

FEDERATED STATES OF MICRONESIA

DEPARTMENT OF HEALTH SERVICES REGULATIONS

ON

LICENSING: FOOD IMPORTATION, PROCESSING, EXPORTATION AND
DISTRIBUTION IN INTERSTATE COMMERCE

DHS REGULATIONS NO. 3 - 1993

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LICENSING REGULATIONS

PART 1 GENERAL PROVISIONS.

1.1 Authority. These regulations have been promulgated and issued by the Secretary of the Department of Health Services pursuant to the authority granted to the Secretary in Sections 24 and 25 of the National Food Safety Act, P.L. No. 7-116.

1.2 Purpose. The purpose of these regulations is to establish minimum standards for the licensing of persons to:

- a. Import food;
- b. Export food;
- c. Distribute food in interstate commerce;
- d. Process food intended for export or interstate commerce.

Any person who has been licensed under these regulations shall be required to comply with the National Food Safety Act, P.L. 7-116, and any regulations adopted by the Department of Health Services of the FSM National Government pursuant thereto.

1.3 Definitions. In addition to the definitions contained in the National Food Safety Act, P.L. 7-116, the following definitions shall apply to this chapter:

"Food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes:

- a. drinks or beverages (except sakau and tuba);
- b. chewing gum and chewing substances (except betel nut and items used to prepare betel nut for consumption); and,
- c. any substance which has been used in the manufacture,

preparation or treatment of "food", including any ingredient, food additive or other substance that enters into or is capable of entering into or is used in the composition or preparation of "food".

"Person" means individuals, partnerships, corporations, associations, joint-ventures, and all other entities.

"To Distribute Food in Interstate Commerce" means to send, mail, deliver, ship, convey or in any manner transport or to cause to be sent, mailed, conveyed or transported from one of the states of the Federated States of Micronesia to another state, any food which is intended for sale, trade, exchange or other consideration.

"To Export Food" means to send, mail, ship, convey or in any manner carry out or to cause to be sent, mailed, shipped, conveyed or carried out of the Federated States of Micronesia, any food which is intended for sale, trade, exchange or other consideration.

"To Import Food" means to bring or carry into, or cause to be brought or carried into the Federated States of Micronesia from another country, any food for sale, trade, exchange or consideration.

"To Process Food for Export or Interstate Commerce" means to prepare, treat, manufacture, package, label or to cause to be

prepared, treated, manufactured, packaged, or labelled any food which is intended for sale, trade, exchange or consideration, in interstate commerce or for export out of the Federated States of Micronesia.

PART 2. DEPARTMENT OF HEALTH SERVICES POWERS AND DUTIES.

The Department of Health Services shall have the following powers and duties.

2.1 Promulgation, Adoption and Enforcement of Regulations, Policies and Procedures. The Department of Health Services is authorized to promulgate, adopt and enforce regulations, policies and procedures as necessary to ensure that the public is protected from consuming imported food that is adulterated or mislabeled, and to ensure that food exported out of the Federated States of Micronesia or distributed in interstate commerce is safe and of the highest quality. Regulations adopted by the Department of Health Services shall have the force and effect of law.

2.2 Compliance with Law and Regulations. The Department of Health Services is authorized to ensure strict compliance with and enforcement of the National Food Safety Act and these regulations by any person or licensed hereunder.

PART 3. LICENSING

3.1 Licenses. The Secretary of Health Services may issue the following licenses, and may stipulate or limit the activities in which the licensee is authorized to engage:

- a. License to Distribute Food in Interstate Commerce;
- b. License to Export Food;
- c. License to Import Food;
- d. License to Process Food for Export or Interstate Commerce.

3.2 License Required; Criminal penalties. A license duly issued by the Department of Health Services pursuant to these regulations shall be required for importation of food into the Federated States of Micronesia, exportation of food out of the Federated States of Micronesia, distribution of food in interstate commerce among and between the States of the Federated States of Micronesia, and processing of food intended for export or interstate commerce.

(a) License to Distribute Food in Interstate Commerce.

No person shall distribute food in interstate commerce without a current, valid "License to Distribute Food in Interstate Commerce" duly issued by the Secretary of the Department of Health Services of the National Government, allowing the licensee to send, mail, deliver, ship, convey or transport from one of the states of the Federated States of Micronesia to another state, any food which is intended for sale, trade, exchange or other consideration.

(b) License to Export Food. No person shall export food out of the Federated States of Micronesia without a current, valid "License to Export Food" duly issued by the Secretary of the Department of Health Services of the National Government, allowing the licensee to send, mail, ship, convey or in any manner carry out of the Federated States of Micronesia, any food which is intended for sale, trade, exchange or other consideration.

(c) License to Import Food. No person shall import food into the Federated States of Micronesia without a current, valid "License to Import Food" issued by the Secretary of the Department of Health Services of the National Government, allowing the licensee to bring or carry into the Federated States of Micronesia from another country, any food for sale, trade, exchange or consideration.

(d) License to Process Food for Export or Interstate Commerce. No person shall process food intended for export or interstate commerce without a current, valid "License to Process Food For Export or Interstate Commerce" issued by the Secretary of the Department of Health Services of the National Government, allowing the licensee to process, prepare, treat, manufacture, package or label, any food which is intended for sale, trade, exchange or consideration, in interstate commerce among or between the States or for export out of the Federated States of Micronesia.

(e) Criminal sanctions. It shall be a National crime, punishable by a fine of not more than \$1,000 or imprisonment for not more than six months, to knowingly do any act for which a license is required under these regulations without a current, valid license issued by the Department of Health Services.

3.3 Criteria. No license shall be issued under these regulations unless satisfactory evidence has been produced that the prospective licensee is capable of compliance with the National Food Safety Act (P.L. 7-116), and all regulations promulgated pursuant thereto. All prospective licensees shall be required to demonstrate to the Secretary of the Department of Health Services, sufficient knowledge of the requirements of the National Food Safety Act (P.L. 7-116), and the regulations, prior to obtaining a license hereunder.

3.4 Minimum Qualifications. To be eligible for a license under these regulations, applicants for must:

- (a) Be a citizen of the Federated States of Micronesia or have a Foreign Investment Permit (for the same business activity for which a license is requested hereunder) duly issued by the National Government under title 32, chapter 2 of the Code of the Federated States of Micronesia;
- (b) Make application to the Department of Health Services on a form prescribed and furnished by the National Government, which form shall require

disclosure of the following information:

- i. Name, address and citizenship of applicant;
- ii. Name of proposed business;
- iii. Address of principal office at which business is to be conducted in the Federated States of Micronesia;
- iv. Address of applicant's businesses offices outside the Federated States of Micronesia;
- v. Name and address of contact person and agent for service of process within the Federated States of Micronesia;
- vi. States of the Federated States of Micronesia in which business will be conducted;
- vii. Countries or nations outside of the Federated States of Micronesia in which business will be conducted;
- viii. Purpose, scope, and objectives of proposed business;
- ix. Total capital investment in the Federated States of Micronesia (including foreign participation and Micronesian citizen participation);

- x. Form of business (e.g., foreign corporation, FSM corporation; partnership; joint foreign and FSM corporation or partnership; joint venture; association; sole proprietorship);
 - xi. Statement of Financial Responsibility (including e.g., balance sheets; profit and loss statements; bank references; bank statements; financial statements);
 - xii. Statement of utilization of human resources (including number of FSM citizens and non-FSM citizens to be employed with wages, positions, benefits, levels of skill, nationalities of prospective employees).
- (c) Pay the application fee;
 - (d) Be determined by the Department of Health Services to be worthy of the public trust and confidence;
 - (e) Sign a written agreement to abide by the National Food Safety Act, and all regulations promulgated pursuant thereto.

3.5 Requests for Additional Information. An applicant for licensure hereunder may be required to provide additional information about the applicant, including without limitation, qualifications, business structure, and financial responsibility.

3.6 Fees. The Department of Health Services may assess application fees, licensing fees, license renewal fees, and other fees. These fees are not refundable, and shall be paid by the applicant/licensee to the Department of Health Services which shall deposit said fees into the General Fund of the Federated States of Micronesia. The schedule of fees shall be as follows:

- (a) Application Fee - \$25.00
- (b) License Fee - \$200.00
- (c) License Renewal Fee - \$200.00
- (d) Late Renewal Fee - \$100.00
- (e) License Certificate Duplication/Replacement Fee - \$25.00.

3.7 Disciplinary Action; Grounds. The Secretary of the Department of Health Services may refuse to issue or renew a license, and the Food Working Group may place a licensee on probation, suspend a license, reprimand a licensee, or revoke a license issued under these regulations for:

- (a) Violating or assisting another to violate the National Food Safety Act, P.L. 7-116 or any regulation promulgated pursuant thereto;
- (b) Circumventing or attempting to circumvent the National Food Safety Act, P.L. 7-116 or any regulation promulgated pursuant thereto;
- (c) Participating, directly or indirectly, in a plan to evade or conspiring to violate or evade the National Food Safety Act, P.L. 7-116 or any

regulation promulgated pursuant thereto;

- (d) Importing, exporting, or distributing into interstate commerce any food which is adulterated, damaged, deteriorated, perished or otherwise unfit for human consumption;
- (e) Preparing, packaging or storing any food which has been imported, or is intended for export or interstate commerce, if that food is in any way adulterated, damaged, deteriorated, perished or otherwise unfit for human consumption;
- (f) Selling, preparing, packaging or storing any imported food, or food intended for export or interstate commerce, if such food has been prepared, packaged, stored, shipped or transported under unsanitary conditions;
- (g) Importing any food or food article into the Federated States of Micronesia which does not comply with the National Food Safety Act, P.L. 7-116, or any regulation promulgated pursuant thereto;
- (h) Importing any food or food article into the Federated States of Micronesia which is restricted or banned in its sales in the country of origin;
- (i) Importing any food or package containing food into the Federated States of Micronesia which is marked with an expiration date which has passed;

- (j) Labeling, packaging, preparing, selling or advertising any food which has been imported, or which is intended for export or interstate commerce, in any manner which is false, misleading, or deceptive about its character, nature, value, substance, quality, composition, merit or safety, or in contravention of the National Food Safety Act, P.L. 7-116, or any regulation promulgated pursuant thereto;
- (k) Failing to cooperate with, assist and/or respond to requests for information by National Food Inspectors in the performance of their duties under the National Food Safety Act, P.L. 7-116, and regulations promulgated pursuant thereto.

PART 4. FOOD WORKING GROUP. The Secretary of the Department of Health Services shall establish a Food Working Group to advise the Secretary and to carry out their duties and perform other functions as assigned by the Secretary.

4.1 Composition. The Food Working Group shall be composed of five members appointed by the Secretary of Health Services. The members of the Food Working Group shall be citizens of the Federated States of Micronesia, and shall be persons experienced in food science, food production, nutrition administration, and any other areas of expertise which the Secretary deems useful.

4.2 Terms of Appointment. Upon appointment to the Food Working Group, the initial term of appointment shall be decided by each member drawing lots. Two members shall serve an initial 1-year term; two members shall serve an initial 2-year term; and one member shall serve an initial 3-year term. After the initial terms have been completed, the regular term of appointment shall be for 3 years. No member of the Food Working Group, including the initial group, shall serve more than two consecutive terms. Members of the Food Working Group may serve beyond the expiration date of their terms until their successors have been appointed.

4.3 Quorum. A quorum of the Food Working Group shall consist of a majority of all members. All official business and any hearings conducted by the Food Working Group shall be conducted by a majority of those voting once a quorum is established.

4.4 Officers. The Food Working Group shall annually appoint three officers: a chairperson to preside at meetings and represent the Food Working Group in its official capacity, including administrative hearings under chapter 1 of title 17 of the Code of the Federated States of Micronesia; a vice chairperson to undertake the activities of the chairperson in the chairperson's absence; and a secretary-treasurer who shall oversee the Board's financial and record-keeping obligations.

4.5 Meetings. The Food Working Group shall hold meetings on a regular basis at least quarterly, and more often, if necessary, to conduct its business. The meetings shall be open to the public unless the Food Working Group is conducting a disciplinary hearing

or is considering business which is confidential or constitutes a trade secret within the meaning of Section 22 of the National Food Safety Act, P.L. 7-116. When the Food Working Group is conducting a hearing regarding a disciplinary matter, the hearing will be closed to the public unless the subject of the disciplinary hearing requests in writing that the hearing be open to the public.

4.6 Expenses - Compensation. The members of the Food Working Group shall receive airfare, per diem and car rental where justified and necessary, at standard National Government rates while on business approved by the Food Working Group. Those members who are employees of the National Government shall be granted administrative leave and receive their regular salaries while on business of the Food Working Group. Other members who are not otherwise being compensated shall receive compensation on a daily basis while on approved business. The rate of compensation will be established by the Food Working Group, not to exceed \$50. per day.

4.7 Indemnification of Members. Every member of the Food Working Group shall be indemnified by the Department of Health Services against all expenses and liabilities reasonably incurred or imposed upon such member of the Food Working Group in connection with any threatened, pending, or completed action, suit or proceeding to which the member may become involved by reason of being or having been a member of the Food Working Group. Indemnity applies whether or not such member of the Food Working Group is a member of the Food Working Group at the time such expenses are

incurred. Indemnity applies only to actions performed within the duties of appointment as a member of the Food Working Group. The right of indemnity shall be in addition to, and not exclusive of all other rights to which such members of the Food Working Group may be entitled.

4.8 Powers and Duties. In carrying out its activities, the Food Working Group shall have the following powers and duties:

- (a) To advise and assist the Secretary of Health Services as requested;
- (b) To prepare annual reports on its activities and an accounting of its expenses and financial condition for submission to the Secretary of Health Services no later than September 1, 1993 of each year;
- (c) To supply the Secretary of the Department of Health Services with a list of the names of all members of the food industry of which they are aware, in instances where regulations proposed under the National Food Safety Act, P.L. 7-116 will affect that food industry;
- (d) To conduct hearings on alleged violations of the National Food Safety Act, P.L. 7-116 or any regulation promulgated pursuant thereto, and upon finding that a violation has occurred, to order that any article, vehicle, or premises involved in the violation be forfeited;

- (e) To conduct hearings upon request by any person aggrieved by the actions of a Food Inspector;
- (f) To conduct appeal hearings upon request by any person aggrieved by the actions of the Secretary of Health Services under Section 20 of the National Food Safety Act, P.L. 7-116, to ban foods which the Secretary has found to be dangerous or injurious to health.

4.9 Administrative procedures; Hearings. The procedures on hearings and licensing set forth in title 17 of the Code of the Federated States of Micronesia, including any amendments thereto, are expressly adopted and incorporated herein by reference as if all of the provisions of that title were included in these regulations, except as is otherwise specified in these regulations.

4.10 Ethical Standards.

Members of the Food Working Group shall be required to abide by the following ethical standards.

- (a) Discrimination not allowed. Members of the Food Working Group shall not discriminate against any person on the basis of sex, race, language or religion.
- (b) Conflict of interest. No member of the Food Working Group may be assigned to or perform duties involving any business or matter in which the member or the member's parents, children or siblings has any pecuniary interest whatsoever.

- (c) Responsibility. Members of the Food Working Group shall maintain objectivity, integrity, and the highest standards in performance of the duties and responsibilities of the Food Working Group.
- (d) Duty to Report Violations. Members of the Food Working Group shall report all violations of the National Food Safety Act, and these regulations to the Department of Health Services;
- (e) Public statements. Members of the Food Working Group shall report information fairly and accurately to the National, State and local governments, members of the food industry, the public, consumers, and others, and shall not make inappropriate, unprofessional, or inaccurate representations;
- (f) Public welfare. Members of the Food Working Group shall respect the dignity of the individuals he or she comes into contact with, and shall not engage in any action injurious to the public welfare, and shall:
- i. maintain professional responsibility at all times, and remain independent and unbiased in the performance of his or her duties;
 - ii. not engage in any activity which could be considered a professional conflict of interest, and shall immediately remove himself

or herself from any such conflict should one arise.

- (g) Confidentiality. Members of the Food Working Group shall protect the confidentiality of trade secrets, and other confidential information, and shall not divulge any confidential information except as necessary to the Department of Health Services in the performance of his or her duties.

FEDERATED STATES OF MICRONESIA
DEPARTMENT OF HEALTH SERVICES REGULATIONS

ON

LICENSING: FOOD IMPORTATION, PROCESSING, EXPORTATION AND

DISTRIBUTION IN INTERSTATE COMMERCE

DHS REGULATIONS NO. 3 - 1993


Pursuant to the authority vested in me by Sections 24 and 25 of the National Food Safety Act, P.L. 7-116, and having complied with the applicable provisions of Title 17 of the Code of the Federated States of Micronesia, these Regulations on Licensing: Food Importation, Processing, Exportation and Distribution in Interstate Commerce are hereby adopted.

Date: 7/19/94

Eliel Pretrick, M.D.
Dr. Eliuel Pretrick, Secretary
Department of Health Services

The provisions of these Regulations on Licensing: Food Importation, Processing, Exportation and Distribution in Interstate Commerce have been reviewed by the Office of the Attorney General, and have been found to be in proper legal form.

Date: 18 July 1994



Attorney General

Effective Date: The effective date of these regulations is

_____, 199__.