To further amend title 41 of the Code of the Federated States of Micronesia, as amended by Public Laws Nos. 5-21, 6-9, 6-38, 8-45 and 8-128, by adding a new chapter 10 to further promote, preserve and protect the public’s health, safety and welfare by regulating the marketing of certain foods, feeding bottles, teats and pacifiers to ensure safe and adequate nutrition for infants and young children, and for other purposes.

BE IT ENACTED BY THE CONGRESS OF THE FEDERATED STATES OF MICRONESIA:

Section 1. Title 41 of the Code of the Federated States of Micronesia, as amended by Public Laws Nos. 5-21, 6-9, 6-38, 8-45 and 8-128, is hereby further amended by adding a new section 1001 of chapter 10 to read as follows:

"Section 1001. Short Title.
This act shall be known and may be cited as the 'Federated States of Micronesia Infant Formula and Food Act'."

Section 2. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1002 of chapter 10 to read as follows:

"Section 1002. Definitions. In this chapter, unless the context otherwise requires, the following words and phrases shall have the following meanings:

1. 'To advertise' means to make any representation by any means whatsoever for the purpose of promoting the sale or disposal of a designated product including but not limited to:

   (a) written publication, television, radio, film, electronic transmission, video or telephone;

   (b) display of signs, billboards, notices;

   (c) exhibition of pictures or models.

2. 'Advisory board' means a board established pursuant to section 1016 of this chapter."
(3) 'Complementary food' means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula.

(4) 'Container' means any form of packaging of a designated product for sale as a retail unit, including wrappers.

(5) 'Designated product' means:
   (a) infant formula;
   (b) any other product marketed or otherwise represented as suitable for feeding infants;
   (c) follow-up formula;
   (d) feeding bottles, teats, pacifiers; and
   (e) such other products as the Secretary may, by regulation, declare to be a 'designated product' for purposes of this chapter.

(6) 'Distributor' means a person, corporation or other entity in the business, whether wholesale or retail, of marketing any designated product.

(7) 'Follow-up formula' means an animal or vegetable-based milk product formulated industrially and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age.

(8) '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.

(9) 'Health professional' means a medical
practitioner, nurse, midwife, nutritionist, hospital
administrator or such other person as may be specified
by the Secretary.

(10) '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.

(11) 'Infant' means a child from birth up to the
age of 12 months.

(12) 'Infant formula' means an animal or
vegetable-based milk product formulated industrially
in accordance with the Codex Alimentarius Standard for
infant formula and intended to: satisfy the
nutritional requirements of infants from birth and/or
during the first six months; or be used as the sole
source of nourishment for infants up to the age of 6
months.

(13) 'Inspector' means a person appointed under
section 1020 of this chapter.

(14) '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.

(15) "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 such entity.

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

(17) "Pacifier" means an artificial teat for babies to suck.

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

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

(20) "Secretary" means the Secretary of the Department of Health, Education and Social Affairs.

(21) "Young Child" means a child from the age of 12 months up to the age of three years (36 months).

Section 3. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1003 of chapter 10 to read as follows:
"Section 1003. Sale of a designated product.

(1) A person shall not distribute for sale, sell, stock or exhibit for a sale any designated product that:

(a) is not registered or is not in accordance with the conditions of its registration;
(b) has reached its expiration date; or
(c) is not in its original container."

Section 4. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1004 of chapter 10 to read as follows:

"Section 1004. Promotion.

(1) A manufacturer or distributor shall not himself, or by any other person on his behalf, promote any designated product at the point of sale, in a health care facility or elsewhere. Prohibited promotional practices include, but are not limited to:

(a) advertising;
(b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss leaders, tie-in sales, prizes or gifts; PROVIDED, that this section shall not restrict the establishment of pricing policies and practices intended to provide designated products at lower prices on a long-term basis;"
(c) giving of one or more samples of a designated product to any person;

(d) donation or distribution of information or educational material regarding infant or young child feeding or performance of educational functions related to infant or young child feeding; PROVIDED, that manufacturers and distributors may provide information about designated products to health professionals if such information is restricted to scientific and factual matters regarding the technical aspects and methods of use of designated products, and is otherwise in accordance with this chapter.

(2) A manufacturer or distributor shall not himself, or by any other person on his behalf:

(a) 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 care facility;

(b) donate to or distribute within a health care facility equipment or services, or materials, including but not limited to pens, calendars, posters, note pads, growth charts, and toys, which may promote the use of a designated product;

(c) offer or give any gift, contribution
or benefit to a health worker or associations of
health workers engaged in maternal and child health,
including but not limited to fellowships, research
grants or funding for attendance of meetings or
seminars, continuing education courses, or
conferences;
(d) sponsor events, contests, or campaigns
aimed at pregnant or lactating women, parents of
infants or young children, or members of their
families, nor sponsor events, contests, or campaigns
related to fertility, pregnancy, childbirth, infant or
young child feeding, or related topics; or
(e) include the volume of sales of
designated products when calculating employee
remuneration or bonuses, nor set quotas for sales of
designated products.
(3) A health worker engaged in maternal and
child health shall not:
(a) accept any gift, contribution or
benefit, financial or otherwise, of whatever value
from a manufacturer or distributor or any person on
his behalf;
(b) accept or give samples of designated
products to any persons; or
(c) demonstrate the use of infant formula
except to individual mothers or members of their
families in very special cases of need, and in such
cases, shall give a clear explanation of the hazards
of the use of infant formula as well as the other
information required by this chapter."

Section 5. Title 41 of the Code of the Federated States of
Micronesia is hereby further amended by adding a new section
1005 of chapter 10 to read as follows:

"Section 1005. Prohibitions related to labels of
designated products. A manufacturer or distributor
shall not offer for sale or sell a designated product,
other than a feeding bottle, teat, or pacifier, unless
the container or label affixed thereto does not have
pictures or graphics of infants, women, or other
graphics that may idealize the use of the product, and
indicates in a clear, conspicuous, and easily readable
manner the following particulars:

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

(2) The age for which the product is recommended
in easily understood symbols according to rules as may
be prescribed by the Secretary;

(3) A warning about the health hazards of
improper preparation and of introducing the product
prior to the recommended age;"
(4) The ingredients used, specifying the origin of any milk product;

(5) The composition and analysis;

(6) The required storage conditions both before and after opening;

(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 address of the manufacturer and the distributor; and

(9) Such other particulars as may be prescribed by the Secretary."

Section 6. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1006 of chapter 10 to read as follows:

"Section 1006. Prohibitions related to labels of infant formula and follow-up formula.

(1) A manufacturer or distributor shall not offer for sale or sell infant formula or follow-up formula for infants up to 1 year of age unless the container or label affixed thereto, in addition to the requirements of section 1005 of this chapter:

(a) contains the words 'important notice' in capital letters and indicated thereunder is the statement 'Breastmilk is the best food for infants.'
it protects against diarrhea 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 3 mm in height:

(b) contains the warning, "This product
should only be used upon the advice of a health
professional. It is important for your baby's health
that you follow all preparation instructions
carefully. If you use a feed bottle, your baby may
refuse to feed from the breast. It is safer to feed
from a cup." In characters no less than one-third the
size of the letters of the product name, and in no
case less than 1.5 mm in height; and

(c) includes a feeding chart in the
preparation instructions and states that leftover
formula should be discarded.

(2) A manufacturer or distributor shall not
offer for sale or sell infant formula or follow-up
formula if the container or label affixed thereto:

(a) includes the terms 'materialized',
'humanized', or their equivalent, or any comparison
with breastmilk;

(b) uses text that may tend to discourage
breastfeeding; or

(c) includes a photograph, drawing, or
other graphic representation other than for illustrating methods of preparation."

Section 7. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1007 of chapter 10 to read as follows:

"Section 1007. Prohibitions related to labels of skimmed or condensed milk. A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words 'This product should not be used to feed infants.' in characters no less than 2 mm in height."

Section 8. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1008 of chapter 10 to read as follows:

"Section 1008. Prohibitions related to labels of low-fat and standard milk. A manufacturer or distributor shall not offer for sale or sell 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 2 mm in height."

Section 9. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section
1009 of chapter 10 to read as follows:

"Section 1009. Prohibitions related to labels of bottles and teats. A manufacturer or distributor shall not offer for sale or sell a feeding bottle or teat unless it has a label that:

(1) Does not contain pictures or other graphics of infants, women, or any other graphic that may idealize the use of the product; and

(2) Indicates in a clear, conspicuous, and easily readable manner the following particulars:

(a) instructions for cleaning and sterilization in words and graphics;

(b) the words 'important notice' in capital letters and indicated thereunder the statement 'Breastmilk is the best food for infants. It protects against diarrhea and other illnesses,' in characters no less than one-third the size of the letters of the product name, and in no case less than 3 mm in height;

(c) the statement '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 1.5 mm in height;

(d) a statement explaining that feeding
with a cup is safer than bottle feeding.
(e) a warning that use with sweetened
liquids, including infant formula, may cause tooth
decay; and
(f) the name and address of the
manufacturer and the distributor."

Section 10. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1010 of chapter 10 to read as follows:

"Section 1010. Prohibitions related to labels of
pacifiers. A manufacturer or distributor shall not
offer for sale or sell a pacifier unless it is labeled
with the words 'Warning: use of pacifier can interfere
with breastfeeding,' in characters no less than
1.5 mm in height."

Section 11. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1011 of chapter 10 to read as follows:

"Section 1011. Health worker responsibilities.

(1) Heads of health care facilities and national
and local health authorities shall take the
appropriate and necessary measures to encourage and
protect breastfeeding and to promote this chapter.
They shall give information and advice to health
workers regarding their responsibilities and ensure
that health workers are familiar with all of the
information specified in this chapter.

(2) Health workers shall encourage, support and
protect breastfeeding. They are expected to know the
provisions of this chapter.

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

(4) Health workers shall make a written report
to the head of his or her work place, who shall in
turn report to the advisory board, on any offer he or
she receives for a sample, gift, or other benefit from
a manufacturer or distributor, or any other
contravention of the provisions of this chapter."

Section 12. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1012 of chapter 10 to read as follows:

"Section 1012. Informational and educational
materials about infant feeding. Informational or
educational materials, whether written, audio, or
visual, on the topic of infant feeding shall:

(1) Contain only correct and current information
and shall not use any pictures or text that encourage
bottle-feeding or discourage breastfeeding;
(2) Not give an impression or create a belief that a designated product is equivalent to, comparable with, or superior to breast milk or to breastfeeding;

(3) Not contain the 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 officials as authorized by section 1004(1)(d) of this chapter; and

(4) Clearly and conspicuously explain each of the following points:

(a) the benefits and superiority of breastfeeding;

(b) the recommended duration of breastfeeding;

(c) how to initiate and maintain breastfeeding;

(d) how and why any introduction of bottle-feeding or early introduction of complementary foods negatively affects breastfeeding;

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

(f) the importance of timely introduction of complementary foods;
(g) that complementary foods can easily be
prepared at home using local ingredients; and

(h) the value of sustaining breastfeeding
for two years or beyond."

Section 13. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1013 of chapter 10 to read as follows:

"Section 1013. Informational and educational
materials about infant formula, follow-up formula or
feeding bottles. If the material referred to in
section 1012 includes the topic of feeding infants
with infant formula, follow-up formula or any other
food or drink by feeding bottle, it must also include
the following points:

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

(2) How to feed infants with a cup;

(3) The health hazards of bottle-feeding and
improper preparation of the product; and

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

Section 14. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1014 of chapter 10 to read as follows:

"Section 1014. Submission of materials 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."

Section 15. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new Section 1015 of chapter 10 to read as follows:

"Section 1015. Implementation.

(1) The Secretary is principally responsible for the implementation of this act.

(2) For the purpose of implementing this act, the Secretary has the following powers and functions:

(a) to promulgate such rules as are necessary or proper for the implementation of this act and the accomplishment of its purposes and objectives;

(b) to call for consultations with government agencies and other interested parties to ensure the implementation of and strict compliance with the provisions of this chapter and the rules promulgated hereunder;

(c) to cause the enforcement of this act;

and

(d) 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 16. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1016 of chapter 10 to read as follows:

"Section 1016. National Advisory Board for the
Promotion and Protection of Breastfeeding.

(1) There shall be a National Advisory Board for
the Promotion and Protection of Breastfeeding to be
composed of representatives from: the Department of
Health, Education and Social Affairs, MCH/Family
Planning, Food and Nutrition, National Food
Inspection; the Department of Finance and
Administration, Revenue and Customs; and the
Department of Justice, Immigration and Labor; and
other persons as the Secretary 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.

(2) The Secretary shall appoint the members of
the Advisory board within 90 days of the date of
enactment of this act.

(3) Any member of the advisory board may, at any
time, resign his or her office by writing to the
Secretary or shall vacate his or her office if the
Secretary so directs. A vacancy shall be filled in
the same manner as the original appointment for the
balance of the unexpired term.

(4) 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."

Section 17. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1017 of chapter 10 to read as follows:

"Section 1017. Administration of the board.

(1) The Secretary shall appoint officers of the
board as he deems necessary to carry out the purposes
of this act.

(2) The advisory board shall hire permanent
staff necessary to carry out its functions, subject to
the budgetary approval of Congress.

(3) The advisory board shall meet as often as it
deems necessary, but not less than once every other
month at such time and place as the Secretary shall
indicate."

Section 18. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1018 of chapter 10 to read as follows:

"Section 1018. Powers and functions of the advisory
board.

(1) The advisory board has the following powers
and functions:

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

(b) to create state committees to carry out
the functions of the advisory board at the state
level, as may prescribed;

(c) to advise the Secretary on designing a
national strategy for developing communication and
public education programs for the promotion of
breastfeeding, informational and educational materials
on the topic of infant feeding, continuing education
for health workers on lactation management and the
requirements of this chapter, and curricula for
students in the health professions which include
lactation management; and to ensure widespread
distribution of and publicity concerning this chapter,
in a method as may be prescribed;

(d) to review reports of violations or
other matters concerning this chapter;

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(e) 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 promulgated pursuant thereto;

(f) to scrutinize materials submitted in accordance with section 1014 and recommend appropriate actions to be taken in the case of a violation of this chapter; and

(g) such other powers and functions, including the powers of an inspector, as are conferred on it by the provisions of this act and as may be prescribed."

Section 19. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1019 of chapter 10 to read as follows:

"Section 1019. Registration of designated products.

(1) The Secretary shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.

(2) The Secretary shall, in accordance with title 17 of the Code, fix the date after which no designated product that is not registered may be imported, manufactured or sold.

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

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

(5) No Certificate of Registration will be granted unless the designated product is in accordance with the requirements contained in this act."

Section 20. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1020 of chapter 10 to read as follows:

"Section 1020. Inspectors. The Secretary shall appoint such persons as he sees fit having the prescribed qualifications to be inspectors for purposes of this act within such local limits as he 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 21. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1021 of chapter 10 to read as follows:

"Section 1021. Powers of inspectors.

(1) An inspector may, within the local limits for which he or she is appointed:
(a) inspect any premises and all relevant records where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted;

(b) make referrals to the Department of Justice for prosecution with respect to violations of this chapter and the rules made pursuant thereto, and

(c) exercise such other powers as may be prescribed."

Section 22. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1022 of chapter 10 to read as follows:

"Section 1022. Procedure for inspectors.

(1) Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.

(2) After such inspection, the inspector shall submit a report, including any finding of a violation of this chapter and the rules made pursuant thereto, to the advisory board and seek instructions as to the action to be taken in respect of such violation."

Section 23. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1023 of chapter 10 to read as follows:

"Section 1023. Penalties."
(1) Any person who individually or on behalf of any other person violates any provision of this chapter shall be punishable with imprisonment for a term which shall not be more than six months or a fine which shall not be more than $1,000, or both.

(2) Any person having been convicted of an offense under subsection (1) of this section and who is again convicted of an offense under that subsection, shall be punishable with imprisonment for a term which shall not be more than one year or with a fine that shall not be more than $3,000, or both."

Section 24. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1024 of chapter 10 to read as follows:

"Section 1024. Cease and desist order. The Secretary 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 chapter or the rules promulgated pursuant thereto."

Section 25. Title 41 of the Code of the Federated States of Micronesia is hereby further amended by adding a new section 1025 of chapter 10 to read as follows:

"Section 1025. Certification of registration may be suspended or revoked. Where any person has been found
to have violated any of the provisions of this
chapter, or the rules promulgated pursuant thereto.
The Secretary, 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 chapter."

Section 26. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1026 of chapter 10 to read as follows:

"Section 1026. Professional or business license may
be suspended or revoked. Where any health
professional has been found to have violated any
provision of this chapter, or the rules pursuant
thereto, the Secretary may recommend to the relevant
authority the suspension or revocation of any license
for the practice of the person’s profession or
business."

Section 27. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1027 of chapter 10 to read as follows:

"Section 1027. Appeal. In accordance with title 17
of the Code, an aggrieved party may appeal an
administrative decision rendered by the Secretary."

Section 28. Title 41 of the Code of the Federated States
of Micronesia is hereby further amended by adding a new section
1028 of chapter 10 to read as follows:

"Section 1028. Public enforcement.

(1) 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 offense under this chapter or rules
made pursuant thereto."

Section 29. This act shall become law upon approval by the
President of the Federated State of Micronesia or upon its
becoming law without such approval.

Date: 6/04/98

Introduced by: Joseph J. Qrusemal
(by request)