



Revised APHIS/CDC Form 1 Informational Session

Agricultural Select Agent Program (USDA/APHIS)
CDC Select Agent Program (HHS/CDC)



Live Meeting: Technical Information

- ❑ **Welcome**
- ❑ **One-way audio available to participants**
 - You must dial 1-877-777-1967 for audio (conference ID# 301491)
- ❑ **Please submit Form 1 questions using the “Q&A” tab**
 - Reminder: this is an open forum. Questions should not contain entity-specific or potentially sensitive information about your select agent program.
- ❑ **Slides and Q&A session will be posted to the select agents website**
- ❑ **Technical support is not available**
 - If you experience technical difficulties with Live Meeting, please follow the Troubleshooting instructions located in the SA GRAM dated 08/27/2013.



Revised APHIS/CDC Form 1 Training

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Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

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Outline

- ❑ **Welcome to APHIS/CDC Form 1 Informational Session**
- ❑ **Transitioning to the Revised APHIS/CDC Form 1**
- ❑ **Review of APHIS/CDC Form 1 Resources**
 - Website, Help and Instructions Documents
- ❑ **Features of Revised APHIS/CDC Form 1**
- ❑ **Demonstration of Revised APHIS/CDC Form 1**
 - Emphasis on major changes
- ❑ **Frequently Asked Questions**



Newly Revised APHIS/CDC Form 1

- ❑ **Published to www.selectagents.gov on 08/13/2013**
- ❑ **Posted as individual sections in fillable pdf format and excel spreadsheets**
 - A comprehensive pdf file will not be available.
- ❑ **No need to submit the new APHIS/CDC Form 1 unless your entity is submitting an amendment or application**
- ❑ **Transition timeline**



Transitioning to newly revised APHIS/CDC Form 1

TYPE OF SUBMISSION	DATE RECEIVED		
	Prior to 10/14/2013	Between 10/14/2013 and 2/14/2014	On or after 2/14/2014 ⁽³⁾
New application or amendment	Newly revised ⁽¹⁾ or old ⁽²⁾	Newly revised	
Update to pending application or amendment	Same version of APHIS/CDC Form 1 as original application or amendment		Newly revised

(1) Newly revised = Form 1 with OMB expiration date of 11/30/2015.

(2) Old = Form 1 with OMB expiration date of 10/31/2014.

(3) The Federal Select Agent Program will not support the old Form 1 after 2/13/2014. For any application or amendment on the old Form 1 pending at 2/14/2014, the entity will be required to resubmit the application or amendment on the newly revised Form 1.



Transitioning to newly revised APHIS/CDC Form 1

- ❑ You **cannot** combine sections from the 10/31/2014 and 11/30/2015 versions of the form in a single amendment or in an application.
- ❑ Once you **begin** using the 11/30/2015 version, you must **continue** using that version for all new amendments.
- ❑ **Entities are required to complete and submit only the applicable sections and attachments of the APHIS/CDC Form 1.**



APHIS/CDC Form 1 Resources: Website Navigation

- ❑ <http://www.selectagents.gov/>
- ❑ **APHIS/CDC Form 1**
 - Old version
 - Newly revised version
 - Resources



APHIS/CDC Form 1 Resources: HELP (Functionality)

❑ Has “smart” features

- Fillable text boxes
- Add/delete rows in tables
- Fields that auto-populate

❑ Has some limitations

- No “undo” action
- Unable to sort rows within tables

❑ “How to” document covers features and limitations for the user

- Tables within the form
- Drop down menus
- Headers
- “Warning” windows
- Excel spreadsheets

APHIS/CDC Form 1 Help (Functionality)	
The purpose of this document is to assist the user with entering data into the APHIS/CDC Form 1. This help document is for technical assistance only and not intended to replace the Instructions for Completion of the APHIS/CDC Form 1 located at http://www.selectagents.gov/RegistrationForm.html .	
Prior to completing APHIS/CDC Form 1, ensure that you are using the current, OMB approved form. Submissions containing expired forms will not be accepted. The current, approved form and optional supplemental spreadsheets can be downloaded from SelectAgents.gov Registration Form .	
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	Version 1.0 June 21, 2013
When using this document, you must first verify that it is the current version available at http://www.selectagents.gov/RegistrationForm.html Destroy obsolete versions unless retained as a historical record.	

http://www.selectagents.gov/resources/APHIS-CDC_Form_1_Functionality_HELP_Guide-English.pdf



APHIS/CDC Form 1 Resources: INSTRUCTIONS

- ❑ **How to complete an application**
 - Additional information for questions
 - Examples provided
 - References other information where appropriate
 - Example: guidance documents
- ❑ **How to complete an amendment**
 - General information
 - Amendment reference table
 - Specific requirements for each amendment type
- ❑ **Navigation**
 - Table of Contents
 - Links to outside resources
 - Links within document

USDA

APPLICATION FOR
REGISTRATION FOR POSSESSION, USE, AND
TRANSFER OF SELECT AGENTS AND TOXINS
(APHIS/CDC FORM 1)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0520-0275
EXP DATE 11/30/2015

The APHIS/CDC Form 1, *Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins*, is provided as individual Sections to assist entities in data input and revisions as necessary. Please enter information into the following sections and attachments, according to your entity's characteristics.

The APHIS/CDC Form 1, Application for Registration, provides a method for entities to register to possess, use, or transfer select agents and toxins (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73). The information requested in this form includes: facility information; a list of select agents or toxins to be possessed, used, or transferred by the entity; a list of individual(s) who will have access to select agents and toxins; characterization of the select agents and toxins and additional laboratory information. Submissions using expired forms or tables will not be accepted. The current, approved form can be downloaded from <http://www.selectagents.gov/RegistrationForm.html>.

If you are completing the APHIS/CDC Form 1 for the first time or as part of your registration renewal, use this document for assistance in completing the APHIS/CDC Form 1 and submitting it to the Federal Select Agent Program (either the Animal and Plant Health Inspection Service, Select Agent Program or Centers for Disease Control and Prevention, Division of Select Agents and Toxins).

Entities may also use this form to amend their registration. To apply for an amendment to a certificate of registration, an entity must submit relevant portion(s) of the APHIS/CDC Form 1 as described in the amendments section of this document to the Federal Select Agent Program.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for these information collections are 0579-0213 for APHIS and 0920-0576 for CDC. The time required to complete the information collection for APHIS ranges from 12 to 19.5 hours per response, and the time required to complete the information collection for CDC ranges from 4 to 31 hours 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.

APHIS/CDC Form 1 Instructions 1 Version 1.0 June 24, 2013

When using this document, first verify that it is the current version available at www.selectagents.gov/RegistrationForm.html
Destroy obsolete versions unless retained as a historical record.

http://www.selectagents.gov/resources/APHIS-CDC_Form_1_Instructions_for_Completion-English_508Compliant.pdf



Structure of APHIS/CDC Form 1

- ❑ **Section 1** – Entity, Responsible Official (RO), Alternate Responsible Official (ARO), Owner/Controller
- ❑ **Section 2** – RO certification statement
- ❑ **Section 3** – List of select agents and toxins
- ❑ **Section 4** – Personnel [excluding RO/ARO, Owner/Controller, Principal Investigator (PI)]
- ❑ **Section 5** – Entity-wide security, incident response, biosafety and entry requirements for inspections
- ❑ **Section 6** – Suite/room information
- ❑ **Section 7** – PI and work (Attachments A-G for specific types of work)



Submitting the new APHIS/CDC Form 1

- ❑ **Redesigned to streamline amendment process**
- ❑ **No comprehensive form**
- ❑ **Total of 7 sections (+ attachments specific to PI work)**
 - Submit just the sections needed for amendment requests
 - Less opportunity for errors
- ❑ **Must manage these separate pieces of the form**



Availability of Excel Spreadsheets

- ❑ **Section 4A – Laboratorians and Animal Care Staff**
 - ❑ **Section 4B – Support Staff**
 - ❑ **Section 4C – Unescorted Visitors**
 - ❑ **Section 7B – Strain or Serotype Designation Information**
-
- ❑ **Excel spreadsheets allows copy/paste and sort**

Section 4A - Laboratorians and Animal Care Staff  

Section 4B - Support Staff  

Section 4C - Unescorted Visitors  

Section 7B - Strain or Serotype Designation Information  



DEMONSTRATION



Entity, RO/ARO, Owner/Controller

❑ Section 1A/1B

- Additional physical address
- Adds Owner/Controller
- Includes Department of Justice (DOJ) #, Date of Birth (DOB), Tier 1 Access for personnel
- Remove registration history
- Same RO/ARO signature page

❑ Section 1C

- New entity abstract

❑ Section 2

- New RO certification page
- Information was previously on Form 1, but as “yes” only questions



Select Agents and Toxins

□ Section 3

- Separated by HHS, Overlap, and USDA Select Agents and Toxins
- Remove Laboratory Area, PI columns
- Adds “Check if possessed”
 - Use to indicate agents/toxins that entity has in its physical possession
 - Update after acquisition/destruction

This submission is: A new registration An update to an existing registration A renewal Date:

Entity Name:

Section 3 - Select Agents and Toxins

HHS Agents and Toxins (Check if Possessed)	Overlap Agents and Toxins (Check if Possessed)	USDA Agents and Toxins (Check if Possessed)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Delete



Personnel

- ❑ **Now separated by role and includes Tier 1 Access**
- ❑ **Section 4A: Laboratorians and Animal Care Staff**
- ❑ **Section 4B: Support Staff**
 - Remove supervising PI column
- ❑ **Section 4C: Unescorted Visitors**
 - Remove role column



Entity-Wide Information

- ❑ **Section 5 (A, B, C)**

- ❑ **Section 5A: Security and Incident Response**
 - New security questions relevant for an entity possessing Tier 1 select agents and toxins
 - Some questions may be checked “no” for an entity that does not possess Tier 1 agents and toxins

- ❑ **Section 5B: Biosafety/Biocontainment**
 - New questions for entity’s biosafety program, occupational health program

- ❑ **Section 5C: Inspector entry requirements**
 - New to the Form 1



Rooms and Suites

- ❑ **Section 6 (A, B)**

- ❑ **Section 6A: Suite/Room Security**
 - New questions for intrusion detection systems, video surveillance

- ❑ **Section 6B: Suite/Room Physical Information**
 - Includes additional “check box” options for laboratory safety levels
 - Additional questions for facility features (sinks, exhaust air, etc.)
 - Some questions may be “no” depending on the laboratory safety level [i.e., biosafety level 2 (BSL2) vs. biosafety level 3 (BSL3)]



Principal Investigator + Work

- ❑ **Section 7 (A, B, C + Attachments)**
- ❑ **Section 7A**
 - Adds PI DOJ#, DOB, Tier 1 Access
 - Designate suite/room as “lab” and/or “storage” in one column
 - Removes strain information from table
 - Includes a legend for suites, if applicable
- ❑ **Section 7B**
 - Separate strain or serotype table
- ❑ **Section 7C**
 - New inventory questions
 - Attachments, if applicable



Attachment A: Work with Toxins

- ❑ **For principal investigators working with select toxins:**
 - New questions for manipulation, production of toxin
 - Animal work with toxins
 - Toxin transfers (aggregate amount above and below permissible limit)

- ❑ **Consider the safety level**
 - May include multiple safety levels if identical procedures in place
 - Submit separate Attachment A's if work objectives/procedures differ by containment level (i.e., production in BSL3 rooms vs. manipulation of dilute toxin in BSL2 rooms)



Attachment B:

Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant/Synthetic Organisms

- ❑ **For principal investigators performing this type of work:**
 - New questions for reverse genetics, restoration/increase in virulence, product of a restricted experiment

- ❑ **Revised question format**

- ❑ **Consider the safety level**
 - May include multiple safety levels if identical procedures in place



Attachment C: Work with Animals

- ❑ **For principal investigators working with select agents or toxins in animals:**
 - New questions for waste handling and inactivation procedures
 - Description of animal handling, monitoring and housing (including euthanasia and necropsy)
 - **Note:** animal work with **select toxins** – not all questions are applicable – please provide answers to questions 1, 2, 4, 6, and 8

- ❑ **Consider the safety level**
 - May include multiple safety levels if identical procedures in place
 - Submit separate Attachment C's if procedures/housing differ by containment level



Attachment D: Work with Plants

- ❑ **For principal investigators performing work with select agents in plants:**
 - New format to describe work in greenhouse, glass house, screenhouse, and growth chamber

- ❑ **Consider the safety level**
 - Submit separate Attachment D's if procedures/structures differ by containment level



Attachment E: Work with Arthropods

- ❑ **For principal investigators performing work with select agents in arthropods:**
 - New to Form 1
 - Indicate both diagnostic work and/or experimental inoculations/infections
 - Describe procedures for primary containment and transfer of infected arthropods
 - Additional arthropod containment practices, facility features

- ❑ **Consider the safety level**
 - Submit separate Attachment E's if procedures differ by containment level



Attachment F: BSL3Ag Laboratories

□ For principal investigators working in BSL3Ag rooms:

- Revised format
- Additional questions on laboratory procedures/design, humane restraining devices, necropsy rooms and equipment

This submission is:	<input type="checkbox"/> A new registration	<input type="checkbox"/> An update to an existing registration	<input type="checkbox"/> A renewal	Date: <input type="text"/>
Entity Name:	<input type="text"/>			
PI(s):	<input type="text"/>			
Attachment F - BSL3Ag Laboratories				
1. Supplies, material and equipment enter and exit BSL3Ag areas only through an airlock, fumigation chamber, an interlocked and double-door autoclave or shower. Yes <input type="checkbox"/> No <input type="checkbox"/>				
For materials which are temperature sensitive, a gas sterilizer, pass-through liquid dunk tank, or a cold gas decontamination chamber are provided. Yes <input type="checkbox"/> No <input type="checkbox"/>				
2. Is a shower required when leaving the containment boundary? Yes <input type="checkbox"/> No <input type="checkbox"/>				
3. Disposable materials are decontaminated by a verified method (check all that apply): Yes <input type="checkbox"/> No <input type="checkbox"/>				
<input type="checkbox"/> Autoclaved				
<input type="checkbox"/> Chemical (disinfectant, concentration, and time)				
<input type="text"/>				
<input type="checkbox"/> Incineration				
<input type="checkbox"/> Other				
<input type="text"/>				
4. All containment areas are designed, constructed and verified to function as a primary containment barrier. All walls are constructed slab-to-slab and walls, floors, and ceilings are sealed. All penetrations into the laboratory are sealed airtight to prevent escape of agents and to allow fumigation for biological decontamination. Yes <input type="checkbox"/> No <input type="checkbox"/>				
5. Differential pressures/directional airflow are monitored and alarmed to indicate system failure. Yes <input type="checkbox"/> No <input type="checkbox"/>				



Attachment G: BSL4/ABSL4 Laboratories

□ For principal investigators working in BSL4/ABSL4 laboratories:

- Removed most of the yes/no questions
- Revised narrative format
- Additional questions

This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal	Date: <input type="text"/>
Entity Name: <input type="text"/>	
PI(s): <input type="text"/>	
Attachment G - BSL4/ABSL4 Laboratories	
1. Will work be performed in a BSL4/ABSL4 Cabinet Laboratory? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, complete questions 2 - 8.	
2. Describe the type of personal protective equipment that will be used.	
<input type="text"/>	
3. Describe the decontamination methods for materials/equipment in the Class III cabinet.	
<input type="text"/>	
4. Describe what liquid effluents are decontaminated and how they are decontaminated.	
<input type="text"/>	
5. Describe the supply and exhaust components of the ventilation system, including how the ventilation system of the Class III cabinet is manifolded to the room ventilation.	
<input type="text"/>	
6. In the event of a ventilation failure, describe what measures are used to prevent reversal of airflow.	
<input type="text"/>	



Frequently Asked Questions

- ❑ **What version of Adobe Acrobat should I use when completing the fillable version of the select agent forms?**

Answer: Adobe Acrobat Reader version 8 or higher should be used when completing fillable versions of the select agent forms.

- ❑ **Can I use both the new and old Forms together in an amendment?**

Answer: No. You cannot combine different forms in the same amendment.



Frequently Asked Questions

- ❑ **Can we still use the old forms, or do you want us to use the new forms?**

Answer: Yes, you may continue to use the old Form 1 to submit a new amendment until 10/14/13 [or until 2/13/14 for any pending amendment submitted on the old Form 1].

- ❑ **Do I have to redo Form 1 if I have no changes to my current approved registration?**

Answer: No. However, you will need to resubmit a complete Form 1 using the revised form at your next renewal.



Frequently Asked Questions

- ❑ **We have multiple buildings across our campus with different addresses. Do I have to list them all on Section 1A, additional physical addresses?**

Answer: No. Please only enter a separate physical address for a satellite site, e.g., off-campus site.

- ❑ **The new APHIS/CDC Form 1 now has a block to check if an entity actually possesses an agent or toxin. My entity's certificate of registration includes select agents and toxins that my entity does not currently possess. What, if any, action do I need to take?**

Answer: If you have already reported these agents as "TBA" (to be acquired) on the old Form 1, you do not need to resubmit this information on the new Form 1. However, it is recommended that you submit a Section 3 to report any changes in this status within 7 days of the status change.



Frequently Asked Questions

- ❑ **I updated my registration to a “non-Tier 1” status clinical laboratory. Occasionally we identify Tier 1 agents, but I am not registered to retain or receive these agents. How should I address questions about Tier 1 on the new Form 1?**

Answer: You should indicate “no” for any specified Tier 1 questions, in accordance with the exemption provisions established for clinical and diagnostic laboratories in Sections 5 and 6 of the select agent regulations.



Frequently Asked Questions

❑ **Some personnel on my registration have more than one job role. How should I enter this information?**

Answer: You may still register multiple roles for a single individual. However, since the revised Form 1 has separate sections based on personnel roles, please submit the applicable sections of Form 1 for each role and include the individual's name, DOJ#, DOB, and Tier 1 Access in each section.

❑ Examples of personnel with multiple roles and necessary sections of Form 1 include:

- ARO and PI: Sections 1, 7
- ARO and laboratorian: Sections 1, 4A
- PI and laboratorian (for another PI): Sections 7, 4A



Frequently Asked Questions

- ❑ **The collection of completed Form 1 pdf files are too large to attach in an email to my file manager. What are my options?**

Answer: It is recommended that an entity package (zip file) the completed sections of the Form 1 for email submissions when the file size exceeds permissible limits. An entity may continue to print, scan to pdf, and email a read only pdf file to the file manager. An entity may also print and fax the completed sections of Form 1.



Question & Answer Session

- ❑ **General questions regarding APHIS/CDC Form 1 ?**
 - Please use the LiveMeeting “Q & A” tab to submit your question.

- ❑ **Entity-specific questions about your registration amendment or application ?**
 - Please contact your APHIS or CDC designated file manager.

- ❑ **Submitted questions will be answered time permitting**
 - Note: All questions received will be answered and posted to the select agents website.





Revised APHIS/CDC Form 1 Informational Session

For more information, please contact the Select Agent Program

Telephone: 301-851-3300 Option 1 (APHIS) or 404-718-2000 (CDC)

E-mail: ASAP@aphis.usda.gov (APHIS) or lrsat@cdc.gov (CDC)

Web: www.selectagents.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.

