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Select Agent Fact Sheet

What are "Select Agents?"

A *select agent* is defined as an agent, virus, bacteria, fungi, rickettsiae or toxin listed in **Appendix A of Federal Register 29327 (42 CFR Part 72)** titled, "[Additional Requirements for Facilities Transferring or Receiving Select Agents.](#)" The term also includes (a) genetically modified microorganisms or (b) genetic elements that contain nucleic acid sequences associated with pathogenicity from organisms listed in Appendix A, (c) genetically modified microorganisms listed in Appendix A, and (d) genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in Appendix A, or their toxic subunits.

Why is there a "Select Agents" law?

In recent years, the threat of illegitimate use of infectious agents has attracted increasing interest from the perspective of public health. In view of concern that certain select agents could have serious adverse consequences for human health and safety, the "*Anti-terrorism and Effective Death Penalty Act of 1996*", (Section 511 of Public Law 104 132) was enacted and listed provisions that regulate the transfer of select agents. In response to this law, the Department of Human Health Services published the Final Rule, "*Additional Requirements for Facilities Transferring or Receiving Select Agents*" (42 CFR Part 72 and Appendix A) which became effective on April 15, 1997. A new law signed in October, 2001, "*Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism of 2001*" Act (USA PATRIOT ACT) establish provisions that regulate the possession, usage, or transfer of hazardous agents, and required the Department of Health and Human Services to issue rules to implement these provisions. The Center for Disease Control proposed new regulations to meet the requirements of this statute. Specifically, the law was designed to (a) establish a system of safeguards to be followed when specific agents are transported; (b) collect and provide information concerning the location where certain potentially-hazardous agents are transferred (c) track the acquisition and transfer of these specific agents; and (d) establish a process for alerting appropriate authorities if an unauthorized attempt is made to acquire these agents. The directive also places additional shipping and handling requirements on facilities that transfer or receive select infectious agents.

What are the "Select Agents?"

<p>Viruses</p> <ol style="list-style-type: none"> 1. Crimean-Congo haemorrhagic fever virus 2. Eastern equine encephalitis virus 3. Ebola virus 4. Equine morbillivirus 5. Lassa fever virus 6. Marburg virus 7. Rift Valley fever virus 8. South American haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, and Guanarito) 9. Tick-borne encephalitis complex viruses 10. Variola major virus (Smallpox virus) 11. Venezuelan equine encephalitis virus 12. Viruses causing hantavirus pulmonary syndrome 13. Yellow fever virus <p>Fungi</p> <ol style="list-style-type: none"> 1. <i>Coccidioides immitis</i> 	<p>Toxins</p> <ol style="list-style-type: none"> 1. Abrin 2. Aflatoxins 3. Botulinum toxins 4. Clostridium perfringens epsilon toxin 5. Conotoxins 6. Diacetoxyscirpenol 7. Staphylococcal enterotoxins 8. Ricin 9. Saxitoxin 10. Shigatoxin 11. Tetrodotoxin 12. T-2 toxin <p>Rickettsiae</p> <ol style="list-style-type: none"> 1. <i>Coxiella burnetii</i> 2. <i>Rickettsia prowazekii</i> 3. <i>Rickettsia rickettsii</i> 	<p>Bacteria</p> <ol style="list-style-type: none"> 1. <i>Bacillus anthracis</i> 2. <i>Brucella abortus</i>, <i>B. melitensis</i>, <i>B. suis</i> 3. <i>Burkholderia (Pseudomonas) mallei</i> 4. <i>Burkholderia (Pseudomonas) pseudomallei</i> 5. <i>Clostridium botulinum</i> 6. <i>Francisella tularensis</i> 7. <i>Yersinia pestis</i> <p>Recombinant organisms/molecules</p> <ol style="list-style-type: none"> 1. Genetically modified microorganisms or genetic elements from agents in these lists that have the potential to encode for a factor associated with disease. 2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on these lists, or their toxic subunits.
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Are there Select Agents that are considered exempt from the standard?

Yes. There are agents that are exempt from the standard:

- The agent is part of a clinical specimen intended for diagnostic reference or verification purposes.
- Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley Fever Virus strain MP-12, Venezuelan Equine Encephalitis Virus strain TC-83, Yellow Fever Virus strain 17D) are exempt.
- Vaccine strains of bacteria listed as described in Title 9 CFR, Part 78.1.
- Toxins used for medical purposes and inactivated for vaccine purposes.
- Toxins used for biomedical research with an LD₅₀ for vertebrates of more than 100 nanograms per kilogram of body weight.
- Clinical Laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, that utilize select agents for diagnostic, reference verification, or proficiency testing purposes.
- Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.).
- Products subject to regulation under the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.).
- Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in Appendix A.

What does a laboratory or facility do to comply with the use of Select Agents?

Harvard facilities that use, handle, transfer, receive, or store these select agents must:

- (1) Register the use in research projects with the Harvard University Committee on Microbiological Safety – Committee for the Regulation of Hazardous Biological Agents (COMS-CRHBA) before work can begin.
- (2) Register the facility with the CDC before transferring the agent to another facility or receiving the select agent in a facility.
- (3) Secure the select infectious agent under lock and key.
- (4) Keep all doors to the laboratory locked.
- (5) Restrict access and allow only authorized individuals.
- (6) Ensure that individuals in the laboratory are aware of restrictions on transferring, receiving, storage, and use of select agents.
- (7) Maintain records of stocks.
- (8) Destroy stocks of unused select agents no longer needed.
- (9) Complete and maintain an annual inventory of select agents.

Do I need to comply with the regulation if I am importing the Select Agent?

Yes. The lab or facility must comply with the requirement of the Select Agent when purchasing them from other countries. The following steps must be taken when importing a select agent:

- (1) The importer must hold a valid import permit from CDC in accordance with 42 CFR Part 71.54 (Importation of etiologic agents, hosts, and vectors). The instructions for obtaining import permit for etiologic agents is available through the CDC web site at www.cdc.gov/od/ohs/biosfty/impertper.htm, or by calling them at 404-639-3235. Additional import permits may be required, such as those of USDA.
- (2) The importer must be registered with CDC in accordance with 42 CFR Part 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Agents).
- (3) A CDC Form EA-101 must be completed for each shipment of select agent under the import permit. Upon receipt of the agent, the receiving Responsible Facility Official (RFO) must complete a CDC Form EA-101, placing the “PHS Permit Number” where a registration number is requested for the transferring facility, and forward the completed Form EA-101 to CDC.

Where can I get more information?

Please contact the Environmental Health and Safety department at 617-495-2060 (Cambridge) or 617-432-1720 (Longwood). Additional resources can be found at:

www.uos.harvard.edu/ehs/biosafety_sel_agent.shtml
www.cdc.gov/od/ohs/biosfty/impertper.htm

www.cdc.gov/od/ohs/lrsat.htm
www.hms.harvard.edu/orsp/coms/BiosafetyResources/Bioterrorism.htm