



**GUIDANCE DOCUMENT FOR REQUEST FOR EXEMPTION
OF SELECT AGENTS AND TOXINS FOR PUBLIC HEALTH
OR AGRICULTURAL EMERGENCY
OR INVESTIGATIONAL PRODUCT
(APHIS/CDC FORM 5)**

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity may apply for an exemption from the requirements of 7 CFR 331, 9 CFR 121, or 42 CFR 73 in order to: (a) use an investigational product that is, bears, or contains select agents or toxins, or, (b) provide a response to a public health or agricultural emergency. This exemption request (APHIS/CDC Form 5) should be sent to either APHIS or CDC for consideration. For HHS agents and toxins, the applicant should contact CDC (telephone: 404-718-2000; facsimile: 404-718-2096; or e-mail: irsat@cdc.gov). For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC. For USDA agents and toxins, the applicant should contact APHIS (telephone: 301-734-5960; facsimile: 301-734-3652; or e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov). A listing of HHS select agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

PURPOSE

The purpose of this form is to request an exemption for the use of an investigational product that is, bears, or contains select agents or toxins or the response to a public health or agricultural emergency. A copy of the completed form and attachments must be maintained by the entity for three years.

This exemption form (APHIS/CDC Form 5) is not to be used if you are applying for an exclusion of an attenuated strain of a select agent or toxin. To apply for an exclusion, an applicant must submit a written request and supporting scientific information to APHIS or CDC (See 9 CFR §§ 121.3(e) and 121.4(e), or 42 CFR §§ 73.3(e) and 73.4(e)).

INSTRUCTIONS

1. The applicant must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration (blocks 1-16).
 - A. For applying for an exemption of an investigational product that is, bears, or contains select agents or toxins, complete sections 1 and 2.
 - B. For applying for an exemption to respond to a public health or agricultural emergency, complete sections 1 and 3.
2. Fax or mail the form to APHIS (facsimile: 301-734-3652) or CDC (facsimile: 404-718-2096).

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 734-5960 or CDC at (404) 718-2000. This guidance document and form are also available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html and <http://www.cdc.gov/od/sap>.

**SECTION 3 – TO BE COMPLETED FOR PUBLIC HEALTH OR AGRICULTURAL
EMERGENCY EXEMPTION**

INFORMATION ON PUBLIC HEALTH OR AGRICULTURAL EMERGENCY

26. Name of person most familiar with public health or agricultural emergency First: _____ MI: _____ Last: _____		27. Title: _____	
28. Name of entity (if different than Section 1): _____		29. Telephone: _____	
30. Address (NOT a post office address): _____	31. City: _____	32. State: _____	33. Zip Code: _____
34. Description of select agent(s) involved in public health or agricultural emergency: _____			
35. Describe public health or agricultural emergency including historical, clinical, and epidemiological details of emergency: _____ _____ _____			
36. Date of first confirmed case: _____	37. Date reported on APHIS/CDC Form 4: _____	38. Number of cases biweekly: _____	39. How diagnosis was made: _____
40. Name of laboratory that confirmed original diagnosis (if different than Section 1): _____			41. Telephone: _____
42. Address (NOT a post office address): _____	43. City: _____	44. State: _____	45. Zip Code: _____
46. Provide a detailed justification to request an exemption in response to a public health or agricultural emergency (attach additional sheets if necessary): _____ _____ _____ _____ _____ _____ _____ _____ _____ _____			

INFORMATION ON SELECT AGENTS AND TOXINS INVOLVED

47. Location where laboratory testing will be conducted Building: _____ Room: _____	48. Biosafety level (BSL) of laboratory or PPQ containment designation: _____
49. Name of Principal Investigator First: _____ MI: _____ Last: _____	
50. Type of specimens that will be received: <input type="checkbox"/> Clinical/diagnostic specimens <input type="checkbox"/> Environmental specimens <input type="checkbox"/> Isolates <input type="checkbox"/> Other (specify): _____	
51. Is this source expected to provide additional specimens? <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, give the anticipated quantity and end date: _____	

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Applicant: _____ Typed or printed name of Applicant: _____

Title of Applicant: _____ Date: _____

Public reporting burden: Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).