MEMORANDUM OF UNDERSTANDING

BETWEEN THE

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

AND THE

MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES THROUGH THE FEDERAL COMMISSION FOR PROTECTION FROM SANITARY RISKS

COVERING THE SAFETY AND QUALITY OF FRESH AND FROZEN AQUACULTURED MOLLUSCAN SHELLFISH EXPORTED FROM THE UNITED MEXICAN STATES TO THE UNITED STATES OF AMERICA

The Department of Health and Human Services of the United States of America, through the Food and Drug Administration (FDA) and the Ministry of Health of the United Mexican States, through the Federal Commission for Protection from Sanitary Risks (COFEPRIS), hereinafter referred as "The Participants",

Desiring to safeguard public health and to ensure the safety and quality of fresh and frozen aquacultured molluscan shellfish that are or may be exported into the United States of America, and

In keeping with the beneficial and cooperative work conducted under the terms of a 1988 Memorandum of Understanding concerning the safety and quality of molluscan shellfish exported to the United States of America from the United Mexican States, and

Recognizing that the Participants have held technical consultations leading to the successful development and implementation of an effective molluscan shellfish sanitation program in the United Mexican States for molluscan shellfish, and

Recognizing that nothing in this Memorandum of Understanding (MOU) will in any way abrogate the responsibility or authority of the FDA under section 801 of the Federal Food, Drug, and Cosmetic Act to examine, and, where appropriate, refuse admission of, any food product being offered for entry into the United States of America or to comply with and enforce any other law administered by the FDA, and

Acknowledging that the FDA recognizes the Mexican Shellfish Sanitation Program (MSSP) and finds that the MSSP adequately meets U.S. National Shellfish Sanitation Program (NSSP) guidelines, and that COFEPRIS retains the overall responsibility for the MSSP and coordinates participation of Mexican State Governments in the Molluscan Shellfish Program;

Have hereby reached the following understanding:

ARTICLE I
Purpose

The purpose of this MOU is to establish the set of guidelines to be implemented for assuring that molluscan shellfish exported from the United Mexican States and offered for import into the United States of America are safe for human consumption and are harvested, processed, transported, and labeled in accordance with the provisions of the NSSP Model Ordinance and the applicable 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 Title 21 of the U.S. Code of Federal Regulations.

ARTICLE II
Definitions

For the purpose of this MOU the words listed below will have the following meaning:

1. Approved means the classification used to identify a growing area where the harvest of molluscan shellfish for direct marketing is allowed.

2. Aquaculture means the cultivation of seed in natural or artificial growing areas, or the cultivation of shellstock other than seed in natural or artificial growing areas.

3. Central file means the single location where COFEPRIS maintains a copy of all information, data, reports, and maps associated with the MSSP.

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

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

6. Marine biotoxins means any poisonous compound produced by marine microorganisms and accumulated by shellstock.

7. Mexican Shellfish Sanitation Program (MSSP) means the regulatory control program in the United Mexican States designed to ensure the safety of molluscan shellfish intended for export to the United States of America through the implementation of control measures set forth in the NSSP.

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

9. National Shellfish Sanitation Program (NSSP) means the cooperative state (domestic and foreign)-FDA-industry program to ensure the safety and quality of molluscan shellfish intended for human consumption. Guidelines for ensuring the safety and quality of molluscan shellfish are set forth in the NSSP Model Ordinance.

10. Patrol means the active control of molluscan shellfish harvesting to ensure that only molluscan shellfish from approved areas are harvested, processed, and shipped.

11. Relay means the transfer of shellstock from unapproved areas to approved areas for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

12. Sanitary Survey Report means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a molluscan shellfish growing area.

13. Shellstock means live molluscan shellfish in the shell.

ARTICLE III
Obligations of the Participants

A. RESPONSIBILITIES OF COFEPRIS

1. COFEPRIS assumes the commitment of overall responsibility for the coordination and implementation of the MSSP.

2. COFEPRIS intends to:

    a. Maintain legal, administrative, safety, quality, and sanitary controls over molluscan shellfish intended for export to the United States of America by certified Mexican processors.

    b. Ensure that the MSSP conforms to the NSSP, including, but not limited to:

        i. classifying molluscan shellfish growing waters;

        ii. preparing sanitary survey reports and maintaining sanitary survey reports and all related data in the central file;

        iii. updating sanitary survey reports annually and triennially for the purpose of ensuring the proper classification of each molluscan shellfish growing area;

iv. approving and supervising harvesting and relaying operations and ensuring proper labeling and identification of molluscan shellfish in accordance with the NSSP;

v. restricting the harvest of molluscan shellfish from unapproved growing areas, controlling the harvest of molluscan shellfish from unapproved growing areas, and taking enforcement action against persons or firms harvesting from unapproved growing areas;

vi. prohibiting the harvest of molluscan shellfish from growing areas in response to contamination emergencies and for rescinding such prohibitions when water quality data or marine biotoxin analyses demonstrate that the area meets NSSP approved area criteria;

vii. recalling unsafe molluscan shellfish when the responsible processor fails to carry out the necessary product recall;

viii. maintaining NSSP conforming laboratories certified to participate in the MSSP;

ix. inspecting processors that process fresh or frozen aquacultured molluscan shellfish for export to the United States of America to ensure compliance with NSSP controls;

x. certifying processors exporting fresh or frozen aquacultured molluscan shellfish to the United States of America in accordance with the NSSP for listing on FDA's Interstate Certified Shellfish Shippers List (ICSSL);

xi. notifying FDA of the name, location and certification number of MSSP certified processors exporting to the United States of America on Form FD-3038, "Shellfish Dealer Certification";

xii. canceling the certification of any processor that:

- operates out of compliance with the NSSP;
- ships molluscan shellfish from unapproved growing areas; or
- ships molluscan shellfish that otherwise do not conform to 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, or Title 21 of the U.S. Code of Federal Regulations.

- fails to recall molluscan shellfish determined to be unsafe for human consumption;

xiii. ensuring that each container in a lot of molluscan shellfish certified for export to the United States of America is properly labeled in accordance with the NSSP;

xiv. maintaining a central file of all MSSP records, including an English version of all sanitary survey reports, patrol reports, and laboratory evaluation reports and make them available to FDA upon request;

xv. providing FDA evaluation reports, interpretations, laboratory quality assurance program information, and other molluscan shellfish program information from FDA to federal and state government agencies having responsibility for the MSSP;

xvi. reviewing, at least annually, the level of conformity with the NSSP and summarizing the findings in a written report and providing an English translation of the report to FDA annually;

xvii. providing FDA with information concerning current or potential public health problems affecting molluscan shellfish intended for export to the United States of America; and

xviii. making travel arrangements in the United Mexican States for, and conducting joint inspections with, FDA evaluation officers at FDA's request. Providing transportation for FDA officials while in the United Mexican States.

c. Permit the harvesting of molluscan shellfish for processing by MSSP certified processors and shipment to the United States of America only from growing areas approved by COFEPRIS with concurrence from the FDA.

d. Within 30 days of written notification from FDA of NSSP deficiencies, develop a written Corrective Action Plan, and submit it to FDA for review and concurrence. If a Plan is not developed within 30 days, FDA will remove Mexican processors from the ICSSL and/or take other appropriate action to stop molluscan shellfish from the United Mexican States from entering the United States of America. Such action should remain in effect until all MSSP deficiencies have been corrected and FDA has determined that the MSSP is in compliance with the NSSP.

3. COFEPRIS may designate a MSSP laboratory evaluation officer to:

a. certify laboratories participating in the MSSP;

b. periodically evaluate certified MSSP laboratories to verify compliance with the NSSP and maintain laboratory quality assurance procedures;

c. maintain a marine biotoxin monitoring program for growing areas where molluscan shellfish are harvested for export to the United States of America;

d. maintain a split-sample program among MSSP laboratories for evaluating uniform microbiological laboratory practices;

e. notify FDA of laboratories not in compliance with the NSSP; and

f. prevent MSSP laboratories not in compliance with the NSSP from participating in the MSSP.

4. COFEPRIS should update the MSSP Model Ordinance to be consistent with published NSSP Model Ordinance revisions. COFEPRIS should provide an English version of all updates to FDA for review and concurrence.

5. Any change in responsibility from COFEPRIS to another authority must be reported to FDA within 30 days of such change. A change from COFEPRIS to a new authority may require re-evaluation of the MSSP by FDA.

6. Mexican states goverments participating in the MSSP are equally responsible for ensuring the safety and quality of molluscan shellfish exported to the United States of America.

B. RESPONSIBILITIES OF THE FDA

FDA intends to:

1. Accept the United Mexican States as a participant in the NSSP and the Interstate Shellfish Sanitation Conference (ISSC), cooperative research programs, seminars, training courses, and other NSSP activities and have COFEPRIS certify Mexican processors for inclusion in FDA's ICSSL.
2. Publish the names, locations, and certification numbers of Mexican firms certified by COFEPRIS in the monthly publication of the ICSSL upon receipt of Form FD-3038.

3. Provide training and technical assistance to COFEPRIS, subject to the availability of funds and personnel for such purposes.

4. Inform COFEPRIS of the reasons for any detention of certified molluscan shellfish shipments from the United Mexican States.

5. Participate with COFEPRIS in joint evaluations of the MSSP. Joint evaluations will be conducted to ascertain the level of conformity with the requirements of the NSSP and

with the responsibilities specified in this MOU. FDA should pay round trip transportation expenses between the United States of America and the United Mexican States and the per diem of the members of the FDA evaluation team while in the United Mexican States.

6. Notify COFEPRIS of NSSP deficiencies and request that COFEPRIS submit, within 30 days, a written Corrective Action Plan to FDA for review and concurrence. If a Plan is not developed within 30 days or if the deficiencies are not corrected in accordance with the Plan, FDA will remove Mexican processors from the ICSSL and/or take other appropriate action to stop Mexican molluscan shellfish from entering the United States of America. In case of a serious public health threat, this 30 day period may be reduced or eliminated. Such action should remain in effect until all NSSP deficiencies have been corrected and FDA has determined that the MSSP is in compliance with the NSSP.

7. Remove individual Mexican processors from the ICSSL when it is determined by FDA or COFEPRIS that a processor is not in compliance with the NSSP or when an imminent health hazard exists with a processor's product.

8. Report any change in responsibility from FDA to another federal authority to COFEPRIS within 30 days of such change.

ARTICLE IV
Technical Information Exchange

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

1. Exchanging information concerning proposed and final changes in MSSP operations and procedures including, but not limited to:

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.

2. Providing written notification to the other Participant within 30 days of changes in liaison officers. Changing liaison officers does not otherwise constitute a change in the provisions of this MOU.

3. Facilitating the exchange of information between COFEPRIS and U.S. Federal and State agencies concerned with the introduction and proliferation of exotic organisms that might be carried by Mexican molluscan shellfish.

ARTICLE V
Liaison Officers

In order to obtain an adequate follow up of the cooperation activities derived from this MOU, the liaison officers will be

A. For COFEPRIS:

Director (a) General de Control Sanitario de Productos y Servicios
Comision Federal para la Proteccion Contra Riegos Sanitarios (COFEPRIS)
Av. Monterrey No. 33
Col. Roma C.P. 06700
Del. Cuauhtemoc
Mexico, D.F., Estados Unidos Mexicanos
Telephone: 011 52 55 5080 5200 ext. 1254; 1259; 1230

B. For the Food and Drug Administration:

Director, Office of Seafood
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5100 Paint Branch Parkway (HFS-400)
College Park, MD 20740
The United States of America
Telephone: 01 301 436-2300

ARTICLE VI
Final Dispositions

Activities under this MOU commence upon signature by both Participants and continue for five (5) years. It may be extended with written consent of both Participants.

The Participants intend to evaluate the MOU during the five-year period. It may be amended by written consent of both Participants, specifying the date in which the activities will commence.

All activities undertaken pursuant to this MOU are to be conducted in accordance with the laws and regulations of the United States of America and the United Mexican States and are subject to the availability of personnel, resources, and appropriated funds.

This MOU is not intended to create any obligations under international or other law.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Government agencies, have signed this Memorandum of Understanding.

Signed in San Antonio, Texas on this Eighteenth day of June, in quadruplicate: two copies each in English and Spanish languages, respectively,

FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

MARK B. MC CLELLAN
Commissioner,
Food and Drug Administration

From the Food and Drug Administration

FOR THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

LIC. ERNESTO ENRIQUEZ RUBIO
Federal Commissioner for the Protection from Sanitary Risks

From the Federal Commission for the Protection from Sanitary Risks