18 USC § 175. Prohibitions with respect to biological weapons

(a) In general. Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same, shall be fined under this title or imprisoned for life or any term of years, or both. There is extraterritorial Federal jurisdiction over an offense under this section committed by or against a national of the United States.

(b) Additional Offense. Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both. In this subsection, the terms 'biological agent' and 'toxin' do not encompass any biological agent or toxin that is in its naturally occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.

(bc) Definition. For purposes of this section, the term "for use as a weapon" does not include the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system other than for prophylactic, protective, bona fide research or other peaceful purposes.

SEC. 175B. POSSESSION BY RESTRICTED PERSONS.

(a) No restricted person described in subsection (b) shall ship or transport interstate or foreign commerce, or possess in or affecting commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent in subsection (j) of section 72.6 of title 42, Code of Federal Regulations, pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132), and is not exempted under subsection (h) of such section 72.6, or appendix A of part 72 of the Code of Regulations.

(b) In this section:

(1) The term 'select agent' does not include any such biological agent or toxin that is in its naturally-occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.

(2) The term 'restricted person' means an individual who--

(A) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(C) is a fugitive from justice;

(D) is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(E) is an alien illegally or unlawfully in the United States;
(F) has been adjudicated as a mental defective or has been committed to any mental institution;
(G) is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or
(H) has been discharged from the Armed Services of the United States under dishonorable conditions.

(3) The term `alien' has the same meaning as in section 1010(a)(3) of the Immigration and Nationality Act (8 U.S.C. 101(a)(3)).
(4) The term `lawfully admitted for permanent residence' has the same meaning as in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(20)).

(c) Whoever knowingly violates this section shall be fined as provided in this title, imprisoned not more than 10 years, or both, but the prohibition contained in this section shall not apply with respect to any duly authorized United States governmental activity.

18 USC Sec. 177. Injunctions

(a) In General. - The United States may obtain in a civil action an injunction against -
   (1) the conduct prohibited under section 175 of this title;
   (2) the preparation, solicitation, attempt, threat, or conspiracy to engage in conduct prohibited under section 175 of this title; or
   (3) the development, production, stockpiling, transferring, acquisition, retention, or possession, or the attempted development, production, stockpiling, transferring, acquisition, retention, or possession of any biological agent, toxin, or delivery system of a type or in a quantity that under the circumstances has no apparent justification for prophylactic, protective, or other peaceful purposes.

(b) Affirmative Defense. - It is an affirmative defense against an injunction under subsection (a)(3) of this section that -
   (1) the conduct sought to be enjoined is for a prophylactic, protective, or other peaceful purpose; and
   (2) such biological agent, toxin, or delivery system is of a type and quantity reasonable for that purpose.

18 USC Sec. 178. Definitions

As used in this chapter -
the term "biological agent" means any micro-organism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, capable of causing -

(A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
(B) deterioration of food, water, equipment, supplies, or material of any kind; or
(C) deleterious alteration of the environment;

(2) the term "toxin" means the toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including -

(A) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or
(B) any poisonous isomer or biological product, homolog, or derivative of such a substance;

(3) the term "delivery system" means -

(A) any apparatus, equipment, device, or means of delivery specifically designed to deliver or disseminate a biological agent, toxin, or vector; or
(B) any vector;

(4) the term "vector" means a living organism, or molecule, including a recombinant molecule, or biological product that may be engineered as a result of biotechnology, capable of carrying a biological agent or toxin to a host; and

(5) the term "national of the United States" has the meaning prescribed in section 101(a)(22) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(22)).
(paragraph (c) of this section) or be approved by the Secretary as equipped and capable of handling the covered agent at Biosafety Level (BL) 2, 3, or 4, depending on the agent.

(2) Registration will include:
   (i) Sufficient information provided by the responsible facility official indicating that the applicant facility, and its laboratory or laboratories, are equipped and capable of handling the agents at BL 2, 3, or 4, depending upon the agent, and the type of work being performed with the agents;
   (ii) Inspection of the applicant facility at the discretion of the Secretary or the registering entity in consultation with the Secretary;
   (iii) Issuance by the registering entity of a registration number unique to each facility;
   (iv) Collection of a periodic site registration fee by the registering entity or the Secretary.

A schedule of fees collected by the Secretary to cover the direct costs (e.g., salaries, equipment, travel) and indirect costs (e.g., rent, telephone service and a proportionate share of management and administration costs) related to administration of this part will be published in the Federal Register and updated annually.

(3) Such registration shall remain effective until relinquished by the facility or withdrawn by the Secretary or the registering entity.

(4) The registration may be denied or withdrawn by the registering entity or the Secretary based on:
   (i) Evidence that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;
   (ii) Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;
   (iii) Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans;
   (iv) Evidence that the facility has failed to comply with any provisions of this part or has acted in a manner in contravention of this part; or
   (v) Failure to pay any required registration fee.

(5) The requirements for BSL-2, 3, and 4 operations pertaining to this section are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Third Edition, May 1993 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 C.F.R. Part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia,
or at the Office of the Federal Register, 800 North Capitol Street N.W.,
Suite 700, Washington D.C.

(6) Additional specific requirements for handling toxins subject to
this part must be met and are found in 29 CFR Sec. 1910.1450,
``Occupational Exposure to Hazardous Chemicals in Laboratories."

(b) Appeals. A decision made by the Secretary or a registering
entity to deny or withdraw registration of a particular facility may be
appealed to the Secretary. An application for appeal must be received by
the Secretary no later than 14 days after the appealing party's
application for registration was denied or no later than 14 days after
the appealing party's registration was
withdrawn. The application must clearly identify the issues presented by
the appeal and fully explain the appealing party's position with respect
to those issues. The Secretary may allow the filing of opposing briefs,
informal conferences, or whatever steps the Secretary considers
appropriate to fairly resolve the appeal.

(c) Authorized registering entities. (1) The Secretary may authorize
a state agency or private entity to register facilities under paragraph
(a) of this section, if the Secretary determines that the registering
entity's criteria for determining the biosafety standards for facilities
handling select agents are consistent with the requirements contained in
the CDC/NIH publication "Biosafety in Microbiological and Biomedical

(2) A registering entity shall maintain:

(i) A database of all facilities formerly and currently registered
as BL 2, 3, or 4 and capable of working with agents in Appendix A of
this part. The database shall include the name and address of the
registered facility, the date the facility was registered, the
facility's registration number, and the name and phone number of the
responsible facility official.

(ii) A copy of each CDC Form EA-101 transmitted by each transferor
registered by that registering entity. Such forms shall be made readily
accessible to the Secretary and to appropriate federal law enforcement
authorities and/or authorized local law enforcement authorities.

(3) In the event the Secretary authorizes more than one registering
entity, or if otherwise necessary, the Secretary may require the
establishment of a consolidated database to carry out the provisions of
Sec. 72.6(c)(2).

(d) Requests for agents. (1) Prior to the transfer of any agent
contained in Appendix A of this part, a CDC Form EA-101 must be
completed for each transfer sought. As specified in CDC Form EA-101, the
information provided must include:

(i) The name of the requestor and requesting facility;
(ii) The name of the transferor and transferring facility;
(iii) The names of the responsible facility officials for both the
transferor and requestor;
(iv) The requesting facility's registration number;
(v) The transferring facility's registration number;
(vi) The name of the agent(s) being shipped;
(vii) The proposed use of the agent(s); and
(viii) The quantity (number of containers and amount per container)
of the agent(s) being shipped.

(2) The form must be signed by the transferor and requestor, and the
responsible facility officials representing both the transferring and
requesting facilities.

(3) A copy of the completed CDC Form EA-101 must be retained by both
transferring and requesting facilities for a period of five (5) years
after the date of shipment or for five (5) years after the agents are
consumed or properly disposed, whichever is longer.

(4) All CDC forms EA-101 must be produced upon request to
appropriate federal and authorized local law enforcement authorities,
officials authorized by the Secretary, and officials of the registering
entity.

(e) Verification of registration. (1) Prior to transferring any
agent covered by this part, the transferor's responsible facility
official must verify with the requestor's responsible facility official,
and as appropriate, with the registering entity:
(i) That the requesting facility retains a valid, current
registration;
(ii) That the requestor is an employee of the requesting facility;
and
(iii) That the proposed use of the agent by the requestor is
correctly indicated on CDC Form EA-101.

(2) In the event that any party is unable to verify the information
required in paragraph (e)(1) of this section, or there is suspicion that
the agent may not be used for the requested purpose, then the party
shall immediately notify CDC.

(f) Transfer. (1) Upon completion of the CDC Form EA-101 and
verification of registration, the transferring facility must comply with
the packaging and shipping requirements in this part

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or other applicable regulations when transferring the agent.

(2) The requesting facility's responsible official must acknowledge
receipt of the agent telephonically or otherwise electronically within
36 hours of receipt and provide a paper copy or facsimile transmission
of receipt to the transferor within 3 business days of receipt of the
agent.
(3) Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed paper copy or facsimile transmission of CDC Form EA-101 within 24 hours to the registering entity (holding that facility's registration), in accordance with Sec. 72.6(c)(2) for filing in a centralized repository.

(g) Inspections. (1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance with this part. All CDC forms EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities, and/or any consolidated database established in accordance with Sec. 72.6(c)(3), to assure compliance with this part.

(h) Exemptions--(1) Exemptions for certain select agents: Select agents otherwise covered by this part are exempt from its provisions if:

(i) The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with Sec. 72.6(i) after diagnostic, reference, or verification procedures have been completed;

(ii) The agent is a toxin having an LD<INF>50</INF> for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or

(iii) The agent(s) is an exempted strain specified in Appendix A of this part and/or CDC Form EA-101. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents (Appendix A of this part). Individuals seeking additions to the list of exemptions should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future changes to the list of exemptions will be published in the Federal Register for review and comment prior to inclusion on Appendix A of this part.

(2) Exemption of CLIA certified laboratories: Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of Sec. 72.6.

(3) Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory: Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with
the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)

(i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic, reference, verification, or proficiency testing purposes, the transferor must:

(A) Provide the following information on CDC Form EA-101:
   (1) The name of the requestor and requesting facility;
   (2) The name of the transferor and transferring facility;
   (3) The name of the transferor's responsible facility official;
   (4) The requesting facility's CLIA certification number (which the transferor must verify as valid and current with the registering entity);
   (5) The transferring facility's registration number;
   (6) The name of the agent(s) being shipped;

   (7) The proposed use of the agent(s); and
   (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Verify receipt of the agent with the CLIA laboratory and note such receipt on CDC Form EA-101;

(C) Transmit a copy of the form, signed by the transferror and the responsible facility official representing the transfering facility, to the registering entity holding the transferring facility's registration; and

(D) Retain a copy of CDC Form EA-101 in accordance with Sec. 72.6(d)(3) and Sec. 72.6(d)(4).

(ii) Prior to receiving a select agent listed in Appendix A of this part from a CLIA laboratory, the requestor must be registered in accordance with Sec. 72.6(a) and comply with the following requirements:

(A) Provide the following information on the CDC Form EA-101:
   (1) The name of the requestor and requesting facility;
   (2) The name of the transferor and transferring facility;
   (3) The name of the requestor's responsible facility official;
   (4) The transferring facility's CLIA certification number;
   (5) The requesting facility's registration number;
   (6) The name of the agent(s) being shipped;
   (7) The proposed use of the agent(s); and
   (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Upon receiving the agent, note such receipt on CDC Form EA-101;

(C) Transmit a copy of CDC Form EA-101, signed by the requestor and the responsible facility official representing the requesting facility, to the registering entity holding the requesting facility's registration;
(D) Retain a copy of the CDC Form EA-101 in accordance with Secs. 72.6(d)(3) and 72.6(d)(4);

(E) Comply with the disposal requirements of Sec. 72.6(i) and all other sections of this part when subsequently transferring the agent.

(i) Agent disposal. (1) Upon termination of the use of the agent, all cultures and stocks of it will be

(ii) Securely stored in accordance with prudent laboratory practices,

(ii) Transferred to another registered facility in accordance with this part, or

(iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

(2) When an agent, previously transferred to a facility in accordance with this part, is consumed or destroyed, the responsible facility official must formally notify the registering entity. Formal notification must be noted on CDC Form EA-101 and a copy kept on record by the responsible facility official for a period of five (5) years and is subject to paragraph (g) of this section.

(j) Definitions. As used in this section:

Facility means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part.

Registering entity means an organization or state agency authorized by the Secretary to register facilities as capable of handling select agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."

Requestor means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

Secretary means the Secretary of the Department of Health and Human Services or her or his designee.

Select agent means a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part. The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic subunits.

Single geographic site means a building or complex of buildings at a
single mailing address.  

Transfer means:
(1) The conveyance or movement from a point or origination to a point of destination either:
   (i) From one state or territory to another or;
   (ii) Entirely within one contiguous state or territory.
(2) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of Sec. 72.6 (d), (e), and (f) provided that:
   (i) The intended use of the agent remains consistent with that specified in the most current transfer form; and
   (ii) For each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

[61 FR 55197, Oct. 24, 1996]

Sec. 72.7  Penalties.

Individuals in violation of this part are subject to a fine of no more than $250,000 or one year in jail, or both. Violations by organizations are subject to a fine or no more than $500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

[61 FR 55199, Oct. 24, 1996]

Appendix A to Part 72--Select Agents

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
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, 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
Exemptions: 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 17-D) are exempt.

Bacteria
1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Burkholderia (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei
5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis
Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae
1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi
1. Coccidioides immitis

Toxins
1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. Clostridium perfringens epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin
Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD<INF>50</INF> for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

**Recombinant Organisms/Molecules**
- Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

**Other Restrictions**
The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH “Guidelines for Research Involving Recombinant DNA Molecules,” if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

**Additional Exemptions**
- Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this Appendix.

[61 FR 55199, Oct. 24, 1996]