DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–01–8001]

Memorandum of Understanding Between the United States Food and Drug Administration and National Fisheries Service, Ministry of Economy, Development, and Reconstruction, Republic of Chile Covering the Sanitary Control of Fresh and Frozen Molluscan Shellfish Exported From the Republic of Chile to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA, Department of Health and Human Services, United States of America and the National Fisheries Service, Ministry of Economy, Development, and Reconstruction, Republic of Chile. This agreement renews the cooperative work arrangement concerning the safety and wholesomeness of fresh and frozen oysters, clams, and mussels exported to the United States from Chile, which expired by its terms on May 18, 1999. The purpose of this agreement is to assist in assuring aquacultural fresh or frozen molluscan shellfish exported from Chile and offered for import into the United States will continue to be safe and wholesome, and will be harvested, processed, transported, and labeled in accordance with the sanitation principles of the United States National Shellfish Sanitation Program and the U.S. Federal Food, Drug, and Cosmetic Act and other related public health laws.

DATES: The agreement became effective February 23, 2001.

FOR FURTHER INFORMATION CONTACT: Angel M. Suarez, Center for Food Safety and Applied Nutrition (HFS–628), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–7338.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register** the agency is publishing notice of this MOU.

Dated: March 14, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

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

AND THE

NATIONAL FISHERIES SERVICE
MINISTRY OF ECONOMY, DEVELOPMENT, AND RECONSTRUCTION
OF THE REPUBLIC OF CHILE

COVERING THE SANITARY CONTROL OF FRESH AND FROZEN MOLLUSCAN SHELLFISH EXPORTED FROM THE REPUBLIC OF CHILE TO THE UNITED STATES OF AMERICA

The Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America and the National Fisheries Service (Servicio Nacional de Pesca or "Sernapesca"), Ministry of Economy Development and Reconstruction of the Republic of Chile, hereinafter referred to as the "Parties",

In keeping with the beneficial and cooperative work conducted under the terms of a 1989 Memorandum of Understanding (MOU) concerning the safety and wholesomeness of fresh and frozen oysters, clams, and mussels to the United States from Chile, which expired by its terms on May 18, 1999,

Recognizing that the Parties have held technical consultations leading to the successful development and implementation of an effective aquaculture program in Chile for oysters, clams, mussels, and scallops (whole or roe-on),

Acknowledging that FDA endorses the Chilean Shellfish Sanitation Program (CNSSP) and finds the Chilean program meets the United States National Shellfish Sanitation Program (NSSP) guidelines that are administered by FDA in cooperation with State agencies, and

Noting that the Parties can and will fulfill their responsibilities as members of the NSSP,

Have reached the following understanding:

I. PURPOSE

The mutual goals of the Parties in entering into this MOU are to:

A. Recognize that the Sernapesca within the Ministry of Economy Development and Reconstruction retains the overall responsibility for the CNSSP and coordinates participation of Chilean Regional governments in the shellfish program. Chilean Regions participating in the NSSP are equally responsible for fulfilling the sanitary control of shellfish in interstate commerce. Sernapesca will provide program direction.

B. Acknowledge that this MOU will permit Sernapesca to certify Chilean shippers for fresh or frozen shellfish and to have these certified shippers listed on FDA's "Interstate Certified Shellfish Shippers List" (ICSSL). FDA will recognize shellfish from certified Chilean shippers as having been certified under NSSP.

C. Recognize that this MOU will assist in assuring aquacultural fresh or frozen molluscan shellfish exported from Chile and offered for import into the United States will continue to be safe and wholesome, and will be harvested, processed, transported, and labeled in accordance with the sanitation principles of the NSSP, and the requirements of 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.

II. DEFINITIONS

A. Approved area means the classification of a state molluscan shellfish growing area that has been approved by the state shellfish control authority for growing or harvesting molluscan shellfish for direct marketing. The classification of an approved growing area is determined through a sanitary survey conducted by the state shellfish control authority in accordance with the NSSP Model Ordinance.

B. Aquaculture means the controlled production of molluscan shellfish in natural or artificial systems. Components of aquaculture may overlap with other activities such as relaying, transplanting, wet storage, growing water classification and labeling.

C. Central file means the location where the enforcement agency stores and maintains program information, data, and reports.

D. Enforcement agency means Sernapesca, which has regulatory authority in Chile over the production, harvesting, processing, transportation, classification, and export of certified shellfish to the United States under the terms of this memorandum; classification and patrol of shellfish growing waters; and the evaluation of shellfish laboratories.

E. Lot of shellstock means a collection of bulk shellstock or containers of no more than one day's harvest from a single defined growing area harvested by one or more harvesters.

F. Lot of shucked shellfish means a collection of shellfish of no more than one day's harvest from a single defined growing area, produced under conditions as nearly uniform as possible, with the shucked shellfish product placed in containers designated by a common container code or marking.

G. Marine biotoxins means poisonous compounds accumulated by shellfish feeding upon toxic microorganisms. The poisons may come from dinoflagellates, e.g., Alexandrium spp. (formerly Protogonyaulax spp., Gonyaulax catenella, Gonyaulax tamarensis), Gymnodinium breve (formerly Ptychodiscus brevis), and Dinophysis spp. as well as diatoms such as *Pseudonitzia*.

H. Molluscan shellfish means all edible species of oysters, clams, mussels, and whole or roe on scallops; either shucked or in the shell, fresh or frozen, whole or in part.

I. Shellstock means live molluscan shellfish in the shell.

III. BASIC OBLIGATIONS

A. RESPONSIBILITIES OF SERNAPESCA

Sernapesca agrees that:

1. Sernapesca shall have overall responsibility for the coordination and implementation of the CNSSP, and develop and maintain interagency agreements and protocols with other government enforcement agencies to implement the CLNSSP controls as necessary. Sernapesca will be the liaison with the FDA and maintain compliance with the administrative/operational and technical aspects of the NSSP and CNSSP.

2. Sernapesca, as the Chilean enforcement agency, shall:

   a. Maintain CNSSP required legal, administrative, and sanitary controls over shellfish exported by certified Chilean dealers.

   b. Ensure that the CNSSP:

(1) Classifies molluscan bivalve growing areas based on comprehensive sanitation surveys;

(2) Prepares sanitation survey reports and maintains survey data in a central file;

(3) Updates survey data annually and periodically review the classification status of each harvest area;

(4) Approves and supervises harvesting and relaying operations and provides proper labeling and identification of source of shellstock;

(5) Restricts harvesting of shellstock from unapproved areas and takes appropriate enforcement action against violations; and

(6) Oversees certification laboratories approved to participate in the shellfish sanitation control program.

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

d. On an annual basis, 1) certify dealers exporting fresh or frozen shellfish to the United States, 2) certify that such dealers comply with NSSP requirements, and 3) notify FDA of the name, location and certification number of those firms on Form FD-3038, "Shellfish Dealer Certification."

e. Cancel the certification of any firm:

1. Operating out of compliance with the requirements of the NSSP;

2. Utilizing shellfish from nonapproved areas; or,

3. Shipping shellfish that do not conform to the requirements of the U.S. Federal Food, Drug, and Cosmetic Act, U.S. Public Health Service Act, and the U.S. Fair Packaging and Labeling Act.

f. Ensure that all containers of each lot of fresh or 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.

g. Provide results of research investigations conducted on live shellfish (tissue and shell material) taken from approved growing areas designated for shellfish harvest for export to the United States.

h. 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 to be made available to FDA for review upon request.

i. Provide inspection results, as appropriate, and other program information, including FDA evaluation reports, interpretations, and laboratory quality assurance program information, to Regional Chile National Fisheries Service offices and other government agencies that have responsibilities in the CNSSP.

j. Review periodically, but at least annually, the level of conformity to NSSP requirements that is being enforced by Sernapesca. Provide a report of the review to FDA as necessary, or at least annually.

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

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

3. Sernapesca is responsible for designating the laboratory officer for:

a. Certification of all laboratories participating in the CNSSP and maintaining appropriate infrastructure, technical materials, equipment, and trained personnel to carry out required NSSP sampling and analytical procedures.

b. Periodic evaluation of certified laboratories to verify compliance with all NSSP requirements and the maintenance of laboratory quality assurance procedures.

4. The Chilean Ministry of Health, through its Health Services, is directly responsible for the prohibition of the harvesting of shellfish from areas in response to contamination emergencies and for reopening such

prohibited areas after water quality data demonstrates the area meets approved criteria.

5. The Chilean Ministry of Health, through its Institute of Public Health, shall serve as the official laboratory of reference for:

   a. Analyzing and maintaining a marine biotoxin monitoring program for those areas where shellfish are harvested for export to the United States.

   b. Analyzing and maintaining a split-sample (cross-sampling) program between designated shellfish laboratories for evaluating uniform laboratory practices in microbiological practices.

B. RESPONSIBILITIES OF THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

FDA agrees to:

1. Recognize the Republic of Chile as a participant in the NSSP with full rights to participate in the Interstate Shellfish Sanitation Conference (ISSC), cooperative research programs, seminars, training courses, and other NSSP activities; to make recommendations for changes or improvements in the procedures, methods, standards, and guidelines of the NSSP; and to have the Sernapesca certify Chilean firms for inclusion in FDA's ICSSL.

2. Publish the names, locations, and certification numbers of Chilean shellfish shipping firms certified by Sernapesca in the monthly publication of the ICSSL upon receipt of Form FD-3038.

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

4. Inform Sernapesca of the reasons for any detentions of certified molluscan shellfish shipments from Chile which have been carried out under the authority of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service (PHS) Act and the U.S. Fair Packaging and Labeling Act. Additional information that FDA should provide may include, but not be limited to:

(a) Commodity identification;

(b) Commodity code, lot, and certification number;

(c) Name and address of the shipper;

(d) Sampling procedures;

(e) Methods of analysis and confirmation; and

(f) Administrative guidelines.

5. Participate with Sernapesca in joint evaluations of the CNSSP as it pertains to certifying firms. Joint evaluations normally will be conducted periodically to ascertain the level of conformity with the requirements of the NSSP and with the responsibilities specified in this memorandum. FDA will pay round trip transportation expenses between the United States and Chile and the per diem of the members of the FDA evaluation team while in Chile.

6. Exchange appropriate information concerning questions by the United States, state or local food control officials regarding the certification, safety, and wholesomeness of shellfish imported from Chile. The FDA will, if requested by the Sernapesca, seek to communicate with state and local authorities in the United States on issues, which may adversely affect the importation of Chilean shellfish to the United States.

IV. TECHNICAL INFORMATION EXCHANGE

The working language for documents exchanged under this MOU shall be English. The Parties agree to share expertise, provide assistance, and exchange information. Such mutual cooperation may include, but shall not be limited to:

A. Exchanging information through designated 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.

B. Providing 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 MOU.

C. Facilitating the exchange of information between Sernapesca and the U.S. Federal and State agencies concerned with the introduction and proliferation of exotic organism that might be carried by Chilean shellfish.

V. PARTICIPATING PARTIES

A. National Fisheries Service (Sernapesca)
Victoria #2832
Valparaiso, Chile

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
The United States of America

VI. LIAISON OFFICERS

A. For the National Fisheries Service (Sernapesca)

Head of Health Fisheries Department
Servicio Nacional de Pesca
Victoria #2832
Valparaiso, Chile

B. For the Food and Drug Administration:

Director, Office of Seafood
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C Street, SW. (HFS-400)
Washington, D.C. 20204
Telephone: (202) 418-3133

VII. PERIOD OF AGREEMENT AND TEXTUAL VERSIONS

This MOU shall enter into force upon signature by both Parties and shall continue for five (5) years. The Parties agree to evaluate the MOU during the five-year period. It may be extended or amended by written consent of the Parties. It may be terminated by either Party upon 30 days written notice to the other.

This MOU is done in duplicate in the English language. A text in the Spanish language shall be considered equally authentic upon written confirmation by the Parties of its substantive conformity with the text in the English language.

His Excellency Andrés Bianchi
Ambassador of Chile

Sharon Smith Holston
Deputy Commissioner
International and Constituent Relations

FOR THE
NATIONAL FISHERIES SERVICE
MINISTRY OF ECONOMY,
DEVELOPMENT, AND RECONSTRUCTION
OF THE REPUBLIC OF CHILE

DATE: February 23, 2001
PLACE: Rockville, MD

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

DATE: February 23, 2001
PLACE: Rockville, Maryland

ANNEX

REFERENCES

1. U.S. Department of Health and Human Services (formerly U.S. Department of Health, Education, and Welfare), PHS, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 1997 Revision.

2. Association of Official Analytical Chemists, Official Methods of Analysis, 16th Edition; 4th Revision, Association of Official Analytical Chemists, Inc., 111 North 19th Street, Suite 210, Arlington, VA 22209, U.S.A., 1998.

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 Safety and Applied Nutrition, Division of Cooperative Programs (HFS-625), 200 C Street, SW., Washington, D.C. 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.

6. Fair Packaging and Labeling Act, Public Law 89-755, approved November 3, 1966.

7. American Public Health Association, Recommended Procedures for the Examination of Seawater and Shellfish, 4th Ed., 1970, APHA, Inc., 1015 15th Street, NW, Washington, D.C. 20036.

8. Food and Drug Administration, "Fish and Fishery Products" regulations, 21 CFR Part 123.

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

10. Food and Drug Administration, "Fish and Shellfish" regulations, 21 CFR Part 161.

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

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

13. 1989 Shellfish Sanitation Agreements between the Government of the United States of America and the Republic of Chile.

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