

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[FDA 225-05-2001]

Memorandum of Understanding on Environmental Contaminants in Fish and Shellfish, Between the United States Food and Drug Administration, Center for Food Safety and Applied Nutrition and the United States Environmental Protection Agency, Office of Water**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's Center for Food Safety and Applied Nutrition (CFSAN) and the U.S. Environmental Protection Agency (EPA), Office of Water (OW). The purpose of this MOU is to establish a greater collaboration between CFSAN and OW regarding environmental contaminants in fish and shellfish and the safety of fish and shellfish for consumption by U.S. consumers.

DATES: The agreement became effective June 8, 2005.**FOR FURTHER INFORMATION CONTACT:** *For CFSAN:* Karen Carson, Center for Food Safety and Applied Nutrition (HFS-022), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park,MD 20740, 301-436-1664, e-mail: Karen.Carson@cfsan.fda.gov.

For EPA: Jeffrey D. Bigler, National Fish and Wildlife Contamination Program, USEPA-4305T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, 202-566-0389, FAX: 202-566-0409, e-mail: bigler.jeff@epa.gov.

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

Dated: July 6, 2005.

Jeffrey Shuren,*Assistant Commissioner for Policy.***BILLING CODE 4160-01-S**

225-05-2001



U.S. Department of Health and Human Services
U.S. Environmental Protection Agency



**MEMORANDUM OF UNDERSTANDING ON ENVIRONMENTAL
CONTAMINANTS IN FISH AND SHELLFISH
BETWEEN THE
U.S. FOOD AND DRUG ADMINISTRATION CENTER FOR FOOD SAFETY
AND APPLIED NUTRITION
AND THE
U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF WATER
June 1, 2005**

Purpose: To establish a greater collaboration between the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA/CFSAN), and the U.S. Environmental Protection Agency's Office of Water (EPA/OW) regarding the activities intended to address: 1) environmental contaminants in fish and shellfish and 2) the safety of fish and shellfish for consumption by U.S. consumers. FDA/CFSAN and EPA/OW commit to work closely with each other to coordinate, in advance of action, activities that are of mutual interest with regard to: 1) environmental contaminants in fish and shellfish and 2) the safety of fish and shellfish for consumption by U.S. consumers. This MOU will provide a mechanism for this coordination and collaboration.

Missions: One of the missions of the FDA is to promote and protect the public's health by ensuring that the nation's food supply, including commercial fish and shellfish, is safe, sanitary, wholesome, and properly labeled. The EPA's mission is to protect human health and the environment. To help achieve this mission, the EPA Office of Water's goals are to restore and maintain water quality, to protect human health and ecosystems, and to provide the public with information on how best to reduce their water-related risks, including risks pertaining to the consumption of noncommercial fish and shellfish.

Goals and Objectives: FDA/CFSAN and EPA/OW acknowledge our responsibilities to serve as leaders in promoting and protecting public health while carrying out our agencies' missions. Close cooperation, collaboration, and interaction between the two agencies will help ensure a more unified U.S. Government message regarding the risks and benefits of consuming commercial and noncommercial fish and shellfish that will be clear and beneficial to people in the U.S. Goals and objectives associated with this partnership will be achieved by:

- Promoting the use of the best available science and public health policies;
- Promoting the sharing and availability of appropriate information among the agencies' health and environmental professionals and the public;
- Encouraging environmental monitoring efforts by FDA/CFSAN and EPA/OW and stakeholders;

- Encouraging the development of public health advice that considers both risks and benefits of consumption of commercial and noncommercial fish and shellfish; and
- Promoting uniformity where appropriate in public health messages regarding consumption of commercial and noncommercial fish and shellfish.

Scope: This agreement builds upon collaborative efforts already underway within and between FDA/CFSAN and EPA/OW. FDA/CFSAN and EPA/OW will strive to incorporate the above goals and objectives that are results oriented and, when appropriate, involve interested stakeholders. This MOU establishes a mechanism for cooperation and coordination of public health issues associated with commercial and noncommercial fish and shellfish.

Interagency Communications: FDA/CFSAN and EPA/OW will establish a framework for coordination and communication pertaining to this MOU and to promote staff exchange, as appropriate, for improved interagency communications. EPA/OW and FDA/CFSAN will each identify a representative to serve as its central point of contact on matters relating to this MOU. The representative will participate in regular meetings to facilitate this MOU, coordinate research, and avoid unnecessary duplication in order to increase efficiency. These points of contact will be used to provide input on FDA/CFSAN and EPA/OW matters regarding contaminants in fish and shellfish, when such matters are of mutual interest. In addition, FDA/CFSAN and EPA/OW will promote staff exchange, as appropriate, for improved interagency communications. Finally, FDA/CFSAN and EPA/OW will develop, within 90 days of signing this MOU and annually thereafter, a joint annual plan that describes planned collaborative activities for the subsequent 12-month period.

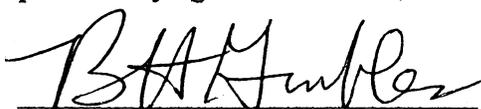
Qualifications and Limitations: This MOU is neither a fiscal nor a funds obligation document, nor does it supplement either EPA's or FDA's existing statutory authorities. All commitments under this MOU made by EPA/OW and FDA/CFSAN are subject to the availability of appropriations. Nothing in this MOU, in and of itself, obligates FDA/CFSAN or EPA/OW to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or other financial obligations. Any endeavor involving reimbursement or contribution of funds between the parties to this MOU or the sharing of non-public information will be set forth in an Interagency Agreement (IAG) or other appropriate agreement entered into under applicable statutes, regulations and policies. The activities, initiatives, or pilot projects contemplated in this MOU will be carried out in accordance with the existing statutory authorities and nothing in this MOU will, in any way, alter the specific statutory or regulatory authorities, rights, requirements, or responsibilities assigned to the FDA/CFSAN, EPA/OW, or other agencies.

This MOU does not create any rights or benefits for any third parties, substantive or procedural, enforceable by law or equity against FDA/CFSAN or EPA/OW, their officers or employees, or any other person. This MOU does not direct or apply to any person outside FDA/CFSAN and EPA/OW. Neither FDA/CFSAN nor EPA/OW may endorse

the purchase or sale of products and services provided by specific commercial entities as part of this effort.

Authority: For EPA: Clean Water Act Section 104, NEPA Section 102(2)(G), For FDA: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393.

Period of Agreement: This MOU will become effective when approved by the indicated signatories for the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition and the U.S. Environmental Protection Agency's Office of Water and will continue in effect for five years. Either party may terminate this MOU by providing written notice to the other party. The termination will be effective upon the sixtieth calendar day following notice, unless a later date is set forth. The parties agree to evaluate the MOU at least once in the five-year period of the MOU at which time the parties may agree to continue, modify, or cancel the MOU.



BENJAMIN H. GRUMBLES
Assistant Administrator for Water

U.S. Environmental Protection Agency

6/8/05
Date



ROBERT E. BRACKETT, Ph D.
Director, Center for Food Safety
and Applied Nutrition

U.S. Food and Drug Administration

6/3/05
Date

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BILLING CODE 4160-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-03-8004]

Memorandum of Understanding Between the Food and Drug Administration and the Food and Drug Administration Alumni Association, Inc.

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 the Food and Drug Administration and the Food and Drug Administration Alumni Association, Inc., (FDAAA). FDA and FDAAA agree to partner on future specific undertakings that are considered beneficial to both organizations, are directly related to the mission of FDA, and are within FDA's statutory authorities.

DATES: The agreement became effective March 3, 2003.

FOR FURTHER INFORMATION CONTACT: Mary Hitch, Office of External Affairs (HF-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4406, e-mail: Mary.Hitch@fda.gov.

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

Dated: June 30, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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