

**U.S. Department of Agriculture
Food Safety and Inspection Service;
U.S. Department of Health and Human Services
U.S. Food and Drug Administration**

MATERIAL TRANSFER AGREEMENT

PARTIES:

FSIS: U.S. Department of Agriculture (USDA)
Food Safety and Inspection Service (FSIS)
Office of Public Health Science
Room 341-E, Whitten Bldg.
1400 Independence Ave, SW
Washington, DC 20250
Phone: (202) 720-2644
Fax: (202) 690-2980

FDA: U.S. Department of Health and Human Services (DHHS)
U.S. Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

PURPOSE:

This document details the procedure for the interagency exchange of biological materials, pathogens, toxins, genetic elements, chemicals and associated knowledge, hereinafter collectively referred to as the "MATERIAL" between U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services, Food and Drug Administration (FDA). Patented material and human materials may not be exchanged under this Material Transfer Agreement (MTA).

DEFINITIONS:

PROVIDER: Party providing the MATERIAL. The name and address of this party will be included in Template 1.

PROVIDER Contact Official: The name and address of the PROVIDER contact official will be included in template 1.

RECIPIENT: Party receiving the MATERIAL. The name and address of this party will be specified in Template 1.

RECIPIENT Scientist: The name and address of the RECIPIENT scientist who will receive the MATERIAL will be included in Template 1.

RECIPIENT Supervisor: The name and address of the RECIPIENT scientist's supervisor will be specified in Template 1.

THIRD PARTY: Organization (typically a university or state public health agency) receiving the MATERIAL from the RECIPIENT with approval from the PROVIDER.

MATERIAL: Biological materials, pathogens, toxins, genetic elements, chemicals and associated knowledge to be shared between Parties. The description of and anticipated use for the material to be transferred will be specified in Template 1.

GENERAL PROVISIONS:

The PROVIDER will release the MATERIAL to RECIPIENT under the following conditions:

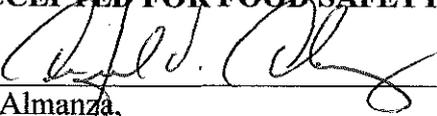
1. The MATERIAL shall be used only by RECIPIENT scientists supervised by the RECIPIENT supervisory scientist identified in Materials Transfer Agreement Template 1. Subsequent distribution may be authorized as specified below.
2. RECIPIENT scientist will send requests for MATERIAL to the PROVIDER contact official using Material Transfer Agreement Template 1: Request for Materials and Data Reporting Requirements.
3. PROVIDER and RECIPIENT shall specify data reporting expectations in Materials Transfer Agreement Template 1, Section B: Data Reporting Requirements in accordance with FSIS-FDA Materials Transfer Agreement (MTA).
4. PROVIDER will transfer the MATERIAL to RECIPIENT after the appropriate Material Transfer Agreement Template 1 is received and the PROVIDER internal documents are completed and approved.
 - a. Copies of the approved Template 1 shall be forwarded via email or fax to the originating RECIPIENT scientist and the RECIPIENT supervisor (as specified on Template 1).
 - b. The PROVIDER Contact Official has the prerogative, after consulting the appropriate scientific and/or administrative staff, to deny, delay, or alter the request as appropriate.
 - c. If the MATERIAL is not received within 14 days of request, the PROVIDER Contact Official will explain via electronic-mail to the RECIPIENT scientist and RECIPIENT supervisor why the MATERIAL cannot be shipped at this time.
 - d. One submitted and approved Materials Transfer Agreement Template 1 will suffice for ongoing requests for the same Material, not to exceed two years from approval date.
5. RECIPIENT will provide the PROVIDER Contact Official with a copy of any communication (e.g. manuscript, abstract and/or document) intended for release outside of the RECIPIENT or PROVIDER organizations that describes the work with the MATERIAL prior to submission for publication. RECIPIENT will acknowledge PROVIDER contribution to the work

(including acknowledgement of PROVIDER as the source of the MATERIAL). On joint FSIS-FDA projects, collaborative authorship is expected.

- a. Prior to the RECIPIENT'S submission of a paper and/or abstract for publication or any other form of public disclosure about data or results generated from the use of the MATERIAL, the PROVIDER will have thirty (30) days to review the proposed manuscript(s), abstract(s), etc.
 - b. If at the end of the review period, there is no comment from the PROVIDER, then the RECIPIENT will be free to publish or otherwise publicly disclose.
 - c. Unresolved disagreements between the PROVIDER's edits/requests and RECIPIENT's paper/abstract author will be resolved by an adhoc committee consisting of FDA Center-Level Leadership and appropriate FSIS Assistant Administrator(s).
6. RECIPIENT shall not transfer the MATERIAL, in whole or in part, to a THIRD PARTY without written consent from PROVIDER. RECIPIENT will use the Material Transfer Agreement Template 2: Request to Transfer Material to Third Party to request such approval from PROVIDER Contact Official.
- a. Copies of the approved Template 2 shall be forwarded via email or fax to the originating RECIPIENT scientist and the RECIPIENT supervisor (as specified on Template 1).
 - b. The PROVIDER Contact Official has the prerogative, after consulting the appropriate scientific and/or administrative staff, to deny, delay, or alter the request as appropriate.
 - c. If the request (Template 2) is not approved within 14 days of being received by PROVIDER, the PROVIDER Contact Official will explain via electronic-mail to the RECIPIENT scientist and RECIPIENT supervisor why the request cannot be approved at this time.
 - d. One submitted and approved Materials Transfer Agreement Template 2 will suffice for ongoing requests for the same Material, not to exceed two years from approval date.
7. When transferring the MATERIAL to a THIRD PARTY, RECIPIENT shall indicate that: 1) the source of the MATERIAL is the PROVIDER, 2) the MATERIAL shall remain the property of PROVIDER and 3) the MATERIAL shall not be used for commercial purposes without appropriate license(s) and/or agreement(s) from PROVIDER. Any THIRD PARTY Recipient of the MATERIAL shall use the same degree of care to protect Confidential or Proprietary Information received under this Agreement as it uses to protect its own information of a similar nature, but in any event not less than reasonable care under the circumstances.
8. If FSIS and FDA decide to engage in additional activities using the MATERIAL, these Agencies will develop a formal Interagency Agreement, Memorandum of Understanding, or other research agreement. Negotiation, execution, and administration of each such agreement must comply with all applicable statutes and regulations.
9. Upon completion of RECIPIENT's activities using the MATERIAL, RECIPIENT and THIRD PARTY shall return, destroy, or otherwise dispose of the MATERIAL as instructed by the PROVIDER.

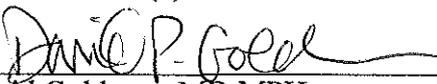
10. FDA and FSIS representative(s) shall meet to determine inventorship if an invention should arise during RECIPIENT's work with the MATERIAL.
11. FDA and FSIS shall exclude MATERIAL from the confidentiality requirements of this Agreement if: (1) RECIPIENT had possession of the MATERIAL prior to the PROVIDER providing the MATERIAL; (2) the MATERIAL is generally available to the public at the time of the PROVIDER provides the MATERIAL; (3) the MATERIAL becomes generally available to the public through no fault of RECIPIENT after PROVIDER provides the MATERIAL; or (4) after PROVIDER provides the MATERIAL, the RECIPIENT receives the MATERIAL from a third party having the right to the MATERIAL and who does not impose a confidentiality obligation upon the RECIPIENT.
12. This research MATERIAL is provided as a service to the research community. It is being supplied to the RECIPIENT with no warranties, expressed or implied, including any warranty of merchantability or fitness for a particular purpose. The PROVIDER makes no representation that the use of the research MATERIAL will not infringe any patent or proprietary rights of third parties.
13. FDA and FSIS acknowledge and agree to comply with all applicable laws, permits, and regulations including those of the USDA Animal and Plant Health Inspection Service, and the Centers for Disease Control and Prevention pertaining to possession, handling, shipment or transfer of technical information, biological materials, pathogens, toxins, genetic elements, genetically engineered microorganisms, vaccines, and similar agents. THE MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.
14. Nothing in this Material Transfer Agreement shall obligate either FDA or FSIS to obligate or transfer any funds.
15. This Material Transfer Agreement shall be construed in accordance with United States of America Federal Law as interpreted by the Federal Courts in the District of Columbia.
16. This Material Transfer Agreement shall become effective upon the date of the final signature and shall continue in effect for a period of five years. Either FDA or FSIS may terminate this Material Transfer Agreement with a 60-day written notice; however, its terms will remain in effect for any MATERIAL that has already been transferred for two years from the date of the transfer.

ACCEPTED FOR FOOD SAFETY AND INSPECTION SERVICE



Al Almanza,
Administrator, FSIS
1400 Independence Ave., SW
Washington, DC 20250-3700
202-720-7025 (o)

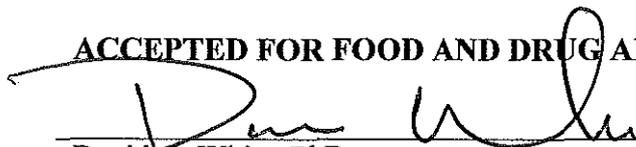
11/13/12
Date



David Goldman, MD MPH
Assistant Administrator, Office of Public Health Science, FSIS
Room 341-E, Whitten Bldg. 1400 Independence Ave, SW
Washington, DC 20250
202-720-2644 (o); 202-720-2644(m)
David.Goldman@fsis.usda.gov

11/7/12
Date

ACCEPTED FOR FOOD AND DRUG ADMINISTRATION



David G. White, PhD
Chief Scientist (Acting)
Office of Foods and Veterinary Medicine
MOD2 G101, HFV-500
8401 Muirkirk Road
Laurel, MD 20708
301-210-4187 (o); 240-475-3597 (m)

9/13/12
Date



Donald L. Zink, PhD
Senior Science Advisor
Center for Food Safety and Applied Nutrition
CPK1 RM4A004, HFS-006
5100 Paint Branch Parkway
College Park, MD 20740
240-402-1693 (o); 240-216-1456 (m)
Donald.Zink@fda.hhs.gov

9-6-12
Date



William B. Martin, PhD
Senior Advisor for Science (Acting)
Office of Regulatory Affairs
W031 Rm3542, HFC-1, 10903 New Hampshire Ave,
Silver Spring, MD 20993
301-796-8802 (o); 2400216-1456 (m)
William.Martin@fda.hhs.gov

9/18/12
Date

FSIS-FDA Materials Transfer Agreement (MTA) Template 1:
Request for Materials and Data Reporting Requirements

Request Date:

PROVIDER: Organization providing MATERIAL

Organization:

RECIPIENT: Organization receiving MATERIAL

Organization:

Section A: Request for Materials

Description of MATERIAL (type, quantity, frequency):

Description of project:

Purpose/Potential Impact:

Analyses to be performed:

Section B: Data Reporting Requirements

PROVIDER will provide RECIPIENT with the following:

Data Description:

Frequency of Data Transfer:

Data Format:

Transfer Procedures:

RECIPIENT will provide PROVIDER with the following:

Data Description:

Frequency of Data Transfer:

Data Format:

Transfer Procedures:

FSIS-FDA Materials Transfer Agreement (MTA) Template 1:
Request for Materials and Data Reporting Requirements

Section C: Contact Information and Signatures

PROVIDER scientist Information:

From: (Name of PROVIDER scientist)
(Lab Name)
(Address)
(Telephone: Number)
(Fax: Number)
(Email)

Through: (Name of PROVIDER supervisor*)
(Agency/Lab Unit)
(Lab Location)

Signature: _____ Date: _____

RECIPIENT Scientist Information:

From: (Name of RECIPIENT scientist)
(Lab Name)
(Address)
(Telephone: Number)
(Fax: Number)
(Email)

Through: (Name of RECIPIENT supervisor*)
(Agency/Lab Unit)
(Lab Location)

Signature: _____ Date: _____

* Supervisor = Branch Chief (FSIS) or Division Director (FDA)

FSIS-FDA Materials Transfer Agreement (MTA) Template 1:
Request for Materials and Data Reporting Requirements

Email scanned copy to appropriate Agency Coordinators:

FDA:

Contact Official

Center for Food Safety and Applied Nutrition

5100 Paint Branch Parkway

College Park, MD 20740

Contact Official

Center for Veterinary Medicine

8401 Muirkirk Road

Laurel, MD 20708

Contact official

Office of Regulatory Affairs

10903 New Hampshire Ave,

Silver Spring, MD 20993

FDA Internal Contract ID: _____

FDA Laboratory(ies) involved: _____

FSIS:

FSIS LQAD Branch Chief/Contact Official

Laboratory Quality Assurance Division

USDA FSIS OPHS

950 College Station Rd.

Athens, GA 30605

Internal References:

FSIS Internal Contract ID: R_____

FSIS Laboratory(ies) involved: _____

FSIS-FDA Materials Transfer Agreement (MTA) Template 2:
Request to Transfer Materials To Third Party Laboratory

Request Date:

PROVIDER: Organization providing MATERIAL

Organization:

RECIPIENT: Organization receiving MATERIAL

Organization:

OTHER LABORATORY: Organization receiving MATERIAL from RECIPIENT

Organization:

PROVIDER Information:

(Name of PROVIDER supervisor*)

(Agency/Lab Unit)

(Lab Location)

(Address)

(Telephone: Number)

(Fax: Number)

(Email)

Signature: _____ Date: _____

RECIPIENT Scientist Information:

(Name of RECIPIENT supervisor*)

(Agency/Lab Unit)

(Lab Location)

(Address)

(Telephone: Number)

(Fax: Number)

(Email)

Signature: _____ Date: _____

FSIS-FDA Materials Transfer Agreement (MTA) Template 2:
Request to Transfer Materials To Third Party Laboratory

Intended OTHER LABORATORY Recipient:

(Name of OTHER LABORATORY supervisor*)

(Agency/Lab Unit)

(Lab Location)

(Address)

(Telephone: Number)

(Fax: Number)

(Email)

Description of Materials:

Description of Other Laboratory project:

Other Laboratory Purpose:

Analyses to be performed by Other Laboratory:

* Supervisor = Branch Chief (FSIS), Division Director (FDA) or equivalent (Other Laboratory)

FSIS-FDA Materials Transfer Agreement (MTA) Template 2:
Request to Transfer Materials To Third Party Laboratory

Email scanned copy to appropriate Agency Coordinators:

FDA:

Contact Official

Center for Food Safety and Applied Nutrition

5100 Paint Branch Parkway

College Park, MD 20740

Contact Official

Center for Veterinary Medicine

8401 Muirkirk Road

Laurel, MD 20708

Contact official

Office of Regulatory Affairs

10903 New Hampshire Ave,

Silver Spring, MD 20993

FDA Internal Contract ID: _____

FDA Laboratory(ies) involved: _____

FSIS:

FSIS LQAD Branch Chief/Contact Official

Laboratory Quality Assurance Division

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950 College Station Rd.

Athens, GA 30605

Internal References:

FSIS Internal Contract ID: R_____

FSIS Laboratory(ies) involved: _____