

MEMORANDUM OF UNDERSTANDING
Between
The Food Safety and Inspection Service
United States Department of Agriculture
And
The Food and Drug Administration
United States Department of Health and Human Services

I. Purpose

This Memorandum of Understanding (MOU) between the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA), United States Department of Health and Human Services, is intended to improve interagency cooperation on food safety and fraud prevention and to maximize the effectiveness of personnel and resources related to examination and inspection of Siluriformes fish and fish products.

II. Background

The Agricultural Act of 2014 (2014 Farm Bill), enacted February 7, 2014, directs USDA to execute an MOU with FDA for the following purposes:

1. To improve interagency cooperation on food safety and fraud prevention, building upon any other prior agreements.
2. To maximize the effectiveness of limited personnel and resources by ensuring that –
 - a. inspections conducted by FSIS satisfy requirements under the Federal Food, Drug, and Cosmetic Act;
 - b. inspections of shipments and processing facilities for fish of the order Siluriformes by the agencies are not duplicative; and
 - c. any information resulting from examination, testing, and inspections conducted is considered in making risk-based determinations, including the establishment of inspection priorities.

This MOU sets forth the working arrangements between the agencies to facilitate each agency's efforts to discharge its responsibilities related to the regulatory oversight of fish and fish products and to achieve the purposes identified in the 2014 Farm Bill. It builds upon other prior agreements between the agencies.

II. Statutory Authorities

FSIS administers the Federal Meat Inspection Act (21 U.S.C. 601-695), as amended, notably, by the 2008 Farm Bill (Pub.L. 110-246, §4(a), title XI, §11016(b)(1)(A), June 18, 2008; 122

Stat. 1664, 2130), and further amended by the 2014 Farm Bill (Pub.L. 113-79, title XII, §12106(a)-(c), February 7, 2014; 128 Stat. 980-982).

FDA operates under authorities including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.), the Public Health Service Act (42 U.S.C. 201, et seq.), and the Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.).

III. Substance of Agreement

A. It is mutually agreed that:

1. The agencies will plan for the orderly transition, in phases, from FDA to FSIS of primary regulatory oversight of domestically produced and imported Siluriformes fish and fish products, as provided in the final rule.
2. The agencies will follow the provisions of this MOU as appropriate during the transition period and fully thereafter.
3. In dual jurisdiction establishments that prepare, pack, hold, or otherwise handle both Siluriformes fish and fish products and other fish and fish products, the agencies will follow the procedures for dual jurisdiction establishments set out in MOU number 225-99-2001, except as superseded for certain information sharing by MOU 225-12-0007 (section IV, paragraph 9 and Appendix B).
4. The agencies will coordinate in issuing regulations and guidance and in conducting outreach specific to Siluriformes fish and fish products.
5. The agencies will exchange information relevant to the regulatory oversight of Siluriformes fish and fish products as set out in MOU number 225-12-0007.
6. Each agency will take advantage of the inspectional capabilities of the other agency to achieve the maximum utilization of resources with regard to Siluriformes fish and fish products, when appropriate and as resources permit.

B. FSIS will:

1. Exercise primary regulatory oversight over Siluriformes fish and fish products.
2. Inform FDA if an apparent violation is encountered involving fish and fish products other than Siluriformes.

C. FDA will:

1. Not inspect Siluriformes fish and fish products at domestic and foreign establishments that grow, slaughter, or process such fish and fish products unless requested by FSIS.
2. Not sample or analyze Siluriformes fish and fish products bearing an official USDA inspection legend or an official USDA import mark, unless requested by FSIS.
3. Continue to exercise regulatory oversight over all other fish and fish products.
4. Inform FSIS when an apparent violation is encountered involving Siluriformes fish and fish products.

IV. Liaison Officers

To facilitate the activities described in this MOU, each agency will establish liaisons specified in Appendix A to this MOU.

V. Effective Date, Termination, and Modification

This MOU will become effective when signed by the designated representatives of both agencies and shall continue in effect unless modified or terminated by mutual written consent of the agencies.

Signed on this 30th day of April, 2014.

FOR THE
Food Safety and Inspection Service



Alfred V. Almanza
Administrator

FOR THE
Food and Drug Administration



Michael M. Landa
Director
Center for Food Safety
and Applied Nutrition

Appendix A

Liaison Officers

Food Safety and Inspection Service

Policy Issues

Assistant Administrator
Office of Policy and Program Development
1400 Independence Avenue, SW.,
Washington, DC 20250
Main #: 202-205-0495

Inspection Issues

Assistant Administrator
Office of Field Operations
1400 Independence Avenue, SW.,
Washington, DC 20250
Main #: 202-720-8803

Enforcement/Compliance Issues

Assistant Administrator
Office of Investigation, Enforcement and Audit
1400 Independence Avenue, SW.,
Washington, DC 20250
Main #: 202-720-8609

Food and Drug Administration

Policy Issues

Director, Division of Seafood Safety
Office of Food Safety
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835
Main #: 240-402-2300

Inspection Issues

Director, Office of Food and Feed Operations
Office of Regulatory Affairs
12420 Parklawn Drive
Rockville, MD 20852
Main #: 240-402-4894

Enforcement/Compliance Issues

Director, Office of Compliance
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835
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