

Justification for Change

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

(OMB Control No. 0920-0576)

Expiration 10-31-2014

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

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This is a request for nonmaterial/non-substantive changes as explained below for OMB Control No. 0920-0576: *Possession, Use, and Transfer of Select Agents and Toxins*. The APHIS/CDC Form 1 is used by the Federal Select Agent Program (i.e., Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Program). Changes consist of correcting grammatical errors and improving instructions, and do not affect the burden to respondents.

The *Application for Registration* (42 CFR, 73.7(d)) is used by entities to register with Federal Select Agent Program and to submit amendments to update any changes that occurred in the information previously. The *Application for Registration* requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. This form is also used by the entity to amend their registration (42 CFR, 73.7(h) (1)), if any changes occur in the information submitted. Requested changes to the form are outlined in the table below.

Form	Current Question/Item	Requested Change	Justification
Application for Registration APHIS/CDC Form 1	Section 1B, Alternate Responsible Official Name (Typed or Printed)	Remove (Typed or Printed)	This change is necessary in order to correct false instructions on the page.
Application for Registration APHIS/CDC Form 1	On Section 5A, Question 6b “Area external connections to systems that control security of the facility (remote log in, work from home).”	“Are there external connections to systems that control security of the facility (remote log in, work from home)?”	This change clarifies the meaning/intent of the question.
Application for Registration APHIS/CDC Form 1	Change headers title that read “Attachment 1-7.”	“Attachment A-G”	This change corrects attachment names to better distinguish them from Sections 1-7.
Application for Registration APHIS/CDC Form 1	Attachment A, Question 2 “Select toxin manipulation or production in the facility”	“Select toxin manipulation or production in the laboratory.”	This change clarifies the intent of the question because facility describes the entity as a whole and should describe laboratory information.
Application for Registration APHIS/CDC Form 1	Attachment A, Question 4 “Select toxin is produced at the entity.”	“Select toxin is produced by PI(s).”	This change clarifies intent of the question because entity describes the facility as a whole and should describe specific individual information (PI).
Application for Registration APHIS/CDC Form 1	Attachment C, Question 3 b Waste Handling Procedures <input type="checkbox"/> Waste decontaminated in animal	Waste Handling Procedures <input type="checkbox"/> Waste decontaminated inside the containment area	This change clarifies the intent of the question to clearly state the request for “containment

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	room (e.g., pass-through autoclave) <input type="checkbox"/> Waste treated in stages and transported from animal room for decontamination. Describe when and how waste is treated before transport out of the animal room and/or the containment barrier and/or the animal facility.”	(e.g., pass-through autoclave loaded within the animal facility) <input type="checkbox"/> Waste transported outside of the containment area for decontamination. Describe when and how waste is treated before transport out of the containment area.”	area” information.
Application for Registration APHIS/CDC Form 1	Attachment C, Question 8 “How are animal restrained for experimental manipulation? <input type="checkbox"/> Not restrained (explain): <input type="checkbox"/> Chemical <input type="checkbox"/> Physical <input type="checkbox"/> Other”	“Are animals restrained for experimental manipulation? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, explain.”	This change clarifies the intent of the question to determine if animals will be restrained, not necessarily how.
Application for Registration APHIS/CDC Form 1	Attachment C, Question 9 “How are animals monitored before experimental endpoint? <input type="checkbox"/> Not monitored (explain): <input type="checkbox"/> Daily visual check by animal care/other trained personnel. <input type="checkbox"/> Daily weight or other physiological monitoring. <input type="checkbox"/> Other”	“Are experimentally infected animals monitored (e.g., daily checks)? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, explain.”	This change clarifies the intent of the question to determine if animals will be monitored, not necessarily how.
Application for Registration APHIS/CDC Form 1	Attachment C, Question 10 “Describe how animals are housed by species and containment level(s), including type of caging, number of animals per cage, if cage or cage rack is HEPA filtered, if there is active or passive ventilation of the cages. Also include a brief description of how food/water and bedding are handled or changed. Species Animal Housing/Husbandry”	“Describe animal housing for each species, including whether cages provide primary containment and a brief description (e.g. cage or cage rack is HEPA filtered, active or passive ventilation of the cages, non-containment caging housed within inward flow ventilated enclosure). Species Animal Housing”	This change clarifies the intent of the question to determine the animal housing.
Application for Registration APHIS/CDC Form 1	Attachment C, Question 11 “Describe how animals will be euthanized.”	“Are animals euthanized? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, explain.”	This change clarifies the intent of the question to determine if animals are euthanized, not necessarily how.
Application for Registration APHIS/CDC Form 1	Attachment F, Question 1 “Supplies, material and equipment enter and exit BSL3Ag areas only through an airlock, fumigation chamber, or interlocked and double-door autoclave, or shower.”	“Supplies, material and equipment enter and exit BSL3Ag areas only through an airlock, fumigation chamber, an interlocked and double-door autoclave, or shower.”	This change clarifies grammatical error.
Application for Registration APHIS/CDC Form 1	Attachment F, Question 3 “Disposable materials are decontaminated by an approved method”	“Disposable materials are decontaminated by a verified method”	This change clarifies grammatical error.

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Application for Registration APHIS/CDC Form 1	Attachment F, Question 5 “Differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure.”	“Differential pressures/directional airflow are monitored and alarmed to indicate system failure.	This change clarifies grammatical error since visual and audible examples should not have been part of the question.
Application for Registration APHIS/CDC Form 1	Attachment F, Question 6 “There is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s).	“There is HEPA filtration of all supply and exhaust air to and from the containment space.”	This change clarifies the intent of the question to clearly state the request for “containment area” information.
Application for Registration APHIS/CDC Form 1	Attachment F, Question 7 “A clean change room outside of the non-containment/ containment boundary. Doors that define a containment boundary have compressible or inflatable gaskets areas. A dirty change room within the non-containment/ containment boundary.	“A clean change room outside of containment. Doors that define a containment boundary have compressible or inflatable gaskets with airtight hinges and latch/knob areas. A dirty change room within containment.”	This change clarifies the intent of the question to clearly state the request for “containment area” information.