BILATERAL

MEMORANDUM OF UNDERSTANDING REGARDING THE INSPECTION OF FISH PRODUCTS BETWEEN THE DEPARTMENT OF HEALTH BUREAU OF FOOD AND DRUGS OF THE GOVERNMENT OF THE REPUBLIC OF THE PHILIPPI...

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I. PURPOSE

The mutual goals of the Bureau of Food and Drugs (BFAD) and the Department of Fisheries and Oceans of Canada (DFO) in entering into this Memorandum of Understanding are to:

1. Provide reasonable assurance that canned or frozen fish products from "Preferred Status" producers in the Philippines will not be tainted, decomposed or unwholesome, and will otherwise meet the requirements of Canada.

2. Minimize the need for extensive sampling in Canada of products produced by "Preferred Status" processors from the Philippines.

II. DEFINITIONS

For the purposes of this memorandum:

Canned fish - means any fish or fish flesh which is in an hermetically sealed glass or metal container and has been commercially sterilized.

Cannery - means an establishment where canned fish is produced for human- consumption

"Chemical Evaluation" denotes the analyses, tests, or observations or series thereof performed on a sample (consisting of a number of sample units) taken to represent a lot to determine the presence of additives or contaminants listed in ANNEX to this document.

Code - A "code" is a quantity of a specific product type and form produced and handled under uniform conditions within a limited time period normally identified by means of a production code.

"Container Integrity Evaluation" denotes the analyses, tests, or observations or series thereof performed on a sample (consisting of a number of sample units) taken to represent a lot, to determine the metal or glass container acceptability as set out in ANNEX to this document.

"Frozen Fish" are fish which have been subjected to a freezing process sufficient to reduce the temperature of the whole product to a level low enough to preserve the inherent quality of the fish and which have been maintained at this low temperature during transportation, storage and distribution up to and including the time of final sale.

"Good Manufacturing Practices" (GMP's) - means those processing requirements, which if applied in the production process should result in products which are safe, wholesome and of good quality.

Inspection - An "inspection" with respect to fish is an evaluation, analysis, test or activity, or a series thereof,

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based on a recognized sampling plan, which leads to a decision on the acceptability of a lot.

"Label Evaluation" denotes the inspection of a sample label carried out to determine compliance of the label with the criteria set out in annex to this document.

Lot - A "lot" is a quantity of a specific product type and form which may be comprised of several production codes.

"Sensory Evaluation" denotes the sensory analysis done on a sample (consisting of a number of sample units) taken to represent a lot, to determine the acceptability to a recognised standard.

"Shipment" is an import of the same product type, arriving to the same location on the same vessel or vehicle at the same time and imported from the same producer by the same importer.

III. SUBSTANCE OF MEMORANDUM OF UNDERSTANDING (MOU)

A. PRINCIPLES

1.The Bureau of Food and Drugs (BFAD) of the Department of Health is the Philippine Government agency responsible for monitoring compliance to the requirements of this document.

2.The Inspection Services Directorate (ISD) of the Department of Fisheries and Oceans (DFO) is the Canadian government agency responsible for the inspection of fish products imported into Canada.

3. Philippine fish processors who wish to have "Preferred Status" pursuant to this Memorandum of Understanding (as included in the Annex to this Memorandum) must:

- adhere to Canadian GMP's, as described in the Annex, for those products being processed for export to Canada;

- have in place a DFO approved quality control program;

- maintain a minimum "B" plant rating as determined by the plant rating system to determine compliance with Schedules I and II of the Canadian Fish Inspection Regulations; and

- submit to periodic audits by DFO or BFAD to ensure the above conditions are being met.

4. Those Philippine fish processors who maintain the conditions set out in section 3 above and who meet the requirements of sec. B(2) will be given "Preferred Status" and will be listed on Schedule A of this MOU.

5. Imports of products of processors on "Preferred Status" will be eligible for reduced inspection and monitoring by the Inspection Services Directorate.

B. APPROVAL PROCEDURE AND COMPLIANCE MONITORING

1. Processors who wish to obtain "Preferred Status" must make application in writing to the Bureau of Food and Drugs (BFAD), who will in turn inform the Department of Fisheries and Oceans of Canada of such applications.

2. Applicants will be subject to a joint DFO, FAD evaluation to verify that:

- the fish processor has a proven record of compliance (as described in the Annex to this Memorandum) with all Canadian regulations, standards and guidelines;

- a satisfactory DFO approved quality control program is in place and is functioning to the satisfaction of the Inspection Services Directorate; the company maintains adequate records confirming processor compliance to GMP's; and

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- the plant facility is inspected and rated by DFO and a minimum, "B" rating as determined by compliance with Schedules I and II of the Canadian Fish Inspection Regulations.

3. Processors on "Preferred Status" will be monitored periodically by the Philippine Bureau of Food and Drugs and may be subject to a joint DFO/BFAD audit to confirm compliance to GMP's. The Philippine Bureau of Food and Drugs will notify DFO of all instances of non-compliance, and actions taken to correct all deficiencies identified.

4. Subject to Section 4 of the Fish Inspection Regulations, DFO will generally monitor imports from "Preferred Status" producers on a reduced inspection basis. A rejection for any reason by DFO Inspection Services of a monitoring sample may constitute non-compliance and may be grounds for suspension from "Preferred Status". Such rejected products will be placed on the Mandatory Inspection List. Processors who have an unacceptable record of performance, as outlined in the administrative procedures, will be removed from "Preferred Status" after consultation between DFO and BFAD.

5. Processors who have been removed from "Preferred Status" may re-apply for "Preferred Status".

6. Processors re-applying for "Preferred Status" may be subject to a joint DFO/BFAD inspection, at the processors expense,to reconfirm compliance with section A-3 and section B-2 of this memorandum.

7. It will be the responsibility of the appropriate Association (as listed in the Annex) to ensure repayment of DFO expenses incurred under section 6 of this memorandum.

8. The Inspection Services Directorate will provide summary results of inspections for "Preferred Status" plants to the Bureau of Food and Drugs upon request.

9. The Inspection Services Directorate will notify the Bureau of Food and Drugs of any detention of fish products produced by "Preferred Status" plants, which are covered by this memorandum.

10. Inspection Services Directorate will provide to BFAD, upon request, a copy of the Fish Inspection Act and Fish Inspection Regulations, and relevant information from other acts, regulations and standards, as well as any modifications or amendments to the acts and regulations. 11. The Inspection Services Directorate will, upon request by BFAD, consider the holding of workshops or seminars with respect to process and product standards.

C. PLANT, PROCESS, AND PRODUCT INSPECTION PROCEDURE

Plant, process and product compliance will be determined as follows:

1. The plant compliance (minimum "B" rating) will be determined in accordance with the Plant Rating System outlined in the Annex to this MOU.

2. Process compliance will be determined in accordance with the criteria outlined in the Annex to this MOU.

3. Product compliance will be determined in accordance with the criteria for product standards, as detailed in the Annex to this MOU.

4. Product sampling will be determined in accordance with the criteria as detailed in the Annex to this MQU.

5. Packaging, labelling and marking requirements will be determined in accordance with the Packaging, Labelling and Marking requirements as indicated in the Annex to this MOU.

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IV. PARTICIPATING PARTIES

A. The Bureau of Food and Drugs of the Department of Health, Alabang, Muntinlupa, Metro Manila, Philippines.

B. Inspection Services Directorate of the Department of Fisheries and Oceans Canada, 200 Kent Street, Ottawa, Ontario, Canada, K1A OE6. .

V. IAISON OFFICERS

A. For the Bureau of Food and Drugs, Department of Health, Philippines-Director, BFAD (currently Cecille Gonzales), Alabang, Muntinglupa, Metro Manila, Philippines, Telephone (632)842-56-35.

B. For the Inspection Services Directorate, Department of Fisheries and Oceans Canada - Director-General, Inspection Services Directorate, [currently B. J. Emberley] 2 00 Kent Street, Ottawa, Ontario, Canada K1A OE6. Telephone (613) 990-0144; Telex 053-4228; Fax (613) 990-4668.

VI. A DMINISTRATIVE PROCEDURES

The parties shall mutually agree on the ways and means of giving instructions and guidance for the implementation of this memorandum through the administrative procedures.

The administrative procedures may be amended on mutual agreement, confirmed by an exchange of letters, specifying the contents and the effective date for such amendments, subject to the requirement that such amendments shall be consistent with the purpose of this Memorandum of Understanding.

This Memorandum of Understanding is limited to fish products covered by Annexes to this Memorandum and may by extended to other products through the establishment of additional Annexes (by the mutual agreement of both participating parties).

VII. PERIOD OF MEMORANDUM OF UNDERSTANDING

This memorandum will become effective upon signature by both parties and will continue indefinitely. It may be reviewed or revised by mutual consent or terminated by either party upon written notice. Inspection Services Directorate reserves the right to change the criteria outlined in the attachments to the Annexes to this document in consultation with the Bureau of Food and Drugs, Philippines.

Either party may, upon written notice, review the policies and procedures in effect in the facilities or installations used to monitor, inspect or produce products covered by the terms of this memorandum.

SIGNED AT OTTAWA this 7th day of November, 1989.

(Sgd.) RAUL S. MANGLAPUS

(Sgd.)

FOR THE DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS OF THE GOVERNMENT OF THE REPUBLIC OF THE PHILIPPINES

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