SUBJECT:

Exportation of Fresh and Fresh Frozen Shellfish to the United States

(FDA Agreement Number 225-81-2000)

(Previously CPG 7156e.02)

Notes:

The FDA contact for this MOU is Phil Spiller, HFS-400

Tel. No. 202-418-3133

This MOU is in effect indefinitely.

MEMORANDUM OF UNDERSTANDING

Between the

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

and the

MINISTRY OF AGRICULTURE AND FISHERIES
GOVERNMENT OF NEW ZEALAND

I. PURPOSE

The purpose of this MOU is to officially recognize the New Zealand Ministry of Agriculture and Fisheries (MAF) as the certifying authority for New Zealand shellfish shippers of fresh and fresh frozen shellfish imports destined for the U.S. market. This document also defines terms and describes the responsibilities of the MAF and FDA in the operation and management of the term of this MOU in accordance with operational guidelines of the National Shellfish Sanitation Program (NSSP).

The New Zealand Ministry of Agriculture and Fisheries (MAF) and the Food and Drug Administration (FDA) of the Department of Health and Human Services of the United States of America affirm by this document their intention to cooperate in assuring that fresh and fresh frozen molluscan bivalves exported to the United States are safe, wholesome, and have been harvested, transported, processed and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and requirements of the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND

Early in the last decade, the New Zealand Department of Marine initiated a shellfish culture program to augment natural production of two commercial species of shellfish, Perna canaliculus (greenlipped mussel) and Crassostre aglomerata (rock oyster).

Responsibilities for fishery development in New Zealand were transferred from the Department of Marine to the MAF in 1973. The MAF, in conjunction with the Department of Health and other agencies, has continued to develop a shellfish control program which could meet or exceed the recommendations of the NSSP. The New Zealand shellfish industry's interest in U.S. shellfish markets resulted in an MAF request for a shellfish evaluation mission in July 1979.

In response to this request, an evaluation of the New Zealand shellfish control program was conducted by a two-person FDA

Notes:

mission in November, 1979. The mission concluded that the New Zealand shellfish control program conforms, in general, to the guidelines of the NSSP and the Federal Food, Drug, and Cosmetic Act. In its final report to the MAF, the mission recommended that the FDA accept the New Zealand program through an MOU with the MAF.

III. SUBSTANCE OF AGREEMENT

A. Terms

For purposes of this Memorandum, both parties agree to the following definitions:

1. Lot.

A collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, no more than a day's production.

2. Central File.

The single location where shellfish control program information, data, and reports are stored and maintained.

3. Bait Shellfish.

Shucked shellfish labeled and intended for bait use only; not for human consumption.

4. Shellfish.

All edible species of molluscan bivalves except scallop species from the family Pectinidae. Only molluscan bivalves that are offered for entry into the United States as fresh or fresh frozen products are intended for coverage under this Memorandum of Understanding.

5. Marine Biotoxins.

Natural toxins produced by marine dinoflagellates such as Gonyaulax catenella, Gonysulax tamarensis, and Gymonodinium breve and concentrated by shellfish during the feeding process.

B. Information Exchange

Both parties agree to provide information concerning proposed changes in the following:

Notes:

1. Methods and procedures for sampling.
2. Methods of analysis.
3. Methods of confirmation.
4. Administrative guidelines, tolerances, specification standards, and nomenclature.
5. Reference standards.
6. Inspectional procedures.
7. Proposed modification of existing Federal or local regulations.
8. Proposed new Federal regulations.
9. Proposed new legislation.
10. Proposed modifications to the National Shellfish Sanitation Program.

C. MAF Responsibilities

1. The MAF agrees to classify its shellfish harvesting waters in accordance with the procedures and standards set forth in the NSSP Manual of Operations. The MAF will assure that only fresh and fresh frozen shellfish harvested from areas which meet NSSP approved water quality and marine biotoxin standards and processed according to NSSP guidelines will be exported to the United States.
2. The MAF agrees to inspect harvesting, transporting, and processing operations of fresh and fresh frozen shellfish at sufficient frequency to assure compliance with NSSP sanitary control practices.
3. The MAF agrees to issue certifications only to those fresh and fresh frozen shellfish shipping firms that comply with NSSP recommended practices and to notify FDA of the name, location, and certification number of those firms on Form FD-3038b "Shellfish Certification." To cancel a firm's certification, the MAF will send to FDA a completed Form FD-3038c "Certification Cancellation."
4. The MAF agrees to require all containers of all lots of fresh and fresh frozen shellfish exported to the United States to be identified by lot number and certification number, together with all other information required by the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act.

Notes:

5. The MAF agrees to facilitate joint FDA-MAF inspections of New Zealand's certified fresh and fresh frozen shellfish processing firms, approved growing waters and related harvesting and handling practices. Such inspections will be made on an annual basis or at a frequency deemed appropriate to determine that the MAF shellfish sanitation control program is equivalent to NSSP recommended practices and that only safe and wholesome fresh and fresh frozen shellfish are exported to the United States.

6. The MAF agrees to make travel arrangements for, and pay transportation expenses of, the FDA inspection team while the team is conducting inspections within New Zealand.

7. The MAF agrees to participate to the maximum extent possible in FDA's laboratory quality assurance programs. These may include:

   a. Participation in the analysis of split samples of:

      (i) Seawater or shellfish meats for indicator bacteria or pathogens.
      (ii) Shellfish meats for heavy metals or other chemical or radionuclide contaminants as may be necessary.

   b. The evaluation of new methods and procedures including reagents, media, or other materials and instruments, and equipment performance.

8. The MAF agrees to the establishment of a central office within New Zealand to collate and maintain a central file of laboratory results, including routine monitoring data and data from quality assurance programs. Standard formats for collecting and reporting data will be used.

9. MAF agrees to assure that if lots of shellfish are imported into the United States for use as bait, each container will be labeled, "Not for human use", and the contents will be decharacterized by use of a permanent colored dye.

10. MAF agrees that the delegation of responsibilities for shell fish control in New Zealand is as given below:

    a. Promulgation and enforcement of regulations governing the growing, harvesting, processing, and shipment of fresh or fresh frozen shellfish produced by New Zealand for export to the United States is the sole responsibility of the MAF.

    b. The principal government agency in the New Zealand shellfish program is the Ministry of Agriculture and Fisheries, with two divisions of the Ministry being directly

Notes:

involved: the Fisheries Management Division and the Meat Division. The responsibilities of the two divisions are set out in a Cooperative Agreement. Meat Division has the overall responsibility for coordination and administration of the New Zealand program.

c. The Public Health Division of the New Zealand Department of Health has direct involvement in the program. Its functions are the classification and continual monitoring of shellfish growing waters as stated in the Memorandum of Understanding between the Ministry of Agriculture and Fisheries and the Department of Health.

d. Laboratory analysis is carried out by Public Health Laboratories of the Department of Health and the Chemistry Division of the Department of Scientific and Industrial Research (DSIR).

e. Research related to the shellfish industry is conducted by Fisheries, the DSIR Fish Processing Unit and Massey University Fish Research Unit.

f. Liaison is maintained with the Fishing Industry Board and the Regional Water Boards.

D. FDA Responsibility

1. FDA agrees to publish the names, locations and certification numbers of certified firms submitted by the MAP. These firms will appear in the monthly INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST.

2. Upon request FDA will provide limited training to technical personnel in laboratory procedures, classification of shellfish growing areas, plant inspection and administrative procedures subject to availability of funds for such purposes.

3. Whenever New Zealand shellfish are detained by FDA due to noncompliance with NSSP agreed upon practices or applicable laws or regulations, FDA will inform MAF of the reason or reasons for the detention. This information will include:

   a. Commodity lot and certification number.
   b. Name and address of the shipper.
   c. Reason for the detention.
   d. Sampling procedure.
   e. Methods of analysis and confirmation.
   f. Administrative guidelines.

4. FDA agrees to make travel arrangements for, and pay round trip transportation expenses of, its inspection team between

Notes:

the United States and New Zealand. FDA will also pay all per diem of the inspection team.

E. National Shellfish Sanitation Program

Upon signing this agreement, the MAF becomes an active participating member of the NSSP. As a full member of the NSSP, the MAF may participate in national workshops, cooperative research programs, seminars, training courses, and other activities designed for the timely exchange of technical information, and provide assistance in the joint resolution of problems confronting the NSSP. The MAF may also:

1. Participate in a joint evaluation of the United States program as it pertains to shellfish exports to New Zealand.

2. Make recommendations for changes and improvements in NSSP guidelines, methods, and standards.

3. Be advised by FDA in the event a State or local food control official questions the certification, safety, or wholesomeness of New Zealand's imported shellfish. FDA will, if so informed, seek to determine the reason for the problem and inform the MAF of any action taken relative to State and local laws or regulations governing such shellfish imports.

REFERENCES

1. US Department of Health and Human Services, Public Health Service (PHS), National Shellfish Sanitation Program, Manual of Operations: Part I Sanitation of Shellfish Growing Areas, 1965 Revision; Part II Sanitation of the Harvesting and Processing of Shellfish, 1965 Revision; Part III Public Health Service Appraisal of State Shellfish Sanitation Programs, 1965 Revision, PHS Publication No. 33.

2. Official Methods of Analysis, 12th ed., Association of Official Analytical Chemists (AOAC), Box 540, Benjamin Franklin Station, Washington, DC 20044, 1975.

3. Food and Drug Administration, "INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST," published monthly and distributed to food control officials and other interested persons by FDA, Bureau of Foods, Fishery Technology Branch (HFF-217), 200 C St. SW., Washington, DC 20204.

4. Federal Food, Drug, and Cosmetic Act, United States Code, Title 21.

5. Fair Packaging and Labeling Act, Pub. L. 89-755, approved November 3, 1966.

2. Official Methods of Analysis, AOAC, 16th Ed., 481 N. Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417

3. FDA, Center for Food Safety and Applied Nutrition, Office of Seafood (HFS-400)

Notes:

6. American Public Health Association, "Recommended Procedures for the Examination of Seawater and Shellfish," 4th ed., 1970, APHA, Inc., 1015 18th St. NW., Washington, DC 20036.

7. Food and Drug Administration, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food" regulations, 21 CFR Part 110.

8. Food and Drug Administration, Definitions and Standards for Food, "Fish and Shellfish" regulations 21 CFR Part 151.

9. Cooperative Agreement between the Meat Division and Fisheries Management Division of the Ministry of Agriculture and Fisheries relative to the sanitary control of the shellfish industry.

10. Memorandum of Understanding between Ministry of Agriculture and Fisheries and Department of Health relative to the certification of export shellfish to the United States of America.

IV. NAME AND ADDRESS OF PARTICIPATING AGENCY

Ministry of Agriculture and Fisheries
P.O. Box 2298
Wellington, New Zealand

V. LIAISON OFFICERS

The liaison officer for each party will be responsible for facilitating exchanges of information and expeditiously informing other interested parties within their respective countries on shellfish control problems requiring prompt attention. Each party agrees to provide notification of any changes in liaison officer appointments. Such notification shall constitute an amendment to, and not require a revision of, this agreement.

A. Liaison Officer for MAF:
Mr. Peter Withers, Second Secretary,
New Zealand Embassy,
37 Observatory Circle, NW.,
Washington, DC 20008.

B. Director, Office of Seafood (Currently Phil Spiller) Center for Food Safety and Applied Nutrition

B. Liaison Officer for FDA
Mr. Daniel A. Hunt, Assistant Chief,
Fishery Technology Branch, Bureau of Foods,
Food and Drug Administration
200 C St. SW.,
Washington, DC 20204.

IV. PERIOD OF AGREEMENT

This agreement when accepted by both parties, will have an

Notes:

effective period of performance from date of signature until terminated by either party. This agreement may be modified by mutual consent of both parties or may be terminated by either party upon a thirty day advance written notice to the other.

APPROVED AND ACCEPTED FOR TH MINISTRY OF AGRICULTURE AND FISHERIES

BY: /s/

TITLE: Director General of Agriculture and Fisheries

COUNTRY: New Zealand

DATE: October 30, 1980

The ACRA is currently Mr. Ronald G. Chesemore

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

BY: Joseph P. Hile /s/

TITLE: Associate Commissioner for Regulatory Affairs

COUNTRY: USA

DATE: October 14, 1980