SUBJECT:

Various Food Products Exported From the Philippines to the United States of America

(FDA Agreement Number 225-86-2002)

(Previously CPG 7156.03)

Notes:

The FDA contact for this MOU is Frank MacKeith, HFS-585

Tel. No. 202-205-4045

This MOU is in effect indefinitely.

MEMORANDUM OF UNDERSTANDING

Between The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA

And The

NATIONAL FOOD AUTHORITY
OF THE REPUBLIC OF THE PHILIPPINES
CONCERNING VARIOUS FOOD PRODUCTS EXPORTED
TO THE UNITED STATES OF AMERICA

I. PURPOSE

The mutual goals of the Food and Drug Administration (FDA) of the United States of America and the National Food Authority (NFA) of the Republic of the Philippines in entering into this agreement are to:

A. Set forth the requirements, which are described on a product-by-product basis in the attachments to this memorandum, that products that are to be exported from the Philippines and offered for import to the United States must meet to be certified under this memorandum. FDA has established these requirements under the laws and regulation that it administers.

B. Minimize the need for these products to be subject to extensive FDA sampling that would be necessary without certification under this memorandum.

C. Provide for the cooperative exchange of technical assistance, information, personnel, and research to help ensure the safety and quality of food products from the Philippines that are certified under this memorandum.

II. DEFINITIONS

For the purpose of this memorandum, both parties agree to the following definition:

Lot: A lot is the quantity of a product produced by one manufacturer during a discrete period of time not exceeding one (1) day. It is produced in one continuous process using a single processing line and packaged in identical containers identified by a unique code traceable to the manufacturer.

Other definitions may be found in the attachments to this memorandum. These additional definitions apply only to the specific

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food product that is the subject of the particular attachment in which the definition appears.

III. SUBSTANCE OF AGREEMENT

The National Food Authority of the Republic of the Philippines

NFA is a government agency of the Republic of the Philippines, responsible for conducting the voluntary inspection of food products that have been imported or that are intended for export. To fulfill its responsibilities under this memorandum, NFA will direct its activities to ensuring that the food products described in the attachments to this memorandum will meet the safety and quality requirements of the United States. NFA will inspect products and collect and examine samples to ensure compliance with those requirements.

To fulfill its commitments and responsibilities under this memorandum, NFA will:

A. Inspect each lot of food product offered to it by a manufacturer for export to the United States. In this inspection, NFA will attempt to determine whether the lot of food meets FDA's requirements as set forth in the attachment for that food product. NFA's laboratory will ensure by appropriate procedures that these analyses are completed as described in Section V., Analytical Methodology.

B. Issue an export certificate only for those lots that meet the requirements stipulated for the particular food in the appropriate attachment.

C. Require that all containers of lots of food products for which an export certificate is issued be identified and marked with a unique lot number, and that all labeling information required by the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act be included on the label of each product that is included in a certified lot.

D. Include the following information on the certificate for each lot of food products that is to be exported to the United States:

1. Lot identification, including name and address of manufacturer;

2. Number and size of containers in the lot;

3. Analytical results of the tests conducted as specified in the attachments to this memorandum;

4. Date of the certificate; and,

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5. Name and stamp or seal of authorizing official.

E. Affix its validated certificate to the shipping manifest and the packing list that are supplied by the manufacturer. The manifest and list will indicate those lots of food that are physically present in each containerized cargo unit.

F. Furnish FDA with a copy of the current Philippine regulations and the procedures used to ensure that each product exported to the United States under certification meets the safety and quality requirements of the United States.

G. Furnish FDA, upon request, with a full description of the manufacturing processes and quality controls procedures that are used to ensure that food products that are described in the attachments to this memorandum are sanitary food products that are fit for human consumption. These processes and quality control procedures will be included as part of each attachment.

H. Share expertise with and provide assistance to FDA when necessary. Such mutual cooperation will include, but will not be limited to, the exchange of information about current, new, and improved methods of sampling and testing of the food products described in the attachments to this memorandum; the exchange of technical information; the exchange of administrative, regulatory and scientific personnel; the exchange of information about quality control operations and procedures; and, the exchange of data and research related to major food-caused health concerns. This sharing will help ensure the quality and safety of food products described in the attachments to this memorandum that are offered for import into the United States.

The Food and Drug Administration of the United States of America

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes. FDA directs its activities toward the protection of the public health of the United States by ensuring that food products are safe and wholesome and are honestly and informatively labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to ensure that there is compliance with the statutes that it enforces. FDA makes a concerted effort to ensure that foods that are imported into the United States meet the same standards as domestic products. To discharge these responsibilities regarding the food products listed in the attachments to this memorandum and to fulfill its commitments under this memorandum, FDA will:

1. Audit sample those products certified under this memorandum to determine whether they comply with the requirements set forth in the attachments that are applicable to the particular food products. FDA may, for any reason, examine lots that have been certified to ensure

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that they comply in all respects with the requirements that FDA has established under the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Public Health Service Act, and other related statutes.

2. Share with NFA any information obtained through its audit sampling.

3. Promptly notify NFA of any detention of a food product described in the attachments to this memorandum and of any modification of the statutes or the regulations that pertain to such a food product.

4. Share expertise with, and provide assistance to, NFA when necessary. Such mutual cooperation will include, but will not be limited to, the exchange of information about current, new, and improved methods of sampling and testing of the food products described in the attachments to this memorandum; the exchange of technical information; the exchange of administrative, regulatory, and scientific personnel; the exchange of information about quality control operations and procedures; and, the exchange of data and research related to major food-caused health concerns. This sharing will help ensure the quality and safety of the food products described in the attachments to this memorandum that are offered for import into the United States.

IV. SAMPLE COLLECTION

Whenever possible, the same subsample will be used by FDA to determine the level, if any, of Salmonella and to determine compliance with the requirements set forth in the attachments to this memorandum and with any other specified FDA requirements. Samples of the food products described in the attachments to this memorandum will be collected in accordance with the applicable portions of the latest edition of (1) "Bacteriological Analytical Manual", Chapter I --"Food Sampling Plans and Initial Sampling Handling, for Salmonella"; (2) FDA's "Inspection Operations Manual", Chapter 4; or (3) the appropriate Compliance Program. For other attributes samples will be collected in accordance with the applicable attachment to this memorandum.

V. ANALYTICAL METHODOLOGY

Compliance with the requirements set forth in the attachment to this memorandum for each food product will be determined in accordance with the methods contained in the latest edition of:

A. BAM, 8th Ed., 1995, AOAC 481 N. Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417

A. "Bacteriological Analytical Manual," (currently 6th Ed., 1984), The Association of Official Analytical Chemists, 1111 No. 19th Street, Arlington, VA 22209

B. "Official Methods of Analysis, Association of Official Analytical Chemists," (currently 14th Ed., 1984), The Association of Official

B. Official Methods of Analysis, 16th Ed., 1995

Analytical Chemists, 1111 No. 19th Street, Arlington, VA 22209.

C. "Macroanalytical Procedures Manual" (FDA Technical Bulletin Number 5), 1984. The Association of Official Analytical Chemists, 1111 No. 19th Street, Arlington, VA 22209.

VI. PARTICIPATING PARTIES

A. The National Food Authority of the Republic of the Philippine
Matimyas Building
101 East Rodrigues Street
Quezon City, Metro Manila
Philippines

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

VII. LIAISON OFFICERS

A. For the National Food Authority, Republic of the Philippines:
Director, Food Research Department
(Currently, Dr. Alicia O. Lustre)
Food Terminal Inc.
National Food Authority
Food Development Center
Taguig, Metro Manila
Philippines
Telephone: 845-1181 (U.S. Night time)
993-992 (U.S. Day time)
Telex: ITT 045684 FTI PM

B. Director, Division of Enforcement, HFS-600 (Currently: Lee Bowers) Center for Food Safety and Applied Nutrition

Tel. No. 202-205-5332
Fax 202-260-0133

B. For the Food and Drug Administration:
Director, Division of Regulatory Guidance (HFF-310),
(Currently, Mr. Howard N. Pippin)
Center for Food Safety and Applied Nutrition
200 C Street, S.W.
Washington, DC 20204
Telephone: 202-485-0187
Telex 197623 PHS PKLN

VIII. ADMINISTRATIVE PROCEDURES

The parties shall mutually agree on the ways and means of giving instructions and guidance for the practical implementation and application of this memorandum. All travel and per diem expenses incurred by FDA personnel for technical assistance or other activities in accordance with this memorandum will be borne by NFA.

Additional products may be added to the list of products subject to certification under this memorandum by agreement of the parties.

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IX. PERIOD OF AGREEMENT

This memorandum will become effective upon acceptance by both parties and will continue indefinitely. It may be revised by mutual consent or terminated by either party upon a 30-day advance written notice to the other.

APPROVED AND ACCEPTED FOR THE NATIONAL FOOD AUTHORITY OF THE REPUBLIC OF THE PHILIPPINES

BY: _____/s/_____

TITLE: NFA Administrator

DATE: Sept 18, 1986

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

BY: Sanford A. Miller /s/

Director, CFSAN (Currently: Dr. Fred Shank)

TITLE: Director, CFSAN, FDA

DATE: September 18, 1986

ATTACHMENT A

I. Product: Shrimp, frozen (raw and cooked)

A. Species: Giant Tiger Prawn (Penaeus monodon - known locally as "sugpo"); Banana Prawn (Penaeus merquienses - known locally as "puti"); Indian Prawn (Penaeus indicus - known locally as "suahe"); and, Green Tiger Prawn (Penaeus semisulcatus - known locally as "bulik").

B. Optional Ingredients: Ascorbic acid, sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite as antioxidants; and, water, free from suspended matter and other substances injurious to health, if used as a glaze.

II. Criteria for Certification

A. Organoleptic attributes

1. Quality: The samples obtained and organoleptically evaluated shall be classified according to the following criteria:

Class 1 - Passable - This category includes fishery products that

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range from very fresh to those that contain fishy odors or other odors characteristic of the commercial product, not definitely identifiable as decomposition.

Class 2 - Decomposed (slight but definite) - The first stage of definitely identifiable decomposition. An odor is present that while not really intense, is persistent and readily perceptible to the experienced examiner as that of decomposition. Shrimp in this category are not fit for human consumption.

Class 3 - Decomposed (advanced) - The product possesses a strong odor of decomposition which is persistent, distinct and unmistakable. Shrimp in this category are not fit for human consumption.

2. Criteria: A lot will be certified for export if the samples obtained and organoleptically evaluated determine that:

For raw shrimp, less than five percent (5%) of the shrimp are Class 3, or, less than twenty percent (20%) of the shrimp are Class 2, or, the percentage of Class 2 shrimp plus 4 times the percentage of Class 3 shrimp is less than twenty percent (20%). NOTE: Percentages are determined on the basis of either weight or count when the shrimp are uniform in size, and on a weight basis when the shrimp are non-uniform in size.

For cooked shrimp, there is no odor of decomposition.

Indole determinations shall be used to confirm Class and Class 3 shrimp. An indole level of 25 micrograms per 100 grams in raw and cooked shrimp having no odor of decomposition shall not be certified.

B. Microbiological Attributes

The samples obtained and evaluated shall not exceed the following average maximum levels for the presence of microorganisms:

For raw and cooked shrimp	Max. allowed as the average of the total number of sub-samples collected
Salmonella	Negative
Vibrio parahaemolyticus	Negative

C. Filth Attributes

Frozen Shrimp samples obtained and evaluated shall be free of filth to the extent indicated below:

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Flies (whole or Equivalent (W/E) - 2 filth flies in a sample; or, 5 incidental flies in a sample

Fly fragments - Any number (excluding setae) in 5 of 6 subs; or, one (1) large body part (i.e., thorax, abdomen) in 3 of 6 subs.

Cockroach - One (1) W/E in the sample; or, one (1) excreta in 2 of 6 subs.

Hairs - Two (2) rat or mouse hairs of any size in a sample; 3 striated, but not rat or mouse, of any size in a sample; or, 4 non-striated of any size in a sample.

D. Food Additives

	Maximum level
Ascorbic Acid	Amount limited by good manufacturing practice
Sulfur dioxide, sodium sulfite, sodium bisulfite, potassuim bisulfite, sodium metabisulfite, or potassium metabisulfite	100 mg/kg in the edible part of the raw product and 30 mg/kg in the edible part of the cooked product, expressed as SO2; singly or in combination.

If any preservative is added, the purpose shall be specified in this manner: ascorbic acid (antioxidant); sulfur dioxide (antioxidant).

E. Labeling

The label of the product shall be in accordance with U.S. Food and Drug Administration labeling regulations (Title 21, Code of Federal Regulations, Part 101). The product identity (name of the food) and the quantity of contents declaration shall be on the principal display panel of the label. The list of ingredients in descending order of predominance and the name and address including country of manufacture, packer or distributor shall either be placed in the principal display panel or the information panel and shall appear in type size not less than 1/16 inch.

NOTE: FDA reserves the right to examine the certified products for attributes other than those listed above.

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III. Sampling

A. Organoleptic Attributes

Raw headless - Whether sampling from bulk or consumer size packages, each sub will consist of a minimum of 100 shrimps or two (2) pounds whichever is the larger amount. Samples will be collected according to the following schedule:

Number of shipping cases in lot	Number of subs
1 to 20	6
21 to 100	12
101 or more	18

Cooked-peeled - Each sub should consist of at least 100 shrimp or two (2) pounds whichever is larger, taken from top, middle and bottom of container. Samples will collected according to the following schedule:

No. of Bulk Ctns.	Number of subs
20 or less	12
21 to 30	14
31 to 40	15
41 to 60	16
61 to 120	17
Over 120	18

B. Microbiological Attributes - A sample subdivision for microbiological analyses of Salmonella and Vibrio parahaemolyticus shall consist of a minimum of 50 grams (approximately 2 oz.).

	Number of Sample Units for Salmonella	for V.parahaemolyticus
Raw and frozen	15	10
Cooked and frozen	30	10

C. Filth Attributes - Six (6) subsamples of two (2) kg (approximately 5 pounds) each will be taken for filth analysis regardless of lot size.

D. Food Additive Attributes - Regardless of lot size, draw at random three (3) subsamples of 100 grams each (approximately 4 oz.) per lot for sulfite analyses.

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IV. Sample Analyses - Except as noted below, samples will be analyzed in keeping with V. ANALYTICAL METHODOLOGY of the Memorandum of Understanding.

A. Organoleptic Attributes - Evaluation shall be made by qualified analysts after the sample is thawed. The procedure of AOAC Section 18.080 - 18.085 is the method of preference for confirming Class 2 and/or Class 3 shrimp. Indole determinations confirm the organoleptic examination only when:

See: AOAC 16th Ed., 1995

1. The indole level of each Class 1 determination which serves as an index for the accuracy of the organoleptic classification, is less than 25 micrograms per 100 grams, and

2. The indole level of each Class 2 determination equals or exceeds 25 micrograms per 100 grams, and

3. The indole level of each Class 3 determination equals or exceeds 50 micrograms per 100 grams.

B. Microbiological Attributes - A procedure that is recognized by the Association of Official Analytical Chemists and that gives equivalent results to those obtained from the "Bacteriological Analytical Manual" method may be used to analyze for Salmonella.

C. Filth Attributes - A block of shrimp can be partially thawed in its own container overnight at refrigerator temperatures or be analyzed directly from frozen storage without pre-thawing. Place about one-half of a block of shrimp (approximately 2 - 2 ½ pounds) on a 12" diameter standard no. 8 mesh sieve nested on top of a standard no. 140 mesh sieve. Wash shrimp thoroughly with a forced stream of hot water. Transfer the material retained on the no. 140 sieve to filter paper if clean or a 1 L trap flask using water. Trap off using the procedure in AOAC (14th Ed.) Section 44.005(b), using water and 30 mL heptane.

See: AOAC, 16th Ed., 1995

D. Food Additive Attributes - Analyze for sulfites by the procedure described in 21 CFR 101.100(a)(4) and Appendix A to part 101.

ATTACHMENT B

I. Product: Fruits and fruit purees, quick frozen

A. Species:

1. Avocado or alligator pear (Persea american Mill);

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2. Banana ("Saba" and "Cavendish" varieties of Musa sapientumLinn)

3. Guava (Psidium guajava Linn);

4. Jackfruit (Artocarpus heterophyllus Linn);

5. Mango ("Carabao" and "Pico" varieties of Mangifera indica Linn);

6. Papaya (Carica papaya Linn);

7. Pineapple (Ananas cososus Linn);

8. Soursop(**) (Anona muricata Linn); and,