SEVENTH OLBIIL ERA KELULAU
RPPL No. 7-23
Fourth Regular Session, October 2005[sic]
(Re; as Senate Bill No. 7-100, SD1, HD1, CD1)

AN ACT

To ensure safe and adequate nutrition for infants and young children by promoting and protecting breast feeding and by regulating the marketing of certain foods for infants and young children, and of feeding bottles, teats, and pacifiers; to authorize and appropriate funding for fiscal year 2007 through a section providing for continuing budget authority; and for other related purposes.

THE PEOPLE OF PALAU REPRESENTED IN THE OLBIIL ERA KELULAU DO ENACT AS FOLLOWS:

Section 1. Amendment. A new Chapter to the Palau National Code is hereby enacted for the purpose of ensuring safe and adequate nutrition for infants as follows:

"CHAPTER I

Section 1. Short title and commencement.
(a) This Act may be called the "Promotion of Optimal Infant and Young Child Nutrition Act of 2006";

(b) This Act shall come into effect 60 days after the date of enactment; and

(c) It extends to the whole of the Republic of Palau.

Section 2. Definitions. For purposes of this Act:

(a) "advertise" means to make any representation by any means whatsoever for the purpose of promoting the sale or use of a designated product, including, but not limited to:

(1) written publication, television, radio, film, electronic transmission, including the internet, video, or telephone;

(2) display of signs, billboards, or notices; or

(3) exhibition of pictures or models.

(b) "Advisory Board" means a board set up under Section 17 of this Act.

(c) "brand name" means a name given by the manufacturer to a product or range of products;

(d) "complementary food" means any food suitable, or represented as suitable, as an addition to breastmilk, infant formula, or follow-up formula.

(e) "container" means any form of packaging of a designated produce: for sale as a retail unit, including wrappers.

(f) "designated product" means:

(1) infant formula;

(2) any other product marketed or otherwise represented as suitable for feeding infants;

(3) follow-up formula;

(4) feeding bottles, teats, pacifiers; and

(5) such other product as the Minister of Health may declare to be a "designated product" for purposes of this Act.

(g) "distributor" means a person, corporation, or other entity engaged in the business, whether wholesale or retail, of marketing any designated product.

(h) "follow-up formula" means a milk, or milk-like product, of animal or vegetable origin formulated industrially and marketed, or otherwise represented, as suitable for feeding infants and young children older than six months of age.

(i) "health care facility" means a public or private institution or organization, or private practitioner, engaged, directly or indirectly, in the provision of health care or in health care education. It also includes day-care centers, nurseries, or other infant-care facilities.

(j) "health professional" means a health worker with a professional degree, certificate, diploma, or license, such as a medical practitioner, certain registered nurses and midwives, licensed practical nurses, or such other person as may be specified by the Minister of Health.

(k) "health worker" means a person providing or in training to provide health care services in a health care facility, whether professional or non professional, including voluntary unpaid workers.

(1) "infant" means a child from birth up to the age of 12 months.

(m) "infant formula" means a milk, or milk-like product, of animal or vegetable origin formulated industrially to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months, and includes those that continue to meet a part of an infant's nutritional requirements after the first six months.

(n) "Inspector" means an inspector appointed under Section 21 of this Act.

(o) "label" means a tag, mark, pictorial, or other descriptive matter, written, printed,

stenciled, marked, embossed, attached, or otherwise appearing on a container of a designated product.

(p) "logo" means an emblem, picture, or symbol by means of which a company is identified.

(q) "manufacturer" means a person, corporation, or other entity engaged in the business of manufacturing a designated product, whether directly, through an agent, or through a person controlled by, or under, an agreement with it.

(r) "market" means to promote, distribute, sell, or advertise a designated product, and includes public relations and information services.

(s) "Minister" means the Minister of Health of the Republic of Palau. (t) "pacifier" means an artificial teat for babies to suck, also referred to as a "dummy".

(u) "prescribed" or "as prescribed" means prescribed or as prescribed by rules or written decision made pursuant to this Act.

(v) "promote" means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

(w) "sample" means a single or small quantity of a designated product provided without cost.

(x) "young child" means a child from the age of 12 months up to the age of three years (36 months).

CHAPTER II
PROHIBITIONS

Section 3. Sale of a designated product.
(a) A person shall not distribute for sale, sell, stock, or exhibit for sale any designated product that:

(1) is not registered according to Section 20 of this Act, or is not in accordance with the conditions of its registration; or

(2) has reached its expiration date.

Section 4. Promotion.
(a) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include, but are not limited to:

(1) advertising;

(2) sales devices, such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes, or gifts;

(3) giving of one or more samples of a designated product to any person;

(4) the donation or distribution of informational or educational material referring to infant or young child feeding, or performance of educational functions related to infant or young child feeding, except as provided in Section 14 of this Act.

(b) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf:

(1) donate, or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 percent of the retail price, any quantity of a designated product to a health worker or health care facility.

(2) donate to, or distribute within, a health care facility: equipment, services, or materials such as pens, calendars, posters, note pads, growth charts, and toys, which refer to or may promote the use of a designated product;

(3) offer or give any gift, contribution, or benefit to a health worker or to associations of health workers engaged in maternal and child health, including, but not limited to, fellowships, research grants, or funding for meetings, seminars, continuing education courses, or conferences;

(4) sponsor events, contests, telephone counseling lines, or campaigns related to reproductive health, pregnancy, childbirth, infant or young child feeding, or related topics; or

(5) include the volume of sales of designated products when calculating employee remuneration or bonuses, nor set quotas for sales of designated products.

(c) A health worker engaged in maternal and child health shall not:

(1) accept any gift, contribution, or benefit, financial or otherwise, of whatever value, from a manufacturer or distributor, or any person on his or her behalf;

(2) accept, or give, samples of designated products to any person; or

(3) demonstrate the use of infant formula, except to individual mothers or member of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula, as well as the other information required by Chapter IV of this Act.

Section 5. Prohibitions related to labels of designated products.
(a) A manufacturer or distributor shall not offer for sale, or sell, a designated product if the container or label affixed thereto includes a photograph, drawing, or other graphic representation, other than for illustrating methods of preparation.

(b) A manufacturer or distributor shall not offer for sale, or sell, a designated product, other than a feeding bottle or pacifier, unless the container or label affixed thereto indicates, in a clear, conspicuous, and easily readable manner, in English, the following particulars:

(1) instructions for appropriate preparation and use in words, and in easily understood graphics;

(2) the age after which the product is recommended, in numeric figures;

(3) a warning about the health risks of improper preparation and of introducing the product prior to the recommended age;

(4) the ingredients used;

(5) the composition and nutritional analysis;

(6) the required storage conditions for both before and after opening, taking into account climatic conditions;

(7) the batch number, date of manufacture, and date before which the product is to be consumed, taking into account climatic and storage conditions;

(8) the name and national address of the manufacturer or distributor; and

(9) such other particulars as may be prescribed.

(c) A manufacturer or distributor shall not offer for sale, or sell, a designated product if the container or label affixed thereto contains any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development, or normal functions of the body.

Section 6. Prohibition related to labels or infant formula and follow-up formula.
(a) A manufacturer or distributor shall not offer for sale, or sell, infant formula or follow-up formula, unless the container or label affixed thereto, in addition to the requirements of Section 5 of this Act, conforms to the following:

(1) contains the words "important notice" in capital letters and indicated thereunder, the statement "Breastfeeding is the best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses.", in characters no less than one-third the size of the characters in the product name, and in no case less than 5mm in height;

(2) contains the word "warning" and indicated thereunder, the statement "Before deciding to supplement or replace breastfeeding with this product, seek the advise of a health professional. It is important for your baby's health that you follow all preparation instructions carefully.

If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup.", in characters no less than one third the size of the characters in the product name, and in no case less than 5mm in height;

(3) includes a feeding chart in the preparation instructions, and states that leftover formula should be discarded;

(4) does not use the terms "maternalized", "humanized", or terms similar thereto, nor any comparison with breastmilk;

(5) does not use text that may tend to discourage breastfeeding;

(6) specifies the source of the protein; and

(7) in the case of follow-up formula, states that the product shall not be used for infants less than six months old.

Section7. Prohibitions related to labels of skimmed or condensed milk. A manufacturer or distributor shall not offer for sale, or sel, skimmed milk or condensed milk, in powder or liquid form, unless the container or label affixed thereto contains the words "This product should not be used as an infant's sole source of nourishment.", in characters no less than one-third the size of the characters in the product name, and in no case less than 5mm in height.

Section 8. Prohibitions related to labels of low-fat or standard milk. A manufacturer or distributor shall not offer for sale low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words "This product should not be used as an infant's sole source of nourishment.", in characters no less than one-third the size of the characters in the product name, and in no case less than 5mm in height.

Section 9. Prohibitions related to labels of feeding bottles and pacifiers.
(a) A manufacturer or distributor shall not offer for sale, or sell, a feeding bottle or pacifier, unless the package or label affixed thereto, in addition to the requirements of Section 5(b)(1) of this Act, indicates in a clear, conspicuous, and easily readable manner, in English, the following particulars:

(1) the words "important notice" in capital letters and indicated thereunder, the statement "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses.", in characters no less than one-third the size of the characters in the product name, and in no case less than 5mm in height;

(2) the statement "Warning: It is important for your baby's health that you follow the cleaning and sterilization instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from. the breast.", in characters no less than one-third the size of the characters in the product name, and in no case less than 5mm in height;

(3) instructions for cleaning and sterilization, in words and graphics;

(4) a statement explaining that feeding with a cup is more hygienic than bottle feeding;

(5) a warning that children should not be left to self-feed for long periods of time because extended contract with sweetened liquids, including infant formula, may cause severe tooth decay; and

(6) the name and national address of the manufacturer or the distributor.

Section 10. Prohibitions related to labels of pacifiers. A manufacturer or distributor shall not offer for sale, or sell, a pacifier unless, in addition to the requirements of Section 5(b)(1), it is labeled with the words "Warning: use of a pacifier can interfere with breastfeeding.", in characters no less than one-third the size of the characters in the product name, and in no case less than 5mm in height.

CHAPTER III
HEALTH WORKER RESPONSIBILITIES

Section 11. Health worker responsibilities.
(a) Heads of health care facilities, and national and local health authorities, shall take measures to encourage and protect breastfeeding and to promote this Act, and shall give information and advice to health workers regarding their responsibilities, and particularly ensure that health workers are familiar with all of the information specified in Chapter IV of this Act.

(b) Health workers shall encourage, support, and protect breastfeeding. They are expected to know the provisions of this Act, particularly the information specified in Chapter IV of this Act.

(c) Health workers shall work to eliminate practices that directly or indirectly retard the initiation and continuation of breastfeeding, such as pre lacteal feeds.

(d) Health workers shall make, in writing, a report to the head of his or her work place, who shall make, in writing, a report to the Advisory Board, of any offer he or she receives for a sample or gift, or other benefit from a manufacturer or distributor, or any other contravention of the provisions of this Act.

CHAPTER IV
INFORMATION AND EDUCATION

Section 12. Informational and educational materials about infant feeding.
Informational or educational materials, whether written, audio, or visual, which refer to infant feeding, shall:

(a) contain only correct and current information, and shall not use any pictures or text that encourage bottle feeding or discourage breastfeeding;

(b) be written in English;

(c) not give an impression or create a belief that a designated product is equivalent to, comparable with, or superior to breastmilk or to breastfeeding;

(d) not contain the brand name or logo of any designated product, nor of any manufacturer or distributor of a designated product, provided that this clause shall not be applicable to information about designated products provided to health professionals as authorized by Section 14 of this Act; and

(e) clearly and conspicuously explain each of the following points:

(1) the benefits and superiority of breastfeeding;

(2) the value of exclusive breastfeeding for six months, followed by sustained breastfeeding for two years or beyond;

(3) how to initiate and maintain exclusive and sustained breastfeeding;

(4) why it is difficult to reverse a decision not to breastfeed;

(5) the importance of introducing complementary foods from the age of six months;

(6) how and why any introduction of bottle feeding, or the early introduction of complementary foods, negatively affects breastfeeding; and

(7) that complementary foods can easily be prepared at home using local ingredients.

Section 13. Informational and educational materials about infant formula, follow-up formula, or feeding bottles. If the material referred to in Section 12 includes the topic of bottle feeding, it must also include the following points:

(a) instructions for the proper preparation and use of the product, including cleaning and sterilization of feeding utensils;

(b) how to feed infants with a cup;

(c) the health risks of bottle feeding and improper preparation of the product; and

(d) the approximate financial cost of feeding an infant with such a product in the recommended quantities.

Section 14. Product information for health professionals. Manufacturers and distributors may give informational materials about designated products to health professionals if such materials:

(a) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;

(b) provide references to published studies to support any representation that states, or suggests, that a relationship exists between the product or constituent thereof and health, growth, or development; and

(c) are otherwise in accordance with Sections 12 and 13 of this Act.

Section 15. Submission of material to Advisory Board. Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Advisory Board according to procedures as shall be prescribed.

CHAPTER V
ADMINISTRATION

Section 16. Implementation.
(a) The Ministry of Health is principally responsible for the implementation of this Act.

(b) The Minister of Health shall, when necessary, call upon other ministries to ensure the implementation of this Act.

(c) For the purpose of implementing this Act, the Minister of Health has the following powers and functions:

(1) to promulgate such rules and regulations that are necessary or proper for the implementation of this Act and the accomplishment of its purposes and objectives, as prescribed under the Administrative Procedures Act, in 6 PNC Chapter 1.

(2) to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of this Act and the rules and regulations promulgated hereunder.

(3) to cause the enforcement of this Act; and

(4) to exercise such other powers and functions that may be necessary for, or incidental to, the attainment of the purposes and objectives of this Act.

Section 17. National Advisory Board for the promotion and protection of breastfeeding. There shall be a National Advisory Board for the promotion and protection of breastfeeding, to be composed of the following inter-disciplinary members, a representative from the:

(a) Ministry of Health.
(b) Ministry of Education.
(c) Ministry of Commerce and Trade.
(d) Belau Medical Association.
(e) Belau Nursing Association.
(f) Mechesil Belau.
(g) Breastfeeding support group.

(h) Such other persons as the Minister may appoint as members of the Advisory Board. Provided that no person shall be appointed who has any direct or indirect financial interest in any designated product.
(i) The Minister of Health, or his representative, shall be its ex officio Chairman;
(j) The Minister shall appoint the members of the Advisory Board within 90 days after the effective date of this Act.
(k) The members of the Advisory Board shall hold office for a term of 3 years, and shall be eligible for renomination.
(l) Any member of the Advisory Board may, at any time, resign his or her office by writing to the Minister, or shall vacate his or her office if the Minister so directs. A vacancy shall be filled in the same manner as the original appointment for the balance of the unexpired term.
(m) The Advisory Board may invite national or foreign experts to take part in the meetings as observers, and may constitute committees, or appoint experts, for the purpose of detailed study of any matter set before it.
(n) The Minister may change the size and composition of the Advisory Board.

Section 18. Administration of the Advisory Board.
(a) The Minister shall appoint the Secretary of the Advisory Board and such other officers as he or she deems necessary to carry out the purposes of this Act.

(b) The Advisory Board shall hire permanent staff necessary to carry out its functions, subject to the budgetary approval of the Minister.

(c) The Advisory Board shall meet as often as it deems necessary, but not less than once every month, at such time and place as the Secretary shall indicate.

(d) The Secretary shall call meetings at the direction of the Chairman, shall maintain minutes of the meeting, and shall perform such other duties as may be directed by the Advisory Board.

(e) Two-thirds of the members of the Advisory Board shall constitute a quorum for a meeting.

(f) A majority vote of the members present shall be sufficient to approve any business presented in a meeting of the Advisory Board.

(g) Decisions of the Advisory Board shall be certified by the Secretary.

(h) The Advisory Board may make such other administrative rules as may be required for its proper functioning.

Section 19. Powers and functions of the Advisory Board.
(a) The Advisory Board has the following powers and functions:

(1) to advise the President and the Minister on national policy for the promotion and protection of breastfeeding;

(2) to create regional committees to carry out the functions of the Advisory

Board at the regional level, as may be prescribed;

(3) to advise the Minister on designing a National strategy for developing communication and public education programs for the promotion of breastfeeding; informational and educational materials on the topics of infant and young child feeding; continuing education for health workers on lactation management and the requirements of this Act; curricula for students in the health professions that include lactation management; and to ensure widespread distribution of and publicity concerning this Act, in a method as may be prescribed;

(4) to review reports of violations or other matters concerning this Act;

(5) to issue instructions to inspectors as to actions to be taken, or take such other actions as the case may be, against any person found to be violating the provisions of this Act or the rules and regulations promulgated pursuant thereto;

(6) to scrutinize materials submitted in accordance with Section 14 of this Act, and recommend appropriate actions to be taken in the case of a violation of Chapter IV of this Act; and

(7) such other powers and functions, including the powers of an Inspector, as are conferred on him or her by the provisions of this Act, and as may be prescribed.

Section 20. Registration of designated products.
(a) The Minister of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.

(b) The Minister of Health shall, by notice in the newspaper, fix the date after which no designated product that is not registered may be imported, manufactured, or sold.

(c) A person applying for registration of a designated product shall furnish such information and samples as may be prescribed.

(d) Once the registration of a designated product has been approved, a Certificate of Registration shall be issued.

(e) No Certificate of Registration will be granted unless the designated product is in accordance with, and has a label which is in accordance with the requirements contained in, Chapter II of this Act.

Section 21. Inspectors. The Minister shall appoint such persons as he or she sees fit, having the prescribed qualifications to be Inspectors for purposes of this Act, within such local limits as he or she may assign to them, respectively, provided that no person who has any direct or indirect financial interest in any designated product shall be so appointed.

Section 22. Powers of inspectors.

(a) An Inspector may, within the local limits for which he or she is appointed:

(1) inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised, or otherwise promoted, and all relevant records;

(2) institute prosecution with respect to violations of this Act and the rules and regulations made pursuant thereto; and

(3) exercise such other powers as may be prescribed.

Section 23. Procedure for inspectors.
(a) Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.

(b) After each inspection, the inspector shall submit a report including any finding of a violation of this Act and the rules and regulations made pursuant thereto, to the Advisory Board, and seek instructions as to the action to be taken in respect of such contravention.

CHAPTER VI
PENALTIES, PROCEDURES

Section 24. Penalties.
(a) Any person who, violates Sections or 4 of this Act shall, upon conviction, be punished with imprisonment for a term which shall not be less than 6 months, or by a fine that shall not be less than $1,000.00, or both.

(b) Any person having been convicted of a violation of Sections 3 or 4 of this Act and who is again convicted of a violation of Sections 3 or 4 of this Act, shall be punished with imprisonment for a term which shall not be less than 1 year, or by a fine that shall not be less than $5,000.

(c) Any person who violates any other provision of this Act or the rules and regulations made pursuant thereto may be subject to a fine of up to $1,000, or a period of imprisonment of up to 6 months.

Section 25. Cease and desist orders, etc. The Minister shall have the power to make cease and desist orders upon receiving a report from an Inspector or the Advisory Board of a violation of the provisions of this Act or the rules and regulations promulgated pursuant thereto.

Section 26. Certificate of registration may be suspended or revoked. Where any person has been found to have violated any of the provisions of this Act, or the rules and regulations pursuant thereto, the Minister, upon written recommendation of the Advisory Board, and after notice and an opportunity to be heard has been given, may suspend or revoke any Certificate of Registration that has been issued to that person pursuant to this Act.

Section 27. Professional license may be suspended or revoked. Where any health

professional has been found to have contravened any provision of this Act, or the rules and regulations pursuant thereto, the Minister may recommend to the relevant authority the suspension or revocation of any license for the practice of that person's profession.

Section 28. Appeal. There shall be a right of appeal to the Court of Appeals within 35 days of the any judgment made under this Act.

Section 29. Strict liability for officers, directors, etc. When the person guilty of an violation of this Act is a corporation, company, partnership, firm, or other association, the officer and directors of the board shall also be liable for that violation, unless he or she proves that the violation was committed without his or her knowledge or consent.

Section 30. Institution of prosecution. Prosecution under this Act may be instituted only by:

(a) an Inspector appointed pursuant to Section 21;

(b) a member of the Advisory Board; or

(c) a representative of such voluntary organization engaged in the field of child welfare and development or child nutrition, as the Minister, by notification in the Official Gazette, may authorize in this behalf.

Section 31. Public enforcement.
(a) Any person has the right to lodge a formal complaint to the Advisory Board, which may recommend that proceedings be instituted against any person relating to a violation of any provision that constitutes an offence under this Act or rules and regulations made pursuant thereto.

(b) Any person has the right to commence an action for damages, in a court of law, against any manufacturer or distributor, or other person, for any harm suffered as a result of a violation of any provision that constitutes an offence under this Act or rules and regulations made pursuant thereto.

Section 32. Power to make rules and regulations.
(a) The Ministry of Health may, under the Administrative Procedures Act, in 6 PNC Chapter 1, make rules and regulations for carrying out the purposes of this Act.

(b) In particular, but notwithstanding the generality of the foregoing provision, such rules and regulations may prescribe:

(1) the functions of the Advisory Board;

(2) conditions and procedures for the registration of designated products;

(3) qualifications and powers of and procedures for Inspectors appointed pursuant to the Act; and

(4) procedures for submitting educational or informational materials to the

Advisory Board."

Section 2. Continuing budget authority for fiscal year 2007. Continuing budget authority for fiscal year 2007 is hereby enacted, pursuant to 40 PNC §327, for all regular budget activities as contained in The Fiscal Year 2006 Annual National Budget Authorization and Appropriation Act. Continuing budget authority shall be provided at the funding level of the total appropriations of the Fiscal Year 2006 Annual National Budget Authorization and Appropriations Act, RPPL No. 7-13, as amended by RPPL No. 7-20, for the first three (3) months of fiscal year 2007. Authorizations and appropriations of United States grant funds and all other such grants and outside assistance are conditional on such funds being made available to the Republic.

Section 3. Effective date. This Act shall take effect upon its approval by the President, or upon its becoming law without such approval.

PASSED: September 30, 2006
Approved this 30th day of Sept. 2006.
/s/

Tommy E. Remengesau, Jr.
President
Republic of Palau