

MEMORANDUM OF UNDERSTANDING

Between

**THE U.S. DEPARTMENT OF AGRICULTURE
FARM AND FOREIGN AGRICULTURAL SERVICES
FOOD, NUTRITION, AND CONSUMER SERVICES
FOOD SAFETY
MARKETING AND REGULATORY PROGRAMS
RESEARCH, EDUCATION, AND ECONOMICS**

And

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

**CONCERNING INFORMATION SHARING RELATED TO
FOOD SAFETY, PUBLIC HEALTH, AND OTHER FOOD-ASSOCIATED
ACTIVITIES**

I. Purpose

This Memorandum of Understanding (MOU) establishes policies and procedures to enhance the exchange of information between participating agencies of the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) related to food safety, public health, and associated regulatory, marketing, trade, and research activities substantially affecting the public health.

II. Background

A. The USDA is the U.S. executive department responsible for developing and executing federal policy and laws for food, agriculture, nutrition, natural resources, rural development, and related areas. The USDA provides leadership in these areas based on sound public policy, the best available science, and efficient management. The USDA mission focuses on several key activities, including expanding markets for agricultural products and international economic development, expanding job opportunities and improving housing, utilities, and infrastructure in rural America, enhancing food safety by taking steps to reduce the prevalence of foodborne hazards from farm to table, improving nutrition and health by providing food assistance and nutrition education and promotion, and managing and protecting America's public

and private lands working cooperatively with other levels of government and with the private sector.

1. The Farm and Foreign Agricultural Services (FFAS) mission area, within USDA, and its agencies – the Farm Service Agency (FSA), the Foreign Agricultural Service (FAS), and the Risk Management Agency (RMA) – enhance the export opportunities for agricultural products and administer programs that deliver commodity, credit, conservation, disaster, marketing, and emergency assistance programs that help keep the Nation’s farmers and ranchers in business and improve the stability and strength of the agricultural economy.
 2. The Food, Nutrition, and Consumer Services (FNCS) mission area, within USDA, and its agencies – the Center for Nutrition Policy and Promotion (CNPP) and the Food and Nutrition Service (FNS) – administer federal domestic assistance programs, provide foods through these assistance programs, and link scientific research to the nutrition needs of consumers in order to harness the Nation’s agricultural abundance to end hunger and improve health in the United States.
 3. The Food Safety (FS) mission area, within USDA, and its public health agency, the Food Safety and Inspection Service (FSIS), ensure that the Nation’s commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled and packaged.
 4. The Marketing and Regulatory Programs (MRP) mission area, within USDA, and its agencies – the Agricultural Marketing Service (AMS), the Animal and Plant Health Inspection Service (APHIS), and the Grain Inspection, Packers and Stockyards Administration (GIPSA) – administer programs that facilitate the efficient, fair domestic and international marketing of the Nation’s agricultural products and ensure the health and care of the Nation’s animals and plants.
 5. The Research, Education, and Economics (REE) mission area, within USDA, and its agencies – the Agricultural Research Services (ARS), the Economic Research Service (ERS), the National Agricultural Statistics Service (NASS), and the National Institute of Food and Agriculture (NIFA) – provide federal leadership in creating and disseminating knowledge spanning the biological, physical, and social sciences related to agricultural research, economic analysis, statistics, extension, and higher education to support the creation of a safe, sustainable, competitive, and nutritious U.S. food and fiber system, as well as strong communities, families, and youth. USDA science informs program, policy, and regulatory decisions.
- B. FDA is responsible for protecting and promoting the public health by ensuring, among other things, the safety of human food and animal feed by administering and enforcing the Federal Food, Drug, and Cosmetic Act (hereinafter the FD&C Act) and several related public health laws. In fulfilling its responsibilities under the FD&C Act, FDA's activities are directed toward protecting the public health by ensuring that

foods are safe and wholesome and truthfully and informatively labeled. This is accomplished, in part, by inspecting the production, processing, and distribution of foods and examining samples thereof to ensure compliance with applicable requirements.

- C. The USDA, FFAS, FNCS, FS, MRP, and REE, and the FDA (hereinafter jointly referred to as “the Participants”), have certain related objectives in carrying out their respective food safety, public health, and associated regulatory, marketing, trade, and research activities. The Participants believe it is desirable, from the standpoint of public health protection, to enhance the exchange of information between the USDA agencies and FDA related to food safety, public health, food defense, disaster and emergency response, and associated activities, that will assist in public health protection and in the effective and efficient execution of the responsibilities of the Participants.

III. Substance of the Understanding

A. Information Sharing

The Participants mutually agree that each agency will:

1. Coordinate, collaborate, and cooperate with each other in the exchange of records, data, reports, and other information, which is otherwise not publicly available, on issues related to food safety, public health, and associated regulatory, marketing, trade, and research activities.
2. Furnish, upon request, pertinent records, data, reports and other information regarding food safety, food defense, facility inspection, surveillance, compliance, enforcement, laboratory, product distribution, disaster and emergency response, audit, research, and other records, data, reports, and other related information, which is otherwise not publicly available, that will assist in public health protection and the effective and efficient execution of the responsibilities of the Participants.
3. Receive, review, and respond, in a timely manner, to requests for records, data, reports, and other non-public information made pursuant to this MOU.
4. Follow the process for information sharing and exchange established by Appendix A to this MOU.
5. Develop internal procedures, including for the receipt, review, and response to requests for information, that each Participant agency will use to facilitate the exchange of non-public information, pursuant to this MOU, and to protect against unauthorized use or disclosure of any non-public information shared or exchanged pursuant to this MOU.

B. Information Safeguards

The Participants mutually agree that:

1. Proper safeguards against unauthorized use and disclosure of the non-public information shared or exchanged pursuant to this MOU are necessary for effective implementation of this MOU.
2. Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be shared and used consistent with the Trade Secrets Act [18 U.S.C. 1905], the FD&C Act as amended [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], the confidentiality provisions of the Food Security Act of 1985 [7 U.S.C. 2276], Section 1619 of the Food, Conservation, and Energy Act of 2008 [7 U.S.C. 8791], the confidentiality or non-disclosure provisions of any other agreement entered into by a Participant, and other applicable Federal laws and implementing regulations. Pursuant to section 301(j) of the FD&C Act [21 U.S.C. 331(j)], FDA will not reveal to any Participant any method or process that is entitled to protection as a trade secret.
3. Access to the non-public information shared under this MOU shall be restricted to the employees, agents, and officials of the Participants, who require access to such information to perform their official duties in accordance with the uses of the information as authorized in this MOU, unless otherwise authorized in writing by the Participant agency that provided the information or as required by law. All 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.
4. The Participants agree to notify promptly each other of any actual or suspected unauthorized disclosure of any information shared pursuant to this MOU.
5. If a Participant agency that has received information under this MOU receives a Freedom of Information Act (FOIA) request where there are responsive records, which originated with another Participant agency, the agency will refer the FOIA request to the other agency for it to respond directly to the FOIA requestor. In such cases, the Participant agency, which received the FOIA request, will notify the FOIA requestor that it has referred the FOIA request to another agency and that a response will issue directly from that agency.

IV. Limitations

- A. This MOU represents the broad outline of the Participants' present intent to share non-public information in areas of mutual interest consistent with programmatic goals

and resources that will assist in public health protection and the effective and efficient execution of the responsibilities of the Participants.

- B. This MOU does not create binding, enforceable obligations against any Participant, and all activities undertaken pursuant to this MOU are subject to the availability of personnel, resources, and funds.
- C. This MOU and all associated understandings or agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Participants operate.
- D. This MOU does not restrict any Participant from protecting any records, data, reports, or other information, which is otherwise not publicly available, when the Participant determines that sharing the information is contrary to law or regulation.
- E. The MOU does not restrict any Participant from protecting information in connection with research that has not been peer reviewed.
- F. Nothing in this MOU shall obligate any Participant to any current expenditure or future expenditure of resources in advance of the availability of appropriations from Congress.

V. Other Understandings and Agreements

- A. This MOU is intended to serve as an overarching statement of the intention of the Participants to enhance information sharing among and between the Participants.
- B. This MOU does not nullify or negate any existing understandings or agreements among or between the Participants.
- C. This MOU amends and supersedes certain specified provisions on information sharing set forth in other understandings or agreements, which are identified in Appendix B to this MOU.
- D. The Participants mutually agree to promote and advance the purpose of this MOU to enhance information sharing, when necessary, beyond any existing understandings or agreements.
- E. This MOU does not preclude any Participant from entering into additional, separate understandings or agreements with another Participant.

VI. Liaison Officers

- A. To facilitate the activities carried out under this MOU, the Participants will establish a single liaison for each agency participating in this MOU.

- B. The initial liaisons are those specified in Appendix C to this MOU.
- C. Each agency may designate a new liaison, at any time, by notifying the Participants in writing. If, at any time, an individual designated as a liaison under this MOU becomes unavailable to fulfill those functions, the participating agency will name a new liaison and notify the other Participants through the designated liaison.

VII. Effective Date, Terms, Termination, and Modification

- A. This MOU will become effective when signed by all the Participants.
- B. This MOU will continue in effect unless modified or terminated by mutual written consent of the Participants upon a 60-day advance written notice to the other Participants.
- C. The Participants agree that they will review this MOU every three years to determine whether it should be modified or terminated.

MOU 225-12-0007

APPROVED AND ACCEPTED FOR THE DEPARTMENT OF AGRICULTURE

By:



Michael T. Scuse
Acting Under Secretary
Farm and Foreign Agricultural Services

Date: 12/22/11



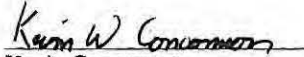
Elisabeth A. Hagen, M.D.
Under Secretary
Food Safety

Date: 12/22/11



Catherine E. Woteki, Ph.D.
Under Secretary
Research, Education, and Economics

Date: 12/22/11



Kevin Concannon
Under Secretary
Food, Nutrition, and Consumer Services

Date: 12/22/11

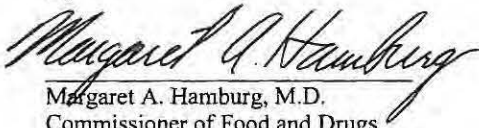


Edward Avalos
Under Secretary
Marketing and Regulatory Programs

Date: 12/22/11

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By:



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
HHS Food and Drug Administration

Date: 1/19/12

APPENDIX A

Process for Information Sharing

When, pursuant to this MOU, a Participant requests, from another Participant, records, data, reports, or other information, which is otherwise not publicly available, and the information requested may include confidential material or confidential commercial information [21 CFR 20.61(b)], the request should be in writing, which includes an informal email, and need only identify the information requested and the purpose for which the information is requested. Although a more specific description of the information asked for may be helpful, it is not required for purposes of making a request. However, the following language is to be included in the written request for information:

"This information is requested and will be shared under the MOU between the U.S. Department of Agriculture and the U.S. Food and Drug Administration Concerning Information Sharing Related to Food Safety, Public Health, and Other Food-Associated Issues. We agree not to disclose any shared information, in any manner, other than within the requesting agency, for official business purposes, without your written permission, with advance written notice to the originating agency."

With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request pursuant to this MOU also should be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information (e.g., record, data, report, or document) provided may be helpful, it is not required for purposes of responding to a request under this MOU. However, the following language is to be included in the written response:

"This information is being provided pursuant to the MOU between the U.S. Department of Agriculture and the U.S. Food and Drug Administration Concerning Information Sharing Related to Food Safety, Public Health, and Other Food-Associated Issues. This communication and the information included may contain privileged and/or confidential material or confidential commercial information exempt from public disclosure. This information may not be disclosed or shared in any manner, other than within the requesting agency, for official business purposes, without our express written consent of the originating agency, with advance notice to the originating agency."

With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

APPENDIX B

Other Understandings and Agreements

Pursuant to paragraph V.C., this MOU amends and supersedes certain specified provisions on information sharing set forth in other understandings or agreements. The following table identifies the specified provisions or paragraphs on information sharing within the listed understandings or agreements that are amended and superseded by this MOU.

Understanding or Agreement	Purpose	Parties and/or Participants	Effective Date	Expiration Date	Provision or Paragraph Amended and Superseded
225-99-2001	Facilitate an exchange of information about establishments that are subject to the jurisdiction of both FDA and USDA.	HHS-FDA and USDA-FSIS	02-23-1999	Indefinite	Section IV, Paragraph 9, and Appendix B
225-72-2009	Cooperation and information sharing in inspection of food products and establishments.	HHS-FDA and USDA-AMS	03-04-2011	Indefinite	Section 4 and Appendix A
225-11-0002	Establishing terms of collaboration in areas of common interest and shared responsibility, and fostering the development of collaborative projects related to food safety and nutrition.	HHS-FDA and USDA-REE	07-01-2011	07-01-2016	Section IV and Appendix A
225-11-0012	Communicate and cooperate in the timely and full exchange of information to optimize controls essential to minimizing potential for the distribution or use of USDA foods which may be unsafe.	HHS-FDA and USDA-AMS, FSA, and FNS	09-29-2011	09-11-2016	Section IV and Appendix B

APPENDIX C

Agency Liaisons

USDA Farm and Foreign Agricultural Services

Farm Service Agency

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Foreign Agricultural Service

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Office of Agreements and Scientific Affairs
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USDA Food, Nutrition, and Consumer Services

Food and Nutrition Service

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USDA Food Safety

Food Safety and Inspection Service

William C. "Bill" Smith

Assistant Administrator
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USDA Marketing and Regulatory Programs

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Animal and Plant Health Inspection Service
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One Health Coordinator
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Animal and Plant Health Inspection Services
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Grain Inspection, Packers and Stockyards Administration
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Director, Departmental Initiatives and International Affairs
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USDA Research, Education and Economics

Agricultural Research Service
Mary E. Torrence, DVM, PhD, DACVPM
National Program Leader, Food Safety

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HHS Food and Drug Administration

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Office of Regulatory Affairs
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APPENDIX D

(As Referenced in Appendix B of MOU 225-12-0007)

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 agreement between the Food and Drug Administration, Department of Health and Human Services (FDA) and the Food Safety and Inspection Service, United States Department of Agriculture (FSIS), is intended to facilitate an exchange of information between the agencies about establishments and operations that are subject to the jurisdiction of both agencies. This exchange of information will permit more efficient use of both agencies' resources and will contribute to improved public health protection.

II. BACKGROUND

In a May 1997 Report to the President entitled "A Food Safety From Farm to Table - A National Food-Safety Initiative," the agencies primarily responsible for food safety made several recommendations to improve public health protection from foodborne illness. Several recommendations addressed the issues of increasing cooperation among agencies and, more specifically, of ensuring that the resources and experience of FDA and FSIS are used as efficiently as possible to avoid duplication of efforts.

To advance the purposes of the President's Food Safety Initiative, FDA and FSIS have re-evaluated a previous Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. The agencies have determined that changes in inspectional activities, available resources, and food safety hazards necessitate updating that agreement. Therefore, FDA and FSIS have entered into this Memorandum of Understanding to address today's public health needs.

III. STATUTORY AUTHORITIES

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*), and parts of the Egg Products Inspection Act (21 U.S.C. 1031, *et seq.*). In carrying out its responsibilities under these acts, FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg processing plants. FSIS also conducts inspections of warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agriculture Marketing Act (7 U.S.C. 1621, *et seq.*).

FDA is responsible for implementing and enforcing 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.*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these acts, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

Nothing in this agreement shall lessen the responsibilities or authorities of FSIS or FDA under their statutory authorities.

IV. SUBSTANCE OF AGREEMENT

1. List of District Level Contacts

The agencies agree to develop, maintain, and annually update a list of their districts and of persons to contact at the district management level. In addition to the annual updates to these lists, each district agrees to promptly inform its counterpart district of any change in the contact person for that district. The agencies also agree to develop and maintain a list of the district offices responsible for each state and territory. Each agency agrees to promptly inform the other agency of any changes in the jurisdiction of district offices or in the field organization of the agency. These lists are to be distributed to the district managers of both FSIS and FDA.

2. List of Dual Jurisdiction Establishments

The agencies agree to develop, maintain, and annually update a list of dual jurisdiction establishments (hereinafter ADJEs@), that is, establishments that prepare, pack, hold, or otherwise handle both foods regulated by FSIS and foods regulated by FDA. This list is to be organized by state and territory and will be distributed to the district managers of both FSIS and FDA. When updating this list, each agency agrees to identify all DJEs that have discontinued operations that are under its jurisdiction.

3. System of Communication

The district offices of each agency agree to promptly report to their counterpart district offices certain findings, as set forth in paragraphs 5, 6, and 7, relating to DJEs. The district office receiving the report agrees to respond with information regarding any planned or completed follow-up action relating to the reported information. District management of both agencies are encouraged to initiate contact and to meet annually, or as frequently as necessary, to facilitate the exchange of information about establishments and foods prepared, packed, held, or otherwise handled by these establishments. The agencies agree to work together to develop, put in place, and maintain a system of electronic communication at the district level to facilitate the exchange of information about the DJEs.

4. Notification of Periodic Inspection

Each agency agrees to attempt to notify the appropriate contact identified in paragraph 1 of this section prior to conducting an inspection of a DJE that is not under continuous FSIS inspection. In addition, FDA agrees to attempt to notify the FSIS inspector prior to inspecting a DJE that is under continuous inspection and to invite the FSIS inspector to accompany the FDA investigator on the inspection.

5. Findings Involving DJEs That Are To Be Reported By Both Agencies

The district office of each agency is to notify its counterpart district office of the following findings in a DJE:

- a. Foods implicated in outbreaks of foodborne illness, injuries, or adverse reactions.
- b. Foods found to be contaminated or mislabeled such that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences. Hazards that

constitute contamination or mislabeling covered under this paragraph are attached as Appendix A.

c. A processing condition or failure that is likely to result in food contamination leading to outbreaks of foodborne illness, injuries, or adverse reactions.

d. Foods that have been recalled.

e. Reports of tampering or threats of tampering.

f. A food handler diagnosed as having a communicable disease that is likely to result in food contamination or outbreaks of foodborne illness (e.g., hepatitis).

g. Convictions of a DJE, or any officer or key employee of a DJE, for any felony or more than one misdemeanor involving the DJE or any food prepared, packed, held, or otherwise handled in the DJE.

h. Convictions of an establishment preparing, packing, holding, or otherwise handling meat, poultry or egg products solely under state regulation and foods regulated by FDA, or any officer or key employee of such an establishment, for any felony or more than one misdemeanor involving the establishment or any food prepared, packed, held, or otherwise handled in the establishment.

6. Additional Findings Involving DJEs That Are To Be Reported By FSIS to FDA

In addition to the findings in paragraph 5, the FSIS district office is to notify its counterpart district office of FDA of the following finding in a DJE:

a. FSIS action to withhold the mark of inspection or to suspend or withdraw the grant of inspection.

7. Additional Findings Involving DJEs That Are To Be Reported By FDA to FSIS

In addition to the findings in paragraph 5, the FDA district office is to notify its counterpart district office of FSIS of the following findings:

a. Any other processing condition in a DJE that could render foods bearing a USDA mark of mandatory or voluntary inspection adulterated or mislabeled.

b. Reason to believe that an FDA-regulated ingredient that would adulterate a meat, poultry, or egg product if used in it has been sent to or received by an FSIS-regulated establishment.

8. Follow-Up Action

- a. The agency receiving notification of a finding listed in paragraphs 5, 6, or 7 agrees to evaluate it and take appropriate action.
- b. For all reported findings listed in paragraphs 5, 6, or 7, the agency receiving the notification agrees to track and use the information in program evaluation, work planning, and consideration of whether action against the establishment is warranted.
- c. The agency receiving the notification of a finding listed in paragraphs 5, 6, or 7 agrees to respond to the notification within 30 days by communicating the disposition of the notification to the notifying agency at the district management level, including, if appropriate, any and all actions planned and taken by the agency receiving notification. In addition, the agencies agree to explore the feasibility of granting each other access to appropriate computer monitoring systems to permit interagency tracking of findings listed in paragraphs 5, 6, or 7.

9. Information Sharing and Confidentiality

To promote increased cooperation and efficient use of enforcement resources, each agency agrees to share information for enforcement purposes upon request by the other agency, to the extent permitted by applicable law. All non-public information shared between the two agencies pursuant to this agreement is subject to all applicable limitations established by statute or regulation on interagency sharing of information. The current policies and procedures for sharing such information are attached as Appendix B.

10. Training

The agencies agree to develop and provide appropriate training in the inspectional techniques and processes of each agency as the agencies determine is necessary to ensure that the contacts for each agency have an appropriate understanding of the workings of the other agency. This understanding will help ensure the successful implementation of this agreement. The agencies agree to develop and initiate the

training as quickly as possible. The district managers of both agencies are encouraged to evaluate training needs during annual meetings, or as frequently as necessary, to determine whether additional training is warranted.

11. Joint Enforcement Activities

The agencies agree to establish a group to explore the feasibility of joint enforcement activities. This group is to report its findings and recommendations by March 1, 1999 to the Commissioner of FDA and the Administrator of FSIS.

12. Re-evaluation of the Agreement

The agencies agree to re-evaluate the effectiveness of this agreement after it has been in effect for one year. The agencies also agree to explore the feasibility of expanding their cooperative activities after one year, or sooner if the agencies agree that it is appropriate to do so.

V. PERIOD OF AGREEMENT

The agencies agree to begin implementing this agreement within 30 days from execution by both parties. This agreement will be effective indefinitely. It may be modified by mutual consent or terminated by either party upon 30 days= written notice to the other.

VI. PREVIOUS AGREEMENTS

This agreement supersedes the Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. This MOU does not modify any other existing agreements between USDA and FDA.

VII. NAME AND ADDRESS OF PARTICIPATING AGENCIES

Food Safety and Inspection Service Food and Drug Administration

1400 Independence Ave., S.W. 5600 Fishers Lane

Washington, DC 20250-3700 Rockville, MD 20857

VIII. LIAISON OFFICERS

For FSIS: For FDA:

John McCutcheon Gary Pierce

Associate Deputy Administrator, Director, Division of Emergency and

Office of Field Operations Investigational Operations

Food Safety Inspection Service Food and Drug Administration
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(202) 720-5190 (301) 827-5655

APPROVED AND ACCEPTED FOR APPROVED AND ACCEPTED FOR
THE FOOD SAFETY INSPECTION THE FOOD AND DRUG
SERVICE ADMINISTRATION

By: By:

Thomas J. Billy Michael A. Friedman, M.D.

Title: Administrator, FSIS Title: Deputy Commissioner
For Operations, FDA

Date:

Updated: 03/15/99

MOU number: 225-72-2009

Memorandum of Understanding

between

the Agricultural Marketing Service

and

the Food and Drug Administration

**Concerning Information Sharing and Other Activities Related to the Auditing, Inspection,
and Grading of Food Products ^{1/}**

1. Purpose

Cooperation and information sharing in the inspection of food products and establishments.¹

2. Background

The Food and Drug Administration (FDA) of the Department of Health and Human Services is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (FFDCA) and other laws. In fulfilling its responsibilities under the FFDCA, FDA's activities are directed toward protecting the public health by ensuring that foods are safe and wholesome and truthfully and informatively labeled. This is accomplished, in part, by inspecting the production, processing, and distribution of foods and examining samples thereof to ensure compliance with applicable requirements. FDA also promulgates under the FFDCA mandatory standards of identity, quality, and fill of containers for food products after appropriate notices and hearings.

The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture, under the authority of the Agricultural Marketing Act of 1946, carries out certain voluntary service functions designed to aid in the efficient marketing of agricultural products. These include developing commercial grade standards and specifications for foods, furnishing auditing, inspection and grading services (including the issuance of certificates of quality and/or condition) and auditing reports to producers, processors, shippers, buyers, or other interested parties. The major purpose is to assist producers in preparing quality wholesome products that meet users' requirements and to provide objective information concerning the grade, quality, or condition of a product, which will assist interested parties engaged in

¹ This agreement does not apply to egg products, inspection of which is covered by the Egg Products Inspection Act; to meat or poultry products, inspection of which is covered by the Meat Inspection Act and the Poultry Products Inspection Act (USDA Food Safety and Inspection Service); nor to grains, including rice, dry beans, peas, or lentils, inspection of which is covered by the U.S. Grain Standards Act (USDA Grain Inspection, Packers and Stockyards Administration).

marketing functions. In addition to inspection and grading services for products, AMS offers voluntary audit, survey, and verification services at product locations and facilities. AMS' regulatory authority facilitates fair trade practices among the industry through education, mediation, arbitration, licensing and enforcement of the Perishable Agricultural Commodities Act of 1930.

The two agencies have certain related objectives in carrying out their respective regulatory and service activities. Therefore, the agencies believe it is desirable from the standpoint of public health protection to set forth in this Memorandum of Understanding (MOU) the working arrangements that are being followed or adopted in the interest of each agency discharging as effectively as possible its responsibilities related to inspection/grading and standardization activities for food products. The MOU recognizes that AMS' audit, survey, and verification services contribute to the protection of consumers by helping agricultural producers fulfill their responsibility to ensure that their products are safe and meet applicable FDA requirements. The MOU also recognizes that FDA may take into consideration information resulting from AMS 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 the safety of these food products, and that determinations made by AMS do not change or diminish FDA's authority under the FFDCFA. Nothing in this MOU, or any determination made by AMS, would restrict FDA from conducting its own inspection or taking regulatory action, nor would it affect the legal responsibilities of establishments under the FFDCFA.

3. Substance of the Agreement

A. The Agricultural Marketing Service will:

- 1) supply to FDA-designated offices, upon request, complete lists of all farms, packing plants, handlers, and food processors that are operating under AMS continuous or other resident or temporary inspection or grading contracts or contractual audit services. This list will include the type of service provided and the food products involved;
- 2) immediately advise the appropriate FDA office of those plants subject to withdrawal or suspension of service, termination of contract, or denial of inspection services because of sanitation or other current good manufacturing practice or good agricultural practice deficiencies. AMS will notify the appropriate FDA office of those facilities that appear not to conform to agricultural best practices that relate to food safety or to FDA's current Good Manufacturing Practice regulation under 21 CFR part 110;
- 3) investigate any report from FDA that a grower, packer, or processor operating under contract with AMS has not corrected objectionable conditions found to exist by FDA, and take action in accordance with AMS regulations and contracts;
- 4) decline to inspect, grade, or audit samples of products that are known to have been seized by FDA, or that are known to be involved in FDA enforcement actions. This does not preclude reinspection of legally authorized samples by AMS if the FDA

seizure or other enforcement action involved products that had previously been inspected or graded by AMS;

- 5) decline to assign a U.S. grade or permit the use of Government official marks or other approved identification on a food product (1) that is known or believed by AMS to be adulterated under the FFDCFA or other applicable federal statute, or (2) that AMS has otherwise found not to be suitable for grade assignment because of possible adulteration, contamination, or food safety risk;
- 6) decline to provide auditing, inspection, and grading services to a facility (1) that is known or believed by AMS to have significant violations of the FFDCFA, or other applicable statute, that are uncorrected or reoccurring, or (2) for which FDA has provided notification to AMS that FDA has found unsanitary conditions;
- 7) notify the appropriate FDA office with information on any lot of product which, upon inspection, is known or believed to fail to comply with FDA requirements, unless AMS verifies, in coordination with FDA, that such product is appropriately reconditioned or relabeled to comply with FDA requirements or is segregated and disposed of for nonfood use or otherwise lawfully shipped or sold;
- 8) furnish to FDA upon request, any pertinent information concerning the grade or quality determination relative to specific lots of products inspected or graded by AMS that have been proceeded against or are being considered for any action by FDA;
- 9) record on the audit, inspection or grading report any pertinent codes or other marks that will serve to identify the specific goods, which are audited, inspected, or graded;
- 10) when requested by FDA, provide assistance necessary to facilitate investigations required to ensure public health;
- 11) for product areas where FDA has provided the appropriate training to AMS, routinely advise contract establishments of pertinent FDA requirements and provide information on compliance and points of contact at FDA;
- 12) upon FDA request, sample and analyze specific lots of agricultural commodities for investigations involving potential regulatory violations; provide feedback to FDA on results of sampling and analysis, if requested; provide support for associated requests for testimony in related court actions; and follow FDA protocols related to chain of custody, sampling, and analysis for lots when samples and analysis are performed for FDA, or obtain approval from FDA for using alternative methodologies;
- 13) notify the appropriate FDA office immediately of any presumptive or confirmed positive findings of human pathogens of public health significance or residues of pesticide and/or environmental contaminants in products inspected by AMS that exceed tolerances, action levels, or otherwise adulterate the food;

- 14) furnish to FDA upon request any pertinent reports AMS generates that include general information on deficiencies in current good manufacturing practice or good agricultural practice;
- 15) notify the appropriate FDA office of those facilities that fail to conform to current good manufacturing practices or good agricultural practices related to food safety;
- 16) cooperate with FDA in responding to food safety emergencies involving food products, within resource constraints;
- 17) notify FDA in writing whenever an employee or AMS 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 §AMS' "Touhy" regulations including issuance of a subpoena (7 CFR §1.214 & §1.215 *et seq.*); and
- 18) inform FDA about firms that have repeated violations of AMS requirements.

B. The Food and Drug Administration will:

- 1) maintain guidance documents on its website or otherwise provide these documents to AMS upon request, which AMS can use in providing audit services for industry;
- 2) as appropriate, invite the AMS inspector/grader present at a plant operating under contract with AMS to accompany the FDA investigator during his or her inspection of such plant. The FDA investigator may point out or discuss with the AMS inspector/grader the conditions noted which may be violations of the FFDCA;
- 3) request from the AMS contact designated in this document any information related to grade, quality or food safety for a specific firms or lot(s) of product(s) against which FDA is taking action or is considering taking action and that is/are known or believed to have been inspected or audited by AMS. FDA may take into consideration the results of AMS inspection certificates and other available data;
- 4) request from the AMS contact designated in this document, for specific facilities under FDA investigation or action, any pertinent information concerning AMS audits related to identity preservation, food safety, or food defense;
- 5) immediately notify the AMS contact designated in this document concerning the details of objectionable conditions whenever such conditions are found to exist in processing or packing plants or primary production locations where AMS is conducting inspections of products or conducting audits of facilities and/or best practices, or in other food plants, when FDA believes such information would be of value to AMS in its auditing, survey, or verification services, or its inspection and grading activities;

- 6) whenever possible, mark the claimant's samples of seized products in such a manner that AMS inspectors will recognize such post-seizure samples;
- 7) provide AMS with access to documented protocols for sampling, analysis, and chain of custody for lots when samples and analyses are performed at FDA's request;
- 8) provide to the AMS contact designated in this MOU to keep AMS informed of the criteria used by FDA to assist AMS in understanding which conditions FDA would consider actionable under the FFDCa and other statutes. FDA will also discuss and identify FDA training information and material that could be beneficial to AMS;
- 9) on request of AMS, review labels, legends, stamps, and other official marks and claims for products packed under the various audit, grading, and/or inspection services of AMS from the standpoint of possible conflict with the misbranding provisions of the FFDCa;
- 10) notify AMS when FDA has sent a warning letter to a facility covered under AMS' inspection and auditing services. Notify AMS when FDA intends to take or is taking regulatory action against a food product or facility, except where it may be inappropriate in the context of criminal action; and
- 11) notify AMS in writing whenever an employee or FDA inspector has been asked to testify in a case in which AMS is a party. Decline to testify for a private entity unless that entity has complied with FDA's "Touhy" regulations, including issuance of a subpoena. (21 CFR 20.1 and 20.2).

C. AMS and FDA mutually agree that each agency will:

- 1) maintain close working relations with each other, both in headquarters as well as in the field. Appropriate AMS 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. Provide a list of regional office contacts;
- 2) 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;
- 3) cooperate in the development of the other's regulations, guidance and programs related to relevant products, as appropriate;
- 4) make formal training courses available to the other's personnel, as resources permit;
- 5) take advantage of the inspectional capabilities of the other to achieve the maximum utilization of resources, when appropriate and as resources permit;

- 6) exchange data and cooperate in the development of sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products audited, inspected, and graded by AMS;
- 7) work with industry toward greater efficiency in connection with improvement in coding and traceability methods;
- 8) cooperate in the handling of those cases of misbranding which also come under the provisions of the Perishable Agricultural Commodities Act of 1930, as amended; and
- 9) develop procedures that include proper safeguards against unauthorized use and disclosure of the non-public information exchanged under this MOU.

4. Information Sharing

The procedures established under Section 3.C. must include proper safeguards against unauthorized use and disclosure of the non-public 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 shared and 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 regulations implementing it. Pursuant to FFDCA section 301(j) [21 U.S.C. 331(j)], FDA will not reveal to AMS any method or process which is entitled to protection as a trade secret. Any Federal partner may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request. See Process for Information Sharing under Appendix A.

Access to the non-public information shared under this MOU shall be restricted to authorized FDA and AMS 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 AMS. 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: 225-72-2009 (dated June 25, 1975), 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 AMS operate. Nothing in this MOU shall obligate FDA and AMS 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:

David Glasgow
Director, Division of Domestic Field Investigations
ELEM, Room 2136, HFC-130
12420 Parklawn Drive
Rockville, MD 20852-1740
Phone: 301-796-5403
Email: David.Glasgow@fda.hhs.gov

For AMS:


Erin Morris
Deputy Associate Administrator
1400 Independence Ave, SW,
Room 3077-S, Mail Stop 0201
Washington, DC 20250-1300
Phone: 202-690-4024
Email: Erin.Morris@ams.usda.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

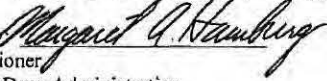
This agreement will become effective when signed by both parties and it will continue in effect unless modified by mutual written consent at any time or terminated by either party upon a 60 day advance written notice to the other. The parties agree that they will review this agreement every three years to determine whether it should be modified or terminated. This MOU supersedes the Memorandum of Understanding (MOU number: 225-72-2009) dated June 25, 1975.

Approved and Accepted for the Agricultural Marketing Service

Signed by: 
Administrator
Agricultural Marketing Service

Date: Feb. 11, '11

Approved and Accepted for the Food and Drug Administration

Signed by: 
Commissioner
Food and Drug Administration
Date: March 4, 2011

APPENDIX A
Process for Information Sharing

Pursuant to Section 4 of the Memorandum of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the Agricultural Marketing Service (AMS) any Federal partner "may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section 4.

When, under the current MOU, staff at the FDA or AMS request from the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, and need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

"Information that is shared under this request will be under the FDA-AMS Memorandum of Understanding. We agree not to disclose any shared information in any manner without your written permission or as required by law with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

"Pursuant to the FDA-AMS Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any manner without our express written consent or as required by law with advance notice to the originating agency." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

MEMORANDUM OF UNDERSTANDING

Between

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

And

THE UNITED STATES DEPARTMENT OF AGRICULTURE
RESEARCH, EDUCATION, and ECONOMICS

I. Purpose

Establishing terms of collaboration in areas of common interest and shared responsibility, and fostering the development of collaborative projects related to food safety and nutrition.

II. Background

The United States Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA), Research Education and Economics Agencies (REE), hereinafter jointly referred to as "the Participants," have a shared interest in scientific progress in the diverse disciplines that directly and indirectly affect human and animal health including food safety and nutrition.

FDA is responsible for protecting and promoting the public health by ensuring, among other things, the safety of human food and animal feed by enforcing the Federal Food, Drug and Cosmetic Act, and several related public health laws. FDA's Office of Foods in the Office of the Commissioner includes the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the foods-related activities of the Office of Regulatory Affairs (ORA). CFSAN's mission includes both food safety and nutrition and includes regulatory and research initiatives and programs that promote and protect the public health by ensuring that the nation's food supply is safe, sanitary, wholesome, and accurately labeled. CVM's mission includes regulatory and research initiatives and programs that ensure the safety and effectiveness of animal drugs, feed additives, animal devices and medicated feeds; animal health; and the safety of human foods derived from animals. ORA is the lead office for all FDA field activities as well as providing FDA leadership on imports, inspections, and enforcement policy.

The USDA agencies within REE – the Agricultural Research Service (ARS), the Economic Research Service (ERS), the National Agricultural Statistics Service (NASS), and the National Institute of Food and Agriculture (NIFA) (replaces former Cooperative State Research, Education, and Extension Service) – provide federal leadership in creating and

disseminating knowledge spanning the biological, physical, and social sciences related to agricultural research, economic analysis, statistics, extension, and higher education. The mission of the ARS intramural food safety program is to provide through research, the means to ensure that the food supply is safe for consumers; and that food and feed meet foreign and domestic regulatory requirements. ERS conducts research to inform public and private decision-making on economic and policy issues. The NASS mission is to support the collection of agricultural food production data to inform research relative to food safety and nutrition issues. The mission of NIFA is to advance knowledge for agriculture, the environment, human health and well-being, and communities by supporting research, education, and extension programs in the Land-Grant University System and other partner organizations.

The Participants have certain related objectives in carrying out their respective regulatory and service activities. Therefore, from the standpoint of public health protection, the Participants believe it is desirable to set forth in this Memorandum of Understanding (MOU) the basis for development of scientific collaborations between the Participants in the areas of food safety and nutrition.

The Participants share a common interest in multiple areas of food safety and nutrition, including training and outreach activities. The Participants hold interests in exploring additional avenues where mutually supportive activities can be collaboratively pursued.

The Participants recognize that cooperation is a matter of working together toward common goals of mutual interest, not merely cooperative financing or sharing of research and related activities. The Participants also recognize that successful cooperation occurs only through mutual understanding and efficient administration of cooperative programs. Nothing in this broad understanding is to be construed as interfering in any way with the basic responsibilities and authority of either Participant for independent action.

III . Substance of Agreement

The Participants agree to collaborate in areas of mutual interest. Areas may include but are not limited to food pathogen and contaminant detection methods, pre- and post-harvest food safety interventions and control strategies, nutrition monitoring methods and data, food composition analyses and databases, biomarkers of exposure, nutritional status, and disease risk, and economic analyses relevant to food safety and nutritional issues. Collaborations are expected to gather scientific data that will provide guidance for regulatory and policy decisions, and may change as priorities in both food safety and nutrition evolve. Collaborations may also include the development and delivery of information and training, education, outreach, and technical assistance on food safety practices for producers and small processors.

In order to assure that these collaborations are pursued in a continual and timely fashion, the Participants may meet twice a year, or more frequently if the need arises, alternating meeting sites between the two agencies, and may share information, reports on progress, and explore new areas for collaboration. These meetings will be coordinated by programmatic leaders in

food safety and nutrition. For the purpose of facilitation in these collaborations, CFSAN and ARS have agreed to be the coordinators for their respective agencies.

Additionally it is agreed that:

1. Rights to any inventions resulting from collaborative research will be determined based on current U.S. Government patent regulations and any other applicable statutes and regulations.
2. Each Participant will comply with the other Participant's security procedures and policies regarding access to and use of facilities. Either Participant may restrict or limit access to its property and facilities, at any time, for any reason.
3. It is recognized that from time-to-time collaborations developed under this MOU between the Participants may include sharing in expenses that may require compensation of either Participant by the other. The sharing of expenses will be agreed to in advance of any collaboration, in compliance with all applicable federal requirements, and subject to the limitations in Section V of this MOU.
4. In accordance with Section 1011 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 399c] and Section 405 of Title IV of the Agricultural Research, Extension, and Education Reform Act [7 U.S.C. § 7625], FDA and NIFA will collaborate on the establishment of a competitive grant program within NIFA to provide food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers, subject to the limitations in Section V of this MOU.

IV. Information sharing

The Participants recognize the need for proper safeguards against unauthorized use and disclosure of non-public information exchanged pursuant to this MOU. Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be shared and 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], and their implementing regulations, and any other applicable Federal law and its implementing regulations. Pursuant to Section 301(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(j)], FDA will not reveal to REE any method or process which is entitled to protection as a trade secret. Either Participant may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request. See Process for Information Sharing under Appendix A.

Access to the information shared under this MOU shall be restricted to authorized FDA and REE employees, agents, and officials who require access to perform their official duties in accordance with the uses of information as authorized by 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 this information; (2) safeguards required to protect the information; and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws. Contractors, their subcontractors, and agents requiring access to the information shared under this agreement will be required to sign a business associate agreement by which they will commit to keep the information confidential.

FDA and REE agree to promptly notify the other agency of any actual or suspected unauthorized disclosure of information shared under this MOU.

If an agency in receipt of information under this MOU receives a FOIA request for shared information, it will refer the request to the agency that shared the information for the latter agency to respond directly to the requestor regarding the releasability of the information at issue. 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.

V. Limitations

This MOU represents the broad outline of the Participants' present intent to enter into specific agreements for collaborative efforts in areas of mutual interest to FDA and REE. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Participants. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the participating U.S. Department of Agriculture's Research, Education and Economic Agencies operate.

VI. Liaison Officers

A. Administrative

Center for Food Safety and Applied Nutrition, Food and Drug Administration

Director
Executive Operations Staff
Center for Food and Applied Nutrition
Food and Drug Administration
5100 Paint branch Parkway
College Park, Maryland 20740-3835
Phone: (301) 436-1600

U.S. Department of Agriculture

Director
USDA Extramural Agreements Division
George Washington Carver Center, Room 3-2169
5601 Sunnyside Avenue
Beltsville, Maryland 20705-5110
Phone: (301) 504-1144
Fax: (301) 504-1262

B. Programmatic

Food and Drug Administration:
Team Leader, Liaison and Partnership Team
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway (HFS-006)
College Park, MD 20740
(301) 436-1981

Deputy Director, Office of Research
Center for Veterinary Medicine
Food and Drug Administration
8401 Muirkirk Rd
Laurel, MD 20708
(301) 210-4213

Director, Office of Regional Operations
Office of Regulatory Affairs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

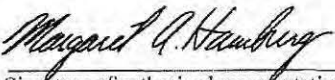
U.S. Department of Agriculture, REE:
ARS National Program Leaders, Food Safety (NP 108)
ARS National Program Leaders, Human Nutrition (NP 107)
George Washington Carver Center
5601 Sunnyside Avenue
Beltsville, Maryland 20705-5110
Phone: (301) 504-7050

Each agency may designate new liaisons 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.

VII. Term, Termination, and Modification

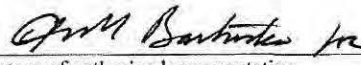
This MOU becomes effective on the date of the last signature and continues for 5 years. It may be modified or terminated by mutual written consent of both parties or may be terminated by either party upon a 60-day advance written notice to the other party.

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

BY:  Date: June 30, 2011
Signature of authorized representative

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE DEPARTMENT OF AGRICULTURE,
RESEARCH, EDUCATION, AND ECONOMICS

BY:  Date: 7/1/2011
Signature of authorized representative

Cathie Woteki, Ph.D.
Under Secretary for Research, Education, and Economics
United States Department of Agriculture

APPENDIX A
Process for Information Sharing

Pursuant to Section IV of the Memorandum of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the United States Department of Agriculture Research Education and Economics Agencies (REE), either Participant "may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section IV.

When, under the current MOU, staff at the FDA or REE request from the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, and need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

"Information that is shared under this request will be under the FDA-REE Memorandum of Understanding. We agree not to disclose any shared information in any manner without your written permission or as required by law with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

"Pursuant to the FDA-REE Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any manner without our express written consent or as required by law with advance notice to the originating agency." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.




United States
Department of
Agriculture

Farm and
Foreign
Agricultural
Services

Farm
Service
Agency

1400 Independence
Avenue, SW
Stop code 0550
Room 3080
Washington, DC
20250-0572

MEMORANDUM FOR THE ADMINISTRATOR

FROM: James W. Monahan  **SEP 29 2011**
Deputy Administrator for Commodity Operations

SUBJECT: Memorandum of Understanding with FSA, AMS, FNS and FDA

Enclosed is a Memorandum of Understanding (MOU) between Farm Service Agency, Agricultural Marketing Service, Food Nutrition Service and the Food and Drug Administration for your signature. The purpose of the MOU is to establish a framework for communication to minimize the potential distribution of unsafe USDA Foods. All of the other agencies have already approved and accepted the MOU.

If you have any questions regarding this document, please contact me.



USDA is an equal opportunity provider and employer.

MEMORANDUM OF UNDERSTANDING

Between

**UNITED STATES DEPARTMENT OF AGRICULTURE'S
AGRICULTURAL MARKETING SERVICE,
FARM SERVICE AGENCY, and
FOOD AND NUTRITION SERVICE**

and

**DEPARTMENT OF HEALTH AND HUMAN SERVICES'
FOOD AND DRUG ADMINISTRATION**

The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS), Farm Service Agency (FSA), Food and Nutrition Service (FNS), and the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), collectively referred to as the Parties, intend to facilitate the exchange of information among the Parties related to FDA-regulated foods procured or subject to procurement by USDA. For the purpose of this Memorandum of Understanding (MOU) the term "USDA Foods" will mean commodities procured by USDA for use in domestic nutrition assistance programs.

I. PURPOSE

The purpose of this MOU is to establish a framework for the Parties to communicate and cooperate in the timely and full exchange of information to optimize controls essential to minimizing potential for the distribution or use of USDA Foods which may be unsafe.

II. STATUTORY AUTHORITIES AND RESPONSIBILITIES

FDA is charged with the enforcement of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 301, et seq.), which defines "food" as any "articles used for food or drink *** [or] for components of any such article" (21 U.S.C. § 321(f)). FDA also implements and enforces the Public Health Service Act (42 U.S.C. § 201, et seq.), the Fair Packaging and Labeling Act (15 U.S.C. § 1451 et seq.), and other statutes. In carrying out its responsibilities under these statutes, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by USDA's Food Safety Inspection Service (FSIS). FDA inspects food and food samples during processing and distribution. When FDA determines that food is not compliant with statutory and regulatory

requirements, FDA works with manufacturers to ensure the removal of the food from the market. FDA can also take enforcement action.

FNS administers the USDA domestic nutrition assistance programs and provides USDA Foods to its programs, such as the National School Lunch Program, the Commodity Supplemental Food Program, The Emergency Food Assistance Program, and the Food Distribution Program on Indian Reservations pursuant to authorities in the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.), the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.), the Agriculture and Consumer Protection Act of 1973 (7 U.S.C. 612c note), and the Emergency Food Assistance Act of 1983 (7 U.S.C. 7501 et seq.).

Pursuant to Section 15 of the Commodity Distribution Reform Act and WIC Amendments of 1987 (7 U.S.C. 612c note), the Secretary of USDA may use funds available to implement Section 32 of the Act of August 24, 1935, (7 U.S.C. 612c), to reimburse State agencies and others for the removal of USDA Foods distributed under a domestic nutrition assistance program if the Secretary determines that the commodities pose a health or safety risk.

USDA, through AMS and FSA, purchases and delivers USDA Foods to State distributing agencies and other entities for donation in the domestic nutrition assistance programs.

In addition to acquiring food products on behalf of FNS using funds appropriated for FNS programs, AMS carries out a wide range of program activities that facilitate the marketing of domestic agricultural products as authorized by Section 32 of the Act of August 24, 1935, the Agricultural Marketing Act of 1946, the Perishable Agricultural Commodities Act, and more than 50 other statutes. Many of the USDA Foods purchased by AMS must meet specific grade and specification requirements established by the various inspections and grading activities of AMS including the Fruit and Vegetable Programs, Poultry Programs, and Livestock and Seed Programs. AMS typically contracts with manufacturers to fulfill program needs. Also, some non-manufacturers participate by utilizing subcontracts to fulfill AMS commodity contracts. AMS procures Group A USDA Foods listed in Appendix A, Section A.

In addition to acquiring food products on behalf of FNS using funds appropriated for FNS programs, FSA is responsible for the management of commodities acquired by the Commodity Credit Corporation under various statutes, including the Food, Conservation and Energy Act of 2008, the Agricultural Act of 1949, as amended, and the Commodity Credit Corporation Charter Act. FSA also contracts for commercial storage and distribution of USDA Foods purchased for the Food Distribution Program on Indian Reservations and the Commodity Supplemental Food Program. FSA procures Group B USDA Foods listed in Appendix A, Section B.

III. SUBSTANCE OF THE AGREEMENT

The Parties agree:

- A. FDA, FNS, AMS, and FSA will maintain points of contact (POC) at the headquarters and district office levels, including email distribution lists, to ensure the agencies can respond effectively to questions that arise regarding the safety or security of FDA-regulated USDA Foods. In addition, the Parties agree to inform their respective counterparts annually, or as necessary, of any change in the designated contact persons or changes in the areas of responsibility or in the organization of the agency.

The names of the POCs will be distributed to the managers of FDA, FNS, AMS, and FSA who have relevant responsibilities.

- B. FDA, FNS, AMS, and FSA will share in a timely manner among respective liaison offices and contacts (provided for under A above) information and updates on complaints, reports, or events that compromise FDA-regulated USDA Foods and may affect the health and safety of USDA nutrition assistance program recipients, and to cooperate on investigations into the food safety significance of complaints and occurrences of outbreaks of foodborne illness, injuries, or adverse reactions in connection with FDA-regulated USDA Foods.
- C. For food products involved in recalls monitored by FDA or subject of an FDA consumer alert, FDA will inquire of the vendor whether the product(s) in question were acquired by any USDA procurement agency or barter partner for use in the domestic nutrition assistance programs. If so, FDA will, in a timely manner, provide to FNS, AMS and FSA complete information about types of FDA-regulated foods procured by USDA that are subject to a recall or an FDA consumer alert, as well as the actual or anticipated distribution of such foods. Upon request, FNS, AMS and FSA will provide information to FDA in a timely manner about how USDA Foods are procured and distributed by USDA.
- D. AMS and FSA will cooperate in obtaining samples for analysis by FDA of those FDA-regulated USDA Foods that FDA believes may pose a health risk. FDA will share the analytical results with affected USDA agencies in a timely manner.
- E. FDA will share with FNS, in a timely manner, information on FDA's investigations regarding foodborne illnesses linked to FDA-regulated USDA Foods. This information may influence whether a USDA procurement agency will place a hold on certain products, pending the analytical results described in D above, or other FDA scientific conclusions or determinations.
- F. When an FDA regulated food that also is a USDA Food is under FDA investigation, FNS will arrange, within 10 business days of notification of the investigation, discussions

between FDA and the affected USDA agencies to determine the course of the FDA investigation and findings. FDA will assist USDA in determining the most appropriate action to take to protect the health of the recipients of the USDA Food(s) in question.

- G. FDA and the appropriate USDA agencies will work cooperatively to develop communication strategies, including FDA press releases and stakeholder announcements, for potential references to USDA Foods.
- H. AMS and FSA will require all of their vendors to comply with all State and Federal guidelines.
- I. As requested by FDA, FNS, AMS, and FSA will assist FDA in conducting recall audits involving FDA-regulated USDA Foods.

IV. INFORMATION SHARING

The terms of this agreement shall include appropriate safeguards against unauthorized use and disclosure of the non-public information exchanged under this MOU. Pursuant to FFDCA section 301(j) [21 U.S.C. 331(j)], FDA will not reveal to FNS, AMS or FSA any method or process which is entitled to protection as a trade secret. FDA, FNS, AMS, and FSA shall establish appropriate safeguards to protect the confidentiality of the information and to prevent unauthorized access to the information provided by other Federal partners. While recognizing that the overall purpose of this MOU is to facilitate information sharing, any Federal partner may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request. See Process for Information Sharing under Appendix B.

Access to the information shared under this MOU shall be restricted to authorized FDA, FNS, AMS, and FSA employees and officials who require access to perform their official duties in accordance with the uses of the information as authorized by this MOU. Such personnel shall be advised of (1) the confidential nature of the information and (2) safeguards required to protect the information.

FDA, FNS, AMS, and FSA agree to promptly notify the other Federal partners of any actual or suspected unauthorized disclosure of information shared under this MOU.

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, it will refer the request to the information-sharing agency for it to respond directly to the requestor regarding whether the information can be released. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will be issued directly from the other agency.

V. LIMITATIONS

This MOU represents the broad outline of the Parties' intent to enter into specific agreements for collaborative efforts in areas of mutual interest to FDA, FNS, AMS, and FSA. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU. This MOU will be subject to the applicable statutes, regulations and policies affecting FDA, FNS, AMS, and FSA.

VI. LIAISON OFFICES AND CONTACTS FOR PARTIES

Recall Operations Staff,
Division of Compliance Management and Operations
Office of Enforcement
Office of Regulatory Affairs
Food and Drug Administration
10903 New Hampshire Avenue
BLDG 32, Room 4353
Silver Spring, MD 20993

Office of Crisis Management
Office of Emergency Operations
Food and Drug Administration
10903 New Hampshire Avenue
Bldg 32
Silver Spring, MD 20993
1-866-300-4374 (24 hours)

USDA FNS
U.S. Department of Agriculture
Food and Nutrition Service
Office of Food Safety
3101 Park Center Drive
Room 628
Alexandria, VA 22302

USDA AMS
U.S. Department of Agriculture
Agricultural Marketing Service
Fruit and Vegetable Programs

1400 Independence Ave., S.W.
Stop 2632
Washington, DC 20250-2632

USDA AMS
U.S. Department of Agriculture
Agricultural Marketing Service
Poultry Programs
1400 Independence Ave., S.W.
Stop 0256
Washington, DC 20250-0256

USDA AMS
U.S. Department of Agriculture
Agricultural Marketing Service
Livestock and Seed Programs
1400 Independence Ave., S.W.
Stop 0249
Washington, DC 20250-0249

USDA FSA
U.S. Department of Agriculture
Farm Service Agency
Deputy Administrator, Commodity Operations
Stop 0550
1400 Independence Ave., S.W.
Washington, DC 20250-0550

VII. EFFECTIVE DATE, DURATION, TERMINATION AND MODIFICATION

This MOU shall become effective upon signature of all Parties and will continue in effect for a period of five years. It will be evaluated after it has been in effect for one year, at which time the agencies agree to explore the feasibility of expanding cooperative activities. The MOU may be extended or modified by mutual written agreement of the Parties. The MOU may be terminated upon a 30-day advance notice by any of the Parties.

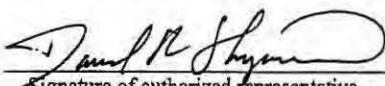
VIII. SIGNATURES OF RESPONSIBLE PARTIES

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By:  Date: September 16, 2011
Signature of authorized representative

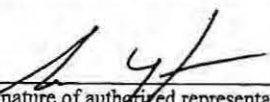
Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
DHHS Food and Drug Administration

APPROVED AND ACCEPTED FOR THE AGRICULTURAL MARKETING SERVICE

By:  Date: September 23, 2011
Signature of authorized representative

David R. Shipman
Acting Administrator
USDA Agricultural Marketing Service

APPROVED AND ACCEPTED FOR THE FOOD AND NUTRITION SERVICE

By:  Date: Sept 21, 2011
Signature of authorized representative

Audrey Rowe
Administrator
USDA Food and Nutrition Service

APPROVED AND ACCEPTED FOR THE FARM SERVICE AGENCY

By: Bruce Nelson Date: 9/29/11
Signature of authorized representative

Bruce Nelson
Administrator
USDA Farm Service Agency

APPENDIX A

List of Foods Procured by USDA Agencies

Additions and deletions to the list of USDA Foods purchased for use in USDA domestic nutrition assistance programs may be modified at any time without notice and shall not require a modification to this agreement. Please refer to the Agency website for a complete list of available products.

A. Agricultural Marketing Service, Group A Commodities

The AMS, Poultry Programs, Commodity Procurement Division acts as the purchasing agent for the following perishable foods that are distributed through FNS administered programs.

Commodity Procurement Division
Telephone: 202/720-4517
<http://www.ams.usda.gov/AMSV1.0/CommodityPurchasing>

Almonds
Canned and frozen apples, including juice
Canned and frozen apricots
Canned and frozen asparagus
Canned and dry beans
Canned and frozen green beans
Frozen blackberries
Dried and frozen blueberries
Canned, fresh and frozen carrots
Canned, frozen and dried cherries, including cherry/apple juice
Canned and frozen corn
Bottled corn syrup
Canned, frozen and dried cranberry products, including cranberry/apple juice
Dried dates
Dried fruit nut mix
Dried figs
Canned grape juice
Canned grapefruit juice
Canned mixed fruit
Canned mixed vegetables
Fresh oranges, including canned and concentrated orange juice
Canned and frozen peaches
Canned and fresh pears
Canned and frozen peas

Dried and canned plums
Canned, dehydrated, fresh and frozen potatoes
Canned pumpkin
Dried raisins
Frozen raspberries
Canned spinach
Frozen strawberries
Canned, fresh and frozen sweet potatoes
Canned and fresh tomato products, including juice
Canned vegetable soup
Walnuts
Fresh, frozen, cooked and canned beef products
Frozen, cooked and canned pork products
Frozen and canned bison products
Canned, frozen and pouch salmon products
Canned and pouch tuna products
Frozen and cooked catfish products
Frozen lamb products
Fresh, frozen and canned chicken products
Fresh, frozen and canned turkey products
Frozen geese products
Frozen egg products
Fresh Shell eggs
Bulk whole eggs
Dried egg mix

B. Farm Service Agency, Group B Commodities
The Domestic Procurement Division
Telephone: 816-926-6124
<http://www.fsa.usda.gov/FSA/webapp?area=home.&subject=coop&topic=pas>

Bakery Flour	Sunflower Seed Products
Bakery Mix	Rice Products
Corn Products	Vegetable Oil Products
Crackers	Bulk Cheddar Cheese
Fortified Ready-to-Eat Cereal	Mozzarella Cheese
Instant Rice Cereal	Process Cheese
Processed Cereals	Evaporated Milk
Macaroni & Cheese	Infant Formula
Pasta Products	Ultra High Temperature Milk
Wheat Flour	Instant Nonfat Dry Milk
Peanut Products	

APPENDIX B

Process for Information Sharing

While recognizing that the overall purpose of this MOU is to facilitate information sharing, pursuant to Section 4 of this MOU, any Federal partner may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request. Nothing in the process described below changes Section 4.

When, under the current MOU, staff at the FDA or the appropriate USDA agency request from the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, and need only identify the subject for which information is requested. Although a more specific description of the information requested may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

"Information that is shared under this request will be under the FDA-AMS-FSA-FNS Memorandum of Understanding. We agree not to disclose any shared information in any manner without your written permission or as required by law with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

"Pursuant to the FDA-AMS-FSA-FNS Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any manner without our express written consent or as required by law with advance notice to the originating agency." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.