No. 30297

UNITED STATES OF AMERICA
and
MEXICO

Memorandum of Understanding to control the sanitary quality of fresh or fresh-frozen bivalve mollusca destined for exportation to the United States of America. Signed at Washington on 15 October 1981

Authentic texts: English and Spanish.

Registered by the United States of America on 28 September 1993.

ÉTATS-UNIS D'AMÉRIQUE
et
MEXIQUE

Mémorandum d'accord sur le contrôle sanitaire des mollusques bivalves frais ou congelés destinés à l'exportation vers les États-Unis d'Amérique. Signé à Washington le 15 octobre 1981

Textes authentiques : anglais et espagnol.

Enregistré par les États-Unis d'Amérique le 28 septembre 1993.

MEMORANDUM[1] OF UNDERSTANDING 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 AND HUMAN SERVICES, UNITED STATES OF AMERICA AND THE SECRETARIAT OF HEALTH AND WELFARE, UNITED STATES OF MEXICO

I. PURPOSE

The Secretariat of Health and Welfare of the United States of Mexico that hereafter will be designated by the initials SSA and the Food and Drug Administration of the Department of Health and Human Services of the United States of America that hereafter will be designated by the initials FDA 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 Mexican Regulations for the Sanitary Control of Seafoods, the Mexican Bivalve Mollusca Sanitation Program (PMSMB), the National Shellfish Sanitation Program (NSSP), and requirements of the Federal Food, Drug, and Cosmetic Act of the United States of America.

II. DEFINITIONS AND RESPONSIBILITIES

A. Terms

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

1. Shellfish. All edible species of molluscan bivalves except scallop species from the family Pectinidae.

2. Lot. Means 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.

3. Marine biotoxins. Toxins produced by marine dinoflagellates such as Gonyaulax catenella, Gonyaulax tamarensis, and Gymnodinium breve and concentrated by shellfish during the feeding process.

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

B. SSA Responsibilities

SSA agrees to:

1. Promulgate and enforce sanitation laws and regulations governing the growing, harvesting, processing, and shipment of shellfish to the United States.

[1] Came into force on 15 October 1981 by signature, in accordance with part III.

2. Classify its shellfish harvesting waters in accordance with the procedures and standards set forth in the NSSP and the PMSMB.

3. Assure that only shellfish harvested from areas which meet NSSP- and PMSMB-approved water quality and marine biotoxin standards and processed according to NSSP and PMSMB guidelines will be exported to the United States of America.

4. Inspect the harvesting, transporting, and processing of shellfish at sufficient frequency to assure compliance with NSSP and PMSMB sanitary control practices.

5. 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, SSA will send a completed Form FD-3038c "Certification Cancellation" to FDA.

6. Require that all containers or units of each lot of shellfish exported to the United States of America be identified by the name, address, and certification number of the shipper and the code or marking of the lot. Any other information required by the U.S. Federal Food, Drug, and Cosmetic Act and Mexican Regulations for the Sanitary Control of Seafoods will also be on each container.

7. Invite technical advisors of FDA to visit the firms or cooperatives which have certificates, and shellfish growing areas which have been identified for export harvesting. Such visits will be made on an annual basis or at a frequency considered appropriate by both parties to observe the operation of the Mexican Bivalve Mollusca Sanitation Program.

8. Make travel arrangements for FDA technical advisors and provide the necessary facilities for carrying out their observations within Mexico.

9. Participate in FDA's laboratory quality assurance programs for seawater or shellfish including indicator and pathogenic bacteria, marine toxins, heavy metals, and radionuclides as considered necessary.

10. Participate as appropriate in the evaluation of new methods and procedures, including reagents, media, or other materials as well as instrument and equipment performance.

11. Establish a central office located in Mexico City in the Office of the Liaison Officer where a central file of laboratory results, including routine monitoring data, and data from quality assurance programs, will be maintained. Standard formats for collecting and reporting data should be used and these will be printed in English and Spanish.

C. FDA Responsibilities

FDA agrees to:

1. Publish the names, locations, and certification numbers of firms or cooperatives submitted by SSA. These will appear in the monthly publication of the Interstate Certified Shellfish Shippers List.

2. Provide training in technical and administrative procedures, including inspection, laboratory methods, and classification of shellfish growing areas, upon request of the SSA.

3. Inform the Mexican Liaison Officer of the reason or reasons for FDA detentions of Mexican shellfish imports. Additional information which will be provided will include, but not necessarily be limited to:

a. Commodity, identification, and the code or marking of the lot.

b. Name, address, and certification number of the shipper.

c. Date and other pertinent information on the shipping label.

d. Sampling procedure.

e. Methods of analysis.

f. Administrative procedures.

4. Recognize the United States of Mexico as a participant in the NSSP with full rights to participate in national workshops, cooperative research programs, seminars, training courses, and other NSSP activities, and to make recommendations for changes and improvements in procedures, methods, standards, and guidelines of the NSSP.

5. Participate in joint FDA/SSA evaluations of NSSP practices as they pertain to Mexican shellfish imports.

6. Make travel arrangements for, and pay round trip transportation expenses of, its advisory team between the United States and Mexico. FDA will also pay all per diem of the advisory team.

7. To exchange appropriate information concerning questions by United States of America State or local food control officials regarding the certification, safety, and wholesomeness of shellfish imported from the United States of 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.

8. The Memorandum of Understanding is subject to the availability of appropriate funds and personnel to each party.

D. Shared Responsibilities

Both parties agree:

1. 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 will provide notification of any changes in liaison officer appointments. Such notification shall constitute a formality and does not require a revision of this agreement.

2. To provide information concerning proposed changes in the following:

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.

f. Inspectional procedures.

3. To inform each other on a timely basis of the fundamentals of the following:

a. Proposed modifications of existing Federal or local regulations.

b. Proposed new Federal regulations.

c. Proposed new legislation.

d. Proposed modifications to the NSSP.

III. PERIOD OF AGREEMENT

This agreement will come into force upon signature of both parties and will remain in force until terminated. It may be modified by mutual written consent or terminated by either party upon a sixty (60) day advance written notice to the other.

IV. This agreement supersedes the Memorandum of Understanding 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[1] which entered into force March 1979, which agreement is hereby terminated.

V. Done at Washington D.C. this 15th day of October 1981, in duplicate in the English and Spanish languages, both texts being equally authentic.

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For the Secretariat of Health and Welfare, United States of Mexico

[3]

For the Food and Drug Administration, Department of Health and Human Services, United States of America

[1] United Nations, *Treaty Series*, vol. 1168, p. 273.
[2] Manuel Lopez Portillo.
[3] Arthur Hull Hays, Jr.