

Cheat Sheet for Permitting of Biological Materials

Permit	Description	Additional Information
<i>Permit to Import or Transport Etiologic Hosts or Vectors of Human Disease</i>	<p>Required for importation, interstate and intrastate transport of human pathogens. Expedites the package through customs.</p> <p>Contact: Centers for Disease Control and Prevention at 404-718-2093.</p>	<p>Materials such as blood, bodily fluid, animals, etc that come from areas of endemic infection should be permitted.</p> <p>Takes 2 weeks to process, expires after movement of material occurs,</p> <p>Examples of materials for permit: blood, serum or plasma from different countries unless verified to be virus free, dengue,</p>
<i>PPQ-526 Permit to Move Live Plant Pests of Noxious Weeds</i>	<p>Required for the importation, transit, domestic movement, possession and environmental release of Organisms that impact plants, and the importation and transit of Plants and Plant Products under authority of the Plant Protection and Honeybee Acts. This is the general permit for the movement, possession, and environmental release of plant pests, plant pathogens, biological control organisms, bees, parasitic plants and noxious weeds.</p> <p>To import or transport plants into the US, see form PPQ 587 or PPQ586</p> <p>Contact: Pest Permit Evaluations at 301-734-0841, Toll Free 866-524-5421</p>	<p>PPQ 526 are also reviewed by the state in which the application is issued, a new permit will need to be filed following changes in location, owner, scope of work, permit is good through the intended use or shipment of materials. A new permit will need to be filed after expiration.</p> <p>Takes at least 4 weeks to process</p> <p>Examples of materials for permit: Wild type, non-genetically altered plant pathogens such as agrobacterium tumefaciens, xanthomonas campestris, etc</p>
<i>VS 16-3-Application to import or transport Controlled Material or organisms or Vectors</i>	<p>Required for the importation of certain animals and animal products. In addition, a permit is required for the importation and interstate movement of bacteria, viruses, and prion agents that are disease agents of animals and poultry.</p> <p>Contact USDA-APHIS-VS-NCIE at 301-734-3277</p>	<p>The application fees are as follows: new application-\$94.00, renewal application fee-\$61.00, and amendment-\$47.00</p> <p>Takes at least 4-6 weeks to process. Additional time may be incurred if USDA Site Facility Inspection required.</p> <p>Examples of materials for permit: Swine Influenza, Duck and Turkey Influenza</p>
<i>VS 16-7-Additional Information for Cell Cultures and their Products (supplement to VS 16-3)</i>	<p>This supplement is needed for all cultured cells/cell lines and the products or extracts of the cells. This includes monoclonal antibodies, recombinant products, DNA, viral agents, etc.</p> <p>Contact USDA-APHIS-VS-NCIE at 301-734-3277</p>	<p>See above</p>
<i>APHIS Form 2000</i>	<p>APHIS issues permits for importation, interstate movement, or environmental release of certain genetically engineered (GE) organisms. Permit applications, which are carefully reviewed by APHIS scientists, provide details about the nature of the GE organism to be introduced and the conditions that will be used to prevent the spread and establishment of the organism in the environment. APHIS issues permits for the introduction of GE organisms that pose a plant pest risk, including plants, insects, or microbes.</p> <p>Contact: BRS Headquarters: (301) 734-7324</p>	<p>For APHIS regulations to apply, there must be a plant pest component involved in the modification process, or the organism used in the engineering process must be an unclassified organism, or there must be reason to believe that the resulting organism is or will be a plant pest. If during any part of the process genetic engineering is used and a plant pest component is involved, the resulting organism will be regulated. Biotechnology Regulatory Service (BRS) also requires notification of genetically altering strains to make less infectious.</p> <p>Two types of regulated articles do not require a permit for interstate movement:</p> <ol style="list-style-type: none"> 1) Strains of Escherichia coli (K12 and its derivatives) that contain genetic material derived from a plant pest and 2) Plants or plant parts of Arabidopsis thaliana containing genetic material derived from a plant pest stably integrated into the plant genome.

		<p>These exemptions from permitting requirements for interstate movement are dependent upon certain conditions for biological and physical containment as specified in 7 CFR 340.2(b) of the regulations.</p> <p>Takes at least 60 days to process</p> <p>Examples of materials for permit: Genetically altered strains of plant pathogens; agrobacterium tumefaciens with deletion of LT1 will require courtesy letter to PPQ verifying it is no longer pathogenic</p>
<i>U.S. Fish and Wildlife Service Permits</i>	U.S. Fish and Wildlife Service permits are required for certain live animals, including bats.	Numerous permits exist for specific animals, plants, biological materials, they primarily issue permits to import and export species that are protected by CITES and by various other wildlife conservation laws. Some examples of other activities permitted are interstate and foreign commerce of non-native species protected by the Endangered Species Act, including a captive-bred wildlife registration; cooperative breeding programs for live exotic birds covered by the Wild Bird Conservation Act; and import and transport of injurious wildlife.
<i>U.S. Department of Commerce Export License</i>	<p>If your item requires a license to be exported, you must apply to BIS for an export license. If your application is approved, you will receive a license number and expiration date to use on your export documents. A BIS-issued license is usually valid for two years. Exporters may prepare an original Form BIS-748P, "Multipurpose Application Form," and submit it for review and approval. The application form can be used for requesting authority to export or reexport, or to request BIS to classify your item for you. Requirements for submitting a license are detailed in Part 748 of the EAR. Exporters may request Form BIS-748P.</p> <p>Contact BIS by phone (202) 482-4811</p>	<p><i>Commerce Control List Categories</i> 0 = Nuclear Materials, Facilities, and Equipment (and Miscellaneous Items) <i>1 = Materials, Chemicals, Microorganisms and Toxins</i> 2 = Materials Processing 3 = Electronics 4 = Computers 5 = Telecommunications and Information Security 6 = Sensors and Lasers 7 = Navigation and Avionics 8 = Marine 9 = Propulsion Systems, Space Vehicles, and Related Equipment</p> <p>Examples of microorganisms requiring export license: dengue virus, yellow fever virus, cholera toxin, abrin, aflatoxins. Most select agents and toxins are listed.</p>
Permit	Description	Additional Information
<i>APHIS FORM 2005-Application for US Veterinary Biological Product</i>	<p>With this permit, biological products produced in other countries may be imported into the United States for research and evaluation, transit shipment, or general sale and distribution.</p> <p>This form should only be used if applying for a permit to import animal vaccine or diagnostic test kits. Permits for other animal products, by-products, or organisms and vectors, apply using VS Form(s) 16-3, 16-7</p> <p>Contact APHIS VS at (301) 734 - 8245</p>	<p>APHIS' Veterinary Services' Center for Veterinary Biologics regulates veterinary biologics including those developed using genetically engineered organisms. APHIS regulates veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin) to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective.</p> <p>Takes at least 4-6 weeks to process</p>