Guidance Document for Completing the Application for Permit to Import Biological Agents into the United States

Please review this guidance document in its entirety before completing and submitting your application to the CDC Import Permit Program (IPP). If you are faxing or emailing your application, *there is no need to send in the original by mail*.

IMPORTANT NOTE: If the material being imported has been rendered sterile (e.g., thermal, chemical, or irradiation treatment) or it has been confirmed not to contain infectious agents for humans, then a CDC issued import permit is not required for importation.

Other examples of material that ***does not*** require a CDC issued import permit include:

- Select agents listed in 42 CFR Part 73 if its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.
- Diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent and is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious.
- Animal or animal product being imported for educational, exhibition, or scientific purposes and is accompanied by documentation confirming that the animal or animal product is not known to contain (or suspected of containing) an infectious biological agent or has been rendered noninfectious.
- Nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.
- Animal or animal product listed in 42 CFR Part 71 if its importation has been authorized in accordance with 42 CFR §§ 71.52, 71.53, or 71.56.
- Product that is cleared, approved, licensed, or otherwise authorized under any of the following laws:
    - The Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), or
    - Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. § 262), or
    - The Virus-Serum-Toxin Act (21 U.S.C. §§ 151-159).

Please Note: The CDC requires that importers of materials that do not require a CDC import permit, include with the shipment an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious.

Table of Contents

Section A - Person Requesting Permit in U.S. (Permittee)

Since all communication with the CDC IPP is completed through the Permittee, it is imperative that the Permittee and the Secondary Contact's information be complete, current and accurate. If any of the *Section A* information changes, you must immediately report the change(s) to the Program by submitting a new Import Permit application amending the current contact information (i.e., fax or phone number). The IPP does not accept verbal change requests.

Blocks 1-3- Permittee's Name

- Please provide the full name of the applicant.
  - For the purposes of completing the Application for Permit to Import Infectious Biological Agents into the United States, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Block 4- Permittee's Organization

- Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Blocks 5-8- Physical Address

- Please provide the complete business address of the individual listed in Blocks 1-3.
- Do not use a Post Office Box address.

Block 9- Telephone Number

- Please provide the direct dial 10-digit telephone number for the Permittee listed in Blocks 1-3; include an extension if applicable.

Block 10- Fax Number

- Please provide the 10-digit facsimile number for the Permittee listed in Blocks 1-3.

Block 11- E-mail Address

- Please provide the e-mail address for the Permittee listed in Blocks 1-3.
- Please print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net)

Block 12- Secondary Contact's Name

- Please provide the full name of the secondary contact.
  - For the purposes of completing the Application for Permit to Import Infectious Biological Agents into the United States, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Block 13- Secondary Contact's Telephone Number

- Please provide the direct dial 10-digit telephone number for the Secondary Contact; include an extension if applicable.

Block 14- Secondary Contact's Email

- Please provide the e-mail address for the Secondary Contact.
- Please print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net)

Block 15- Courier

- Will the Permittee listed in Blocks 1-3 be the courier of the imported biological Agent(s) or Vector(s)? Check Yes or No.

Blocks 16-17- Other Authorized Individuals

- If there are other members of your organization who will be authorized to use the approved permit select "Yes", check the box in Block 17, and list all additional authorized users on the CDC Form 0.753. A continuation form is available at http://www.cdc.gov/od/eaipp/importApplication/.
  - Please include all required information (*Blocks 1-15* of Section A Continuation Form) for each additional authorized user.
- Otherwise select "No".

Section B - Sender of Imported Infectious Biological Agent(s) or Vector(s)

The CDC import permit is for material being imported into the United States (U.S.). In addition to any State, the "United States" includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands of the United States, and any other territory or possession of the United States.

Blocks 1-3- Sender's Name

- Please provide the full name of the sender.
  - For the purposes of completing the application for Permit to Import Infectious Biological Agents into the United States, the term "full name" refers to an

individual's first name, middle initial(s), and last name or surname, without use of nicknames.

- If the sender is also the person requesting the permit, please check the box labeled "Check if same as Sec A" and complete Blocks 4-12 only if this information differs from Section A, Blocks 4-11.

Block 4- Sender's Organization

- Please provide the complete name of the entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Blocks 5-7- Physical Address

- Please provide the complete address of the organization.
- Do not use a Post Office Box address.

Block 8- Country

- Please provide the unabbreviated country name.

Block 9- Postal Code

- Please provide the complete Postal Code.

Block 10- Telephone Number

- Please provide the direct dial telephone number for the sender listed in Section B, Blocks 1-3; include the appropriate international prefixes and an extension if applicable.

Block 11- Fax Number

- Please provide the facsimile number for the sender listed in Section B, Blocks 1-3, if known.

Block 12- Email Address

- Please provide the email address for the sender listed in Section B, Blocks 1-3, if known.
- Please print or type clearly and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net)

Block 13- Additional Senders

- If the infectious biological agent(s) or vector(s) are coming from more than one sender, please check the box in Block 13 and list all additional senders on the CDC Form 0.753 EAIPP Continuation form available at http://www.cdc.gov/od/eaipp/importApplication/.
    - Please include all required information (*Blocks 1-12 of Section B Continuation Form*) for each additional sender.

Section C - Shipment Information

Block 1- Method of Shipment

- Please select only one method of shipment.
  - **Commercial Carrier**, select if the biological agent(s) or vector(s) to be imported will be transported using a common commercial carrier such as FedEx or World Courier.
  - **Hand-carried**, select if the biological agent(s) or vector(s) to be imported will be transported into the United States under the control of an individual authorized under the issued permit.

PLEASE NOTE: Hand carrying material into the United States is subject to International Air Transport Association (IATA) regulations and will not be permitted on commercial flights. Please check the IATA website for more information.

Block 2- Number of Shipments

- Please select "single" or "multiple" shipments.
  - **Single shipment**, select if one shipment of material will be imported into the U.S. under the issued permit.
  - **Multiple shipments**, select if more than one shipment of material imported into the U.S. is anticipated. For multiple importations, check box and indicate the number of estimated shipments.

Block 3- Shipment Temperature

- Please select the shipment temperature(s) required for the biological agent(s). Check all that apply.
  - **Ambient**, shipped under surrounding temperature conditions (i.e., no temperature control).
  - **Frozen/Refrigerated**, shipped under refrigerated or frozen conditions (i.e., wet ice, dry ice, cold packs).

Block 4- Anticipated U.S. Port(s) of Entry

- List the port(s) of entry where the biological agent(s) or vector(s) are expected to enter into the U.S.
  - A "U.S. Port of Entry" means one of the 329 official ports of entry designated by the U.S. Customs and Border Protection (CBP). Further information is available at http://www.cbp.gov/xp/cgov/toolbox/contacts/ports/.
  - If unknown, please type "unknown" in this section.

Section D - Final Destination of Imported Infectious Biological Agent(s) or Vector(s)

Complete this section only if the final destination differs from the address listed in Section A.

Block 1- Final Destination Address

- If the final destination of the biological agents is the same address listed in Section A select “No” and do not complete Blocks 2-13 of Section D and continue to Section E.
- Otherwise select “Yes” and complete Blocks 2-13.

Blocks 2-4- Name of Recipient at Destination

- Please provide the full name of the Recipient.
  - For the purposes of completing the application for Permit to Import or Transport Infectious Biological Agents into the United States, the term “full name” refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Block 5- Destination Organization

- Please provide the complete name of the entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Blocks 6-9- Final Destination Address

- Please provide the complete address for the final destination of the imported biological agent(s) or vector(s).
- Do not use a Post Office Box address.
- Zip Code, it is only necessary to provide the five-digit Zip code.

Block 10- Telephone Number

- Please provide the direct dial 10-digit telephone number for the recipient listed in Blocks 2-4 of Section D; include an extension if applicable.

Block 11- FAX Number

- Please provide the 10-digit facsimile number for the individual listed in Blocks 2-4 of Section D.

Block 12- Email Address

- Please provide the email address for the recipient listed in Blocks 2-4 of Section D.
- Please print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net)

Block 13- Additional Final Destinations

- If the biological agent(s) or vector(s) will be transferred to more than one final destination, please check the box in Block 13 and list all additional final destinations on the CDC Form 0.753 Continuation form available at http://www.cdc.gov/od/eaipp/importApplication/.
    - Please include all required information (*Blocks 1-11* of Section D Continuation Form), (*Blocks 1-2* of Section E) and (*Blocks 1-4* of Section G) for each final destination.

Section E - Description of Infectious Biological Agent(s)

This section should contain the information describing the biological agent(s) to be imported and the intended use of the agent(s). Any incomplete or illegible entries will result in delay or denial of your application. If the biological agent(s) being imported has been rendered sterile (e.g., thermal, chemical, or irradiation treatment) or has been confirmed not to contain infectious agents for humans, then a permit is not required for importation.

Block 1- Intended Use(s) of Imported Agent(s)

- When completing Block 1, please refer to the definitions listed below for indicating the intended use(s) of the agent being imported:
    - **Diagnostic:** Clinical/laboratory testing to identify a particular biological agent, disease, and/or characteristic of the agent/disease.
    - **Research:** Basic or applied scientific investigation and/or experimentation following a defined protocol and other standards for research projects that is intended to advance scientific knowledge and/or to explore scientific theories/hypotheses.
    - **Clinical trials:** Controlled studies to evaluate the effects, safety, and efficacy of a drug, vaccine, medical device, or therapy protocol.
    - **Education:** Teaching of a defined educational program or part of an educational display by a non-profit, commercial, or sole proprietor institution.
    - **Production:** Activities related to the processing of the imported biological agent(s) as a raw material into semi finished or finished goods.
    - **Other:** Any other previously undefined intended use of the material/biological agent(s) that does not fall under one of the five types listed above. If “Other” is selected, please provide a detailed description.

Block 2- Detailed Description of Work Objectives

- Please clearly and thoroughly describe the objectives of the work intended for the biological agents being imported (e.g., pharmaceutical/clinical trials testing, susceptibility testing, recombinant DNA work, etc.)
- Also, ensure to include information regarding the background, purpose, objectives and methods of your intended work with the imported biological agent(s).

- *Example:* We intend to test the susceptibility of *Staphylococcus aureus* as part of a new clinical trial using drug susceptibility plating and PCR testing.

Block 3- Additional Agents

- If additional biological agents will be imported, please check the box in Block 3 and list all additional biological agents on the CDC Form 0.753 Continuation form available at http://www.cdc.gov/od/eaipp/importApplication/.
    - Please include all required information (*Blocks 4-9* of Section E Continuation Form).

Block 4- Scientific Name of Known/Suspected Biological Agent(s)

- Please list the complete (unabbreviated) taxonomic genus and species names or the common name of the known/suspected biological agent(s) to be imported.
    - *Examples*: *Plasmodium falciparum*, *Escherichia coli*, Human Immunodeficiency Virus
- Please do not list the disease. (For example: Do not list "Cholera", list "*Vibrio cholera*.")

Block 5- Strain Designation

- For purposes of completing the application for Permit to Import or Transport Infectious Biological Agents into the United States, a strain is defined as a group of organisms of the same species, sharing certain hereditary characteristics not typical of the entire species but minor enough not to warrant classification as a separate breed or variety (e.g., Sterne strain of *Bacillus anthracis*).
- If the strain is unknown or undetermined to date, please enter "N/A" in the strain column.

Block 6- Location

- Complete this column for any buildings and suites/rooms that will be used for working or storing the imported material.
- Enter only one building for each row entry.
- It is acceptable to enter more than one room in a single row entry.

Block 7- Laboratory or Storage

- Select laboratory or storage (or both) for each building/room designation.
- For buildings/rooms that are only used for storing and not actively working with infectious agents, leave the "Lab" column blank and enter "Storage" in the column.

Block 8- Laboratory Safety Level

- Please indicate the biosafety level (e.g. BSL-2, BSL-3) of the laboratory(s) where the work with the imported agent(s) will occur. Descriptions of laboratory biosafety levels are published in the *Biosafety in Microbiological and Biomedical Laboratories, 5th*

Edition (BMBL). The current version of the BMBL is available at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm.

Block 9- Person Responsible for Laboratory

- Please provide the full name of the person responsible for the laboratory or storage area.
    - Examples include: Biosafety Officer, Principal Investigator, etc.

Section F - Description of Material(s) Containing the Infectious Biological Agent(s) or Vector(s) to be Imported

This section should contain the information describing the material or vector(s) containing the biological agent(s) to be imported and its origins. Any incomplete or illegible entries will result in delay or denial of your application. If the biological agent(s) contained in the material or vector(s) being imported has been rendered sterile (e.g., radiation or chemical treatment) or has been confirmed not to contain infectious agents for humans, then a permit is not required for importation.

Block 1- Source of Material(s) Being Imported

- When completing Block 1, please refer to the definitions listed below for indicating the source of the material being imported:
    - **Infected or suspected infected human:** Material collected/obtained from a living or deceased human being that is known or suspected to contain one or more disease-causing biological agents
        - *Examples*: Infected sputum sample known to contain *Mycobacterium tuberculosis*.
    - **Infected or suspected infected vector:** Material collected/obtained from a living or deceased animal (including insects) or thing which conveys or is capable of conveying biological agents from a person or animal to another person or animal that is known or suspected to contain one or more disease-causing biological agents.
        - *Examples*: Culex mosquitoes (*Culex quinquefasciatus*) known to contain West Nile Virus.
    - **Environment:** Material collected/obtained from natural surroundings that are known or suspected to contain one or more disease-causing biological agents.
        - *Examples*: Soil, ground/surface water, sediment, effluent suspected to contain a biological organism capable of causing disease in humans.
    - **Other:** Any other previously undefined material source that does not fall under one of the four types listed above. If “Other” is selected, please provide a detailed description.

Block 2- Description of Material(s) Containing Biological Agent(s)

- When completing Block 2, please refer to the definitions listed below for indicating the description of the material containing the biological agent being imported:
    - **Field-collected specimen:** Infectious material or specimens gathered in a natural setting other than research facility, laboratory, hospital, etc.
        - *Examples*: Soil sample suspected to contain a biological organism capable of causing disease in humans.
    - **Laboratory Isolate/culture:** Biological agent streaked onto or placed in a medium to obtain an independent isolate or purified culture that contains a microorganism.
        - *Examples*: Agar plate containing bacterial growth
    - **Blood/Blood products:** Whole blood or the constituents of whole blood such as plasma or platelets.
        - *Examples*: Blood sample drawn from infected patient
    - **Other Body Fluids:** A natural bodily fluid or secretion of fluid such as lymph, urine or saliva.
        - *Examples*: Sputum sample from infected patient
    - **Tissues/organs:** Unsterilized material of animal or human origin known or suspected of containing a biological organism capable of causing disease in humans.
        - *Examples*: Muscle tissue, lung, skin biopsy suspected of containing a biological organism capable of causing disease in humans.
    - **Body parts:** Unsterilized specimens of animal or human origin known or suspected of containing a biological organism capable of causing disease in humans.
        - *Examples*: head, arm suspected of containing a biological organism capable of causing disease in humans or body parts that have not been embalmed.
    - **Vector:** Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.
        - *Examples*: Mosquitoes suspected of containing a biological organism capable of causing disease in humans.
    - **Other:** Anything containing infectious material or microorganisms capable of causing disease, and/or death or other biological malfunction in humans.
        - *Examples*: Compost, cell lines, biosolids
- Please include a detailed written description of the material being imported.

Block 3- Fetal Calf Serum or Bovine Serum Albumin

- If the material contains any amount of fetal calf serum or bovine serum albumin, please select “Yes”, otherwise select “No”.
    - Please be reminded that any material containing fetal calf serum or bovine serum albumin may require a permit from the U.S. Department of Agriculture, http://www.aphis.usda.gov/permits/.

Section G - Biosafety Measures

This section should contain the information describing the receiving laboratory’s capabilities and protocols. Any incomplete or illegible entries will result in delay or denial of your application.

Block 1- Primary Containment to be Used

- Please select the primary containment measure(s) to be used for working safely with the imported agent(s). Refer to the table listed below and the *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* (BMBL) for more information on the types of biosafety cabinets and fume hoods at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf.
    - For any biological agent that will require the use of a high-containment facility (ABSL-3/BSL-3 or ABSL-4/BSL-4) or that poses an aerosol risk, please provide a detailed, written description of the primary containment measures to be used.
    - If the information provided is inadequate or incomplete, you may be asked to provide additional information regarding the primary containment measure(s) utilized at your facility.

Biological Risk Assessed	Protection Provided			BSC Class
	Personnel	Product	Environmental	
BSL 1-3	Yes	No	Yes	I
BSL 1-3	Yes	Yes	Yes	II (A1, A2, B1, B2)
BSL 4	Yes	Yes	Yes	III; II–When used in suit room with suit

Source: *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* (BMBL)

Block 2- Personal Protective Measures to be Used

- Please select the personal protective measure(s) to be used for working safely with the imported agent(s).
    - For any biological agent that will require the use of a high-containment facility (ABSL-3/BSL-3 or ABSL-4/BSL-4) or that poses an aerosol risk, please provide a detailed, written description of the personnel protective measures to be used.
    - If the information provided is inadequate or incomplete, you may be asked to provide additional information regarding the personal protective measure(s) utilized at your facility.

Block 3- Personnel Training Provided

- When completing Block 3, please refer to the statements listed below for indicating the personnel training provided to the individuals that will be handling the imported agent(s). *Please check all that apply*.
    - **Risk(s) associated with the imported biological agent(s):** Personnel have received training regarding the hazardous characteristics of the known or suspected biological agents or material, the activities that can result in a person's exposure to the known/suspected agents, the likelihood that such an exposure will cause a Laboratory Acquired Infection (LAI), and the probable consequences of such an infection.
    - **Hazardous Material Packing/Shipping:** Personnel have received training on how to correctly package, mark, label, and document hazardous biological material shipments in accordance with U.S. Department of Transportation regulations and International Air Transport Association (IATA) requirements.
    - **Laboratory Standard Practices:** Personnel have received training on how to safely handle, manipulate, and store the imported biological agent(s) to control the hazards associated with the agent(s) and to prevent direct and/or indirect exposure to the agent (e.g. agent and/or procedure specific Standard Operating Procedures, operation of containment/safety equipment, correct use of personal protective equipment, facility safeguards).
    - **Hazardous Waste Handling/Disposal:** Personnel have received training on the principles of and procedures for biological agent decontamination, sterilization, disinfection, waste handling, and waste disposal specific to the imported agent(s) to prevent injury, minimize personal and environmental health hazards.
    - **Emergency Response Procedures:** Personnel have received training on the appropriate response procedures that are specific for the hazards associated with the imported biological agent(s) and the necessary actions to contain the agent(s) in the event of an incident. Training should address response procedures for severe weather/natural disasters, workplace violence, bomb threats, suspicious packages, fire, gas leak, explosion, flood, power outage, etc.
    - **Spill Procedures:** Personnel have received training on the appropriate spill response and clean-up procedures based upon the physical characteristics and volume of the agent(s)/materials being handled, their infective potential, the damage potential for releases to the environment, and the location of the spill.
    - **Other:** Any other personnel training provided that does not fall under one of the six categories listed above. If "Other" is selected, please provide a detailed description.

Block 4- Implementation of Biosafety Measures

- If the Permittee has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use, check “Yes”. If not, check “No”

PLEASE NOTE: The Permittee may be required to provide additional information (e.g. Biosafety Plan, SOP, etc.) to confirm implementation of the proper biosafety measures.

Block 5- Anticipated disposition of Biological Agent(s) (and material containing it) when work is completed

- When completing Block 5, please refer to the definitions listed below for indicating the final disposition of the material being imported:
    - **Retained:** Retaining material onsite for an extended period of time (e.g. greater than 30 days or retaining material after completion of the project for which it was used).
    - **Transferred:** Relocation of material to another facility. This address must be listed in *Section D*.
    - **Destroyed:** Indicate the method of destruction by checking the appropriate box in Block 6.

Block 6- Method(s) of Destruction

- When completing Block 6, please refer to the definitions listed below for indicating the method of destruction of the agent(s) being imported:
    - **Thermal**: Exposure of the agent to dry heat, moist heat (e.g., autoclave), or incineration at an appropriate temperature, pressure, and time to kill the entire specific biological agent.
    - **Chemical:** Exposure of the agent to a proven chemical at an appropriate concentration and for the appropriate exposure time to kill the entire specific biological agent.
    - **Irradiation:** Exposure of the agent to radiation of an appropriate type and for the appropriate exposure time to kill the entire specific biological agent.
    - **Other:** If “Other” is selected you must provide a detailed description of the destruction method.

Section H - Signature of Permittee

IMPORTANT NOTE: By signing and submitting the completed *Application for Permit to Import Infectious Biological Agents into the United States* to the CDC Import Permit Program, the requestor (permittee) is certifying that all individuals listed in the application have the appropriate qualifications, experience and training to safely handle the agents being imported and that the information submitted in the application is complete and accurate to the best their knowledge and belief. They are also agreeing to comply with all conditions, restrictions, and precautions that may be specified in any permit that may be issued. Additionally, the requestor is agreeing to comply with all applicable regulations and guidelines that govern the

importation and acknowledging that failure to comply with the importation requirements may subject them to criminal penalties pursuant to *42 U.S.C. 271(Penalties for violation of quarantine laws)*. The requestor is also acknowledging that any false statement made in the signed/submitted application may subject them to criminal penalties pursuant to *18 U.S.C. 1001*.

Block 1- Signature (REQUIRED)

- The Requestor listed in Section A, Blocks 1-3, must sign in Section H, Block 1.

Block 2- Requestor (Permittee)

- Please type or print the Requestor's name as it appears in Section A, Blocks 1-3.

Block 3- Date Signed

- Please enter the date the Requestor signs the application.

Document Change History

Version	Date	Summary of Changes
1.0	February 2014	Initial Release