United States Department of Agriculture
Research, Education, and Economics

ARS ■ CSREES ■ ERS ■ NASS

Policies and Procedures

Title: Transfer of Biological Agents and Related Information to Non-USDA Locations or Individuals

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This P&P describes new requirements on transfer of biological agents to non-USDA locations or individuals.

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Introduction

The purpose of this policy and procedure is to describe new security related requirements for the transfer of biological agents and related information to non-USDA locations or individuals.

World events since September 11, 2001, and recent requests from individuals, especially at foreign locations, asking ARS scientists to supply various biological materials, such as pathogens or related information, have necessitated greater controls on access and availability. This policy is not intended to impede, restrict, or prevent scientific exchange of products of ARS collections and research. Rather, it has been designed to exercise due diligence to be reasonably sure that our biological materials and related information are not accessible to terrorist or others who would misuse them. Scientific need should be the reason for transferring the biological material and/or related information. ARS should not distribute such items simply because they have been requested.

Authorities, References, and Organizations

- Authorities. All Code of Federal Regulation (CFR) citations can be accessed via the Internet at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

- Biosafety Levels, Risk Assessment, and Agent Summary Statements.

  Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition
  Published by the Office of Health and Biological Safety, Centers for Disease Control and Prevention (CDC)
  Stock number 0 17-040-00547-4 available from: U.S. Superintendent of Documents
  US. Govt. Printing Office Washington, D.C. 20402 202-275-3318

- Control List.

  7 CFR 330.200 Subpart M-Movement of Plant Pests Regulated; permits required;
  7 CFR 331, Possession, Use, and Transfer of Biological Agents and Toxins.

  USDA, APHIS
  Plant Protection and Quarantine
  4700 River Road, Unit 133
  Riverdale, Maryland USA 20237-1236
  http://www.aphis.USDA.gov/ppq/permits

9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins; 9 CFR 122,

APHIS Veterinary Services, National Center for Import and Export.
USDA, APHIS
Veterinary Services, National Center for Imports and Exports, Products Program
4700 River Road, Unit 40
Riverdale, Maryland USA 20737-3277
http://www.aphis.USDA.gov/OA/imexdir.html

42 CFR 73, Possession, Use and Transfer of Select Agents and Toxins

U.S. Department of Health and Human Services
Office of Health and Safety, Center for Disease Control & Prevention
1600 Clifton Road, N.E.
Atlanta, GA 30333
http://www.cdc.gov/sa

29 CFR 1910.1030

Export Advisory Act of 1999
Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Agricultural Bioterrorism Protection Act of 2002

15 CFR 742,744, and 774, Department of Commerce (DOC) Control Policy and Commerce**.**

2. Statement of Policy

This policy sets forth the requirements for the transfer of any biological agent (see definition in Glossary) or biological toxin and/or related information, to a non-ARS facility or person. This policy does not apply to the transfer of plant or animal germplasm, Biosafety Level (BSL)-1 agents, and certain other exemptions listed listed below. There must be line management approval such as the (Area Director, Center Director, Location Leader, Research Leader) for all other transfers of biological agents and related information. ARS scientists are expected to be knowledgeable regarding the proper procedures to follow for shipment of dangerous goods (Select Agents, biological agents, pathogens and biological information) and each location or appropriate subunit must have a certified shipper.

An ARS scientist should not respond to requests for biological agents and/or related information from unknown parties, without following the procedure given below The ARS scientists must have prior professional or personal familiarity of the requesting party or organization. Personal knowledge of the use that will be made of the biological agent and or relevant information is also required.

Casual contact with a previously unknown individual, for example at a meeting, or an unsolicited request does not meet that requirement. All request from unknown parties should be sent to the Area Director for further review by the National Program Staff (NPS) and ARS Homeland Security (ARSHS).

Ban on Shipments.

Under no circumstances does this policy allow any biological agents and/or related information to be shipped to countries, or individuals from countries, on the Department of State (DOS) List of Countries that Sponsor Terrorism, http://www.state.gov/s/ct/rls/pgtrpt/2000/2441.htm. There are no exceptions to this ban.

Transfer of Select Agents (BSL-2 or BSL-3), BSL-3 Agents that are Not Select Agents, and/or Related Information.

Transfer of 1) any BSL-3 agent, regardless of whether or not it is a Select Agent or toxins, and 2) any BSL-2 Select Agents or toxin, and/or related information, to non-USDA locations or individuals requires written permission from 1) the AD, 2) NPS, and 3) ARSHS. These permissions include agent tracking requirements and other administrative controls. In addition to requirements set forth in this policy, shipment transfer of any Select Agents must adhere to the requirements of the Select Agent Act as detailed for APHIS agents in 7 CFR 331.3 and 9 CFR 121.3 and CDC agents at 42 CFR 73. Select Agent transfer regulations also require tracking and additional administrative controls beyond those listed in this policy. Select Agent Ttransfers should be completed through the Responsible Official at the registered Select Agent location.

Transfer of non-Select Agent BSL-2 Agents and/or Related Information.

Transfer of non-Select Agent BSL-2 biological agents and/or related information only requires

written approval of the Area Director (AD).

Variation in Policy.

The above approvals from line and program management are not needed if a formal agreement is in place that addresses the transfer of the biological agent and/or related information. A Blanket Authorization also covers repeated transfers of such materials.

If the transfer involves biological agents and/or related information that requires an OTT related agreement, such as an MTA, then the scientist must consult their Area Technology Transfer Coordinator (TTC).

The policy described in this document may be modified, on a case by case basis, to accommodate unusual circumstances with the joint recommendation of the AD, NPS, and ARSHS, and approval of the Associate Administrator or Administrator of ARS. When in doubt, input may be sought from line management, Area, NPS, or ARSHS as needed.

Exceptions to this Policy.

This P&P is not intended to address the following:

- Public Information. Information that is available to the public such as publications, information on the web, and public presentations is excluded.
- Intellectual Property Rights (IPR). The broad area of IPR is addressed as a separate issue by OTT in P&P Technology Transfer number 141.2-ARS, dated 9-11-2000.
- Germplasm. This P&P does not apply to plant and animal germplasm.

- BSL-1 Pathogens. This P & P does not apply to BSL-1 agents because of their low virulence, wide distribution in nature, and general broad availability from multiple sources.

- Transfers within USDA. The requirements described in this P&P do not apply to transfers of biological agents and/or relevant information within USDA, but assume that all requirements such as Select Agent regulations and dangerous goods shipping requirements are met. Also, the AD and NPS must concur, in writing, and so inform ARSHS, that there is a programmatic justification for the transfer of the BSL-3 or Select Agents or biological materials to an ARS laboratory not previously possessing them. The receiving USDA laboratory must then follow the procedures in the P&P before transferring the material to an outside party.

- E-mails or other correspondence of a general nature on pathogens that does **NOT** involve infromation on infectivity, pathogenicity, growth, culture, diagnostics, and similar areas.

3. Summary of Responsibilities

ARS Homeland Security Office

- Along with the AD and NPS, approves the transfer of BSL-3 and Select Agents and/or related information by ARS scientists.

- Verifies legitimacy of requestor if institution or individual is not known by the requesting scientist.

- Maintains a database on such shipments. Works with ADs and NPS to resolve HS issues concerning shipment of biological agents and/or related information.

Area Director

- Approve the transfer of BSL-2 non-Select Agents and/or related information. Is responsible for establishing an Area record system for such transfers. This should include at the minimum, the biological agent and/or related information, the recipient, their affiliation, the proposed use of the agent/information copies of any required documents including MTAs and Export Control Licenses or waivers, and any other pertinent facts.

- For BSL-3 pathogens and all Select Agents, the AD obtains additional approvals from NPS and ARSHS. Provides information described above to ARSHS. This may be done by hard copy, fax, or e-mail. A copy of an MTA also meets this requirement. Copies of documents and permits will be retained at the Area, but are subject to verification by ARSHS on request.

National Program Staff

- Along with the AD and ARSHS, approves the transfer of BSL-3 and Select Agent, biological agents and/or related information. Determines, in consultation with the AD, that the transfer of biological agent and/or related knowledge fits the programmatic needs and/or mission of the ARS laboratory and the Agency.

Research Leader (RL) and Location Leader/Center Director, (if applicable)

- Makes sure that all needed information and permits are collected and passed to the AD. Recommends approval or disapproval of request to transfer agents or information.

Technology Transfer Coordinator (TTC)

- The TTC responsible for the Area where the ARS scientist is located will assist the scientist in preparing and finalizing an MTA if needed.

- The TTC will, with the help of the scientist, obtain a DOC Export Control License or waiver, if needed.

ARS Scientist

- Submits request to transfer the biological agent and/or related information to the AD through RL and LL/CD.

- Upon approval provides needed information to ship biological agents to an ARS certified shipper.

- Obtains necessary forms and permits from APHIS/CDC, and DOC as needed for shipping. The TTC responsible for the Area where the ARS scientist is located will assist the scientist in preparing and finalizing an MTA if needed.

- **DOES NOT** ship biological agents and/or related information until the appropriate approvals including proper shipping documents are obtained. Should advise the recipient of th expected level of actions to keep the material secure.

4. Glossary

Agreement - Formal. A document signed by an Authorized Departmental Officer on behalf of ARS, and a Responsible Individual of one or more organizations outside of ARS. For the purpose of this P&P, the agreement must address the need for ARS to transfer biological agents and/or related information to another party, the purpose for which they will be used, and any handling or disposal restrictions. The agreement should also include, as appropriate, restrictions on: 1) transfer of the material to a third party; 2) intellectual property rights; and 3) non-commercialization. Examples of such agreements are a CRADA, Cooperative Research Agreement, MOA, MOU, RSA, SCA, contract, or grant. If the above provisions are in the formal agreement, then a separate MTA will not be required for any shipments of biological agents or knowledge. However, an Export Control License or waiver may be required by DOC (see below).

ARS. Agricultural Research Service.

ARSHS. ARS Office of Homeland Security.

APHIS. Animal and Plant Health Inspection Service.

AD. Area Director.

Biological Agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or biological toxin, or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant or a another living organism or deterioration of food, water, equipment, supplies, or material of any kind;
or;
(2) Deleterious alteration of the environment.

BSL. BioSafety Level. A combination of work practices and physical containment requirements designed to reduce the risk of laboratory infection when working with infectious material. The degree of protection recommended is proportional to the risk associated with an agent. There are four biosafety levels**.** For agriculture there is an additional concern with environmental protection. Thus for agriculture a risk assessment takes into account the potential for an agent to escape and infect other animals or plants in the facility or surrounding environment and the economic or trade consequences.

Factors to be considered in the placement of an agent in a risk group or at a biosafety level may include; virulence, pathogenicity, communicability, studies to be conducted, endemicity, and available vaccine or therapy.

BSL-1. For very low risk microbes. The level contains well characterized agents not known to cause disease in healthy humans, plants or animals so of minimal potential risk to laboratory personnel and the environment.

BSL-2. For agents of moderate potential hazard to people or animals, that are generally found in the community, cause mild illness, and are treatable or preventable. Most research and diagnostic labs are at this level.

BSL-3. Agents placed at this level may be indigenous or exotic agents with a potential for aerosol transmission, and which may cause serious and potentially lethal infections or grave economic consequences if released. BSL-3 practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, research, or production facilities in which work is done with these agents. Precautions include inward directional airflow, separation from non-laboratory areas, and special laboratory protective clothing.

BSL-3-Agriculture (BSL-3-Ag). For agricultural pathogens special requirements for environmental protection at this level have been set forth. Agents at this level have the potential to cause economic and trade problems in crops or animals. Therefore, BSL-3-Ag criteria enhance containment described for BSL-3 by adding filtration of supply and exhaust air, sewage decontamination, exit personnel showers, and facility integrity testing.

BSL-4. These are dangerous and exotic agents that pose high individual risk of life threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or treatment. While there is no BSL-4 requirement for solely agricultural agents, recently two viruses have been discovered that are highly lethal for agricultural species and for humans (Nipah and Hendra viruses), and these can only be manipulated at laboratories having BSL-4 capability. Less than 20 viruses are currently designated at this level.

Blanket Authorization. When a scientist identifies a colleague to whom regular shipments of covered materials are shipped he/she may request a blanket authorization for shipment of identified materials by procedures described herein.

CDC. Centers for Disease Control and Prevention, Federal Agency under HHS.

Certified Shipper. In accordance with 49 CFR, personnel involved in the preparation of shipping parcels, transportation, receipt, or other handling of dangerous goods in relation to shipment must attend and receive certification in training.

CFR. Code of Federal Regulations.

CRADA. Cooperative Research and Development Agreement.

DOC. Department of Commerce.

DOS. Department of State.

EAR. Export Administration Regulations.

Export Control License. The release of information to persons in foreign countries, on the replication, production, or isolation of materials covered by EAR99 (Export Advisory Act 99) that is not in the public domain or being put in the public domain, require an Export Control License or waiver from DOC. A similar release to a foreign national residing in the U.S. may require a Deemed Export Control License or a waiver from DOC. The TTC of OTT who is assigned responsibility for the Area where the ARS scientist is located will assist, provide guidance, and obtain the Export Control License or waiver.

HHS. U.S. Department of Health and Human Services.

Information-Related. Knowledge about, or related to, a biological agent either written or verbal. This may include plans, protocols, or directions that permit or enhance use of the biological agent or improper purposes. The guide provided by the OCIO on web content gives a general idea of what should be restricted.

Material Transfer Agreement (MTA). A formal document used to define the nature, use, recipient, and other information, related to shipping a biological agent, and/or related information. The MTA for this purpose has been slightly modified from standard MTA used by OTT to protect intellectual property rights and commercialization of ARS Technology. The TTC of OTT who is assigned responsibility for the Area where the ARS scientist is located will assist, provide guidance, and obtain the Export Control License or waiver. The MTA and associated regulatory documents must be completed and signed by all parties before the biological agent is shipped

MTA. Material Transfer Agreement.

MOA. Memorandum of Agreement.

MOU. Memorandum of Understanding.

NPS. National Program Staff.

OCIO. Office of the Chief Information Officer.

OTT. Office of Technology Transfer

RL. Research Leader.

RSA. Research Support Agreement.

SCA. Specific Cooperative Agreement.

Select Agent. In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PUB.L.107-188) HHS and USDA have established a Select Agent listing of biological agents and toxins and established regulations and requirements for handling these agents. Select Agents, which are human pathogens, are handled according to USPHS requirements. Agricultural Select Agents are handled according to APHIS requirements. Agricultural Select Agents are defined by the Secretary under the authority of the Agricultural Bioterrorism Protection Act of 2002, which is a subtitle of the Public Health Security and Bioterrorism Preparedness and Response Act. Some Select Agents are not restricted to the USDA but are found on both lists (Overlap Agents) - *Bacillus anthracis* is an example. A list of Select Agents can be found in 7CFR 331.3 for plant biological agents and toxins, 9 CFR 121.3 for animal biological agents and toxins, and 42 CFR 73 for human biological agents.

TTC. Technology Transfer Coordinator.

USDA. U.S. Department of Agriculture