**SUBJECT:**

**Fresh and Fresh Frozen Oysters, Clams, and Mussels**

**FDA Agreement No. (FDA-225-79-4008**

**(Previously CPG 7156k.01)**

**Notes:**

**The contact person for this MOU is Phil Spiller, HFS-400**

**Tel. No. 202-418-3133**

**This MOU is effective indefinitely.**

**Dept. of Health, Educ., & Welfare is now Dept. of Health and Human Services**

MEMORANDUM OF UNDERSTANDING

Between The

MINISTRY OF FISHERIES
GOVERNMENT OF ICELAND

And the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
UNITED STATES OF AMERICA

The Ministry of Fisheries of Iceland 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 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.

I. TERMS

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

Lot - 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.

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

Coliform group- All of the aerobic and facultative anaerobic, gram-negative, nonsporeforming bacilli which ferment lactose with gas formation within 48 hours at 35° C.

Fecal coliform group- Any bacteria as defined under the coliform group which will produce gas in E. coli medium within 24 hours at 44.5 C (+0.2 ) in a water bath.

Bait shellfish- Shucked shellfish labeled and intended for bait use only: not for human consumption.

Shellfish- All edible species of molluscan bivalves except scallop species from the family Pectinidae. Only molluscan bivalves that are offered for entry into the United States as fresh or fresh frozen

Notes:

products are intended for coverage under this Memorandum of Understanding.

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

II. FOOD AND DRUG ADMINISTRATION AND MINISTRY OF FISHERIES

A. Both parties agree to provide information concerning proposed channels in the following:

1. Methods and procedures for sampling.

2. Methods of analysis.

3. Methods of confirmation.

4. Administrative guidelines, tolerance, specification standards, and nomenclature.

5. Reference standards.

6. Inspectional procedures.

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

1. Proposed modification of existing Federal or local regulations.

2. Proposed new Federal regulations.

3. Proposed new legislation.

4. Proposed modifications to the National Shellfish Sanitation Program.

C. Both parties agree to name a liaison officer who will coordinate all 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 an amendment to, and not require a revision of, this agreement.

Notes:

The Iceland liaison officer is:

Thordur Asgeirsson
Deputy Secretary General

The FDA liaison officer is:

Director, Office of Seafood (Currently: Phil Spiller)

J. David Clem
Chief, Shellfish Sanitation Branch.

D. Both parties agree that the working language for documents exchanged under this Memorandum shall be in English.

III. MINISTRY OF FISHERIES

A. The Ministry of Fisheries agrees to classify its shellfish harvesting water in accordance with the procedures and standards set forth in the National Shellfish Sanitation Program (NSSP). The Ministry of Fisheries will assure that only fresh and fresh frozen 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.

B. The Ministry of Fisheries agrees to inspect harvesting, transporting, and processing operations of fresh and fresh frozen shellfish at sufficient frequency to assure compliance with the NSSP sanitary control practices.

C. The Ministry of Fisheries agrees to issue certifications only to those fresh and fresh frozen shellfish shipping firms that comply with NSSP recommended practices and to notify FDA of the name, location, and certification number of these firms on Form FD-3038b "Shellfish Certification". To cancel a firm's certification, the Ministry of Fisheries will send a completed Form FD-3038c "Certification Cancellation" to FDA.

D. The Ministry of Fisheries agrees to require all containers of all lots of fresh and fresh frozen shellfish exported to the United States of America to be identified by lot number and certification number, together with all other information required by the Federal Food, Drug, and Cosmetic Act.

E. The Ministry of Fisheries agrees to facilitate joint inspections by FDA and Ministry of Fisheries officials of Iceland's certified fresh and fresh frozen shellfish processing firms, approved growing waters, and related harvesting and handling practices. Such inspections will be made on an annual basis or at a frequency deemed appropriate to determine that the Ministry of Fisheries shellfish sanitation control program is equivalent to the NSSP recommended practices and that only safe and wholesome fresh and fresh frozen shellfish are being exported to the United States.

Notes:

F. The Ministry of Fisheries agrees to make travel arrangements for, and pay transportation expenses of, the FDA inspection team while the team is conducting inspections within Iceland.

G. The Ministry of Fisheries agrees to participate to the maximum extent possible in FDA's laboratory quality assurance programs. These may include:

1. Participation in the analysis of split samples of:

a. Seawater and shellfish meats for indicator bacteria or pathogens.

b. Shellfish meats for heavy metals or other chemical or radionuclide contaminants as may be necessary.

2. The evaluation of new methods and procedures, including reagents, media, or other materials and instruments and equipment performance.

H. The Ministry of Fisheries agrees to the establishment of a central office within Iceland to collate and maintain a central file of laboratory results, including routine monitoring data and data from quality assurance programs. Standard formats for collecting and reporting data will be used.

I. If lots of shucked shellfish are imported into the United States for use as bait, the Ministry of Fisheries will assure that each container is labeled "Not for human use" and the contents are decharacterized by use of a permanent colored dye.

J. Promulgation and enforcement of regulations governing the growing, harvesting, processing, and shipment of fresh or frozen shellfish produced by Iceland for export to the United States are the sole responsibility of the Ministry of Fisheries.

K. The Ministry of Fisheries cannot be held liable for damages resulting from defects or noncompliance of Icelandic fresh or fresh frozen shellfish products produced under the provisions of this MOU.

IV. FOOD AND DRUG ADMINISTRATION

A. FDA agrees to publish the names, locations, and certification numbers of certified firms submitted by the Ministry of Fisheries. The firms will appear in the monthly INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST.

Notes:

B. Upon request FDA will provide limited training to technical personnel in laboratory procedures, classification of shellfish growing areas, and inspection and administrative procedures.

C. Whenever Icelandic shellfish are detained by FDA due to noncompliance with NSSP agreed upon practices or applicable laws or regulations, FDA will inform the Ministry of Fisheries of the reason or reasons for the detention. This information will include:

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 guidelines.

D. FDA agrees to make travel arrangements for, and pay round trip transportation expenses of, its inspection team between the United States and Iceland. FDA will also pay all per diem of the inspection team.

V. NATIONAL SHELLFISH SANITATION PROGRAM

Upon signing this agreement, the Ministry of Fisheries becomes an active participating member of the National Shellfish Sanitation program (NSSP). As a full member of the NSSP, the Ministry of Fisheries may participate in national workshops, cooperative research programs, seminars, training courses, and other activities designed for the timely exchange of technical information, assistance, and joint resolution of problems confronting the NSSP. The Ministry of Fisheries may also:

A. Participate in a joint evaluation of the United States program as it pertains to shellfish exports to Iceland.

B. Make recommendations for changes and improvements in NSSP guidelines, methods, and standards.

C. Be advised by FDA in the event a State or local food control official questions the certification, safety or wholesomeness of Iceland's imported shellfish. FDA will, if so informed, seek to determine the reason for the problem and inform the Ministry of Fisheries of any action taken relative to State and local laws or regulations governing such shellfish imports.

Notes:

Both parties agree that this Memorandum shall become effective on the date it is signed by both parties. It shall remain in effect, and govern all fresh and fresh frozen shellfish exported to the United States of America, pending revision or revocation at the request of either agency. Upon signature of both parties, this Memorandum of Understanding will be published in the FEDERAL REGISTER. A copy of the Memorandum will be available for public review at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD.

In witness whereof, the agencies have executed this Memorandum.

Jon L. Arnalds /s/
Secretary General
Iceland Ministry of Fisheries

Date: October 25, 1978.

Donald Kennedy /s/
Commissioner
Food and Drug Administration
Department of Health
Education, and Welfare
Date: December 28, 1978.

Secretary General, Iceland Ministry of Fisheries is currently: Mr. Arni Kolbeinsson

FDA Commissioner is currently David A. Kessler, M.D.

Dept. of Health, Educ., & Welfare is now Dept. of Health and Human Services

Effective date. This Memorandum of Understanding became effective December 28, 1978.

References[1]


1. U.S. Department of Health, Education, and Welfare, Public Health Service, 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 Program, 1965 Revision, PHS Publication ND. 33.

2. "Official Methods of Analysis," 12th Ed., Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044, 1975.

3. Food and Drug Administration, "Interstate Certified Shellfish Shippers List," published monthly and distributed to food control officials and other interested persons by FDA, Bureau of Foods, Shellfish Sanitation Branch (HFF-417), 200 C St. SW., Washington, D.C. 20204.

4. Federal Food, Drug, and Cosmetic Act, as amended, United States Code, Title 21.

5. Fair Packaging and Labeling Act, Pub. L. 89-755, approved November 3, 1966.

6. American Public Health Association, "Recommended Procedures for the Examination of Seawater and Shellfish," 4th Ed., 1970, APHA, Inc., 1015 18th St. NW., Washington, D.C. 20036.


2. Official Methods of Analysis, 16th Ed., AOAC 481 N. Frederick Rd., Gaithersburg, MD 20877-2417

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

Notes:

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

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

[1]Filed as part of the original document