MEMORANDUM OF UNDERSTANDING

BETWEEN

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

AND

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. Purpose

Cooperation and information sharing in the inspection of fish and fishery products and establishments.

2. Background

The National Marine Fisheries Service's (NMFS) Seafood Inspection Program in the National Oceanic and Atmospheric Administration of the Department of Commerce, operating under authority of the Agriculture Marketing Act and the Fish and Wildlife Act, is responsible for the development and advancement of commercial grade standards for fishery products, better health and sanitation standards in the industry, and for furnishing inspection, evaluation, analytical, grading, and certification services to interested parties. The NMFS Seafood Inspection Program's major purpose is to encourage and assist the industry in improving the quality, wholesomeness, safety, proper labeling, and marketability of fish and fishery products for the benefit of the consumer.

The Food and Drug Administration (FDA) of the Department of Health and Human Services, operating under the authority of the Federal Food, Drug, and Cosmetic Act (the Act) and several related public health laws, is responsible for protecting and promoting the public health by, in part, helping to ensure that foods, including fish and fishery products, are safe, sanitary, wholesome, and honestly and otherwise properly labeled. FDA has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but it is primarily the responsibility of industry to ensure that food products are safe and meet applicable regulatory FDA requirements.

The two agencies have certain common and related objectives in carrying out their respective regulatory and service activities that lend themselves to cooperation under this Memorandum of Understanding (MOU). This MOU sets forth the working arrangements between the agencies that facilitate each agency's efforts to discharge its responsibilities related to the inspection of fish and fishery products. The MOU recognizes that NMFS inspection services contribute to consumer protection by helping establishments fulfill their responsibility to ensure that fish and fishery products are safe and meet

applicable FDA requirements. The MOU also recognizes that FDA may take into consideration information resulting from NMFS inspection services in making risk-based determinations, such as in establishing inspection priorities. In addition, the MOU recognizes that FDA is the competent authority in the United States for safety of fish and fishery products and that determinations made by NMFS inspection services do not change or diminish FDA's authority under the Act. Nothing in this MOU, or any determination made by NMFS, would restrict FDA from conducting its own inspection or taking regulatory action, nor would it affect the legal responsibilities of establishments under the Act.

3. Substance of the Agreement

A. The National Marine Fisheries Service will:

1. Maintain a complete list of *Approved Establishments* (those processing establishments or vessels that have voluntarily contracted with NMFS for inspection services and have been sanitarily inspected, approved, and certified by NMFS as being capable of producing safe, wholesome products in accordance with specific quality regulations promulgated by the U.S. Department of Commerce) on its website[1] or otherwise provide this list electronically to FDA upon request.

2. As part of its inspection, approval, and certification, verify that *Approved Establishments* are in compliance with FDA's Current Good Manufacturing Practice regulation,[2] FDA's seafood HACCP regulation,[3] and NMFS' Inspection and Certification regulations[4].

3. Verify that all *Approved Establishments* correct objectionable conditions and practices of public health significance, that have been listed in Inspectional Observations (FDA 483) issued by FDA or that have been identified by NMFS, in a timely manner, unless action is taken consistent with items A.4 and A.6, below.

4. Issue a written notice of suspension or termination of contract to an *Approved Establishment* in accordance with NMFS' Inspection and Certification regulations, if the establishment fails to correct objectionable conditions and practices of public health significance in a timely manner, unless otherwise agreed upon by each agency.

5. Issue a written notice of suspension or termination of contract to an *Approved Establishment* in accordance with NMFS' Inspection and Certification regulations, once FDA has informed NMFS in writing that FDA either 1) has sent a Warning Letter to the establishment unless that establishment has resolved the violations in the Warning Letter to FDA's satisfaction, or 2) intends to take or is taking a regulatory action (e.g., injunction or prosecution) against the operators of the establishment, unless otherwise agreed upon by each agency.

6. Immediately notify the appropriate FDA field office when a contract with an *Approved Establishment* has been terminated, or services have been suspended, as a result of items A.4 or A.5, above.

7. Reject all applications for inspection services from an establishment in accordance with NMFS' Inspection and Certification regulations, once FDA has informed NMFS in writing that FDA either 1) has sent a Warning Letter to the establishment unless that establishment has resolved the violations in the Warning Letter to FDA's satisfaction, 2) intends to take or is taking regulatory action (e.g., injunction or prosecution) against the operators of the establishment; or 3) intends to take or is taking seizure action against a product of the establishment, unless otherwise agreed upon by each agency.

8. As part of its inspection, approval, and certification, verify that all products that bear Federal inspection and grade marks from *Approved Establishments* are in compliance with FDA regulations (e.g., food labeling, food additive and standard of identity), where applicable.

9. Decline to permit the use of Federal inspection and grade marks on food products and prevent distribution of such products, if appropriate, that are known or believed by NMFS to be adulterated or misbranded under the Act or for which FDA has provided written notification that FDA intends to take or is taking a seizure action against the product as provided for in B.3 below.

10. Notify the appropriate FDA field office whenever any food products examined by NMFS are known or believed to be adulterated or misbranded under the Act, unless NMFS verifies that such products are appropriately reconditioned or relabeled to comply with FDA requirements or are segregated and disposed of for non-food use or otherwise lawfully shipped or sold.

11. Decline to examine, or reexamine, any food products once FDA has informed NMFS that FDA intends to take or is taking a seizure action against such products, or intends to take or is taking other regulatory action (e.g., injunction or prosecution) against the operators of the establishment that processed such products, unless otherwise agreed upon by each agency.

12. Provide information to FDA concerning specific establishments or products that have been inspected by NMFS relevant to compliance with FDA regulatory requirements, when requested by FDA.

13. For fish and fishery products for export to the European Union and the European Free Trade Association, or any other mutually agreed upon certification scheme, issue public health safety certifications only to those domestic seafood processors that have been identified by FDA on the list described in B.7, below.

14. Cooperate with FDA in responding to food safety emergencies involving fish and fishery products, within resource constraints.

15. Perform sample analysis and/or conduct inspections of fish and fishery product processors, as appropriate, on FDA's request and upon mutual agreement.

16. Notify FDA in writing whenever an employee or U.S. Department of Commerce inspector has been asked to testify in a case in which FDA is a party. Decline to testify for a private entity

unless that entity has complied with the Department of Commerce's "Touhy" regulations[5], including issuance of a subpoena.

B. The Food and Drug Administration will:

1. Maintain guidance documents on its website or otherwise provide these documents to NMFS upon request, which NMFS can use to help evaluate an establishment's compliance with FDA's Current Good Manufacturing Practice regulations and seafood HACCP regulation.

2. Maintain guidance documents on its website or otherwise provide these documents to NMFS upon request, which NMFS can use to assist NMFS in determining whether a product may be regarded as adulterated or misbranded under the Act

3. Notify NMFS in writing when FDA has sent a Warning Letter to a fish or fishery product establishment. Notify NMFS in writing when FDA intends to take or is taking a regulatory action (e.g., seizure, injunction or prosecution) against a fish or fishery product or establishment, except where it may be inappropriate in the context of a criminal action.

4. As resources permit, respond to inquiries from NMFS about whether process controls, product labels, legends, stamps, and other official marks for products packed under the various inspection services of NMFS conflict with the adulteration and/or misbranding provisions of the Act.

5. Invite the NMFS inspector assigned to and present in a processing plant to accompany the FDA investigator during his or her inspection of such plant, upon initiating an inspection.

6. Offer to discuss observations with the NMFS inspector assigned to and present in a processing plant at the conclusion of the inspection and prior to the discussion with plant management. Provide a copy of Inspectional Observations (FDA 483) to the NMFS inspector at the conclusion of the inspection, after the discussion with plant management. If the NMFS inspector is not present at the conclusion of the inspection, FDA will provide a copy of Inspectional Observations (FDA 483) to the appropriate NMFS field office.

7. Maintain a list of domestic seafood processors on its website or otherwise provide this list electronically to NMFS, which NMFS can use to assist NMFS in determining whether to issue public health safety certifications for establishments exporting fish or fishery products to the European Union and the European Free Trade Association, or any other mutually agreed upon certification scheme.

8. Invite NMFS personnel to attend training in FDA's Office of Regulatory Affairs (ORA) Investigator Certification Program and related activities, as resources permit.

9. Notify NMFS in writing whenever an employee or FDA inspector has been asked to testify in a case in which NMFS is a party. Decline to testify for a private entity unless that entity has complied with FDA's "Touhy" regulations[6], including issuance of a subpoena.

C. It is mutually agreed that:

1. Both agencies will maintain close working relations with each other, both in headquarters as well as in the field. Appropriate NMFS and FDA personnel will meet periodically, as resources permit, for purposes of program planning, coordination, evaluation, and review concerning inspectional matters of mutual interest and to serve as a clearinghouse for questions and problems as may arise.

2. Each agency will participate in meetings with industry, as resources permit, to promote better communication and understanding of regulations, policy, and statutory responsibilities, and to improve sanitation and food-handling practices in processing plants.

3. Each agency will cooperate in the development of the other's regulations and guidance related to fish or fishery products, as appropriate.

4. Each agency will make formal training courses available to the other's personnel, as resources permit.

5. Each agency will take advantage of the inspectional capabilities of the other to achieve the maximum utilization of resources, when appropriate and as resources permit.

6. Each agency will exchange with each other information concerning respective international fish or fishery product inspection related activities to facilitate achieving common goals and to promote efficient use of resources.

7. Each agency will immediately notify the other agency if it is unable to carry out any or all of its responsibilities under this MOU.

4. Information Sharing

The procedures established under Section 3 must include proper safeguards against unauthorized use and disclosure of the information exchanged under this MOU. Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be used consistent with the Trade Secrets Act [18 U.S.C. § 1905], the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], the Privacy Act of 1974, as amended [5 U.S.C. § 552a], the Freedom of Information Act [5 U.S.C. § 552], any other applicable Federal law and their implementing regulations. Pursuant to FDCA section 301(j) [21 U.S.C. 331(j)], FDA will not reveal to NMFS any method or process which is entitled to protection as a trade secret.

Access to the non-public information shared under this MOU shall be restricted to authorized FDA and NMFS employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this MOU, unless authorized in writing by the agency that provided the information or otherwise required by law. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards against unauthorized disclosure of confidential information, and (3) the administrative, civil and criminal penalties contained in applicable Federal laws for the unauthorized disclosure of confidential information.

If an agency that has received information under this MOU receives a Freedom of Information Act (FOIA) request for which there are responsive records that originated with the other agency, to the extent practicable, it will refer that request to the other agency for it to respond directly to the requestor regarding the releasability of the information. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will issue directly from the other agency.

5. Limitations

This MOU represents the broad outline of the Parties' present intent to collaborate in areas of mutual interest to FDA and the NMFS. It does not create binding, enforceable obligations against either Agency. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. With the exception of MOU number: 225-76-2001 (dated October 10, 1974), this MOU does not affect or supersede any existing agreements or arrangements between the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA, and NMFS operate. Nothing in this MOU shall obligate FDA and the NMFS to any current expenditure or future expenditure of resources in advance of the availability of appropriations from Congress.

6. Liaison Officers

To facilitate the activities carried out under this MOU, each agency will establish a single agency liaison. The initial liaisons will be:

For FDA:

William Jones, Ph.D.
Director, Division of Seafood Safety, Office of Food Safety
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740
301-436-2300
William.Jones@fda.hhs.gov

For NMFS:

Timothy E. Hansen
Director, Seafood Inspection Program
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
301-713-2355
Timothy.Hansen@noaa.gov

Each agency may designate a new liaison at any time by notifying the other in writing. If at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the agency will name a new liaison and notify the other agency through the designated liaison.

7. Effective Date, Terms, Termination and Modification

This agreement will become effective when signed by both parties and published in the Federal Register, and it will continue in effect unless modified by mutual written consent at any time or terminated by either party upon a 60 day advance written notice to the other. The parties agree that they will review this agreement every three years to determine whether it should be modified or terminated. This MOU supersedes the Memorandum of Understanding (MOU number: 225-76-2001) dated October 10, 1974.

(Signatures of Authorized Representatives Begin on the Next Page.)

SIGNATURE OF RESPONSIBLE PARTIES

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 09/16/09
Signature of authorized representative Date

MARGARET A. HAMBURG, M.D.
Commissioner of Food and Drugs
Department of Health and Human Services

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

BY: _____ OCT -9 2009
Signature of authorized representative Date

JANE LUBCHENCO, Ph.D
Under Secretary of Commerce for Oceans and Atmosphere
National Oceanic and Atmospheric Administration

[1] Available at: http://seafood.nmfs.noaa.gov (*"USDC Participants List of Firms, Facilities and Products"*)
[2] Title 21 of the Code of Federal Regulations (CFR) Part 110 [21 CFR 110]
[3] Title 21 of the Code of Federal Regulations (CFR) Part 123 [21 CFR 123]
[4] Title 50 of the Code of Federal Regulations (CFR) Part 260 [50 CFR 260]
[5] Title 15 of the Code of Federal Regulations (CFR) § 15.11 *et seq.* [15 CFR 15.11 *et seq.*]
[6] Title 21 of the Code of Federal Regulations (CFR) §§ 20.1 and 20.2 [21 CFR 20.1 and 20.2]