

**No. 18589**

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**UNITED STATES OF AMERICA  
and  
MEXICO**

**Memorandum of Understanding relating to shellfish sanitation. Signed at Mexico City on 7 March 1979**

*Authentic texts: English and Spanish.*

*Registered by the United States of America on 18 April 1980.*

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**ÉTATS-UNIS D'AMÉRIQUE  
et  
MEXIQUE**

**Mémorandum d'accord relatif au contrôle sanitaire des mollusques. Signé à Mexico le 7 mars 1979**

*Textes authentiques : anglais et espagnol.*

*Enregistré par les États-Unis d'Amérique le 18 avril 1980.*

MEMORANDUM OF UNDERSTANDING<sup>1</sup> TO CONTROL THE SANITARY QUALITY OF FRESH OR FRESH FROZEN BIVALVE MOLLUSCA DESTINED FOR EXPORTATION TO THE UNITED STATES OF AMERICA BETWEEN THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, UNITED STATES OF AMERICA, AND THE SECRETARIAT OF HEALTH AND WELFARE OF THE UNITED STATES OF MEXICO

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The Secretariat of Health and Welfare of the United States of Mexico (SSA) and the Food and Drug Administration (FDA) of the Department of Health, Education and Welfare of the United States of America affirm by this document their intention to cooperate in assuring that fresh and fresh frozen oysters, clams and mussels exported to the United States of America 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 of the United States of America.

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

“Lot”: A number of shellfish from no more than one day’s harvest, from a single growing area, produced under conditions as nearly uniform as possible, placed in a collection of primary containers or units of the same size, type and style, and identified by a common container code or marking.

“Central file”: The location where shellfish control program information, data, and reports are stored and maintained.

“Shellfish”: All edible species of molluscan bivalves except scallop species from the family *Pectinidae*. Only shellfish that are offered for entry into the United States of America as fresh or fresh frozen products are covered under this Memorandum of Understanding.

“Marine biotoxins”: Natural toxins produced by marine dinoflagellates such as *Gonyaulax catenella*, *Gonyaulax tamarensis*, and *Gymnodinium breve* and concentrated by shellfish during the feeding process.

II. FOOD AND DRUG ADMINISTRATION AND THE SECRETARIAT OF HEALTH AND WELFARE. A. Both parties agree to provide information concerning proposed changes in the following:

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.

B. Both parties agree to inform each other on a timely basis of the fundamentals of the following:

1. Proposed modification of existing Federal or local regulations.

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<sup>1</sup> Came into force on 7 March 1979 by signature, in accordance with its provisions.

2. Proposed new Federal regulations.
3. Proposed new legislation.
4. Proposed modifications to the national shellfish sanitation programs.

C. Both parties agree to name a liaison officer who will coordinate all operational matters relating to this Memorandum. The liaison officers 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 a formality and does not require a revision of this agreement.

The Secretariat of Health and Welfare liaison officer is the *C. Director General de Coordinación y Control Ambiental*.

The Food and Drug Administration liaison officer is the Director, Mexican Liaison Staff.

D. Both parties agree that the language used for the documents which are interchanged within this Memorandum is that of the country of origin, accompanied by a first (rough) draft translation in the language of the country it is destined [for].

### III. The Secretariat of Health and Welfare agrees to:

- A. Classify its shellfish harvesting waters in accordance with the procedures and standards set forth in the NSSP.
- B. Assure that only 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 of America.
- C. Inspect the harvesting, transporting and processing of shellfish at sufficient frequency to assure compliance with NSSP sanitary control practices.
- D. Issue sanitation quality certificates for harvesting areas, only to those shellfish exporting firms and cooperatives that comply with NSSP recommended practices and to notify FDA of the name, location and certification number of these firms or cooperatives on Form FD-3038b "Shellfish Certification". To cancel a firm's certification, the SSA will send a completed Form FD-3038c "Certification Cancellation" to FDA.
- E. Require that all containers or units of all lots of shellfish exported to the United States of America be identified by lot number and certification number, together with all other information required by the U.S. Federal Food, Drug and Cosmetic Act.
- F. Invite technical observers of the FDA to visit the firms or cooperatives which have certificates, as well as the shellfish growing areas. Such visits will be made on an annual basis or at a frequency deemed appropriate by both parties to observe the operation of the Mexican Bivalve Mollusca Sanitation Program.
- G. Make travel arrangements for the FDA technical observers and provide the necessary facilities for carrying out their observations within Mexico.
- H. Participate in FDA's laboratory quality assurance programs.

These include:

1. Participation in the analysis of split samples of:
  - a. Seawater or shellfish meats to determine indicator bacteria or pathogens.
  - b. Shellfish meats to determine heavy metals and other chemical or radionuclide substances as may be deemed necessary.
2. The evaluation of new methods and procedures, including reagents, media, or other materials as well as instruments and equipment performance.

- I. The establishment of a central office that will maintain a central file of laboratory results, including routine monitoring data and data from quality assurance programs. Standard formats for collecting and reporting data should be used and these will be printed in English and Spanish.
- J. Promulgation and enforcement of sanitation laws and regulations governing the growing, harvesting, processing and shipment of shellfish to the United States of America are the sole responsibility of the SSA.

IV. Food and Drug Administration (FDA) agrees to:

- A. Publish the names, locations and certification numbers of firms or cooperatives submitted by the SSA. These will appear in the monthly *Interstate Certified Shellfish Shippers List*.
- B. Upon request of the SSA, the FDA will provide training to technical personnel on administrative procedures, inspection and laboratory procedures, and classification of shellfish growing areas.
- C. Whenever shellfish are detained by FDA due to noncompliance with recommended NSSP practices, FDA will inform SSA of the reason or reasons for the detention.  
This information includes:
  1. Commodity, lot and certification number.
  2. Name and address of the shipper.
  3. Reason for the detention.
  4. Sampling procedure.
  5. Methods of analysis and confirmation.
  6. Administrative procedures.
- D. FDA agrees to make travel arrangements for, and pay round-trip transportation expenses of, its observation team between the United States of America and Mexico. FDA will also pay all per diem of the observation team.

V. NATIONAL SHELLFISH SANITATION PROGRAM (NSSP) OF THE UNITED STATES OF AMERICA. The SSA may participate in workshops of the United States of America, cooperative research programs, seminars, training courses and other activities designed for the timely interchange of technical information, assistance and joint resolution of problems confronting the NSSP.

The SSA may participate in a joint evaluation of the United States of America's program as it pertains to shellfish imports from Mexico.

The SSA may also:

- A. Make recommendations for changes and improvements in NSSP procedures, methods and standards.
- B. Be advised by FDA in case of questions by state or local food control officials regarding the certification, safety and wholesomeness of shellfish imported from Mexico. FDA will, if so requested, seek to determine the reason for the problem and inform the SSA of any action taken relative to United States of America state and local laws governing such shellfish imports.

This document will become effective on the date it is signed by both parties and shall remain in effect until one of the parties gives 60 days' notice to the other of its intention to terminate or modify it.

IN WITNESS WHEREOF, both parties sign this Memorandum of Understanding in the City of Mexico, on the 7th day of the month of March of 1979.

For the SSA, Mexico:

[Signed]

Ing. HUMBERTO ROMERO ALVAREZ  
Subsecretario de Mejoramiento del  
Ambiente<sup>1</sup>

For the FDA, United States of America:

[Signed]

SHERWIN GARDNER  
Deputy Commissioner

[Signed]

Dr. RAMÓN ALVAREZ GUTIÉRREZ  
Director General  
de Asuntos Internacionales<sup>2</sup>

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<sup>1</sup> Assistant Secretary for Environmental Improvement — Sous-Secrétaire à l'amélioration de l'environnement.

<sup>2</sup> Director General for International Affairs — Directeur général des affaires internationales.