SUBJECT:

Fresh Frozen Molluscan Shellfish

(FDA Agreement Number 225-86-2001)

(Previously CPG 7156f.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

EXPORT INSPECTION SERVICE,
DEPARTMENT OF PRIMARY INDUSTRY, AUSTRALIA
CONCERNING THE SANITARY CONTROL OF FRESH FROZEN MOLLUSCAN SHELLFISH
DESTINED FOR EXPORTATION FROM AUSTRALIA TO THE UNITED STATES

I. PURPOSE

The Food and Drug Administration (FDA) and the Department of Primary Industry (DPI) affirm by this Memorandum their intention to cooperate in seeking to assure that fresh frozen molluscan shellfish exported from Australia and offered for import into the United States of America (U.S.) are safe and wholesome and have been harvested, processed, transported, and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and the requirements of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and the Australian Export Control Act. This memorandum defines the sanitation practices and administrative controls and describes the responsibilities of FDA and DPI in implementing these practices and controls. By this document, under the NSSP, FDA officially recognizes DPI as the authority for certifying shellfish shippers intending to export fresh frozen shellfish from Australia to the United States.

II. BACKGROUND

The sanitary control of shellfish in interstate commerce in the United States is administered by FDA in cooperation with the American States under the NSSP. The NSSP provides the States and industry with a mechanism by which shellfish dealers can be "certified" as shipping shellfish that have been harvested, handled, and processed in conformity with the sanitation and administrative guidelines of the NSSP. In most instances, food control authorities rely on the integrity of the NSSP certification controls to determine the acceptability of the shellfish product.

FDA, the States, and many foreign control authorities recognize the substantial benefit that can result from the use of a similar procedure

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for imported shellfish. Therefore, it is FDA's policy to enter into the memoranda of understanding with foreign control authorities willing to apply the sanitation and administrative controls of the NSSP to exported lots of shellfish that are to be offered for import to the United States. These agreements permit the foreign control authorities to certify foreign processors and shippers of fresh frozen shellfish and to have these dealers listed on FDA's "Interstate Certified Shellfish Shippers List (ICSSL). FDA and American State authorities, in turn, will recognize these shipments as being certified under the NSSP.

Certification of foreign shellfish dealers exporting to the United States is normally limited to those dealers shipping fresh frozen products. This limitation is based on fishery conservation concerns over the possible introduction of exotic infectious organisms into U.S. fishery stocks from foreign fishery stocks. The processing and freezing of shellfish substantially reduce the possibility that such introductions will occur.

The sanitary control of shellfish in Australia is administered by DPI in cooperation with Australian State control agencies. DPI has authority under the Australian Export Control Act of 1982 to inspect shellfish processors preparing products for export, to set quality standards, and to certify compliance of export lots with these standards. Australian State public health and fishery authorities have jurisdiction under various Australian Federal and State public health and fishery regulations to survey and classify shellfish growing areas and to control harvesting and shipping operations. Laboratory support is provided by private laboratories under agreements with Australian Federal and State authorities.

III. SUBSTANCE OF AGREEMENT

A. DEFINITIONS

1. Advisory agencies - Advisory agencies are the Australian Government Analytical Laboratories or other laboratories accredited by the Australian National Association of Testing Authorities that provide analytical support to shellfish control authorities associated with this memorandum.

2. Central file - Central file is the location where each shellfish sanitation authority stores and maintains program information, data, and reports.

3. Enforcement agencies - Enforcement agencies are the Department of Primary Industry (DPI) and the Australian State enforcement agencies having regulatory authority over the production, harvesting, processing, transport, classification, and export of certified shellfish to the United States under the terms of this memorandum.

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4. Lot - A lot is 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, containing no more than a day's production.

5. Shellfish - Shellfish are edible species of oysters; clams, including cockles; and mussels.

6. State enforcement agencies - State enforcement agencies are the Australian State departments that have regulatory authority over the production, harvesting, transport, and processing of shellfish and the classification, monitoring, and control of harvest areas, and that have entered into an agreement with DPI for the purposes of this memorandum.

B. DPI RESPONSIBILITIES

DPI will:

1. Develop and maintain interagency agreements and protocols with Australian State enforcement agencies to coordinate Australian Federal and State implementation of NSSP controls, as necessary.

2. Maintain NSSP required legal, administrative, and sanitation controls over shellfish exported by certified Australian dealers by ensuring that Australian State enforcement agencies:

   a. Classify shellfish harvesting areas based upon comprehensive sanitation surveys;
   b. Prepare sanitation survey reports and maintain survey data in a central file;
   c. Update survey data annually and periodically review the classification status of each harvest area;
   d. License and supervise harvesting and relaying operations and provide proper source labeling for shellstock;
   e. Restrict harvesting of shellfish from unapproved areas and take appropriate enforcement action against violators; and
   f. Evaluate laboratory practices at least annually and encourage participation in FDA's voluntary quality assurance programs.

3. Inspect firms processing fresh frozen shellfish for export to ensure compliance with NSSP controls.

4. Certify dealers exporting fresh frozen shellfish that comply with NSSP requireinents on an annual basis and notify FDA of

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the name, location, and certification number of those firms on Form FD-3038B, "Shellfish Certification."

5. Cancel the certificate of any firm operating out of compliance with the requirements of the NSSP, utilizing shellfish from nonapproved areas, or shipping shellfish that do not conform to the requirements of the U.S. Federal Food, Drug, and Cosmetic Act and the U.S. Public Health Service Act.

6. Ensure that all containers of each lot of fresh frozen shellfish certified for export are identified with the shipper's address, certification number, and lot number or code, together with all other information required by the U.S. Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, and the U.S. Fair Packaging and Labeling Act.

7. Maintain a central file of program records including but not necessarily limited to sanitation survey reports, inspection reports, laboratory evaluation reports, and enforcement actions. These records are made available to FDA for review upon request.

8. Provide inspection results, as appropriate, and other program information, including FDA evaluation reports, interpretations, and laboratory quality assurance program information, to Australian State enforcement and advisory agencies.

9. Review periodically, but at least annually before recertification, the level of conformity to NSSP requirements that is being enforced by DPI and the Australian State enforcement and advisory agencies and provide a report of the review to FDA as necessary, or at least annually.

10. Provide FDA with information about current or potential new public health problems affecting shellfish intended for export to the United States.

11. Make travel arrangements in Australia for, and conduct joint inspections with, FDA evaluation officers at FDA's request. Meet transportation expenses in Australia of FDA officials making inspections in accordance with this memorandum.

C. FDA RESPONSIBILITIES

FDA will:

1. Recognize Australia as a participant in the NSSP with full rights to participate in national workshops, cooperative research programs, seminars, training courses, and other

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NSSP activities; to make recommendations for changes or improvements in the procedures, methods, standards, and guidelines of the NSSP; and to have DPI certify Australian dealers for inclusion in FDA's ICSSL.

2. Publish the names, locations, and certification numbers of Australian shellfish shippers certified by DPI in the monthly publication of tbe ICSSL upon receipt of Form FD-3038B.

3. Provide limited training and technical assistance to enforcement agency personnel in shellfish sanatation program administration, laboratory procedures, and growing area classification procedures upon request of DPI and subject to availability of funds for such purposes.

4. Inform DPI of the reasons for any FDA detentions of certified frozen shellfish shipments from Australia. Additional information that FDA will provide shall include, but not necessarily be limited to:

   a. Commodity identification;
   b. Commodity code, lot, and certification number;
   c. Name and address of the shipper;
   d. Sampling procedure;
   e. Methods of analysis and confirmation; and
   f. Administrative guidelines.

5. Advise DPI of any questions that FDA has received from U.S. food control officials concerning the safety or wholesomeness of frozen shellfish imported into the United States from Australia. Upon receiving such questions, FDA will seek to determine the reason for the problem and will inform DPI of any action taken under American State and local laws or regulations with regard to such frozen shellfish imports.

6. Participate with DPI in joint evaluations of the Australian shellfish sanitation program as it pertains to certifying dealers. Joint evaluations normally will be conducted at 2-year intervals to ascertain Australia's level of conformity with the requirements of the NSSP and the responsibilities specified in this memorandum. FDA will pay round trip transportation expenses between the United States and Australia and the per diem of the members of the FDA evaluation team while in Australia.

7. Facilitate the exchange of information between DPI and U.S. Federal and State agencies concerned with the introduction and proliferation of exotic infectious organisms that might be carried by Australian shellfish.

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D. SHARED RESPONSIBILITIES

DPI and FDA will:

1. Exchange information through nominated liaison officers concerning significant proposed and final changes in program operations and procedures including:

   a. Methods and procedures for sampling;
   b. Methods of analysis;
   c. Methods of confirmation;
   d. Administrative guidelines, tolerances, specification standards, and nomenclature;
   e. Reference standards; and
   f. Inspection procedures.

   Final changes will be considered incorporated into the appropriate provisions of this memorandum 90 days after receipt unless written objection is provided to the other party.

2. Provide written notification to the other party of any changes in liaison officers. Changing liaison officers will not otherwise constitute a change in the provisions of this memorandum.

E. REFERENCES

1. U.S. Department of Health and Human Services (formerly U.S. Department of Health, Education, and Welfare), 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. Association of Official Analytical Chemists, Official Methods of Analysis, 14th Ed., Association of Official Analytical Chemists, Inc., IIII North 19th St., Suite 210, Arlington, VA 22209, U.S.A., 1984.

3. Food and Drug Administration, "Interstate Certified Shellfish Shippers List," published monthly and distributed to food control officials and other interested persons by FDA, Center for Food Satety and Applied Nutrition, Shellfish Sanitation Branch (HFF-344), 200 C St., SW., Washington, DC 20204.

4. Federal Food, Drug, and Cosmetic Act, 1938, as amended, U.S. Code, Title 21.

5. Public Health Service Act, as amended, U.S. Code, Title 42.

2. See: Official Methods of Analysis - AOAC, 16th Ed., 1995

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

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6. Fair Packaging and Labeling Act, Public Law 89-755, approved November 3, 1965.-

7. American Public Health Association, Recommended Procedures for the Examination of Seawater and Shellfish, 4th Ed., 1970, APHA, Inc., IO15 15th St. NW., Washington, DC 20036.

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

9. Food and Drug Administration, "Definitions and Standards for Food," "Fish and Shellfish" regulations, 21 CFR Part 161.

10. Food and Drug Administration, "Specific Administrative Decisions Regarding Interstate Shipments," "Shellfish," 21 CFR 1240.60.

11. Food and Drug Administration, "Food Service Sanitation on Land and Air Conveyances, and Vessels," "Special Food Requirenents," 21 CFR 1250.26.

12. Export Control Act, 1982.

13. Prescribed Goods (Orders) Regulations.

14. Prescribed Goods (General) Orders.

15. Fish Orders.

IV. PARTICIPATING PARTIES

A. Export Inspection Service
Department of Primary Industry
Edmund Barton Bldg.
Canberra ACT 2600
AUSTRALIA.

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

Notes:

Australian Quarantine and Inspection Service, Executive Director (Currently: Mr. Paul Hickey) Dept. of Primary Industries and Energy

B. Director, Office of Seafood (HFS-400) (Currently: Phil Spiller)

202-205-4133

V. LIAISON OFFICERS

A. For Department of Primary Industry:
Director Fish Export Standards
(currently David Walter)
Export Inspection Service
Department of Primary Industry
Canberra ACT 2600
Australia
Telephone: 062-725399
Telex: 62188

B. For Food and Drug Administration:
Chief, Shellfish Sanitation Branch
(currently J. David Clem)
Center for Food Safety and Applied Nutrition
Food and Drug Aininistration
200 C St. S4., Washington, DC 20204
202-485-0149

VI. PERIOD OF AGREEMENT

This agreement will become effective upon acceptance by both parties and will remain in effect indefinitely. It may be modified by mutual consent or terminated by either party upon a 30-day advance written notice to the other.

APPROVED AND ACCEPTED FOR THE DEPARTMENT OF PRIMARY INDUSTRY OF AUSTRALIA

BY: /s/

TITLE: Director, Export Inspection Service

DATE: Ninth of June 1986

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA

BY: John M. Taylor /s/

TITLE: Acting Associate Commissioner for Regulatory Affairs

DATE: September 12, 1986

The ACRA is currently: Mr. Ronald G. Chesemore