) fishing vessels shall have freezing equipment sufficiently powerful:
 - i. to achieve rapid reduction in temperature to -18°C or less;
 - ii. keep products in storage rooms at -18°C or less; or,
 - iii. freeze whole fish in brine intended for canning at -9°C or less;
- b) temperature recording devices in storage rooms shall be located in a place where they can easily be read. All establishments shall be equipped with automated temperature recording device (ATRD) which cannot be manipulated. The temperature sensor of the recorder shall be located in the area furthest away from the cold storage, where the temperature in the storage room is the highest;
- c) freezing machinery shall be physically separated from the hold in which frozen product is stored;
- d) a waterproof, hygienic and separate storage room shall be provided for the storage of all packaging materials; and,
- e) when brine- freezing, the brine shall not be a source of contamination.

(7.4.8) If fish and fisheries products are chilled on board to keep fish and fisheries products fresh for more than 24 hours, the vessels shall comply with the following requirements:

- a) tanks shall be equipped with adequate seawater filling and drainage installations and shall incorporate devices for achieving uniform temperature throughout the tanks;
- b) tanks shall have a means of recording temperature connected to a temperature sensor positioned in the section of the tank where temperatures are highest;

- c) the operation of the tank or container system shall secure a chilling rate which ensures the mix of fish and seawater reaches 3°C or less within six hours after loading and not more than 0°C after sixteen hours;
- d) after each unloading, the tank's circulation systems and containers shall be completely emptied and thoroughly cleaned using potable or clean seawater and shall only be re-filled with clean seawater; and,
- e) the date and reference number of the tank shall be clearly indicated on the temperature records.

These records shall be kept and made available to an authorized officer.

7.5 Requirements for Factory Vessels

(7.5.1) Factory vessels must have at least:

- a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;
- b) a hygienic system for conveying fishery products from the receiving area to the work area;
- c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;
- d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;
- e) a place for storing packaging materials that is separate from the product preparation and processing areas;
- f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;
- g) a water intake situated in a position that avoids contamination of the water supply; and,
- h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.

(7.5.2) However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of subpart (7.5.1) if no other form of handling or processing takes place on board such vessels.

(7.5.3) Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Regulation.

7.6 Requirements for Fish Landings and Auctions Premises

(7.6.1) Lots of fish and fisheries products from different harvests or from different fishing boats shall not be mixed together.

(7.6.2) Unloading and landing equipment shall be constructed of corrosive resistant material that is easy to clean, disinfect and shall be kept in a good state of repair and cleanliness.

(7.6.3) During unloading and landing, contamination of fish and fisheries products shall be avoided. It shall be ensured that:

- a) unloading and landing operations proceed rapidly;
- b) fish and fisheries products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product; and,
- c) equipment and handling practices that damage fish and fisheries products are prohibited.

(7.6.4) If fish and fisheries products are displayed for sale at fish landings or auctions, the fish landings or auctions premises shall:

- a) have water-proof flooring which is easy to wash and disinfect;
- b) be equipped with adequate sanitary facilities;
- c) be well lit to facilitate the inspection of fish and fisheries products;
- d) when they are used for display or storage of fish and fisheries products, not be used for other purposes, such as vehicles which may contaminate the fish and fisheries products;
- e) have displayed in a prominent position, signs prohibiting smoking, spitting, eating or drinking;
- f) be closable and be kept closed when an authorized officer considers it necessary;
- g) have facilities to provide adequate supplies of potable water, clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity; and,
- h) have special watertight receptacles made of corrosion-resistant materials for fish and fisheries products which are unfit for human consumption.

(7.6.5) Crates shall, after each sale, be cleaned and rinsed inside and outside with potable water or clean sea water; where required, they shall be disinfected.

7.7 Physical Requirements of Processing Establishments - Location, Construction and Design

(7.7.1) The areas directly surrounding the establishment shall be suitably paved or concreted, unless otherwise permitted by Competent Authorities, after being provided evidence by the food business operator that the alternative surroundings will not contribute to contamination of the fish or fisheries products.

(7.7.2) Where the surrounding area is suitably paved or concreted the surrounding grounds and concreted surfaces shall be inclined towards trapped gullies and provided with adequate drainage to permit rapid evacuation of rainwater.

(7.7.3) If the facility's grounds are boarded by property not under the operator's control and not maintained in the manner described in these Regulations, extra care shall be taken by the operator to inspect, exterminate or other methods to exclude pests, dirt and filth that may be a source of food contaminations within their premises.

(7.7.4) The construction and design of processing establishments shall ensure that:

- (A) there is separation by walls, locations, air flow enclosed systems or other effective means:
 - i. between clean and dirty areas;
 - ii. between dry and wet areas;
 - iii. between cold and hot areas; and
 - iv. between operations which may cause contamination of food.
- (B) there is good lay-out and flow from raw materials through finished products and dispatch;
- (C) the distribution of equipment and processing activities facilitates the rapid processing of fish;
- (D) there is adequate working space to allow for satisfactory performance of all operations connected with the preparation and or processing of food; and,
- (E) all liquid and solid waste, storm-water and sewerage are adequately and appropriately disposed of.

(7.7.5) Working rooms shall be of sufficient size to permit the processing of fish and fisheries products without overcrowding of personnel and shall be designed for work to be carried out in logical sequence and under satisfactory conditions;

(7.7.6) The main processing area in which fish is handled shall have only one entrance for personnel being independent and separate from any entrances and exits used for raw materials, finished products and other materials used during processing.

(7.7.7) In rooms where products are handled, prepared and processing, the establishment and shall afford at least the following facilities, floors shall have:

- (A) hard impact resistant surfaces, impermeable to grease and water, which permit easy cleaning and disinfection and laid down in such a way as to facilitate the drainage of the water. Concrete floors shall have a high density, impermeable finish that is maintained in good condition;
- (B) a sufficiently graded and have a gradient of at least 1:100 towards drainage channels;
- (C) floor joints sealed with impervious materials, finished flush with the surface;
- (D) junctions between floor and walls curved to facilitate cleaning; and,
- (E) all drainage channels, gullies and gully traps covered with removable grills.

(7.7.8) In addition to the general requirements related to walls, ceilings, doors, windows, window sills, ventilation, and illumination the following specific additional requirements shall apply:

- (A) the doors of the reception room by which raw materials enter, and the doors by which the finished products leave the premises shall possess plastic curtains or air curtains or a self-closing curtain or a self-closing device, in order to minimize the entry of flying insects, when they are opened;
- (B) any window which may be opened, or which does not have glass (Plexiglas) and vents shall be covered with an insect-proof mesh screen;
- (C) if any services, chutes, conveyors or the like pass through external walls, the gap where they pass through, if any, shall be sealed against the entry of pests and dust.

(7.7.9) Establishments shall have a loading dock and the loading dock shall be:

- (A) located in an area that is convenient to the stored products;
- (B) enclosed or provided with a protective shelter to protect fish from contamination during loading and unloading; and,
- (C) shall have an illumination of at least 250 lux.

7.8 Physical Requirements of Processing Establishments - Hygiene, Drain and Effluent Disposal Facilities

(7.8.1) In addition to the general requirements of these Regulations related to hand washing facilities the following specific additional requirements shall apply:

- (A) The location of hand washing facilities shall be arranged in a way that they are:
 - (i) sufficient in number;
 - (ii) provided in places just before personnel enter the preparation or processing room;
 - (iii) provided in accessible locations throughout the preparation and processing areas, readily accessible from work areas for all staff to wash their hands; and,
 - (iv) also located adjacent to the social amenities.
- (B) Hand washing facilities shall be provided with:
 - (i) non-hand operated wash basins in work rooms, toilets and in the hand washing room before entering wherever possible, and when not possible, the food business operator shall be required to satisfy an authorized officer that personal hygiene can be met by alternative means;
 - (ii) a suitable pressured hot and cold running potable water supply over a sink;
 - (iii) soap contained within a dispenser;

- (iv) single use paper hand towels held in a dispenser and a sufficient number of receptacles for disposing of used towels or air dryer
- (v) properly trapped waste pipes leading to drains; and,
- (vi) signs advising persons to wash their hands on entering or re-entering fish preparation or processing rooms provided in a prominent position near food preparation/processing entrance.

(7.8.2) Where applicable, boot disinfecting facilities or a suitable permanent bath, fitted with a drainage facility, for the washing of boots shall be installed at the staff entrance in such a manner that persons entering the preparation/processing rooms cannot avoid passing through the bath.

(7.8.3) Effluent disposal systems and drains have to comply with the following requirements. The establishment shall have:

- (A) an efficient and hygienic effluent and waste water disposal system maintained in good order and repair;
- (B) effluent lines large enough to carry peak loads and constructed so as to avoid contamination of the potable water supply;
- (C) an adequate drainage system, especially in the areas and rooms that involve wet operations;
- (D) a storm water drainage system, if applicable, not connected to the effluent treatment system;
- (E) floor drains which shall be adequate in size, number and location:
 - (i) to allow the rapid removal of all liquid wastes arising from all processing operations;
 - (ii) to cope with the maximum flow of water under normal working conditions but also to carry peak loads;
 - (iii) and be effectively sealed by gully traps installed;
 - (iv) to prevent the return of gases and odors from the drainage system; and,
 - (v) and designed to prevent the entry of rodents.
- (F) floor drains which:
 - (i) have easily cleanable solid traps to prevent the passage of solid materials to the external sewage system;
 - (ii) have adequate access for cleaning;
 - (iii) flow from clean to dirty areas;
 - (iv) not be connected to sanitary drainage; and

- (v) not be connected to the storm water and site drainage system.

7.9 Physical Requirements of Processing Establishments - Temperature Control Facilities

(7.9.1) For chill stores, cold stores, chillers and freezers, the food business operator shall provide the following facilities:

- (A) waterproof flooring that is easy to clean and disinfect and laid down in such a way as to facilitate drainage;
- (B) walls that have smooth durable, impermeable surfaces that is easy to clean;
- (C) ceilings that are easy to clean;
- (D) doors made from durable materials that are ease to clean;
- (E) plastic strip curtains or similar shall be installed to assist in air retention and to minimize temperature fluctuations when cold stores or freezer doors are open; and
- (F) other internal structures constructed of smooth, impervious and corrosion resistant material.

(7.9.2) Where refrigeration equipment is installed in a processing or packing area, sufficient space shall be allowed for cleaning around and between the equipment. No free space shall be allowed on top of the equipment.

(7.9.3) In chill stores used for the storage of raw material the food business operator shall provide facilities able to store all the raw material arriving at the establishment and which is not processed immediately, in such a manner as to ensure adequate protection from contamination.

(7.9.4) In cold stores, the food business operator shall ensure:

- (A) adequate permanent cold storage facilities for the storage of finished products are provided in all establishments producing frozen fish;
- (B) freezing equipment sufficiently powerful and capable of maintaining products in cold stores at an internal temperature below - 18°C, whatever the ambient temperature may be, however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than – 9 °C.
- (C) doors to the cold store shall be provided with plastic curtains or equivalent system including adequate door management policy in place; and,
- (D) a temperature recording device in a place where it can easily be read. The temperature sensor of the recorder shall be located in the area furthest away from the cold source.

(7.9.5) In freezers, food business operator shall ensure:

- (A) a freezing facility appropriate to the presentation of the fish and fisheries products and its packaging; and,

- (B) a freezing facility with sufficient capacity to freeze the fish to a temperature of a least -18°C within 8 hours of loading the freezer.

(7.9.6) In brine freezing rooms, the food business operator shall ensure:

- a) brining tanks, tanks surfaces and coverings are constructed in such a way that they are not a source of contamination for the fish and fisheries product;
- b) the brine is checked at regular intervals and in such a way that the brine will not be a source of contamination for the fish and fisheries products; and,
- c) the freezing temperature shall not be higher than -9°C.

(7.9.7) In ice plants and ice storage rooms, the food business operator shall ensure:

- (A) an ice making facility, able to produce ice in quantities adequate to satisfy all the needs of the process, including:

- (i) transport of raw material from the port;
- (ii) storage of raw material before processing; and
- (iii) chilling of fish during processing.

- (B) insulated ice storage rooms and storage facilities are available:

- i. where ice can be stored and removed in an efficient, hygienic manner and can be protected from contamination at all times;
- ii. ensuring that ice is not stored on the floor where workers have to walk on it to remove the ice; and
- iii. with the capacity to store sufficient ice to satisfy needs.

7.10 Physical Requirements of Processing Establishments - Equipment Design, Construction and Installation

(7.10.1) All machinery, tools, utensils, equipment, instruments, and product holding, handling and conveying systems in the establishments shall be designed, constructed and so as to:

- (A) prevent the contamination and adulteration of the products with toxic materials, lubricants, fuel, metal fragments, contaminated water or other contaminants;
- (B) avoid the accumulation of dirt which could contaminate the product and be the source of hygiene hazards; and,
- (C) permit and enable:
 - (i) easy and thorough cleaning and disinfection with hot water, detergent and disinfectant;
 - (ii) accessibility for inspection where necessary; and,
 - (iii) maintenance in appropriate sanitary conditions.

(7.10.2) The use of wood and timber in general and other materials that cannot be adequately disinfected is prohibited. This applies in particular to knife-handles, spades for ice handling and filleting or cutting boards.

(7.10.3) Notwithstanding subpart (7.10.2), timber that is used in doors, doorjambs, windows in areas shall be sealed by a durable non-toxic surface coating (e.g., gloss enamel, epoxy or polyurethane paint).

(7.10.4) Notwithstanding subsection (7.10.2), clean and sound wooden pallets are permitted:

- (A) for the transport and the storage of processed food packed in carton boxes, provided no unpacked products are handled or stored in these areas;
- (B) for the transport and export of fresh products, packed in foam boxes; and,
- (C) for the racks and storage systems in cold stores used to store packed products.

(7.10.5) Equipment or fittings adjacent to a wall or other equipment shall have any gaps sealed to prevent entry of moisture and dirt or have sufficient space to permit cleaning.

(7.10.6) Equipment standing directly on the floor shall be installed:

- (A) by sealing directly to the floor to prevent the entry of moisture;
- (B) on a raised platform covered at the junction between it and the floor; or,
- (C) on legs with a minimum of 300 mm clearance between the underside of the equipment and the floor.

(7.10.7) Fish boxes, sufficient in number, shall be provided for the needs of the process and they shall only be used within the plant and not for external transport of fish.

(7.10.8) Fish boxes, which are used to transport product to the plant, and for the movement of fish within the plant, shall be constructed of a high-density plastic and be of a light colour. They shall have a smooth finish and their design shall avoid areas that could retain particles of product, grease and dirt. The boxes shall be designed to permit drainage of any liquid.

(7.10.9) If trolleys, barrows, supports or bearers are used to carry large fish or to feed blast freezers or chillers, they shall be made of non-corrodible material and have a smooth finish.

(7.10.10) If conveyors are utilized, they shall be constructed of non-corrodible impermeable materials.

(7.10.11) Ice shovels shall be made of a light coloured plastic, or of stainless steel. Wood is not permitted in any part of the construction.

(7.10.12) Chutes and other enclosed transport systems shall be:

- (A) constructed with inspection and cleaning hatches;
- (B) easily dismantled for cleaning; and,

(C) made of high-density nylon, stainless steel or fiberglass, free of crevices and have all internal junctions rounded out.

(7.10.13) Where compressed air is used, the compressed air shall have a filtered air intake located in a clean place, contain no oil or substances hazardous to health or shall be treated or otherwise controlled in such a way that food is not contaminated with unlawful indirect food additives.

(7.10.14) All equipment to be used for monitoring or measuring purposes where accuracy is important shall:

- (A) be checked to ensure their accuracy is sufficient for the task in hand and records kept; and,
- (B) be calibrated regularly and records kept.

7.11 Physical Requirements of Processing Establishments - Water Supply, Storage and Chlorination

(7.11.1) The establishment shall possess adequate water storage tanks or cisterns with sufficient capacity to supply the requirements of the establishment when operating at maximum capacity and to allow in case of chlorination sufficient contact time.

(7.11.2) The tanks or cisterns shall be well constructed and the internal surfaces shall be smooth, impermeable, easily to clean and disinfect.

(7.11.3) Each water tank or cistern shall be provided with an inspection hatch that permits entry for cleaning purposes. The design of the hatch shall protect against the entry of rainwater, ground water and any process water that may flow out of the establishment.

(7.11.4) Each water tank or cistern shall be protected against the entry of insects, rodents, other animals and dust.

(7.11.5) The area surrounding each water tank or cistern shall be maintained clean and free of accumulations of rubbish, dust, water and other materials that could contaminate the water.

(7.11.6) Water tanks shall be inspected at regular intervals with the objective of keeping them in good conditions.

(7.11.7) The chlorination system shall comply with the following:

- (A) chlorine shall be added in- line by dosing or injection prior to intermediary storage to permit sufficient contact time with the water in order to allow the chlorine to react with the organic matter;
- (B) the retention tank shall have to retain for 30 minutes water together with the chlorine added; and,
- (C) the management of an establishment shall put in place measures to ensure the functioning of the chlorination system, and the free residual chlorine shall be checked

at intervals of not less than 8 hours or at the start of each shift but at least once a day and shall never be less than 3 ppm.

7.12 Requirements of Processing Establishments - Processing Operations

(7.12.1) Instructions for raw material inspection, handling and storage procedures shall be documented. Records of delivery and product quality shall be kept to enable traceability of the products.

(7.12.2) During reception and unloading in the processing plant, the doors of the reception of the establishment shall be open for the minimum time possible.

(7.12.3) The vehicle shall be unloaded immediately after the approval of the batch. Fish never be stored in the vehicle whilst awaiting processing nor shall fish be left outside the establishment.

(7.12.4) Before unloading, each vehicle arriving at the establishment with fish for processing, shall be inspected to ensure that:

- (A) the fish has not been exposed to detrimental climatic conditions; and,
- (B) other materials that could contaminate the fish are not carried together with the fish and fisheries products.

(7.12.5) Before unloading commences:

- (A) a sample of fish shall be collected from the vehicle, and the internal temperature measured. The mean temperature shall be 0°C or approaching temperature of melting ice. The temperature of brine frozen fish and fisheries products shall not be higher than -9°C; while temperature of frozen fish shall be \leq -18°C.
- (B) before unloading commences, a representative sample of each batch of fish shall be taken for sensory evaluation of smell and appearance; and,
- (C) the quality control manager shall indicate his approval of the batch based on the results of the above test. He or she shall sign an inspection form and assign a batch code to the fish before the unloading of the vehicle commences.

(7.12.6) The initial stages of processing (washing of raw material, separation of extraneous material and gutting) shall commence as soon as possible after unloading the vehicle.

(7.12.7) Fish and fisheries products which are not processed immediately upon arrival at the establishment shall be washed with clean water at 0°C (if necessary), and stored with ice in suitable reception tanks or put in bins, iced and stored in a chill room.

(7.12.8) The storage of raw material shall comply with the following requirements:

- (A) if more fish shall arrive at the establishment than can be processed immediately, the excess shall be stored in suitable tanks with ice and water, or alternatively be held in a chill storage room, in order that the temperature of the product is kept at 0°C;

- (B) the evisceration of the fish shall be done carefully in order to avoid the contamination of the fish flesh;
- (C) all products unfit for human consumption shall be removed and kept separately in the designated room;
- (D) fish shall not be stored in heaps, and the depth of storage tanks shall be kept to a minimum to prevent damage. Tanks shall contain water before filling with fish in order to prevent damage;
- (E) the duration of storage of raw material shall be kept to a minimum; and,
- (F) the water contained in the storage tanks shall be changed at regular intervals during the storage period, and also between the storage of different batches of fish.

(7.12.9) Raw material shall be assessed for its freshness, physical soundness, sanitary soundness and temperature.

(7.12.10) The temperature of fish and fisheries products shall be taken on the level of the bone (Back Bone Temperature) and under the skin to control whether the fish and fisheries products are in the condition of warming up or cooling down.

(7.12.11) When thawing is undertaken as part of the processing:

- (A) the thawing method shall be clearly defined and shall address the time and temperature of thawing, temperature measuring instrument used and placement of device for measurement;
- (B) the thawing process shall be carefully monitored;
- (C) selection of the thawing method shall take into account in particular the thickness and uniformity of size of the products to be thawed;
- (D) thawing time and temperature and fish temperature critical limits shall be selected so as to control the development of micro-organisms, histamine, where high risk species are concerned, and persistent and distinctive objectionable odors or flavours indicative of decomposition or rancidity;
- (E) where water is used as the thawing medium, it shall be of potable quality;
- (F) where recycling of water is used, care shall be taken to avoid the build-up of microorganisms;
- (G) where water is used, circulation shall be sufficient to produce even thawing;
- (H) during thawing, according to the method used, products shall not be exposed to excessively high temperatures;
- (I) particular attention shall be paid to controlling condensation and drip from the fish.
- (J) an effective drainage system shall apply; and,
- (K) after thawing, fish shall be immediately processed or refrigerated.

(7.12.12) When washing and gutting an adequate supply of clean sea water or potable water shall be available for washing of:

- (A) whole fish to remove foreign debris and reduce bacterial load prior to gutting;
- (B) gutted fish to remove blood and viscera from the belly cavity;
- (C) the surface of fish to remove any loose scales; and
- (D) gutting equipment and utensils to minimize build-up of slime and blood and offal.

(7.12.13) To minimize time delays, the design of the filleting line and candling line, where applicable, shall be continuous and sequential to permit the uniform flow without stoppages or slowdowns and removal of waste.

(7.12.14) When trimming and filleting, an adequate supply of clean sea water or potable water shall be available for washing of:

- (A) fish prior to filleting or cutting especially fish that have been scaled;
- (B) fillets after filleting or skinning or trimming to remove any signs of blood, scales or viscera; and,
- (C) filleting equipment and utensils to minimize build-up of slime and blood and offal.

(7.12.15) For fillets to be marketed and designated as boneless, fish handlers shall employ appropriate inspection techniques and use the necessary tools to remove bones not meeting commercial specifications.

(7.12.16) The candling of skinless fillets by skilled personnel, in a suitable location which optimizes the illuminating effect, is an effective technique in controlling parasites and shall be employed when implicated fish species are being processed.

(7.12.17) The candling table shall be frequently cleaned during operation in order to minimize the microbial activity of contact surfaces and the drying of fish residue due to heat generated from the lamp.

7.13 Requirements of Fish and Fisheries Products Processing Establishments - Smoking, Salting, Cooking, Canning

(7.13.1) Smoking shall be carried out in separate premises or a special place equipped with a ventilation system to prevent the smoke and heat from affecting other premises or places where fish and fisheries products are prepared, processed or stored.

(7.13.2) Materials used for the smoking of fish shall be stored away from the place of smoking and shall be used in such a way that they do not contaminate products.

(7.13.3) Wood that has been painted, varnished, glued or undergone any chemical preservation treatment shall not be used for fish smoking.

(7.13.4) After smoking products shall be cooled rapidly to the temperature required for their preservation before being packaged.

(7.13.5) Salting operations shall take place in different premises sufficiently faraway from premises where other processing operations are carried out.

(7.13.6) Salt used in the treatment of fish and fisheries products shall be clean and stored in such a way as to preclude contamination. It shall not be re-used.

(7.13.7) Any container used for salting or brining shall be constructed in such a way as to preclude contamination during the salting or brining process.

(7.13.8) Containers or areas used for salting or brining shall be cleaned before use.

(7.13.9) Where products are being heated in any way, such as blanching or retorting, there shall be adequate control to ensure that the correct temperature/time regime is used to achieve the desired functionality and shelf- life without jeopardizing consumer health.

(7.13.10) Any cooking shall be followed by rapid cooling. Water used for this purpose shall be potable water or clean seawater. If no other method of preservation is used, cooling shall continue until the temperature approaches that of melting ice.

(7.13.11) Shelling or shucking of cooked product shall be carried out under hygienic conditions to avoid the contamination of product. Where such operations are done by hand, workers shall pay particular attention to proper hand washing and all working surfaces shall be cleaned thoroughly. If machines are used, they shall be cleaned at frequent intervals and disinfected after each working day.

(7.13.12) After shelling or shucking, cooked products shall immediately be frozen or kept chilled at a temperature that will preclude the growth of pathogens, and be stored in appropriate premises.

(7.13.13) In the canning of fish and fisheries products, hygienic practices shall be in accordance with the canning requirement under this Regulation including Codex and other specific market access requirements.

7.14 Requirements of Processing Establishments - Specific to Shrimp Processing

(7.14.1) All tanks or sinks used for the washing of shrimp shall be supplied with a constant flow of water, sufficient to replace the contents of the tank every 30 minutes.

(7.14.2) Tanks used for washing shrimp shall be emptied and cleaned between different batches of shrimp.

(7.14.3) All products stored for more than one day before processing shall be beheaded. The priority shall be to behead the shrimp as soon as possible after arrival at the plant (if not done previously).

(7.14.4) If shrimp intended for peeling and de-veining is not to be processed immediately, it shall be stored with a sufficient quantity of ice to maintain a temperature of 0°C (close to temperature of melting ice)

(7.14.5) Shrimp shall be peeled and de-veined rapidly in order to minimize the rise in temperature.

(7.14.6) Peeled and de-veined shrimp not frozen immediately shall be stored at 0°C (close to temperature of melting ice) with adequate quantities of ice.

(7.14.7) Higher Standards of hygiene and cleanliness shall be maintained at the work tables on which shrimp is peeled and de-veined, due to the higher risk of contamination of the shrimp flesh itself.

(7.14.8) If the final product is to be head-on shrimp, the processing of the raw material shall commence as soon as possible after arrival at the plant. The nature of the product demands rapid processing with rigorous temperature control.

(7.14.9) Chilled water shall be used for the washing of head-on shrimp at all stages of the process.

(7.14.10) Any areas in which cooked or head-on shrimp is processed shall be air-conditioned in order to maintain an air temperature of less than 25°C.

(7.14.11) Cooked shrimp shall only be handled in an area separated from areas where raw product is processed. There shall be no direct access for workers between the two areas.

(7.14.12) All personnel who handle cooked shrimp, or who work in or enter the area in which it is being processed shall wear coats, boots, hats and aprons that are used exclusively by such personnel, and are kept separate from the protective clothing used in the processing of raw shrimp. In order to avoid confusion, it is recommended that the uniforms, boots, etc. shall be of a different colour.

(7.14.13) All persons entering the cooked products area shall wash their hands and boots.

(7.14.14) No equipment or other article (including fish boxes, knives etc.) shall be transferred from an area in which raw shrimp is handled to the cooked product area, without first receiving a thorough cleaning and disinfecting.

7.15 Requirements of Processing Establishments - Packaging

(7.15.1) Packaging shall be carried out under satisfactory conditions of hygiene, to preclude contamination of the fish and fisheries products.

(7.15.2) Packaging materials and products liable to enter into contact with fish and fisheries products shall comply with all the rules of hygiene and in particular:

- (A) they shall not be such as to impair the organoleptic characteristics of the fish and fisheries products;
- (B) they shall not be capable of transmitting to the fish and fisheries products substances harmful to human health:
 - (i) the ink used to apply description markings, inks and colours applied to food shall not contaminate the food and shall be nontoxic;

- (ii) inks applied to food or packaging shall not contain any of the following substances: antimony; arsenic; cadmium; chromium; lead; mercury; other toxic materials; and,
 - (iii) be compatible and non-toxic with the food being packed.
- (C) lacquer applied to the inner surface or part of the inner surface of covering shall uniformly cover and adhere to the inner surface in continuous film; and
- (D) they shall be strong enough to protect the fish and fisheries products adequately.

(7.15.3) Fish and fisheries products shall not be transported unless they are packed and covered in such a way that will enable the goods to reach their destination in a satisfactory and wholesome condition.

(7.15.4) With the exception of certain containers made of impervious, smooth and corrosion resistant materials that are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used;

(7.15.5) Packaging materials used for fresh products held under ice shall provide adequate drainage of melt water.

(7.15.6) Unused packaging materials shall be stored in premises connected with the production area and shall be protected from dust and contamination.

7.16 Storage Requirements

(7.16.1) Storage of product, materials and containers shall be such that it will protect product and materials against physical, chemical and microbiological contamination, as well as against deterioration of the materials and the containers.

(7.16.2) Fresh or thawed fish and fisheries products and cooked and chilled crustaceans and molluscan shellfish products shall be kept at the temperature of melting ice.

(7.16.3) Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than – 9 °C.

(7.16.4) To prevent Scombrototoxin formation of fish that has first been chilled and then frozen for a long time, fish shall not be exposed to a temperature rise above that of melting ice which is equivalent to 4.4°C from the time it is frozen for a cumulative period of more than 12 hours and an uninterrupted period of exposure shall not exceed 6 hours.

(7.16.5) Fish and fisheries products may not be stored with any other products that may contaminate them or affect their hygiene, unless they are packed in such a way as to provide satisfactory protection.

(7.16.6) No materials other than those used for immediate processing shall be stored in an area in use or in processing.

(7.16.7) Products shall be stacked so that air circulation within the storage room is not impaired.

(7.16.8) No direct contact with ceiling and floors shall be allowed, unless otherwise permitted by an authorized officer.

7.17 Transport

(7.17.1) During transport, fish and fisheries products shall ensure compliance with the followings:

- a) fresh or thawed fish and fisheries products and cooked and chilled crustacean and molluscan shellfish products shall be kept at the temperature of melting ice;
- b) frozen fishery products, with the exception of whole fish initially frozen in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than – 18 °C in all parts of the product.
- c) when frozen fish and fisheries products are transported from a cold storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing and where the distance to be covered is short, the Competent Authority may grant a derogation from the conditions laid down in this Regulation; and,
- d) processed products shall be kept at the temperature specified by the manufacturer.
- e) If fishery products are kept under ice, melt water must not remain in contact with the products.

Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability

(7.17.2) Vehicles shall be designed and constructed such that walls, floors and ceilings, where appropriate, are made of a suitable corrosion-resistant material with smooth non-absorbent surfaces.

7.18 Requirements of Processing Establishments - Personnel Hygiene

(7.18.1) All personnel and visitors entering the preparation/processing rooms shall at all times wear:

- a) suitable clean protective working clothing of a light colour, which covers the minimum outdoor clothing or replaces it,
- b) impermeable boots or footwear which are kept clean and in good condition;
- c) head coverings that completely enclose all hair;
- d) if involved in medium or high risk processing, personnel shall wear a head covering that encloses the scalp, hair, beard and moustache; and,
- e) a water impermeable apron for personnel who handle fish and unpacked fish products.

(7.18.2) If personnel who handle fish also wear gloves, such gloves:

- a) shall be made of plastic or rubber;

- b) be either a disposable type or, alternatively, be capable of being easily cleaned and disinfected; and,
- c) shall be in a sound, clean and sanitary condition.

7.19 Requirements of Processing Establishments - Pest Control

(7.19.1) All food business operators involved in processing of fish and fisheries products shall:

- a. take effective measures to exclude pests and animals from the processing areas and to protect products against contamination by pests and animals; and
- b. shall implement and maintain a pest control plan, containing an effective and continuous Schedule for the detection, control and eradication of pests, to avoid contamination of the products by pests on two levels:
 - i. on a passive level that means prevention, protection, proofing, construction measures; and,
 - ii. on an active level that means extermination by use of: - mechanical methods: trapping (rodents) - electrical methods: electrocutor (insects) - chemical methods: poisons (rodenticides & insecticides).

(7.19.2) Prevention and extermination of pests shall be carried out in a manner that will not constitute a hazard to human health and product safety.

(7.19.3) The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces and food-packaging materials.

(7.19.4) Control measures involving treatment with chemical shall only be undertaken by personnel who have a complete understanding of the health hazards these chemicals may pose to the product.

(7.19.5) When a door is closed, it shall fit so that there is no gap between the door and the frame more than 3 mm.

(7.19.6) Doors to the outside shall be kept closed at all times when not in use.

(7.19.7) All windows that can be opened shall be covered with a tight fitting fly screen of mesh size no larger than 1mm. The fly-screened frames shall be removable for ease of cleaning.

(7.19.8) Ventilation outlets shall be screened with a screen whose mesh size is no larger than 1 mm.

(7.19.9) All drain openings shall be covered with grating with hole sizes no larger than 10 mm across.

7.20 Product Tracing and Recall Procedures

(7.20.1) Managers of food business operations shall ensure effective procedures are in place to effect the complete product tracing and rapid recall of any lot of fish and fisheries product from the market.

(7.20.2) Appropriate records of processing, production and distribution shall be kept and retained for a period that exceeds the shelf-life of the product.

(7.20.3) Each container of fish, shellfish and their products intended for the final consumer or for further processing shall be clearly marked to ensure the identification of the producer and of the lot.

(7.20.4) Where there is a health hazard, products produced under similar conditions, and likely to present a similar hazard to public health, may be withdrawn.

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

7.21 Training

(7.21.1) All personnel shall be aware of their role and responsibility in protecting fish and fisheries products from contamination and deterioration.

(7.21.2) Handlers shall have the necessary knowledge and skill to enable them to handle fish and fisheries products hygienically.

(7.21.3) Those who handle strong cleaning chemicals or other potentially hazardous chemicals shall be instructed in safe handling techniques.

7.22 Operator Verification

(7.22.1) Food business operators must have a perform regular operator verification.

(7.22.2) Operator verification must include regular checks on:

- a) places of food business, facilities and equipment.
- b) staff and visitors.
- c) practices, procedures and activities.

7.23 Registration of Premises

(7.23.1) Food businesses must be registered with the relevant Authority (Competent Authority or equivalent) before commencing operation.

(7.23.2) Food business operators must apply to the relevant Authority using forms and pay the fees specified in Regulations or Standards promulgated under the Act.

(7.23.3) Food business operators must re-apply for registration at the frequency specified in Regulations or Standards promulgated under the Act.

7.24 Record-Keeping

Food business operators must ensure adequate records are kept to provide evidence of compliance with the Act and subsequent Regulations and standards.

7.25 Offences

7.25.1 Any food business operator who does not ensure that good hygienic practices as prescribed in Part 7 of these Regulations and associated Schedules are applied at all stages of production, processing, handling, storage and distribution of food under their control,

(a) CA officers may deal with him or her in accordance to the requirements of the National Control Plan and Industry Standard.

(b) Failure to adhere to part (a), the food business operator shall commits an offence and is liable to pay prescribed penalties or serve imprisonment terms specified in Schedule 13 of this regulation.

PART 8. IMPORTED FOOD

8.1 High Risk Food

FSM Health Authorities shall determine if a food belongs on a High Risk Food List which shall be published from time to time.

8.2 Food of Regulatory Interest

(8.2.1) FSM Health Authorities shall establish a List of Food of Regulatory Interest so designated because of being food:

- (A) with a non-compliance history;
- (B) food that is required to be fortified; and
- (C) food that is being targeted to reduce the population's exposure to fat, sugar or sodium in priority foods.

8.3 Informing of Intention to Import Food

(8.3.1) A person intending to import a food for sale that is either on the High Risk Food List or Food of Regulatory Interest List shall notify the FSM Department of Health and Social Affairs (National Food Safety Program) of his/her intention to import food in writing via email, fax or other documented means with an attached intent to import notification at least 72 hours prior to the food being imported into Federated States of Micronesia.

(8.3.2) Along with the notice of intent to import specified in subpart (8.3.1), the importer shall provide the invoices associated with the product to be imported.

(8.3.3) The National Food Safety Program shall, in such cases, direct and cause an appropriate National Food Inspector to carry out any inspection and sampling required. The importer shall comply also to any standard operation procedures for imported food products develop by the National Food Safety Program.

(8.3.4) The National Food Inspector shall review relevant documents including export certifications provided by competent authorities overseas and carry out any inspection and sampling required, as soon as possible and in a manner so as not to unnecessarily delay the release of the food from customs and quarantine.

(8.3.5) All bills of lading or airway bills for imported food consignment shall be stamped by National Food Inspector prior to release from port of entries.

(8.3.6) The National Food Inspector shall select and stamp “hold for inspection” on bills of lading or airway bills of food consignment for inspection at the port of entry or business premises.

(8.3.7) the National Food Inspector may lock any food container that is place on hold for inspection.

(8.3.8) Any food business operator or persons who contravenes 8.3.5 and/or 8.3.7 commits an offence.

(8.3.9) All fish and fisheries products imported into FSM for either sale or for further processing and/or re-export shall only be carried out with the approval of the competent authority and should be accompanied by a health certificates and should also comply with other requirements of this Regulation.

(8.3.10) With reference to (8.3.9) above, any importation of fish for further export to any EU market shall only be from any EU listed country. Hence the fish to be sourced from legal source and from a CA and EU approved and listed vessel. Such export needs to be accompanied by a health certificate from the country of export/origin with an attestation that confirms the legality and eligibility of the fish.

(8.3.11) The importer shall ensure that the fish or fish product imported into FSM have adequate information on the product for its traceability throughout the supply chain.

(8.3.12) An authorized officer may, for the purpose of the Act or these regulations, enter and inspect any premises, boat, vessel, transport vehicle, reefer container, warehouse or cold storage facility where the fish or fish product is stored.

(8.3.13) On arrival of the consignment, the registered person, importer or his agent shall –
(a) notify the authorized officer of the date of arrival of the consignment at least 48 hours in advance;
(b) submit relevant import documents for verification;
(c) request for an inspection at the port of entry; and
(d) make arrangement for inspection of the consignment at the port of entry.

(e) The importer shall ensure that the consignment of fish, or fish product, is not removed from the port before it is inspected and approved by an authorized officer.

(f) Any consignment of fish or fish product, landed at the port of entry, shall be inspected in the presence of the importer or his agent.

(g) Where an inspection is being carried out, the authorized officer may –

- (a) require the importer to produce any document in relation to the business;
- (b) check the whole consignment, or parts thereof, as may be deemed appropriate;
- (c) open as many boxes, containers or packages as he may deem fit;

- (d) collect appropriate number of samples for identification and laboratory analysis.
- (h) The authorized officer may carry out a physical check on the consignment to verify
 - (a) the species of fish in the consignment;
 - (b) the quantity as mentioned in the import documents;
 - (c) the quality of the product through organoleptic assessment whenever possible;
 - (d) compliance with temperature requirements;
 - (e) the cold chain during transport;
 - (f) the freshness criteria (organoleptic) for fresh or chilled fish
 - (g) the safety of the fish through laboratory analysis;
 - (h) packaging and labelling of the products; or
 - (i) the importer shall not be entitled to any compensation for the fish or fish products forfeited and seized.

(8.3.14) For all new imports, to facilitate the competent authority decision making process, an import risk assessment may be carried out. The cost of such activity shall be met by the customer.

8.4 Personal Import of Food

(8.4.1) Foods imported into Federated States of Micronesia for personal consumption are exempt from food legislation requirements.

(8.4.2) For chilled and frozen meat and chilled and frozen fish personal imports shall not exceed 10kg in total per person.

(8.4.3) For meat products, dairy products, fishery products e.g. processed fish (dried, cooked, cured or smoked), lobsters and prawns personal imports shall not exceed 5kg in total per person and shall also comply with the following:

- (A) the product does not require refrigeration before consumption;
- (B) the product is in commercially branded packaging; and
- (C) the packaging is unbroken unless in current use.

(8.4.4) For powdered infant formula, and infant food, personal imports shall not exceed 5 kg in total per person.

(8.4.5) For other foods, personal imports shall not exceed 2 kg in total per person.

If the food shall be consumed by the person bringing the food into Federated States of Micronesia and/or consumed by his/her family and complies with the aforementioned quantities, the National Food Inspector shall not hold the product for further assessment.

8.5 Product Identity

(8.5.1) If the food is not a food for personal import, National Food inspectors shall inspect the documents accompanying the food to confirm the specific product identity.

(8.5.2) Product identity checks require the inspector to check:

- (A) the name;
- (B) quantity (weight);

- (C) serial number of the container; and
- (D) the name or registration number of the processing factory.

(8.5.3) A National Food Inspector may also check to verify that the product, health marks, stamps and other necessary product and or package information conforms to the declaration on the health certificates for the products as well as any accompanying documentation.

8.6 Health or Sanitary Certificates

(8.6.1) National Food Inspectors shall inspect any accompanying health or sanitary certificate to determine that:

- (A) it is from a recognized competent authority and is signed;
- (B) it is relevant to the specific product for which it is associated;
- (C) Certification is in English and in an agreed format;
- (D) Certification contains a statement of the controls in place at the food business e.g., good hygienic practice, good manufacturing practice, and a HACCP program is implemented;
- (E) product is safe and fit for purpose;
- (F) Certification confirms that an audit or inspection has been undertaken in a reasonable time frame prior to product being distributed from the premises;

(8.6.2) If the certificate is unsatisfactory a National Food Inspector shall ensure the food is detained until the importer can provide such a certificate.

(8.6.3) If no certificate can be provided by the importer in a timely manner the product be shall be re-exported or rejected and destroyed.

(8.6.4) If the product is likely to deteriorate while being detained, it shall be rejected and destroyed.

8.7 Analytical Certificates

(8.7.1) National Food Inspectors may evaluate the food analysis certificates to determine that: Certification shall cover the microbiological, chemical or physical parameters required by these regulations.

(8.7.2) Certification must be in English and in an agreed format.

(8.7.3) Testing must be conducted by an accredited or approved laboratory.

(8.7.4) The test methodology is to be defined on the certificate and approved.

(8.7.5) If the certificate is unsatisfactory a National Food Inspector shall ensure the food is detained until the importer can provide such a certificate or until the food is analysed.

(8.7.6) If no certificate can be provided by the importer in a timely manner the product be shall be re-exported or rejected and destroyed.

(8.7.7) If the product is likely to deteriorate while being detained, it shall be rejected and destroyed.

8.8 Holding for Physical Checks

If, after documentary and identity checks there is a need to hold the products for physical checks, the National Food Inspector shall notify the importer and Customs in writing of the intent to physically examine the product.

8.9 Permitting Foods to Be Moved

(8.9.1) Where it is necessary to conduct a physical check and it is not possible to do so in a timely manner while in the Customs controlled area, the National Food Inspector can establish an agreement with the importer for the product to be moved to another location within Federated States of Micronesia and to be held without further distribution until a permit to import has been provided.

(8.9.2) The National Food Inspector shall apply a lock/seal/tape to the container or product of interest to ensure it is not further distributed before examination.

8.10 Physical Checks

When physical checks are carried out they can include any physical observation or test appropriate to assess compliance with the regulations.

8.11 Sampling Food

(8.11.1) If the specific product is not accompanied by adequate documentation showing the safety of the food, the National Food Inspector or National Food Analyst shall take samples in a manner and quantity as prescribed in from time to time in the High Risk Food List and in the Food of Regulatory Interest List.

(8.11.2) The National Food Inspector shall advise the importer that samples of the food have been collected for further testing. As a consequence, the inspector shall complete a collection report and provide copies as directed in the collection report.

(8.11.3) The National Food Inspector shall also discuss with the importer the need to detain the product until the analysis has been completed. Detention of the product can take place in an agreed location pending the receiving of the analytical results.

8.12 Satisfactory Checks

The inspector shall permit the importer to place the food in free circulation by issuing an import permit.

8.13 Re-labelling

(8.13.1) Where the food is rejected but the National Food Inspector considers it suitable for re-labelling the importer may re-label the food in accordance with the requirements of the Regulations.

(8.13.2) The National Food Inspector shall discuss with the importer the need to detain the product until the re-labelling has been completed and provide the importer a copy of the detention report.

(8.13.3) Detention of the product can take place in an agreed location pending the receiving of proof that the product has been re-labelled appropriately. Local authorities and the National Food Inspector who has permitted relocation shall cooperate to monitor compliance with the detention report.

(8.13.4) Where the food is not re-labelled within a given period, the food shall be re-exported by the importer. Such a period shall be within a period of three months or such other period as the National Food Safety Program may determine.

(8.13.5) Where a food is to be re-exported, the importer or other person in charge of the food needs to inform the Competent Authority of the proposed importing country of the reason for re-export and be in receipt of an agreement for such action to be taken.

(8.13.6) The National Food Inspector who has requested the re-labelling shall cooperate with other relevant authorities and the importer to ensure the product is not exported without evidence that the Competent Authority of the proposed importing country is in receipt of this information and there is an agreement for such action to be taken.

(8.13.7) As a result of not re-labelling or re-exporting as agreed between the National Food Inspector and importer the food shall be sent for destruction by crushing and burial; or by incineration; or other suitable means.

(8.13.8) The National Food Inspector shall cooperate with the appropriate other authorities to have the product destroyed by crushing and burial; or by incineration; or other suitable means.

8.14 Rejection and Destruction

(8.14.1) Where the National Food Inspector is of the opinion that an article for import does not meet the requirements of the Act or this Regulation, he/she may reject any or all the lots in that article found deficient.

(8.14.2) The relevant invoice and manifest in respect of that article shall be marked "REJECTED" and a National Food Inspector shall issue a notice of rejection of article for import.

(8.14.3) The rejection notice shall be delivered to the importer with a copy to Customs and if relevant Quarantine, in the form set out in the legislation.

(8.14.4) Once rejected, the National Food Inspector shall cooperate with the appropriate other authorities to have the product destroyed by crushing and burial; or by incineration; or other suitable means. All costs for destruction are to be met by the importer.

(8.14.5) In the situation of import rejections caused due to failure of a food item to comply with requirements, it is necessary for a National Food inspector to provide information on the rejection to all relevant parties including:

- (A) the importer;
- (B) the exporter; and,
- (C) the exporting government

8.15 Offences

8.15.1 Any food business operator or person who imports, produces, harvests, prepares, processes, handles, packs, keeps, conveys, or sells any food contaminated in a manner contrary to Part 8 of these Regulations commits an offence and is liable to pay prescribed penalties or serve imprisonment terms specified in Schedule 13 of this regulation.

PART 9. EXPORT AND PLACING OF PRODUCT IN THE MARKET

(9.1) General

(9.1.1) The placing on the market of the following products shall be prohibited:

- (A) Poisonous fish of the families Tetraodontidae, Molidae, Diadontidae, Balistidae, Murenidae and Canthigasteridae and
- (B) Fishery products containing bio-toxins such as ciguatera toxins or muscle paralysing toxins.

(9.1.2) All the exports of fishery products and other foods from FSM to other countries shall comply with the conditions laid down in these Regulations and with the requirements of the legislation of the country to which FSM exports.

(9.1.3) No person shall export process for export or attempt to export or process for export, any fishery products or any foods for export and or to be commercially traded unless that fishery product is prepared or processed in an establishment in accordance with the

requirements laid down in these Regulations including the National Control Plan and Industry Standard.

(9.1.4) No person shall export, process for export or attempt to export, process for export any fish or food that is tainted, decomposed or unwholesome or otherwise fails to meet the requirements of these Regulations.

(9.1.5) All shipments of fishery products of any type, in any presentation, quantity, and by any means, should be accompanied by a Health Certificate issued by the Competent Authority.

In case of failure to present this certificate, exportation of products shall be forbidden.

9.2 EU Eligibility

(9.2.1) No fish or fishery product can be exported to the EU if that fish or fishery product has not been caught, handled, stored, transported, unloaded or processed in EU approved facilities.

9.3 Certification

(9.3.1) Fish and fishery products must not be exported unless it is accompanied by any certification required by these Regulations, National Control Standards, Industry Standards or overseas market requirements.

(9.3.2) The Competent authority or Food Authority shall not issue a health certificate to any food business operator exporting from the Federated States of Micronesia if;

(9.3.2.1) fish and fishery or any products have been exported and have left the country to its final destination without prior approval of the Competent Authority or Food Authority; or

(9.3.2.2) fish and fishery products have reached its destination without health certificate;

(9.3.2.3) it shall not be lawful to issue a health certificate to any foreign flagged vessel transshipment of fish and fishery products within the Federated States of Micronesia.

(9.3.2.4) The Competent Authority or Food Authority shall only issue a hygiene certificate under 9.3.2.3 to certify compliances to hygienic requirements of all transhipped fish and fishery products and also to confirm that transhipped products do not undergo any further processes.

(9.3.2.5) Food Business Operators shall make prior arrangement with the Competent Authority or Food Authority to ensure proper verifications are done to meet hygiene requirements under these regulations. Consent from other relevant authorities shall be sought.

(9.3.2.6) Food Business Operators seeking certificates for transshipment of fish and fishery products shall assist Competent Authorities or Food Authority to ensure required certificates are issued smoothly.

(9.3.3) Any request by any food business operator for re-printing of health certificate due to changes of export information after the health certificate have been signed and issued shall

be chargeable to a rate which will be endorsed by the Secretary for Health & Social Affairs;
and

(9.3.4) The additional charges have to be directed to the government consolidated fund.

(9.3.5) Contravention of sub-section (9.3.2.1) and (9.3.2.2) of these Regulations becomes an offence .

9.4 Offences

9.4.1 Any food business operator who does not comply with Part 9 of this Regulation commits an offence and has to be dealt with by CA officers in accordance with the requirements of the National Control Plan and Industry Standard; or

9.4.2 The food business operator commits an offence when noncompliance continues, he or she is liable to pay penalties or serve imprisonment terms specified under Schedule 13 are applied.

PART 10 COMPETENT AUTHORITY CONTROLS

10.1 Delegation of Responsibilities and Authorities.

(10.1.1) The Secretary for Health can delegate his or her duties under the Act to authorized officers in the Competent Authority.

10.2 Powers of Officers

(10.2.1) Competent Authority officers will have the following powers under the delegation from the Secretary for Health and for the purposes of this Act and subsequent Regulations and Standards:

- a) Power to inspect facilities, equipment and premises.
- b) Power to halt an operation who fails, or is suspected of failing, to meet the legislative requirements.
- c) Power to access and review records, documents and information.
- d) Power to sample, examine and test any raw materials, work-in-progress or finished product to confirm the suitability or safety of that product.
- e) Any other powers given in Regulations and standards to the Act.

10.3 Training and Competencies of Officers

(10.3.1) Competent Authority Officers must meet minimum competency standards as set by Regulation and or National Control Plan or Standards under the Act.

10.4 Sampling, Inspection and Analysis

(10.4.1) Competent Authority Officers can sample, inspect or analyze any raw material, work-in-progress or finished product to verify compliance to food safety legislation. The results of testing do not need to be shared with the food business if that information could be used in a court of law.

10.5 Quality Management System

(10.5.1) Competent Authorities must operate according to a documented Quality Management System (also known as a National Control Plan). The Quality Management System must cover the following:

- a) The structure and organization of the Competent Authority.
- b) The legal background of the Competent Authority.
- c) The structure and organization of official controls performed to verify compliance to food safety legislation.
- d) The functions, powers and competency requirements of authorized officers.
- e) Controls on Competent Authority facilities and equipment.
- f) Procedures for approval and registration of premises and establishments.
- g) Regulatory verification procedures.
- h) Certification procedures, if required.
- i) Sampling and testing requirements
- j) Official controls for specific overseas markets.
- k) Procedures for appeals and complaints.

PART 11 OFFENSES AND PENALTIES

Any food business or food business operator who fails to meet the requirement of the Act, these Regulations or any food safety standard commits an offense and shall be liable to pay the penalty under Sections 1031 and 1032 of Title 41 of the FSM Code and as further elaborated under Schedule 13 of these Regulations.

PART 12 MISCELLANEOUS

12.1 Presumptions

(12.1.1) For the purposes of these regulations:

- (A) any food commonly used for human consumption, shall, if sold or offered, exposed or kept for sale be presumed, until the contrary is proved, to have been sold, or as the case may be, to have been intended for sale for human consumption;
- (B) any food commonly used for human consumption which is found on any premises or in any vehicle used for the handling, preparation, processing, storage, importation transportation, distribution, display or the sale of that food shall be presumed, until the contrary is proved, to be intended for human consumption; and,
- (C) any article commonly used in the manufacture, handling, processing, preparation, storage, display, transportation, distribution, serving or sale that food shall be presumed until the contrary is proved to be used for food intended for human consumption.

(12.1.2) Where any food for human consumption is sold or deposited with or consigned to any person for the purpose of sale for human consumption, contained in an unopened package, any person who appears from any statement on the package or on a label attached to the package, to have imported, manufactured or prepared such food or to have enclosed

it in such package, shall, until the contrary is proved, be deemed to have so imported, manufactured, prepared or enclosed the food.

(12.1.3) Where any article used in the manufacture, handling, processing, preparation, storage, display, transportation, distribution, serving or sale of food for human consumption is sold or deposited with or consigned to any person for the purpose of sale or for use in the manufacture, handling, processing, preparation, storage, display, transportation, distribution, serving or sale of food for human consumption, contained in an unopened package, any person who appears from any statement on the package or on a label attached to the package, to have imported manufactured or prepared such article or to have enclosed it in such package, shall, until the contrary is proved, be deemed to have been so imported, manufactured, prepared or enclosed these articles, as the case may be.

(12.1.4) If a National Food Inspector:

- (A) has made a copy of any record or part of a record pursuant to this Act or regulations; and,
- (B) has certified the copy to be a true and correct copy of that record or part of a record, the copy is admissible in evidence in any proceedings under this Act and regulations as evidence of the matters contained in the copy and, unless the contrary is proved, may be taken to be a true and correct copy.

12.2 Sampling and Analysis

For those Standards where Codex Standards are adopted within these Regulations, their adoption shall not be taken to include Codex requirements for sampling or for methods of analysis.

12.3 Interference with Official Marks

(12.3.1) A person who, willfully removes, erases, alters, breaks or opens a label, mark, seal, lock or fastening placed by a food inspector on any food, article, container or record without authority is guilty of an offense.

(12.3.2) Subpart (8.3.1) does not apply in respect of a part given to that person or his agent by a National Food Inspector.

12.4 Interference with official duties

(12.4.1) Any person who:

- (A) assaults, intimidates, obstructs or attempts to obstruct in any manner any National Food Inspector in the exercise of his/her duties under the Regulations;
- (B) refuses to allow, retakes-or attempts to retake any food, article or record seized, condemned, sold, obtained or sampled under the Regulations;
- (C) refuses to state, or states falsely, his or her name and place of residence upon demand by a National Food Inspector;
- (D) gives, procures, offers or promises a bribe, recompense or reward to influence any National Food Inspector in the exercise of his/her duties under the Regulations; or,

- (E) fails to comply with any order or demand given by a National Food Inspector authorized under the Regulations, is guilty of an offense.

12.5 Defences

(12.5.1) In any proceedings for an offense under the Regulations it shall be a defense for the defendant to prove:

- (A) that he could not with due diligence have ascertained that the sale of the article would be in contravention of the Regulations; and,
- (B) that in relation to an offense relating to the publication of an advertisement, the advertisement was received for publication in the ordinary course of business and he had no reason to believe that an offense would be committed by publishing such an advertisement.

(12.5.2) In any proceedings for an offense under these Regulations it shall be a defense for the defendant to prove that:

- (A) he committed the act or default constituting the offense in the course of acting as an agent or employee of another person and without knowledge of one or more of the facts constituting the offense; and,
- (B) the other person or employer is a firm or corporation having a place of business in Federated States of Micronesia.

12.6 Conviction Forfeiture and Costs

(12.6.1) On the conviction of a person for an offense against the Regulations, any food or article to which the conviction relates may, by order of the court, be forfeited for destruction or disposal.

(12.6.2) The costs incurred by the State local or provincial authority in connection with sampling, analysis and the lawful destruction or disposal of the food or article shall be ordered by the court to be a debt due to the state, local or provincial authority by the person against whom the conviction is made.

12.7 General Penalty

A person who is guilty of an offense against the Regulations for which no other penalty is prescribed is liable to a Minimum penalty of \$500

12.8 Cost Recovery

(12.8.1) The Secretary for Health and Social Affairs may charge extra or additional fees to recover cost for other services render by National Food Inspectors or Competent Authority Officers while performing their official duties.

(12.8.2) Under 12.8.1, the Secretary for Health and Social Affairs may explore the option of having an established revolving fund in close consultation with Congress in order to collect the extra or additional funds recover from the services render by National Food Inspectors or Competent authority officers to sustain operation costs.

PART 13 - SCHEDULES

SCHEDULE 1

MAXIMUM PERMITTED LEVELS OF CHEMICAL CONTAMINANTS

- (1) Maximum permitted levels of arsenic in edible fats and oils, named animal fats, named vegetable oils, olive oils and olive pumice oils, and fats spreads and blended spreads shall be 0.1 mg/Kg.
- (2) Maximum permitted levels of arsenic in salt shall be 0.5 mg/Kg.
- (3) Maximum permitted levels of cadmium in salt shall be 0.5 mg/Kg.
- (4) Maximum permitted levels of **cadmium in fish** and fisheries products shall be as prescribed below:

Product	Max level (mg/Kg)
Muscle meat of fish, excluding those listed below	0.05
Muscle meat of: bonito (<i>Sarda sarda</i>), horse mackerel or scad (<i>Trachurus, trachurus</i>), sardine (<i>Sardina pilchardus</i>), sardinops (<i>Sardinops species</i>), spotted seabass (<i>Dicentrarchus punctatus</i>), tuna (<i>Thunnus species</i> and <i>Euthynnys species</i>)	0.1
Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)	0.5
Muscle meat of swordfish (<i>Xiphias gladius</i>), anchovy(<i>Engraulis species</i>) and sardine (<i>Sardina pilchardus</i>)	0.25
Cephalopods (without viscera) and bivalve molluscs	1.0

- (5) Maximum permitted levels of copper in anhydrous milkfat, milkfat, anhydrous butter oil and butteroil and ghee shall be 0.05 mg/Kg.
- (6) Maximum permitted levels of copper in edible animal fats not elsewhere specified shall be 0.4 mg/Kg.
- (7) Maximum permitted levels of copper in salt shall be 2.0 mg/Kg.
- (8) Maximum permitted levels of iron in anhydrous milkfat, milkfat, anhydrous butter oil and butter oil and ghee shall be 0.2 mg/Kg.
- (9) Maximum permitted levels of lead in edible fats and oils shall be 0.2 mg/Kg unless otherwise stated as with the named animal fats and vegetable oils and olive oils and olive pumice oils.
- (10) Maximum permitted levels of lead in named animal fats, named vegetable oils, olive oils and olive pumice oils, and fats spreads and blended spreads shall be 0.1 mg/Kg.

- (11) Maximum permitted levels of lead in canned corned beef, canned luncheon meat and sugars shall be 0.5 mg/Kg.
- (12) Maximum permitted levels of lead in salt shall be 2 mg/Kg.
- (13) Maximum permitted levels of lead in infant formula shall be 0.02mg/Kg.
- (14) Maximum permitted levels of **lead in fish** and fisheries products shall be as prescribed below:

Product	Max Level (mg/Kg)
Muscle meat of fish, excluding those listed below.	0.3
Muscle meat of: bonito (<i>Sarda sarda</i>), horse mackerel or scad (<i>Trachurus, trachurus</i>), sardine (<i>Sardina pilcardus</i>), sardinops (<i>Sardinops species</i>), spotted seabass (<i>Dicentrarchus punctatus</i>), tuna (<i>Thunnus species</i> and <i>Euthynnys species</i>)	0.4
Crustaceans, excluding brown meat of crab	0.5
Cephalopods (without viscera)	1.0

- (15) Maximum permitted levels of mercury in fish and fisheries products shall be as prescribed below:

Product	Max level (mg/Kg)
Muscle meat of: anglerfish (<i>Lophius species</i>) atlantic catfish (<i>Anarhichas lupus</i>) bonito (<i>Sarda sarda</i>) eel (<i>Anguilla species</i>) emperor, orange roughy, rosy soldierfish (<i>Hoplostethus species</i>) grenadier (<i>Coryphaenoides rupestris</i>) halibut (<i>Hippoglossus hippoglossus</i>) marlin (<i>Makaira species</i>) megrim (<i>Lepidorhombus species</i>) mullet (<i>Mullus species</i>) pike (<i>Esox lucius</i>) plain bonito (<i>Orcynopsis unicolor</i>) poor cod (<i>Tricopterus minutes</i>) portuguese dogfish (<i>Centroscymnus coelolepis</i>) rays (<i>Raja species</i>) redfish (<i>Sebastes marinus</i> , <i>S. mentella</i> , <i>S. viviparus</i>) sail fish (<i>Istiophorus platypterus</i>) scabbard fish (<i>Lepidopus caudatus</i> , <i>Aphanopus carbo</i>) seabream, pandora (<i>Pagellus species</i>) shark (all species) snake mackerel or butterfish (<i>Lepidocybium flavobrunneum</i> , <i>Ruvettus pretiosus</i> , <i>Gempylus serpens</i>) sturgeon (<i>Acipenser species</i>)	1.0

swordfish (<i>Xiphias gladius</i>) tuna (<i>Thunnus</i> species, <i>Euthynnus</i> species, <i>Katsuwonus pelamis</i>)	
Fishery products and muscle meat of crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)	0.5

- (16) Maximum permitted levels of total mercury in all other species of fish other than those described in subpart (15) above shall be 0.5 mg/Kg.
- (17) Maximum permitted levels of mercury in salt shall be 0.1 mg/Kg.
- (18) Maximum permitted levels of tin in canned corned beef and canned luncheon meat shall be 50 mg/Kg unless it is in tinplate containers when the maximum permitted shall be 200 mg/Kg.
- (19) Maximum permitted levels of 3-chloro-1,2-propanediol in acid hydrolyzed foods such as, but not limited to, soy sauce and fish sauce shall be 0.2mg/Kg.
- (20) Maximum permitted levels of 1,3-dichloro-2-propanol in acid hydrolyzed foods such as, but not limited to, soy sauce and fish sauce shall be 5µg/Kg.
- (21) Smoked fish may contain formaldehyde incidentally absorbed in the processing in a proportion not exceeding 5 mg/Kg.
- (22) While not being permitted to be purposefully added to food, in recognition that some foods may become contaminated accidentally, the maximum permitted levels for melamine in food are 1mg/Kg in food for infants up to 3 years and 2.5mg/Kg for all other food.
- (23) While not being permitted to be purposefully added to animal feed, in recognition that some feed may become contaminated accidentally, the maximum permitted levels for melamine in feed for food animals is 2.5mg/Kg.
- (24) Mycotoxins shall not be at levels above those permitted by the Codex Alimentarius
- (25) Smoked meat may contain formaldehyde incidentally absorbed in the processing in a proportion not exceeding 5 mg/Kg.
- (26) For other environmental contaminants in Fish:
- (A) Dioxin and PCBs

Dioxins and PCBs	1 sample per species per year	3.5 pg/g dioxins (sum of dioxins) 6..5 pg/g wet weight dioxins and PCBs (sum of dioxins and dioxin-like PCBs) 75 ng/g wet weight (sum of PCB28, PCB52, PCB101, PCB138, PCB153, PCB180)
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(B) Benzo(a) pyrene

Benzo(a) pyrene (ONLY FOR SMOKED FISH PRODUCTS)	1 sample per species per year	Benzo(a)pyrene: 5.0 ug/kg smoked fish Sum of benzo(a)- pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: 12.0 ug/kg	LOD less than 0.3 ug/kg LOQ less than 0.9 ug/kg
Inorganic tin (only for canned fish)	Canned tuna: 10 cans per lot per year (1 sample)	200 ppm canned tuna	LOD less than 5 mg/kg LOQ less than 10 mg/kg

(27) Scombrototoxin

Histamine	9 samples every 6 months per species per company exporting	No more than 2 samples with results between 100 and 200 ppm and no results over 200 ppm
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The frequency of sampling could be altered based on satisfactory risk assessment carried out by the competent authority.

SCHEDULE 2

MAXIMUM LIMITS ON MICROBIOLOGICAL CONTAMINANTS IN FOODS

Food	Where criterion applies	Microorganism or microbial toxin/sample size	n	c	m	M
Milk powder, cream powder, and whey powder	Products prior to import, at point of import, and at the point of sale	<i>Salmonella</i> /25 g	5	0	0	
Powdered infant formula products		<i>Bacillus cereus</i> /25g	5	0	10 ² /g	10/g
		Coagulase-positive staphylococci/25g	5	1	0/g	
		<i>Salmonella</i> /25 g	5	0	0	
Egg products		<i>Salmonella</i> /25 g	5	0	0	
Packaged natural mineral water		<i>Escherichia coli</i> /250 ml	2	0	0	
		Total coliforms/100mL	2	0	0	
Packaged water and packaged waters defined by origin other than natural mineral water		<i>Escherichia coli</i> /250 ml	2	0	0	
		Total coliforms/100mL	2	0	0	
Packaged ice for human consumption		<i>Escherichia coli</i> /100 ml	2	0	0	
Ice cream	<i>Escherichia coli</i> /100g	2	0	0		
	<i>Salmonella</i> /25g	5	0	0		
Meat products intended to be eaten cooked sampled prior to cooking, including minced meat and meat preparations made from poultry meat and other species	<i>Salmonella</i> /10 g	5	0	0		
	<i>Salmonella</i> /10 g	5	0	0		
Turkey tails and other poultry tail products , intended to be eaten cooked, sampled prior to cooking						

Ready-to-eat meat not elsewhere addressed	<i>Salmonella</i> /25 g	5	0	0	
	<i>Escherichia coli</i> /100g	2	0	0	
Ready-to-eat cooked crustaceans including crabs, lobster, shrimp and prawns	Staphylococcal enterotoxins/25g	5	0	0	
	<i>Salmonella</i> /25 g	5	0	0	
Bivalve molluscs intended to be eaten raw	<i>Escherichia coli</i> /100g	1 ¹	0	230 MPN/100g	
	<i>Salmonella</i> /25 g	5	0	0	
Pre-cut fruit and vegetables (ready-to-eat)	<i>Escherichia coli</i> /25g	2	1	0	10
	<i>Salmonella</i> /25 g	5	0	0	
Ready-to-eat spices	<i>Salmonella</i> /25 g	5	0	0	
Battered and otherwise heavily handled food prior to or after cooking	Staphylococcal enterotoxins/25g	5	0	0	
	Coagulase-positive staphylococci/25g	5	1	0/g	10/g
Marine fish (other than bivalve molluscs) to be eaten raw	<i>Vibrio parahaemolyticus</i>	5	0	0	
	<i>Escherichia coli</i> /100g	1 ²	0	230 MPN/100g	

Where: n means the minimum number of sample units which shall be examined from a lot of food; c means the maximum allowable number of sample units with microbiological levels above m; M means the level that if exceeded in any one sample would cause the lot to be rejected as not meeting these Regulations.

¹ pooled from a minimum of 10 animals

² pooled from a minimum of 10 samples

SCHEDULE 3

TABLE OF CONDITIONS FOR NUTRIENT CONTENT CLAIMS

COMPONENT	CLAIM	CONDITIONS
		NOT MORE THAN
Energy	Low	40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
	Free	4 kcal per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.5 g per 100 g (solids) or 100 ml (liquids)
Saturated Fat	Low ³	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy
	Free	0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)
Cholesterol	Low ³	0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids)
	Free	0.005 g per 100 g (solids) 0.005 g per 100 ml (solids) and, for both claims, less than: 1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 ml (liquids) and 10% of energy of saturated fat
Sugars	Free	0.5 g per 100 g (solids) 0.5 g per 100 ml (liquids)
Sodium	Low	0.12 g per 100 g
	Very Low	0.04 g per 100 g
	Free	0.005 g per 100g
		NOT LESS THAN
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	2 times the values for “source”
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving
	High	2 times the value for “source”

³ In the case of the claim “low in saturated fat”, trans fatty acids should be taken into account where applicable. This provision consequentially applies to foods claimed to be “low in cholesterol” and “cholesterol free”.

SCHEDULE 4

STANDARDS ON MEAT AND MEAT PRODUCTS

1. Standard on Canned Corned Beef

(1.1) Without limitation to the generality of these Standards and the Codex Standard on canned corned beef, the following specific product requirements for product labeled as canned “corned beef” apply:

- (A) the total protein content in the final product shall not be less than 21% of the total mass;
- (B) the total fat content shall not exceed 21% of the total mass;
- (C) the date of minimum durability shall be indicated by the year; and,
- (D) all meat used in the manufacture of corned beef shall have been subjected to the inspection processes and it shall have been passed by an inspector as fit for human consumption.

(1.2) Wherever canned corned beef with a fat content exceeding 20% of the total mass is stored for display for sale to the consumer there shall be an associated shelf notice visible to consumers informing consumers that “This brand of canned corned beef is high in fat. For a healthy diet eat less”. Such a shelf notice shall be in a form prescribed by the health authorities in a brochure available to food businesses or on its website.

2. Standard on Canned Luncheon Meat

(2.1) Without limitation to the generality of these Standards and the Codex Standard on luncheon meat, the following specific product requirements for product labeled as canned “luncheon meat” shall apply:

- (A) the maximum percentage of fat content permitted in a product shall be 30% of the total mass;
- (B) in the final product, the meat and poultry shall be uniformly and thoroughly cured and the product shall be capable of being sliced;
- (C) all meat and poultry meat used in the manufacture of luncheon meat shall have been subjected to the inspection processes and it shall have been passed by an inspector as fit for human consumption; and,
- (D) raw or semi-processed meat and poultry meat, and luncheon meat shall be handled, stored or transported in an establishment in a manner that will protect the meat, poultry meat and the luncheon meat from contamination and deterioration.

(2.2) For shelf-stable products the date of minimum durability shall be declared by the year.

- (2.3) For products which are not shelf-stable i.e. which may be expected not to keep for at least 18 months in normal conditions of storage and sale, the date of minimum durability shall be declared by day, month and year.
- (2.4) Wherever canned luncheon meat with a fat content exceeding 20% of the total mass is stored for display for sale to the consumer there shall be an associated shelf notice visible to consumers informing consumers that "This brand of canned luncheon meat is high in fat. For a healthy diet eat less". Such a shelf notice shall be in a form prescribed by the health Authority in a brochure available to food businesses or on its website.

3. Standard on Sausages

(3.1) Sausage(s) means meat that is minced, or comminuted meat or a combination thereof, which may be combined with other foods, encased or formed into discrete units, but does not include meat formed or joined into the semblance of cuts of meat.

(3.2) Sausages shall contain:

- (A) no less than 500g/Kg of fat free meat flesh; and,
- (B) the proportion of fat in sausage shall be no more than 400g/Kg of the fat free meat flesh content.

4. Standard on Minced Meat or Sausages Labeled or Advertised in Such a Way as to Reference the Fat Content of the Meat or Sausage

(4.1) Where express or implied reference is made in relation to the fat content of minced meat or sausage, the maximum proportion of fat in the minced meat or sausage, expressed in g/100g, shall be:

- (A) declared on the label on package of the food; or,
- (B) where the food is not packaged, and is stored for display for sale to consumers, declared on an associated shelf notice visible to consumers.

5. Standard on Canned Meat with Other Food

(5.1) Canned meat with other food shall be the meat product prepared from meat, manufactured meat or smoked meat with other food, packed in clean containers that are hermetically sealed and processed by heat to ensure preservation. Where the meat is named first in the description or name on the container, the product shall contain not less than 45 per cent of meat of the kind so named.

(5.2) There shall be written in the label on a package containing canned meat with other food the words "meat with (state the name of the other food)" or any other word or words having the same or a similar effect.

(5.3) For shelf-stable products the date of minimum durability shall be declared by the year.

(5.4) For products which are not shelf-stable i.e., which may be expected not to keep for at least 18 months in normal conditions of storage and sale, the date of minimum durability shall be declared by day, month and year.

(5.5) Wherever food in this category, with a fat content exceeding 20% of the total mass, is stored for display for sale to the consumer there shall be an associated shelf notice visible to consumers informing consumers that "This brand of canned "meat with (state the name of the other food)" is high in fat. For a healthy diet eat less". Such a shelf notice shall be in a form prescribed by the health authorities in a brochure available to food businesses or on its website.

SCHEDULE 5

STANDARDS ON POULTRY AND POULTRY PRODUCTS, EGGS AND EGG PRODUCTS

5.1 Standard on turkey tails and other poultry tails

(1) No turkey tail or other poultry tail products shall be permitted for importation into or sale in FSM without having been produced and processed at least according to the requirements of Codex' Recommended International Code of Hygienic Practice.

(2) No turkey tail or other poultry tail products shall be permitted for importation into or sale in FSM without having been certified by the Competent Authority of the exporting country as being compliant with section (1) of this Standard and as being compliant with microbiological requirements of these Regulations.

(3) All turkey and other poultry tail products produced within FSM for domestic consumption shall comply with the good hygienic practices requirements specified in the Fourth Schedule and the microbiological criteria specified in the Twelfth Schedule.

(4) Wherever turkey tails or other poultry tails are stored for display for sale to the consumer there shall be an associated shelf notice visible to consumers informing consumers that "Poultry [Turkey] tails are high in fat. For a healthy diet eat less".

5.2 Standard on fluid loss from thawed poultry

(1) Frozen poultry when thawed shall yield no more than 60g/Kg of fluid as determined by any method approved by the Board.

5.3 Standard on eggs

- (1) Eggs shall only be displayed for sale and sold if -
- a. there is no putrefaction;
 - b. the eggs are stored under refrigeration;
 - c. the package has not been used previously;
 - d. the package carries an appropriate date marking;
 - e. no development of the embryo has begun; and
 - f. the shell is free from extraneous matter and unbroken

SCHEDULE 6

STANDARDS ON FISH AND FISHERIES PRODUCTS

1. Standard on Fresh Fish and Fish Products

(1.1) The term “fresh” shall only be used to refer to fish and fish products that are untreated except for refrigeration, storage on ice, or freezing upon catching at sea or in lakes or other bodies of water in order to prevent decomposition and spoilage.

(1.2) For fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Ponatomidae*, *Scombrosidae* and *Coryphaenidae*. **Sampling criteria:** Based on 9 samples, the mean value must not exceed 100 ppm, but 2 samples may exceed 100 ppm but no sample may exceed 200 ppm.

2. Standard on Canned Tuna and Bonito

(2.1) Without limitation to the generality of the Codex Standard on canned tuna and bonito, the following specific product requirements for canned tuna and bonito shall apply:

- (A) canned tuna and bonito are products consisting of the flesh of any of the species identified as tuna and bonito in Codex Standard 70 of 1981 and its revisions and are packed in hermetically sealed containers;
- (B) the name of the product as declared on the label shall be "tuna" or "bonito", and may be preceded or followed by the common or usual name of the species in a manner not to mislead the consumer;
- (C) the name of the product may be qualified or accompanied by a term descriptive of the color of the product, provided that the term "white" shall be used only for *Thunnus alalunga* (Albacore);
- (D) when the term “white” is used in accordance with subsection (2.1) (C), the flesh shall be predominantly white;
- (E) the form of presentation shall be declared in close proximity to the common name and shall be presented as “solid”, “chunk”, “flake”, “flakes”, “grated” or “shredded” as specified in Codex Standard 70 of 1981 and its revisions;
- (F) where the form of presentation is declared as prescribed in subsection (2.1) (E) it shall not be used in a misleading manner;
- (G) the name of the packing medium (water, oil or other) shall form part of the name of the food and shall not be misleading;
- (H) it shall be free of organisms capable of growth under normal storage conditions; and,
- (I) the product shall be free from container integrity defects which may compromise

the hermetic seal.

(2.2) In addition to the requirements specified in section (2.1), canned tuna and bonito with the following characteristics will be considered to be non-compliant with this Standard when more than one sample unit in a lot or consignment has any of the following characteristics. The samples:

- (A) are affected by persistent and distinct objectionable odors or flavors indicative of decomposition or rancidity;
- (B) contain excessively mushy or tough ingredients uncharacteristic of the product;
- (C) are affected by discoloration indicative of decomposition or rancidity or by sulfide staining of more than 5% of the fish by weight; or,
- (D) are affected by struvite crystals greater than 5 mm in length.

(2.3) Canned tuna and bonito shall comply with the maximum limits on histamine specified in this regulation and or standard.

3. Standard on Canned Sardine and Sardine-type Products

(3.1) Without limitation to the generality of the Codex Standard on canned sardine and sardine-type products, the following specific product requirements for canned sardine and sardine-type products shall apply:

- (A) canned sardines and sardine type products are products consisting of the flesh of any of the species identified in Codex standard 94 of 1981 and its revisions and are packed in hermetically sealed containers;
- (B) the name of the packing medium (water, oil or other) shall form part of the name of the food and shall not be misleading;
- (C) if the fish has been smoked or smoke flavored, this information shall appear on the label;
- (D) the product shall be free of organisms capable of growth under normal storage conditions; and,
- (E) the product shall be free from container integrity defects which may compromise the hermetic seal.

(3.2) In addition to the requirements specified section (3.1), canned sardines and sardine-type products with the following characteristics will be considered to be non-compliant with this Standard when more than one sample unit in a lot or consignment has any of the following characteristics. The samples:

- (A) are affected by persistent and distinct objectionable odors or flavors indicative of decomposition or rancidity;
- (B) contain excessively mushy or tough ingredients uncharacteristic of the product; are affected by discoloration indicative of decomposition or rancidity or by sulfide staining of more than 5% of the fish by weight; or,
- (C) are affected by struvite crystals greater than 5 mm in length.

(3.3) Canned sardines and sardine-type products shall comply with the maximum limits on histamine specified in this regulation and or standards.

4. Standard on Canned Mackerel

(4.1) Without limitation to the generality of the Codex Standard on canned finfish, the following specific product requirements for canned mackerel shall apply:

- (A) canned mackerel are products consisting of the flesh of any one of the fish genera commonly identified as mackerel including, but not limited to, members of the genera *Scomber* and *Scomberomorus* and species *Pneumatophorus diego* and *Auxis thazard* and are packed in hermetically sealed containers and have received a processing treatment sufficient to ensure commercial sterility;
- (B) the product shall be prepared from sound mackerel from which the heads, tails and viscera have been removed;
- (C) the name of the packing medium (water, oil or other) shall form part of the name of the food and shall not be misleading;
- (D) if the fish has been smoked or smoke flavored, this information shall appear on the label;
- (E) the product shall be free of organisms capable of growth under normal storage conditions; and,
- (F) the product shall be free from container integrity defects which may compromise the hermetic seal.

(4.2) In addition to the requirements specified in section (4.1), canned mackerel with the following characteristics will be considered to be non-compliant with this Standard when more than one sample unit in a lot or consignment has any of the following characteristics. The samples:

- (A) are affected by persistent and distinct objectionable odors or flavors indicative of decomposition or rancidity;

- (B) contain excessively mushy or tough ingredients uncharacteristic of the product;
- (C) are affected by discoloration indicative of decomposition or rancidity or by sulfide staining of more than 5% of the fish by weight; or,
- (D) are affected by struvite crystals greater than 5 mm in length.

(4.3) Canned mackerel shall comply with the maximum limits on histamine specified in this regulations and or standard.

5. Standard on Canned Finfish

(5.1) Without limitation to the generality of the Codex Standard 119 for canned finfish and its revisions, the following specific product requirements for canned finfish products (other than canned finfish covered by other product Standards) shall apply:

- (A) canned finfish products are products consisting of the flesh of finfish which is suitable for human consumption and may contain a mixture of species, with similar sensory properties, from within the same genus, and are packed in hermetically sealed containers and have received a processing treatment sufficient to ensure commercial sterility;
- (B) the product shall be prepared from sound finfish from which the heads, tails and viscera have been removed;
- (C) where a mixture of species of the same genus is used, the species used shall be indicated on the label;
- (D) the name of the product declared on the label shall be the common or usual name applied to the fish in the country and shall be presented in a manner not to mislead the consumer;
- (E) the name of the packing medium (water, oil or other) shall form part of the name of the food and shall not be misleading;
- (F) if the fish has been smoked or smoke flavored, this information shall appear on the label; and,
- (G) the product shall be free from container integrity defects which may compromise the hermetic seal.

(5.2) In addition to the requirements specified section (5.1), canned finfish products with the following characteristics will be considered to be non-compliant with this Standard when

more than one sample unit in a lot or consignment has any of the following characteristics.
The samples:

- (A) are affected by persistent and distinct objectionable odors or flavors indicative of decomposition or rancidity;
- (B) contain excessively mushy or tough ingredients uncharacteristic of the product;
- (C) are affected by discoloration indicative of decomposition or rancidity or by sulfide staining of more than 5% of the fish by weight; or,
- (D) are affected by struvite crystals greater than 5 mm in length.

(5.3) Canned finned fish of the relevant families shall comply with the maximum limits on histamine specified in this regulations and or standard.

SCHEDULE 7

STANDARD ON FROZEN FISH AND FISHERIES PRODUCTS

1. This Standard applies to all quick frozen fish; quick frozen lobster; quick frozen blocks of fish fillet, minced fish flesh and mixtures of fillets and minced fish; eviscerated and un-eviscerated quick frozen finfish; and quick frozen fish sticks (fish fingers), fish portions and fish fillets - breaded or battered.
2. The following specific product requirements shall apply for all fish and fish products under the scope of this Standard:
 - (A) if glazed, the water used for glazing or preparing glazing solutions shall be of potable quality or shall be clean sea-water; and,
 - (B) in addition to the general requirements on labeling, the following provisions shall apply:
 - (i) if the product has been glazed with sea-water, a statement to this effect shall be made;
 - (ii) where the food has been glazed, the declaration of net contents of the food shall be exclusive of the glaze; and,
 - (iii) the label shall include terms to indicate that the product shall be stored at a temperature of minus 18°C or colder.
3. In addition to the requirements specified in section 2, product referred to in section 1 shall be considered to be non-compliant with this Standard when more than one sample unit has any of the following characteristics:
 - (A) greater than 10% of the surface area of the sample unit exhibits excessive loss of moisture clearly shown as white or yellow abnormality on the surface;
 - (B) the presence of two or more parasites per kg of the sample unit with a capsular diameter greater than 3 mm or a parasite not encapsulated and greater than 10 mm in length;
 - (C) a bone or bones is/are present in product labeled boneless;
 - (D) affected with pasty texture resulting from parasitic infestation affecting more than 5% of the sample unit by weight;
 - (E) the presence of ruptured bellies in un-eviscerated fish, indicative of decomposition; and,
 - (F) Specifically, for quick frozen lobster, distinct blackening of more than 10% of the

surface area of the shell of individual whole or half lobster, or in the case of tail meat, distinct black, brown, green or yellow discolorations singly or in combination, of the meat affecting more than 10% of the weight.

4. Frozen fish of the relevant families shall comply with the maximum limits on histamine specified in this regulation and standard.

SCHEDULE 8

STANDARDS ON CEREAL AND CEREAL PRODUCTS

1. Standard on Rice

- (1.1) This Standard applies to husked rice, milled rice, and parboiled rice, all for direct human consumption; i.e., ready for its intended use as human food, presented in packaged form or sold loose from the package directly to the consumer. It does not apply to other products derived from rice or to glutinous rice.
- (1.2) Milled rice shall not be contaminated with more than 0.1% m/m extraneous inorganic matter (such as sand, stones, dust etc).
- (1.3) Milled rice shall not be contaminated with more than 1.5% m/m organic extraneous matter (such as seeds, straw, bran, husk etc).
- (1.4) In addition to the general requirements on labeling, the following provisions shall apply:
- (A) Fortified rice shall be labeled as “Fortified” or “Enriched” and shall identify the ingredient added for fortification purposes and shall specify the concentration in which it is present in the final product;
- (B) If rice is classified as long grain, medium grain or short grain, the classification used on the label on the product shall be in accordance with the specifications for such in Codex Standard 198.

2. Standard on Wheat Flour

- (2.1) This standard applies to:
- (A) Wheat flour for direct human consumption prepared from common wheat, *Triticum aestivum* L., or club wheat, *Triticum compactum* Host., or mixtures thereof, by grinding or milling processes in which the bran and germ are partly removed and the remainder is comminuted to a suitable degree of fineness, and which is prepackaged ready for sale to the consumer or destined for use in other food products; and,
- (B) Whole meal, whole-wheat flour or semolina, milled from common wheat, *Triticum aestivum* L., or club wheat, *Triticum compactum* Host., or mixtures thereof, and which is prepackaged ready for sale to the consumer or destined for use in other food products.
- (2.2) It does not apply to:
- (A) Any product prepared from durum wheat, *Triticum durum* Desf., singly or in combination with other wheat;
- (B) Wheat flour destined for use as a brewing adjunct or for the manufacture of starch and/or gluten; or,
- (C) Wheat flour for non-food industrial use.

(2.3)The following specific product requirements shall apply:

- (A) Wheat flour shall have a maximum moisture content of 15.5% m/m;
- (B) Wheat flour and any added ingredients shall be safe and suitable for human consumption;
- (C) Wheat flour shall be free from abnormal flavors, odors, and living insects;
- (D) Wheat flour shall be free from filth (impurities of animal origin, including dead insects) in amounts not consistent with good manufacturing practice;
- (E) Wheat flour shall be packaged in containers which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product;
- (F) The containers, including packaging material, shall be made of substances which are safe and suitable for their intended use. They shall not impart any toxic substance or undesirable odor or flavor to the product;
- (G) When the product is packaged in sacks, these shall be clean, sturdy and strongly sewn or sealed; and,
- (H) In addition to general requirements on labeling, the following provisions shall apply:
 - (i) The name of the product to be shown on the label shall be "wheat flour."; and,
 - (ii) Fortified wheat flour shall be labeled as "Fortified" or "Enriched" and shall identify the ingredients added for fortification purposes and shall specify the concentration in which it is present in the final product.

(2.4) The following specific product requirements shall apply only to wheat flour for direct human consumption prepared from common wheat, *Triticum aestivum* L., or club wheat, *Triticum compactum* Host., or mixtures thereof, by grinding or milling processes in which the bran and germ are partly removed and the remainder is comminuted to a suitable degree of fineness, and which is prepackaged ready for sale to the consumer or destined for use in other food products:

- (A) All such wheat flour imported, processed, displayed and/or sold in the country and/or exported from the country shall be prepared so as to provide the following minimum levels of micronutrients, including all nutrients naturally present, in the wheat flour at the point of import, the point of export and the point of sale:
 - (i) 6.0 mg/Kg of Thiamin from a source of thiamin mononitrate;
 - (ii) 2.0 mg/Kg of Riboflavin;
 - (iii) 55 mg/Kg of Niacin;
 - (iv) 2.0 mg/Kg of Folic acid;
 - (v) Iron from a source of elemental iron powder of 45 microns average diameter or similar made by an electrolytic reduction process at levels of 60mg/Kg or from ferrous fumarate at levels of 45mg/Kg or from other subsequently approved sources; and
 - (vi) 30 mg/Kg of zinc from a source of zinc oxide.
- (B) Notwithstanding subsection (2.4)(A), where such flour is to be exported and the requirements of the importing country are in conflict with this Standard, the wheat flour shall comply with the requirements of the importing country.

(2.5) Where whole meal, whole-wheat flour or semolina, milled from common wheat, *Triticum aestivum* L., or club wheat, *Triticum compactum* Host., or mixtures thereof, for sale or use in the country is enriched or fortified, it shall be prepared so as to provide the same minimum levels of micronutrients as specified in subsection (2.4)(A), including all nutrients naturally present, in the wheat flour at the point of import, the point of export and the point of sale.

SCHEDULE 9

STANDARD ON SALT AND SPICES

1 Standard on Salt and Reduced Sodium Salt Mixtures

(1.1) All salt for import into, and for use and sale in the country for processing of food and for direct human consumption shall:

- (A) be salt to which has been added potassium iodide or iodate, or sodium iodide or iodate;
- (B) contain potassium iodide or iodate, or sodium iodide or iodate equivalent to not less than 20 mg/Kg and not more than 30 mg/Kg of iodine; and,
- (C) contain no less than 97% sodium chloride on a dry matter basis, exclusive of permitted food additives.

(1.2) Reduced sodium salt mixtures shall contain no more than 200g/Kg sodium and 400g/Kg potassium.

(1.3) The addition of iodine-containing compounds to reduced sodium salt mixtures shall be in conformity with the aim of ensuring salt is iodized.

(1.4) In addition to general requirements on labeling, the following provisions shall apply:

- (A) Salt shall be labeled as “Fortified” or “Enriched” or “Iodized” and shall identify the ingredients added for fortification purposes and shall specify the concentration in which it is present in the final product; and,
- (B) Reduced sodium salt mixtures shall declare the sodium and potassium content, expressed per 100 g. This shall not constitute a nutrition claim.

(1.5) If necessary in order to avoid the loss of iodine, iodized salt shall be packed in air tight bags of either high density polyethylene (HDPE) or polypropylene (PP) (laminated or non-laminated) or LDPE-lined jute bags (Grade 1803 DW jute bags lined with 150 gauge polyethylene sheet) unless the food business is able to demonstrate consistently that it is able to meet the iodine concentrations specified in these Regulations with alternative packing approved by the Secretary of Health.

(1.6) Bags that have already been used for packing other articles such as fertilizers, cement, or chemicals shall not be reused for packing iodized salt.

(1.7) Iodized salt shall not be exposed to rain, excessive humidity or direct sunlight at any stage of storage, transportation or sale.

(1.8) Bags of iodized salt shall be stored only in covered rooms that have adequate ventilation.

2 General standards on spices and aromatic plants

2.1 The scope of this Standard applies to all spices imported, exported for sale, including but not limited to dried aromatic plants.

2.2 In addition to the general provisions on good hygienic practices in these Regulations, the following shall apply for spices under this Standard –

- A. Spices shall not be grown or produced in areas where the water used for irrigation might constitute a hazard to health to the consumer through the spices;
- B. Plants or parts of plants used for the preparation of spices may be dried naturally or artificially, provided adequate measures are taken to prevent contamination or alteration of the raw material during the process.
- C. If dried naturally, plants or part of plants shall not be in direct contact with the soil. They shall be placed on raised platforms or on a floor made of a suitable material.
- D. New concrete floors shall be used for drying only when it is absolutely certain that the new concrete is well-cured and free of excess water. It is safer to use an approved plastic cover spread over the entire new concrete floor as a moisture barrier prior to use for spices.
- E. Excessive heating/drying of material shall be avoided in order to retain its aromatic principles.
- F. Suitable precautions shall be taken to protect the spices from contamination by domestic animals, rodents, birds, mites and other arthropods or other objectionable substances during drying, handling and storage.
- G. Contamination from mineral oils used for processing natural fibre bags shall be prevented by the use of liners where appropriate. Reusable containers shall be properly cleaned and disinfested before reuse.
- H. The conveyances for transporting the harvested, cleaned, dried and packed spices from the place of production to storage for processing shall be cleaned and, as appropriate, well ventilated with dry air to remove moisture resulting from the respiration of spices, and to prevent moisture condensation,
- I. Raw materials shall be inspected and sorted prior to processing and where necessary, laboratory tests shall be conducted.
- K. Whenever spices have been treated with antimicrobial or pesticide, the type of treatment shall be stated explicitly in an accompanying certificate.
- L. Products which affect the storage life, quality or flavor of spices shall not be stored in the same room or compartment as spices. For example, such items as fruits, vegetables, fish, fertilizer, gasoline or lubricating oils, etc. shall not be stored along with spices.
- M. Spices and their products shall be stored at a moisture low enough so that the product can be held under normal storage conditions without development of mold or significant deterioration by oxidative or enzymatic changes.
- N. A storage environment shall be such that it can maintain relative humidity between 55 and 60% to protect quality and prevent mold growth. Where this is not practicable, spices shall be packed in waterproof and gas-proof containers and stored in a proper warehouse.
- O. Spice products shall be stored and transported under conditions that maintain the integrity of the container and the product within it. Carriers shall be clean, dry, weatherproof, free

from infestation and sealed to prevent water, rodents or insects from reaching the products.

2.3 In the absence of national standards on imported products shall meet label requirements and specific compositional requirements for spices, the codex standards shall be adopted.

SCHEDULE 10
STANDARDS ON EDIBLE FATS AND OILS

1 Standard on vegetable oils

(1) This Standard applies to the vegetable oils described in section (2) presented in a state for human consumption.

(2) The vegetable oils addressed in this Standard shall be -

- a. Arachis oil (peanut oil; groundnut oil) is derived from groundnuts (seeds of *Arachis hypogaea* L.).
- b. Coconut oil is derived from the kernel of the coconut (*Cocos nucifera* L.).
- c. Maize oil (corn oil) is derived from maize germ (the embryos of *Zea mays* L.).
- d. Shallardseed oil is derived from the seeds of white shallard (*Sinapis alba* L. or *Brassica hirta* Moench), brown and yellow shallard (*Brassica juncea* (L.) Czernajew and Cossen) and of black shallard (*Brassica nigra* (L.) Koch).
- e. Palm kernel oil is derived from the kernel of the fruit of the palm oil (*Elaeis guineensis*).
- f. Palm oil is derived from the fleshy mesocarp of the fruit of the oil palm (*Elaeis guineensis*).
- g. Palm oelin is the liquid fraction derived from the fractionation of palm oil (described above).
- h. Palm stearin is the high-melting fraction derived from palm oil (described above).
- i. Palm superolein is a liquid fraction derived from palm oil (described above) produced through a specially controlled crystallization process to achieve an iodine value of 60 or higher.
- j. Rapeseed oil (acid turnip rape oil; colza oil; ravisson oil; sarson oil; toria oil) is produced from seeds of *Brassica napus* L., *Brassica campestris* L., *Brassica juncea* L. and *Brassica tournefortii* Gouan species.
- k. Rapeseed oil - low erucic acid (low erucic acid turnip rape oil; low erucic acid colza oil; canola oil) is produced from low erucic acid oil-bearing seeds of varieties derived from the *Brassica napus* L., *Brassica campestris* L, and *Brassica juncea* L., species.
- l. Safflowerseed oil (safflower oil; carthamus oil; kurdee oil) is derived from safflower seeds (seeds of *Carthamus tinctorious* L.).
- m. Safflowerseed oil - (high oleic acid (high oleic acid safflower oil; high oleic acid carthamus oil; high oleic acid kurdee oil) is produced from high oleic acid oil-bearing seeds of varieties derived from *Carthamus tinctorious* L.
- n. Sesameseed oil (sesame oil; gingelly oil; benne oil; ben oil; till oil; tillie oil) is derived from sesame seeds (seeds of *Sesamum indicum* L.).
- o. Soya bean oil (soybean oil) is derived from soya beans (seeds of *Glycine max* (L.) Merr.).
- p. Sunflowerseed oil (sunflower oil) is derived from sunflower seeds (seeds of *Helianthus annuus* L.).
- q. Sun flowerseed oil - high oleic acid (high oleic acid sunflower oil) is produced from high oleic acid oilbearing seeds of varieties derived from sunflower seeds (seeds of

Belianthus annuus L.).

r. Sunflowerseed oil - mid oleic acid (mid-oleic acid sunflower oil) is produced from mid-oleic acid oilbearing sunflower seeds (seeds of Belianthus annuus L.).

- (3) Edible vegetable oils are foodstuffs which are composed primarily of glycerides of fatty acids being obtained only from vegetable sources. They may contain small amount of other lipids such as phosphatides, of unsaponifiable constituents and of free fatty acids naturally present in the fat or oil.
- (4) Virgin oils are obtained, without altering the nature of the oil, by mechanical procedures, e.g. expelling or pressing, and the application of heat only. They may have been purified by washing with water settling, filtering and centrifuging only.
- (5) Cold pressed oils are obtained, without altering the oil, by mechanical procedures only, e.g. expelling or pressing, without the application of heat. They may have been purified by washing with water, settling, filtering and centrifuging only.
- (7) Low-erucic acid rapeseed oil shall not contain more than 2% erucic acid (as % of total fatty acids).
- (8) High oleic acid safflower oil shall contain not less than 70% oleic acid (as a % of total fatty acids).
- (9) High oleic acid sunflower oil shall contain not less than 75% oleic acid (as % of total fatty acids).
- (10) The arachidic and higher fatty acid content of arachis oil shall not exceed 48g/Kg.
- (11) No food additives are permitted in virgin or cold pressed oils.
- (12) Food additives added to these oils shall comply with the Codex General Standard on Food Additives (192-1995) and its revisions.
- (13) Vegetable oils shall be produced in accordance with the general principles of hygienic practice as prescribed in the Fourth Schedule of these Regulations.
- (14) The color, odor and taste of each product shall be characteristic of the designated product.
- (15) Each product shall be free from foreign matter, foreign odor, rancid odor and foreign and rancid taste.
- (16) In addition to the general requirements on labeling of pre-packaged foods the name of the oil shall conform to the descriptions given in section (2).
- (17) Where more than one name is given for a product in section 2.1 of the Codex Standard, the labelling of that product shall include one of those names.

1.2 Standard on olive oils and olive pomace oils

- (1) This Standard applies to the olive oils and olive-pomace oils defined in section (2) and presented in a state for human consumption.
- (2) For the purposes of this Standard -
 - a. "olive oil" is the oil obtained solely from the fruit of the olive tree (*Olea europaea* L.), to the exclusion of oils obtained using solvents or re-esterification processes and of any mixture with oils of other kinds;
 - b. "virgin olive oils" are the oils obtained from the fruit of the olive tree solely by mechanical or other physical means under conditions, particularly thermal conditions, that do not lead to alterations in the oil, and which have not undergone any treatment other than washing, decanting, centrifuging and filtration; and
 - c. "olive-pomace oil" is the oil obtained by treating olive-pomace with solvents or other physical treatments, to the exclusion of oils obtained by re-esterification processes and of any mixture with oils of other kinds.
- (3) Composition, quality factors and food additives permitted for use in olive oils and olive pomace oils shall comply with Codex Standard 33-1981 and its revisions.
- (4) Notwithstanding the generality of section (3) -
 - a. extra virgin olive oil shall be virgin olive oil with a free acidity, expressed as oleic acid, of not more than 0.8 grams per 100 grams and whose other characteristics correspond to those laid down for this category;
 - b. virgin olive oil shall be virgin olive oil with a free acidity, expressed as oleic acid, of not more than 2.0 grams per 100 grams and whose other characteristics correspond to those laid down for this category.
 - c. ordinary virgin olive oil shall be virgin olive oil with a free acidity, expressed as oleic acid, of not more than 3.3 grams per 100 grams and whose other characteristics correspond to those laid down for this category
 - d. refined olive oil shall be olive oil obtained from virgin olive oils by refining methods which do not lead to alterations in the initial glyceridic structure it has a free acidity, expressed as oleic acid, of not more than 0.3 grams per 100 grams and its other characteristics correspond to those laid down for this category.
 - e. olive oil shall be oil consisting of a blend of refined olive oil and virgin olive oils suitable for human consumption, it has a free acidity, expressed as oleic acid, of not more than 1 gram per 100 grams and its other characteristics correspond to those laid down for this category.
 - f. refined olive-pomace oil shall be oil obtained from crude olive-pomace oil by refining methods which do not lead to alterations in the initial glyceridic structure. It has a free acidity, expressed as oleic acid, of not more than 0.3 grams per 100 grams and its other characteristics correspond to those laid down for this category.
 - g. olive-pomace oil shall be oil consisting of a blend of refined olive-pomace oil and virgin olive oils. It has a free acidity, expressed as oleic acid, of not more than 1 gram per 100 grams and its other characteristics correspond to those laid down for this category.
- (5) No food additives are permitted in virgin or cold pressed oils.

- (6) The addition of alpha-tocopherol to refined olive oil, olive oil, refined olive-pomace oil and olive-pomace oil is permitted to restore natural tocopherol lost in the refining process. The concentration of alpha-tocopherol in the final product shall not exceed 200 mg/Kg.
- (7) For the oils under this Standard, the maximum content of each halogenated solvent shall be 0.1 mg/Kg and the maximum content of the sum of all halogenated solvents shall be 0.2 mg/Kg.

1.3 Standard on animal fats Standard applies to the animal fats presented in a state for human consumption.

- (1) The fats addressed in this standard shall be -
- a. pure rendered lard is the fat rendered from fresh, clean, sound fatty tissues from swine (suscrofa) in good health, at the time of slaughter, and fit for human consumption. The tissues do not include bones, detached skin, head, skin, ears, tails, organs, windpipes, large blood vessels, scrap fat, skimmings, settlings, pressings, and the like, and are reasonably free from muscle tissues and blood.
 - b. Lard subject to processing may contain refined lard, lard stearin and hydrogenated lard, or be subject to processes of modification provided that it is clearly labeled.
 - c. Rendered pork fat is the fat rendered from the tissues and bones of swine (sus scrofa) in good health, at the time of slaughter, and fit for human consumption it may contain fat from bones (properly cleaned), from detached skin, from head skin, from ears, from tails and from other issues fit for human consumption.
 - d. rendered pork fat subject to processing may also contain refined lard, refined rendered pork fat, hydrogenated lard, hydrogenated rendered pork fat, lard stearin and rendered pork fat stearin provided that it is clearly labeled.
 - e. Premier jus (oleo stock) is the product obtained by rendering at low heat the fresh fat (killing fat) of heart, caul, kidney and mesentery collected at the time of slaughter and fit for human consumption, as well as cutting fats.
 - f. edible tallow (dripping) is the product obtained by rendering the clean, sound, fatty tissues (including trimming and cutting fats), attendant muscles and fatty tissues of bovine animals and/or sheep (ovisaries) in good health at the time of slaughter and fit for human consumption.
 - g. edible tallow subject to processing may contain refined edible tallow, provided that it is clearly labeled.
- (3) Fatty acid composition (expressed as percentage) for each fat shall be as prescribed in Codex Standard 211 and its revisions. Samples falling within the appropriate ranges specified therein are in compliance with this Standard.
- (4) Food additives shall comply with the Codex General Standard on Food Additives (192-1995) and its revisions.
- (5) The color, odor and taste of each product shall be characteristic of the designated product. It shall be free from foreign and rancid odor and taste.

- (6) In addition to the general requirements on labeling of pre-packaged foods, the name of the fat shall conform to the descriptions given in section (2).

1.4 Standard on butter

- (1) This Standard applies to butter principally in the form of an emulsion of the type water-in-oil, and intended for direct consumption.
- (2) Ingredients permitted for use in butter shall include a fatty product derived exclusively from milk and/or products obtained from milk, sodium chloride and food grade salt, starter cultures of harmless lactic acid and/or flavor producing bacteria, and potable water in accordance with Codex Standard A-1-1971 and its amendments.
- (3) Butter shall have a minimum milkfat content of 80% m/m, a maximum water content of 16% m/m and maximum milk solid-not-fat content of 2% m/m.
- (4) Food additives permitted for use in butter shall comply with the Codex General Standard on Food Additives (192-1995 and its revisions).
- (5) In addition to the general requirements on labelling of pre-packaged foods -
- A. the name of food shall be "butter";
 - b. the name "butter" with a suitable qualification shall be used for butter with more than 95% fat;
 - c. the product shall be labelled to indicate whether it is salted or unsalted;
 - d. the milkfat content shall be declared either as a percentage by mass, or in grams per serving as quantified in the label provided that the number of servings is stated.

1.5 Standard on dairy fat spreads

- (1) This Standard applies to dairy fat spreads intended for use as spreads for direct consumption, or for further processing.
- (2) Dairy fat spreads are milk products relatively rich in fat in the form of a spreadable emulsion principally of the type of water-in-milk fat that remains in solid phase at the temperature of 20°C.
- (3) Raw materials shall be milk and/or products obtained from milk that may have been subjected to any appropriate processing (e.g. physical modifications including fractionation) prior to its use.
- (4) Only the following ingredients may be added -
- a. flavors and flavorings;
 - b. safe and suitable processing aids;
 - c. sodium chloride and potassium chloride as a salt substitute;
 - d. sugars (any carbohydrate sweetening matter);
 - e. inulin and malto-dextrins (limited by GMP);
 - f. starter cultures of harmless lactic acid and/or flavor producing bacteria;
 - g. water;
 - h. gelatine and starches (limited by GMP). These substances can be used in the same

- function as thickeners, provided they are added only in amounts functionally necessary as governed by GMP; and
- i. other ingredients only as permitted by the Board.

- (5) The milk fat content shall be no less than 10% and less than 80% (m/m) and shall represent at least 2/3 of the dry matter.
- (6) Food additives shall comply with the Codex General Standard on Food Additives (192-1995) and its revisions.
- (7) The color, odor and taste of each product shall be characteristics of the designated product. It shall be free from foreign and rancid odor and taste.
- (8) In addition to the general requirements on labelling of pre-packaged foods -
 - a. The name of the food shall be "Dairy Fat Spread" or other alternative permitted by the Secretary for Health or delegate.
 - b. Dairy fat spreads with reduced fat content may be labelled as "reduced fat" in line with the Regulation on nutrition and health claims.
 - c. Dairy fat spread shall be labelled to indicate whether it is salted or unsalted.
 - d. Dairy fat spreads that have been sweetened shall be labelled to indicate that they have been sweetened.
 - e. The milk fat content shall be declared either (i) as a percentage by mass, or (ii) in grams per serving as quantified in the label provided that the number of servings is stated.

1.6 Standard on fat spreads and blended spreads

- (1) This Standard applies to fat products, containing not less than 10% and not more than 90% fat, intended primarily for use as spreads. However, this Standard does not apply to fat spreads derived exclusively from milk and/or milk products to which only other substances necessary for their manufacture have been added. Butter and dairy spreads are not covered by this Standard.
- (2) For the purposes of this Standard -
 - a. "edible fats and oils" means foodstuffs composed of glycerides of fatty acids they are of vegetable or animal (including milk) or marine origin they may contain small amounts of other lipids such as phosphatides, of unsaponifiable constituents and of free fatty acids naturally present in fat or oil;
 - b. fats of animal origin shall, if originating from slaughtered animals, be obtained from animals in good health at the time of slaughter and fit for human consumption;
 - c. fats and oils that have been subjected to processes of physical or chemical modification including fractionation, inter-esterification or hydrogenation are included;
 - d. fat spreads shall be products in which any milk fat content shall be no more than 3% of the total fat content; and
 - e. blended spreads shall be products in which milk fat is more than 3% of the total fat content.
- (3) Composition, quality factors and food additives permitted for use in fat spreads and blended spreads shall comply with the relevant Codex Standard and its revisions.

- (4) No withstanding the generality of section (3), margarine shall be a fat spread with equal to or greater than 80% fat, unless otherwise specified, and whose other characteristics correspond to those laid down for this category.
- (5) For the oils under this Standard, the maximum content of each halogenated solvents shall be 0.1 mg/Kg and the maximum content of the sum of all halogenated solvents shall be 0.2 mg /Kg.
- (6) In addition to the general requirements on labeling of pre-packaged foods, the labeling of fat spreads and blended spreads shall conform to -
 - a. the descriptions given in sections (2) and (4) of this Standard; and
 - b. Codex guidance, and
 - c. The requirements of these Regulations on nutrition claims
- (7) The term "margarine" may be used for a fat spread with a fat content of less than 80% provided that the term is qualified to make clear the lower fat content.
- (8) Fat spreads with a fat content of 39 to 41% may be designated as "Margarine" or Halvarine".
- (9) The product shall be labeled to indicate fat content in a manner that is clear and not misleading to the consumer.
- (10) The product shall be labeled to indicate salt content in a manner that is clear and not misleading to the consumer.

1.7 Standard on edible fats and oils not addressed in other Standards

- (1) This Standard applies to oils and fats and mixtures thereof in a state for human consumption. It includes oils and fats that have been subjected to processes of modification (such as transesterification or hydrogenation) or fractionation. This Standard does not apply to any oil or fat which is covered by other Standards.
- (2) For the purposes of this Standard -
 - a. "Virgin" fats and oils are edible vegetable fats and oils obtained, without altering the nature of the oil, by mechanical procedures, e.g. expelling or altering and the application of heat only. They may be purified by washing with water, settling, filtering and centrifuging only.
 - b. "Cold pressed" fats and oils are edible vegetable fats and oils obtained, without altering the oil, by mechanical procedures, e.g. expelling or pressing, without the application of heat. They may have been purified by washing with water, settling, filtering and centrifuging only.
- (3) No additives are permitted in virgin or cold pressed oils covered by this Standard.
- (4) No colors are permitted in vegetable oils covered by this Standard.

- (5) Additives are permitted only in accordance with Codex Standard 19-1981 and its revisions.
- (6) In addition to the general requirements on labeling of pre-packaged foods the following specific provisions apply -
- a. The designation "virgin fat" or "virgin oil" may only be used for individual fats or oils conforming to the definition in section (2) of this Standard.
 - b. The designation "cold pressed fat" or "cold pressed oil" may only be used for individual fats or oils conforming to the definition in section (2) of this Standard

SCHEDULE 11
SUGAR AND HONEY

1. Standard on sugars- All sugar for import into or export into and for use and sale in the country for processing of food and for direct human consumption shall:

(1) Sugars shall not contain more sulphur dioxide (or sulphites calculated as sulphur dioxide) than prescribed below -

- a. 15 mg/kg in white sugar, powdered sugar, dextrose anhydrous, dextrose monohydrate, powdered dextrose and fructose
- b. 20 mg/kg in soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup and raw cane sugar
- c. 70 mg/kg in plantation or mill white sugar
- d. 150 mg/kg in dried glucose syrup used to manufacture sugar confectionery
- e. 400 mg/Kg in glucose syrup used to manufacture sugar confectionery

(2) In addition to the general requirements on labeling of pre-packaged food, the following provisions shall apply -

- a. The name of the product shall conform to the product composition prescribed in Codex Standard 212.
- b. The presence of sulphite shall be declared on the label if the level exceeds 10 mg/Kg.

2. Standard on honey- All honey for import into or export into and for use and sale in the country for processing of food and for direct human consumption shall:

(1) The scope of this Standard applies to all honey for sale, including but not limited to coconut honey, blossom honey, nectar honey and honeydew honey.

(2) Honey consists essentially of different sugars, predominantly fructose and glucose as well as other substances such as organic acids, enzymes and solid particles derived from honey collection. The color of honey varies from nearly colorless to dark brown. The consistency can be fluid, viscous or partly to entirely crystallized. The flavor and aroma vary, but are derived from the plant origin.

(3) Honey sold as such shall not have added to it any food ingredient, including food additives, nor shall any other additions be made other than honey. This includes but is not limited to sugars.

(4) Honey shall not have any objectionable matter, flavor, aroma, or taint absorbed from foreign matter during its processing and storage.

(5) Honey shall not have begun to ferment or effervesce.

(6) No pollen or constituent particular to honey may be removed except where this is

unavoidable in the removal of foreign inorganic or organic matter.

- (7) Honey shall not be heated or processed to such an extent that its essential composition is changed and/or its quality is impaired.
- (8) Chemical or biochemical treatments shall not be used to influence honey crystallization.
- (9) Honey shall not have a moisture content of more than 20% with the exception of heather honey (*Calluna*) which shall not exceed 23% moisture content.
- (10) The fructose and glucose content (summed together) shall not be less than 60g/100g with the exception that blends of honeydew honey with blossom honey shall not be less than 45g/100g.
- (11) The sucrose content of honey shall not be more than 5g/100g unless otherwise exempted.
- (12) Honey of Alfalfa (*Medicago sativa*), Citrus spp., False Acacia (*Robinia pseudoacacia*), French, Honeysuckle (*Hedysarum*), Menzies Banksia, (*Banksia menziesii*), Red Gum (*Eucalyptus camaldulensis*), Leatherwood (*Eucryphia lucida*), and *Eucryphia milligani* shall not have a sucrose content in excess of 10 g/100g.
- (13) The water insoluble content of honeys other than pressed honey shall not be more than 0.1 g/100g while pressed honey shall not be more than 0.5 g/100g.
- (14) Honey shall comply with the appropriate sections of the general principles of hygiene established in these Regulations.
- (15) Exporters of honey, where necessary for the purposes of meeting the needs of an importing country's requirements, shall apply all good hygienic practices including the principles of HACCP to all steps for which they are responsible from production to distribution and sale.
- (16) In addition to the general provisions on labelling -
 - a. honey may be designated by the name of the geographical or topographical region only if the honey was produced exclusively within the area referred to in the designation;
 - b. honey may be designated according to floral or plant source only if it comes wholly or mainly from that particular source and has the organoleptic, physicochemical and microscopic properties corresponding with that origin;
 - c. where honey has been designated according to floral or plant source then the common name or the botanical name of the floral source shall be in close proximity to the word "honey";
 - d. where honey has been designated according to floral, plant source, or by the name of a geographical or topological region, then the name of the country where the honey has been produced shall be declared;
 - e. product may be designated as "extracted honey" provided the honey is

- obtained by centrifuging decapped broodless combs;
- f. product may be designated as "pressed honey" provided the honey is obtained by pressing broodless combs;
 - g. product may be designated as "drained honey" provided the honey is obtained by draining decapped broodless combs;
 - h. it shall not be permitted to label honey as described in sections (e)-(g) unless the particular method of removal from the comb has been applied;
 - i. honey may be designated as "honey" if it is honey in liquid or crystalline state or a mixture of the two;
 - j. honey shall be designated as "comb honey" if it is honey stored by bees in the cells of freshly built broodless combs and which is sold in sealed whole combs or sections of such combs;
 - k. honey shall be designated as "cut comb honey" or "chunk honey" if it is honey containing one or more pieces of comb honey;
 - l. honey which has been filtered in such a way as to result in the significant removal of pollen shall be designated filtered honey.

SCHEDULE 12

STANDARDS ON BEVERAGES

1 Standard on packaged waters (other than natural mineral waters)

(1) In this Standard, unless the context otherwise requires

"Packaged waters", other than natural mineral waters, are waters packaged or bottled for human consumption and may contain minerals, naturally occurring or intentionally added; may contain carbon dioxide, naturally occurring or intentionally added; but shall not contain sugars, sweeteners, flavorings or other foodstuffs.

"Prepared waters" are packaged waters that may originate from any type of water supply. Packaged waters that are "Waters defined by origin", whether they come from the underground or from the surface, share the following characteristics:

- a. they originate from specific environmental resources without passing through a community water system;
- b. precautions have been taken within the vulnerability perimeters to avoid any pollution of, or external influence on, the chemical, microbiological and physical qualities of water at origin;
- c. collecting conditions which guarantee the original microbiological purity and essential elements of their chemical make-up at origin; and
- d. is constantly fit for human consumption at source.

(2) Without limitation to the generality of these Standards and the Codex Standard on bottled/package water (Codex Standard 227), the following specific product requirements for bottled/package water shall apply:

- a. No packaged water shall contain substances or emit radioactivity in quantities that may be injurious to health.
- b. All packaged water shall comply with the microbiological criteria specified in these Regulations.
- c. Any addition of minerals to water before packaging shall comply with the provisions in the Codex General Standard on Food Additives (STAN 192-1995, Rev. 1-1997) and its revisions.
- d. When prepared water is supplied by a public or private tap water distribution system and subsequently packaged, but has not undergone further treatment that would modify its original composition or to which carbon dioxide or fluoride have been added, the wording "From a public or private distribution system" shall appear on the label.
- e. No claims concerning medicinal (preventive, alleviative or curative) effects shall be made in respect of the properties of the product covered by this Standard. Claims of other beneficial effects related to the health of the consumer shall not be made unless true and not misleading.
- f. The use of any statement or of any pictorial device which may create confusion in the mind of the public or in any way mislead the public about the nature,

origin, composition and properties of packaged waters put on sale is prohibited.

- (3) For packaged water defined by origin, the following additional specific product requirements shall apply -
- a. Waters defined by origin shall not, prior to packaging, be modified or subjected to treatments other than those described in the Codex Standard with the proviso that these modifications or treatments and the processes used to achieve them do not change the essential physicochemical characteristics nor compromise the chemical, radiological and microbiological safety of these waters when packaged:
 - b. Antimicrobial treatments may be used singly or in combination solely in order to conserve the original microbiological fitness for human consumption, original purity and safety of waters defined by origin.
 - c. Any water labeled "spring" in any manner that might leave the consumer with the impression that the water's origin is a natural spring, when it is not from such a source shall not be permitted.
 - d. The name given to packaged water defined by origin shall not be misleading to consumers as to the origin of the water.
 - e. Only waters defined by origin can be represented by names that refer to the origin or give an impression of specific origin.
- (4) The following specific hygienic practices shall be applied by food business operators to packaged water other than natural mineral water and these shall be applied in addition to the general hygiene requirements specified in these Regulations -
- a. The food business operator shall implement a documented food safety plan based upon good hygienic practices and HACCP principles and this plan shall be being actively implemented.
 - b. All possible precautions shall be taken to avoid any pollution of, or external influence on, the quality of the water source.
 - c. Disposal of liquid, solid or gaseous waste that could pollute ground or surface water shall be controlled. Disposal of pollutants such as microorganisms, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic and inorganic substances in the watershed shall be avoided.
 - d. Drinking water resources shall not be in the path of potential sources of underground contamination, such as sewers, septic tanks, industrial waste ponds, gas or chemical tanks, pipelines and solid waste disposal sites.
 - e. Water supplies shall be tested by food business operators regularly for constancy of biological (including microbial), chemical, physical and, where necessary, radiological characteristics. The frequency of testing shall be adequate to ensure the safety of the water supplies and shall be prescribed in the food safety plan.
 - f. If contamination is detected, production of bottled water shall cease until the water characteristics have returned to established parameters.
 - g. Any water source shall be approved by relevant authority prior to commencement of operation.
 - h. The extraction or collection of water intended for bottling shall be conducted

in such a manner as to prevent other than the intended water from entering the extraction or collection device. The extraction or collection of water intended for bottling shall also be conducted in a hygienic manner to prevent any contamination. Where sampling points are necessary, they shall be designed and operated to prevent any contamination of the water.

- i. The immediate surroundings of the extraction or collection area shall be protected by limiting access to only authorized persons. Wellheads and spring outflows shall be protected by a suitable structure to prevent entry by unauthorized individuals, pests, dust and other sources of contamination such as extraneous matter, drainage, floodwaters, and infiltration water.
- j. Methods and procedures for maintaining the extraction facilities shall be hygienic. They shall not be a potential hazard to humans or a source of contamination for the water.
- k. Wells shall be properly disinfected following construction and development of new wells nearby, after pump repair or replacement, or any well maintenance activity such as testing for and finding indicator organisms, pathogens, or abnormal plate counts in the water, and whenever biological growth inhibits proper operation.
- l. Water collection chambers shall be disinfected within a reasonable time before use.
- m. Extraction devices such as those used for bore holes shall be constructed and maintained in a manner that avoids contamination of the water and minimizes hazards to human health.
- n. When storage and transport of the water intended for bottling from the point of origin to the processing plant is necessary, these operations shall be conducted in a hygienic manner to prevent any contamination.
- o. Where or when they are necessary, bulk containers and conveyances such as tanks, pipings and tanker trucks shall be designed and constructed so that they –
 - i. do not contaminate the water intended for bottling;
 - ii. can be effectively cleaned and disinfected;
 - iii. provide effective protection from contamination, including dust and fumes; and
 - iv. allow any situation that arises to be checked easily.
- p. Means of transport of water intended for bottling shall be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances, particularly in bulk transport, shall preferably be used only for transporting water intended for bottling. When this cannot be achieved, conveyances and bulk containers shall be used exclusively for food transportation and shall be cleaned and disinfected as necessary to prevent contamination.
- q. In those areas of the processing establishment where containers are exposed to the external environment (i.e., on the loading dock), especially prior to filling and sealing, specific preventive measures shall be incorporated into the facility's design to avoid contamination of the containers used for bottled

water.

- r. No waters intended for bottling shall be accepted by an establishment if it is known to contain pathogens or excessive residues of pesticides or other toxic substances.
- s. Water intended for bottling shall be such (i.e. microbiologically, chemically, physically, and radiologically), that treatment if necessary (including multiple barrier treatments such as combination of filtration, chemical disinfection, etc.) of that water during processing results in finished bottled drinking water products that are safe and suitable for consumption.
- t. Bottling operations (i.e. filling and sealing of containers) shall be conducted in a manner that protects against contamination. Control measures include the use of an enclosed area and a containment enclosed system separate from other operations of the processing plant to protect against contamination. Dust, dirt, microorganisms in the air, and condensation shall be controlled and monitored.
- u. Reusable containers shall not have been used for any purpose that may lead to contamination of the product and shall be individually inspected for suitability. New containers shall be inspected and, if necessary, cleaned and disinfected.
- v. Closures are generally supplied in a ready to use state and shall be tamper resistant; they are not reusable.

SCHEDULE 13

OFFENCES AND PENALTIES

Section	Offences	Penalties
3.17.1 (a)	Any food business operator or any person who prepares, processes, manufactures, packs, keeps, conveys, exports, imports or sells any food locally or distributes food for sale to other states that - is in a manner which is unsafe and unfit for human consumption;	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
(b)	have been adulterated;	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
(c)	stores, advertises for sale, displays for sale or sells a food past its-expiration (use-by date);	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
(d)	advertises for sale, displays for sale or sells a food past its date of minimum durability (best before) or the quality has deteriorated to such an extent that, in the opinion of an authorized officer, a consumer would be misled as to the quality of the food;	Fine of up to \$1,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 6 months.

(e)	advertises for sale, displays for sale or sells a food past its baked on date or the quality has deteriorated to such an extent that, in the opinion of an authorized officer, a consumer would be misled as to the quality of the food;	Fine of up to \$1,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 6 months.
(f)	intentionally remove and replace expiration date (use-by date) or date of minimum durability (best before) or baked on dates, or other date markings in order to continue the sales of the food product(s);	Fine of up to \$10,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
(g)	stores or displays for sale a food in a manner contrary to storage requirements prescribed on its label or associated labeling;	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
(h)	labels on pre-packaged products are all in foreign language;	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
(i)	importers not in compliances with re-labelling conditions; or	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or

		food products; or, imprisonment for not more than 1 year.
(j)	contrary to the other requirements prescribed in Part 3 of these Regulations;	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
4.2.1	Any food business operator or any person who does not prepare, process, manufacture, handle, keep, store, distribute, display food for sale, sell, import, export or distribute food for sale to other states that is in a manner contrary to prescribed standards and conditions on Part 4 of this regulation and associated Schedules.	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
5.31.1	Any food business operator who does not ensure that good hygienic practices as prescribed in Part 5 of these Regulations s are applied at all stages of production, processing, handling, storage and distribution of food under their control.	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
6.2.1	Any food business operator or person who operate a business without a valid health license issued by Department of Health and Social Affairs in respect of such premise in accordance with Part 6.	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
6.2.2	Contravenes any other provision under Part 6 .	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell,

		ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
7.25.1 (b)	Any food business operator who does not ensure that good hygienic practices as prescribed in Part 7 of these Regulations and associated Schedules are applied at all stages of production, processing, handling, storage and distribution of food under their control, or (b) Failure to adhere to (a) above.	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
8.3.8	Any food business operator or persons who contravenes 8.3.5 and/or 8.3.7	Fine of up to \$500 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 6 months.
8.15.1	Any food business operator or person who imports, produces, harvests, prepares, processes, handles, packs, keeps, conveys, or sells any food contaminated in a manner contrary to Part 8 of these Regulations	Fine of up to \$2,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
9.3.5	Contravention of (9.3.2.1) and (9.3.2.2).	Fine of up to \$5,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
9.4.2	The food business operator commits an offence when	Fine of up to \$2,000

	noncompliance continues, he or she is liable to pay penalties or serve imprisonments specified under Schedule 13 are applied.	for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.
12.7	A person who is guilty of an offence against the Regulations for which no other penalty is prescribed.	Fine of up to \$10,000 for each offense; loss of license to import, export, sell, resell, ship, advertise, label, or put into interstate commerce food or food products; or, imprisonment for not more than 1 year.

Schedule 14
Annual License Fee for Seafood Establishment

ID	Type of License	Fee(s)
01	Application	\$25.00
02	Freezer Vessel 1 (Long liner-Individual)	\$200.00
03	Freezer Vessel 2 (Purse seiner-Individual)	\$250.00
04	Freezer Vessel 3 (EU Approved Purse seiner-Individual)	\$350.00
05	Processing plant (Including fresh whole, fresh and frozen loining)	\$200.00
06	Processing plant (Including fresh whole, fresh and frozen loining for EU Approved)	\$350.00
07	Frozen fish processing (Landed for container loading before export)	\$100.00
08	Ice plant (Detached)	\$100.00
09	Cold store (Detached)	\$200.00
10	Transport (Individually hired)	\$50.00
11	Cannery/Cooked loin	\$500.00
12	Late Renewal	\$100.00
13	License/Certificate Replacement	\$25.00