DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–2000]

Memorandum of Understanding Between the Food and Drug Administration and the Ministry of Maritime Affairs and Fisheries of the Republic of Korea

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 and the Ministry of Maritime Affairs and Fisheries of the Republic of Korea. The purpose of the MOU is to ensure that fresh, frozen molluscan shellfish that are imported from Korea are safe and wholesome.

DATES: The agreement became effective October 28, 1998.

FOR FURTHER INFORMATION CONTACT: Scott R. Rippey, Office of Seafood (HFS–415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3174.

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

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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225-99-2000

MEMORANDUM OF UNDERSTANDING

between the

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

and the

MINISTRY OF MARITIME AFFAIRS AND FISHERIES
OF THE
REPUBLIC OF KOREA

CONCERNING THE SANITARY CONTROL OF FRESH FROZEN MOLLUSCAN SHELLFISH DESTINED FOR EXPORTATION FROM KOREA TO THE UNITED STATES

The Food and Drug Administration (FDA) of the Department of Health and Human Services and the Ministry of Maritime Affairs and Fisheries (MOMAF) of the Republic of Korea;

Desiring to continue the 1987 Memorandum of Understanding Concerning the Sanitary Control of Fresh Frozen Molluscan Shellfish Destined for Exportation from Korea to the United States between the Government of the United States of America and the Government of the Republic of Korea;

Recognizing that since 1967 both the Government of the United States and the Government of Korea have undertaken technical consultations on the development of an effective oyster production program in Korea and that in 1970 the FDA endorsed the Korean Shellfish Sanitation Program (KSSP) and concluded that the Korean program met or exceeded U.S. National Shellfish Sanitation Program (NSSP) guidelines and that the Korean Government can fulfill its responsibilities as a member of the National Shellfish Sanitation Program;

Understanding that on November 24, 1972, the Government of the United States signed the Shellfish Sanitation Agreement with the Government of Korea in which both governments agreed to cooperate in seeking to assure that fresh frozen molluscan shellfish are safe and wholesome and that in 1987 both governments affirmed their intention to continue the 1972 agreement by signing a Memorandum of Understanding between FDA and the Korean National Fisheries Administration Concerning the Sanitary Control of Fresh Frozen Molluscan Shellfish Destined for Exportation from Korea to the United States;

Recognizing that in 1996, the Korean National Fisheries Administration was reorganized into the new MOMAF and the shellfish program was then placed under the direction of the Fisheries Policy Bureau within MOMAF and that the sanitary control of shellfish in interstate commerce in the United States continues to be administered by FDA in cooperation with state agencies under the NSSP;

Acknowledging that this agreement will permit MOMAF to certify Korean firms and shippers of fresh frozen shellfish and to have these firms and shippers listed on FDA's "Interstate Certified Shellfish Shippers List" (ICSSL) and FDA and U.S. state authorities will recognize shellfish from such shipments as having been certified under the NSSP;

Recognizing that this agreement will assist in assuring that fresh frozen molluscan shellfish exported from the Republic of Korea and offered for import into the United States continue to be safe and wholesome and are harvested, processed, transported, and labeled in accordance with the sanitation principles of the U.S. NSSP and 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, and the Korean Ministry of Maritime Affairs and Fisheries Ordinance Number 53;

Have agreed as follows:

I. SUBSTANCE OF MEMORANDUM OF UNDERSTANDING

A. DEFINITIONS

1. **Central file.** The "central file" is the location where the enforcement agency stores and maintains program information, data, and reports.

2. **Enforcement agency.** The "enforcement agency" is the Ministry of Maritime Affairs and Fisheries, which has regulatory authority in Korea over the production, harvesting, processing, transportation, classification, and export of certified shellfish to the United States under the terms of this memorandum.

3. **A Lot of Shucked Shellfish.** A "lot" is 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.

4. **Marine biotoxins.** 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*), and *Gymnodinium breve* (formerly *Ptychodiscus brevis*).

5. **Shellfish.** All edible species of oysters, clams, mussels, and scallops — except when the final scallop product is the adductor muscle only; either shucked or in the shell, fresh or frozen, whole or in part.

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B. MOMAF RESPONSIBILITIES

MOMAF will:

1. Maintain the legal, administrative, and sanitation controls over shellfish exported by Korean firms that are required by the NSSP and the KSSP. These controls include:

(a) Classifying shellfish harvesting areas based upon comprehensive sanitation surveys;

(b) Preparing sanitation survey reports and maintaining survey data in a central file;

(c) Updating survey data annually and periodically reviewing the classification status of each harvest area;

(d) Assuring that only shellfish harvested from approved areas that meet NSSP-KSSP approved water quality and marine biotoxin standards are exported to the U.S.;

(e) Evaluating laboratory practices used to test shellfish and seawater at least annually and encouraging participation in FDA's voluntary Quality Assurance Program. The Quality Assurance Program includes examination of standardized laboratory specimens supplied by FDA.

2. Inspect firms processing fresh frozen shellfish for export to the U.S. to ensure compliance with NSSP/KSSP controls.

3. Certify on an annual basis those firms that wish to process and to export fresh or frozen shellfish to the U.S. that comply with NSSP/KSSP requirements and notify FDA of the name, location, and certification number of those firms on Form FD-3038, "Interstate Shellfish Dealers Certification".

4. Cancel the certificate of any firm that does not comply with the requirements of NSSP/KSSP, that obtains shellfish from non-approved areas, or that ships shellfish that do not conform to appropriate program standards.

5. Ensure that all containers of each lot of fresh frozen shellfish certified for export are identified with the shipping firm's address, certification number, and lot number or code, as specified by the NSSP Guide for the Control of Molluscan Shellfish, and including other information required by the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, and U.S. Fair Packaging and Labeling Act.

6. Maintain a central file of program records including but not limited to sanitation survey reports, inspection reports, laboratory evaluation reports, and enforcement actions. MOMAF will make these records available to FDA upon request.

7. Responsibilities for the management of various components of the KSSP may be delegated to subagencies or administrative units of MOMAF..

8. Provide FDA with an annual status report describing current or potential new public health problems affecting shellfish intended for export to the United States. The report should present information on the level of conformity with NSSP requirements enforced by the MOMAF and a summary of the analysis of

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water and shellfish data to substantiate new designated area classifications as specified in the NSSP Guide for the Control of Molluscan Shellfish.

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

C. FDA RESPONSIBILITIES

FDA will:

1. Recognize the Republic of Korea as a participant in the NSSP with full rights to participate in the Interstate Shellfish Sanitation Conference, 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 MOMAF certify Korean firms for inclusion in FDA's ICSSL.

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

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

4. Inform MOMAF of the reasons for any detentions of certified frozen shellfish shipments from Korea which have been carried out under FDA's authority. Additional information that FDA will provide will include, but not necessarily 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 MOMAF in joint evaluations of the shellfish sanitation program 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 Korea and the per diem of the members of the FDA evaluation team while in Korea.

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D. SHARED RESPONSIBILITIES

MOMAF and FDA will:

1. Exchange 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.

2. Provide 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 memorandum.

3. Facilitate the exchange of information between MOMAF and the U.S. federal and state agencies concerned with the introduction and proliferation of exotic organism that might be carried by Korean shellfish.

E. OTHER PROVISIONS

The working language for documents exchanged under this memorandum shall be English.

V. LIAISON OFFICES

A. Liaison Offices for MOMAF:

Ministry of Maritime Affairs and Fisheries
826-14 Yoksam Dong Kangnam Ku
135-080, Seoul, Korea

and

First Secretary for Maritime Affairs and Fisheries
Embassy of the Republic of Korea,
2450 Massachusetts Avenue
Washington, D.C. 20008 U.S.A.
Telephone: (202) 939-5676.

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B. Liaison Office for FDA:

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

IV. ENTRY INTO FORCE

This Memorandum enters into force upon signature for a period of five years. It may be extended or amended by written agreement of both parties. It may be terminated by either party upon a 30-day advance written notice to the other party's liaison office.

FOR THE MINISTRY OF MARITIME AFFAIRS AND FISHERIES OF THE REPUBLIC OF KOREA:

By: Hyuck Choi

Title: Minister for Economic Affairs
Embassy of Korea

Date: October 28, 1998

Place: Washington D.C.

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

By: Sharon Smith Holston

Title: Deputy Commissioner for External Affairs
Food and Drug Administration

Date: October 28, 1998

Place: Rockville, Maryland

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ANNEX

REFERENCES

1. U.S. Department of Health and Human Services (formerly U.S. Department of Health, Education, and Welfare), Public Health Service, 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. 1972 and 1987 Shellfish Sanitation Agreement between Government of the United States of America and the Government of the Republic of Korea.

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