

SUBJECT:

**Fresh and Fresh
Frozen Shellfish**

**(FDA Agreement
Number 225-80-
2001)
(Modification #1)**

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

Notes:

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

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

**This MOU is
effective
indefinitely.**

**MEMORANDUM OF UNDERSTANDING
CONCERNING THE SANITARY CONTROL OF FRESH
AND FROZEN MOLLUSCAN SHELLFISH DESTINED FOR
EXPORTATION FROM ENGLAND TO THE UNITED STATES**

Between The

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

And The

**DEPARTMENT OF HEALTH AND SOCIAL SECURITY
UNITED KINGDOM**

I. PURPOSE

The Food and Drug Administration (FDA) and the Department of Health and Social Security (DHSS) affirm by this memorandum their intention to cooperate in seeking to assure that fresh and fresh-frozen molluscan shellfish exported from England to the United States of America, are safe, wholesome, and have been harvested, processed, transported, and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This document also defines terms and describes the responsibilities of FDA and DHSS in operation and management of the terms of this memorandum. By this document FDA officially recognizes DHSS as the certifying authority of shippers of fresh and frozen shellfish imports destined for United States markets.

II. BACKGROUND

This document is a modification of the original memorandum signed by both parties in September 1980, and supersedes that document.

III. SUBSTANCE OF AGREEMENT**A. TERMS**

1. **Advisory Agencies:** Means the Fisheries Research Laboratory, Burnham-on-Crouch, and the laboratories of the Public Health Laboratory Service that provide analytical support to local shellfish control authorities associated with this memorandum.
2. **Shellfish:** Means all edible species of bivalved molluscus (i.e., oysters, clams, mussels, and cockles) except species of scallops.

Notes:

3. Enforcement Agencies: Means Port Health Authorities and District, City, or Borough councils that have regulatory authority over the production, processing, and exportation of certified shellfish to the United States under the terms of this memorandum.
4. 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.
5. Central File: The single location where shellfish control program information, data, and reports are stored and maintained.

B. DHSS RESPONSIBILITIES

DHSS signs this memorandum on the basis that:

1. The respective enforcement agencies have agreed to use their best endeavors to ensure that shellfish exported to the United States originate from harvesting areas within waters that meet the terms of this memorandum.
2. The enforcement agencies have agreed to inspect the harvesting, relaying, transporting, and processing of fresh shellfish intended for export to the United States at sufficient frequency to confirm compliance with NSSP sanitary control practices. The enforcement agencies have agreed to make all records of their inspections available to advisory agencies to facilitate evaluations of those procedures.
3. The enforcement agencies have agreed to collate and maintain files of laboratory results including routine data and data from quality assurance programs. Copies of appropriate enforcement agency data will be maintained in a central file by DHSS for review and evaluation by FDA as necessary.
4. Advisory agencies concerned with this program may participate in FDA quality assurance programs, including but not necessarily limited to pathogenic and indicator bacteria, heavy metals, radionuclides, shellfish toxins, and/or other toxic chemicals as may be necessary. They may also participate in the evaluation of methods, media and reagents, and equipment.
5. Enforcement agencies have agreed to use their best endeavors to ensure that exporters will export only shellfish that conform in all respects to the following conditions:
 - a) Harvesting, relaying, and/or depuration are in accordance with the applicable food and shellfish laws, regulations, and orders of the English central and local

Notes:

government enforcement agencies having jurisdiction and of the NSSP guidelines.

- b) All containers of all lots of shellfish exported to the United States are identified by the shippers address, certification number, and lot number or code, together with all other information required by the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.
 - c) Any container of shellfish exported to the United States for use as bait is labeled, "Not for Human Use", and the contents decharacterized by coloring with a permanent dye.
6. At the request of FDA, joint inspections may be made by FDA and DHSS officials of certified premises and growing and relaying areas used for the production of shellfish destined for export to the United States. Arrangements will be made to meet travel expenses of FDA officials making inspections in accordance with this memorandum while the officials are in England.
 7. The DHSS will certify only those shellfish shipping firms that comply with NSSP recommended practices and notify FDA of the name, location, and certification number of those firms on FD-3038B "Shellfish Certification". If DHSS becomes aware that conditions required by the NSSP are not subsequently being met, the Department will cancel the certificate by sending a completed Form FD-3038C "Certification Cancellation" to FDA.

C. FDA RESPONSIBILITIES

FDA agrees to:

1. Publish names, locations, and certification number of shellfish shippers certified by DHSS upon receipt of Form FD-3038B. These firms will appear in the monthly publication of the Interstate Certified Shellfish Shippers List.
2. Provide limited training to technical personnel in laboratory procedures, growing area classification procedures, and shellfish sanitation program administration upon request of DHSS and subject to availability of funds for such purposes.
3. Inform DHSS of the reason or reasons for all FDA detentions of certified shellfish shipments from England. Additional information that will be provided will include but may not necessarily be limited to:
 - a. Commodity identification.
 - b. Commodity code, lot and certification number.
 - c. Name and address of the shipper.

Notes:

- d. Sampling procedure.
 - e. Methods of analysis and confirmation.
 - f. Administrative guidelines.
4. Make travel arrangements for, and pay round trip transportation expenses of its inspection team between the United States and England. FDA will also pay all per diem of the inspection team.
 5. Participate with DHSS in a joint evaluation of the NSSP as it pertains to shellfish exports to England.
 6. Advise DHSS of any questions from local food control officials concerning the safety or wholesomeness of shellfish imported into the United States from England. FDA, if it receives such questions, will seek to determine the reason for the problem and inform the DHSS of any action taken under State and local laws or regulations with regard to such shellfish imports.
 7. Recognize England 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 or improvements in procedures, methods, standards and guidelines of the NSSP.

D. SHARED RESPONSIBILITIES

1. Both parties agree to an exchange of information concerning proposed changes in the following:
 - a. Methods and procedures for sampling.
 - b. Methods of analysis.
 - c. Methods of confirmation.
 - d. Administrative guidelines, tolerance, specification standards and nomenclature.

IV. LIAISON OFFICERS

For Department of Health and Social Security:

Environmental Health Officer
(currently, Mr. Michael Jacob)
Department of Health and Social Security
Room A322, Alexander Fleming House
Elephant and Castle
London SE1, England
01-407-5522, Ext 7315

Notes:

Director, Office of Seafood (HFS-400) (Currently: Phil Spiller) Center for Food Safety and Applied Nutrition (202) 418-3133

For Food and Drug Administration: Chief, Fisheries Technology Branch (currently, Mr. J. David Clem) Bureau of Foods Food and Drug Administration 200 C Street, S.W. Washington, DC 20204 (202) 245-1557

V. PERIOD OF AGREEMENT

This document will become effective upon acceptance by both parties and will remain in effect indefinitely. It may be modified by mutual consent or terminated by either party upon a 30 day advance written notice to the other.

APPROVED AND ACCEPTED FOR THE DEPARTMENT OF HEALTH AND SOCIAL SECURITY, OF THE UNITED KINGDOM

_____/s/_____
By:

Title: Assistant Secretary

Date: 7 September 1982

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA

_____/s/_____
By: Joseph P. Hile

Title: Associate Commissioner for Regulatory Affairs

Date: JUL 29 1982

The ACRA is currently Mr. Ronald G. Chesemore

