

107TH CONGRESS
1ST SESSION

H. R. 3306

To set up a certification system for research facilities that possess dangerous biological agents and toxins, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 15, 2001

Mr. SCHIFF introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To set up a certification system for research facilities that possess dangerous biological agents and toxins, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Deadly Biological
5 Agent Control Act of 2001”.

1 **SEC. 2. BIOLOGICAL WEAPONS.**

2 (a) SELECT AGENTS.—Section 175 of title 18,
3 United States Code, is amended by striking subsection (b)
4 and inserting the following:

5 “(b) SELECT AGENTS.—

6 “(1) UNCERTIFIED POSSESSION.—Whoever
7 knowingly possesses a select agent without obtaining
8 a certification from the Department of Health and
9 Human Services under section 511(f) of the
10 Antiterrorism and Effective Death Penalty Act of
11 1996, shall be fined under this title, imprisoned for
12 not more than 5 years, or both.

13 “(2) TRANSFER TO UNCERTIFIED PERSON.—
14 Any research facility that knowingly transfers a se-
15 lect agent to an entity that has not obtained a cer-
16 tification from the Department of Health and
17 Human Services under section 511(f) of the
18 Antiterrorism and Effective Death Penalty Act of
19 1996, shall be fined under this title, imprisoned for
20 not more than 5 years, or both.

21 “(c) DEFINITIONS.—In this section:

22 “(1) BIOLOGICAL AGENT; TOXIN.—The terms
23 ‘biological agent’ and ‘toxin’ have the same mean-
24 ings given those terms in section 178, except that,
25 for purposes of subsection (b), if the biological agent
26 or toxin has not been cultivated, cultured, collected,

1 or otherwise extracted from its natural source, those
2 terms do not include any biological agent or toxin
3 that is in its naturally occurring environment.

4 “(2) FOR USE AS A WEAPON.—The term ‘for
5 use as a weapon’ includes the development, produc-
6 tion, transfer, acquisition, retention, or possession of
7 any biological agent, toxin, or delivery system, other
8 than for prophylactic, protective, or other peaceful
9 purposes.

10 “(3) SELECT AGENT.—The term ‘select agent’
11 means a biological agent or toxin that—

12 “(A) is included on the list established
13 under section 511(d)(1) of the Antiterrorism
14 and Effective Death Penalty Act of 1996; and

15 “(B) is not possessed by a health, re-
16 search, or other entity listed under subpara-
17 graph (C) or (D) of section 511(f)(2) of that
18 Act.”.

19 (b) LIST OF BIOLOGICAL TOXINS.—Section 511(d)
20 of the Antiterrorism and Effective Death Penalty Act of
21 1996 (42 U.S.C. 262 note) is amended to read as follows:

22 “(d) REGULATORY CONTROL OF BIOLOGICAL
23 AGENTS.—

24 “(1) LIST OF BIOLOGICAL AGENTS AND TOX-
25 INS.—The Secretary, in consultation with the Sec-

1 retary of Defense, Attorney General, and other ap-
2 propriate Federal officials, shall—

3 “(A) annually review the existing list of se-
4 lect agents; and

5 “(B) if necessary, revise that existing list
6 of select agents.

7 “(2) CRITERIA.—In determining whether to in-
8 clude a biological agent or toxin on the list estab-
9 lished under paragraph (1), the Secretary shall—

10 “(A) consider—

11 “(i) the effect on human health of ex-
12 posure to each biological agent or toxin;

13 “(ii) the degree of contagiousness of
14 each biological agent or toxin and the
15 methods by which each biological agent or
16 toxin is transferred to humans;

17 “(iii) the availability and effectiveness
18 of vaccines and therapies to treat or pre-
19 vent any illness resulting from infection by
20 or exposure to each biological agent or
21 toxin;

22 “(iv) the potential use of each biologi-
23 cal agent or toxin in a bioterrorist attack
24 on the civilian population; and

1 “(v) any other criteria that the Sec-
2 retary considers appropriate; and

3 “(B) consult with scientific experts who
4 represent appropriate professional groups.

5 “(3) PRIORITIZATION OF COUNTER-
6 MEASURES.—The Secretary shall prioritize counter-
7 measures, including vaccines, therapies, medical de-
8 vices, and diagnostic tests which must be developed,
9 produced, or obtained in preparation for a bioter-
10 rorist attack or other significant disease emergency
11 in order to treat, prevent, or identify infection by, or
12 exposure to, biological agents and toxins, listed pur-
13 suant to this subsection.”.

14 (c) REGULATION OF POSSESSION OF BIOLOGICAL
15 AGENTS AND TOXINS.—Section 511(f) of the
16 Antiterrorism and Effective Death Penalty Act of 1996
17 (42 U.S.C. 262 note) is amended to read as follows:

18 “(f) POSSESSION AND USE OF LISTED BIOLOGICAL
19 AGENTS AND TOXINS.—

20 “(1) STANDARDS AND PROCEDURES.—The Sec-
21 retary shall provide for the establishment and en-
22 forcement of standards and procedures governing
23 the possession and use of biological agents and tox-
24 ins listed pursuant to subsection (d)(1), in order to
25 protect the health and safety of the public, including

1 safeguards to prevent access to those biological
2 agents and toxins for use in domestic or inter-
3 national terrorism, or for any other criminal pur-
4 pose.

5 “(2) CERTIFICATION.—

6 “(A) IN GENERAL.—The Secretary shall
7 establish a certification process for the posses-
8 sion and use of biological agents and toxins list-
9 ed pursuant to subsection (d)(1).

10 “(B) POSSESSION.—Except as provided in
11 subparagraph (C), the certification process es-
12 tablished under subparagraph (A) shall prohibit
13 any individual from knowingly possessing bio-
14 logical agents or toxins listed pursuant to sub-
15 section (d)(1).

16 “(C) EXCEPTION.—A health, research, or
17 other entity may possess a biological toxin or
18 agent listed pursuant to subsection (d)(1), if
19 that entity is described in subparagraph (D) or
20 (E).

21 “(D) LEGITIMATE PURPOSE.—A health,
22 research, or other entity is described in this
23 subparagraph, if—

1 “(i) the health, research, or other en-
2 tity is certified as legitimate by the De-
3 partment of Health and Human Services;

4 “(ii) the research facility has a legiti-
5 mate research or other peaceful purpose
6 for possessing the biological agent or toxin;

7 “(iii) the research facility submits to
8 periodic site inspections; and

9 “(iv) the health, research, or other en-
10 tity demonstrates the establishment and
11 enforcement of safety procedures for the
12 possession of biological agents or toxins
13 listed pursuant to subsection (d), including
14 measures to ensure—

15 “(I) proper training and appro-
16 priate skills for handling the biological
17 agents and toxins;

18 “(II) proper laboratory facilities
19 to contain and dispose of the biologi-
20 cal agents and toxins; and

21 “(III) safeguards to prevent ac-
22 cess to the biological agents and tox-
23 ins for use in domestic or inter-
24 national terrorism, or for any other
25 criminal purpose.

1 “(E) DIAGNOSTIC OR VERIFICATION PUR-
2 POSE.—A health, research, or other entity is
3 described in this subparagraph, if the entity—

4 “(i) possesses the biological agent or
5 toxin as part of a clinical specimen in-
6 tended for diagnostic or verification pur-
7 poses;

8 “(ii) transfers the biological agent or
9 toxin to another entity that is certified
10 under this subsection, or disposes of the bi-
11 ological agent or toxin within 72 hours in
12 accordance with section 72.6(i) of title 42,
13 Code of Federal Regulations; and

14 “(iii) reports the presence of the bio-
15 logical agent or toxin to the Centers for
16 Disease Control.

17 “(3) RESEARCH FACILITIES.—

18 “(A) IN GENERAL.—Any individual who
19 handles biological agents or toxins in an entity
20 certified under this subsection shall—

21 “(i) pass a criminal background
22 check, which shall include a determination
23 of whether that individual is a restricted
24 person (as that term is defined in section
25 175b of title 18, United States Code); and

1 “(ii) be registered with the Depart-
2 ment of Health and Human Services for
3 the specific research project that requires
4 the use of biological agents or toxins.

5 “(B) PENALTIES.—

6 “(i) RESEARCH FACILITIES.—Any en-
7 tity that is certified under this subsection
8 and permits a restricted person, as that
9 term is defined in section 175b of title 18,
10 United States Code, to handle or access bi-
11 ological agents or toxins may be subject to
12 decertification by the Department of
13 Health and Human Services and civil pen-
14 alties in an amount not to exceed
15 \$500,000.

16 “(ii) SUPERVISORY PERSONNEL.—Su-
17 pervisory personnel in an entity that is cer-
18 tified under this subsection, who knowingly
19 permit a restricted person, as that term is
20 defined in section 175b of title 18, United
21 States Code, to handle or access biological
22 agents or toxins shall be subject to civil
23 penalties in an amount not to exceed
24 \$250,000 and shall be imprisoned for not
25 more than 1 year.”.

1 (d) CIVIL PENALTIES.—Section 511 of the
2 Antiterrorism and Effective Death Penalty Act of 1996
3 (42 U.S.C. 262 note) is amended by—

4 (1) redesignating subsection (g) as subsection
5 (h); and

6 (2) inserting after subsection (f) the following:

7 “(g) CIVIL PENALTY.—A person who violates sub-
8 section (e) or (f) shall be subject to the United States for
9 a civil penalty in an amount not to exceed \$250,000 in
10 the case of an individual and \$500,000 in the case of an
11 entity certified under subsection (f).”.

12 (e) SECTION 511.—

13 (1) IN GENERAL.—Section 511 of the
14 Antiterrorism and Effective Death Penalty Act of
15 1996 (42 U.S.C. 262 note) is amended—

16 (A) in subsection (e)—

17 (i) by inserting “and toxins” after
18 “agents” each place that term appears;

19 and

20 (ii) by inserting “or toxin” after
21 “agent” each place that term appears; and

22 (B) in subsection (h)(1), as redesignated
23 by this Act, by striking “the term ‘biological
24 agent’ has” and inserting “the terms ‘biological
25 agent’ and ‘toxin’ have”.

1 (2) **EFFECTIVE DATE.**—The amendments made
2 by this subsection shall be deemed to have the same
3 effective date as section 511 of the Antiterrorism
4 and Effective Death Penalty Act of 1996 (42 U.S.C.
5 262 note).

6 (f) **CONFORMING AMENDMENTS.**—Section 511(e) of
7 the Antiterrorism and Effective Death Penalty Act of
8 1996 (42 U.S.C. 262 note) is amended—

9 (1) in the matter preceding paragraph (1), by
10 striking “, through regulation promulgated under
11 subsection (f),”; and

12 (2) in the heading, by striking “AGENTS” and
13 inserting “AGENTS AND TOXINS”.

14 **SEC. 3. INTERIM RULE.**

15 (a) **IN GENERAL.**—Not later than 30 days after the
16 date of enactment of this Act, the Secretary of Health and
17 Human Services shall promulgate an interim final rule for
18 carrying out section 511(d) of the Antiterrorism and Ef-
19 fective Death Penalty Act of 1996 (42 U.S.C. 262 note),
20 as amended by this Act.

21 (b) **EFFECTIVE DATE.**—The interim final rule pro-
22 mulgated under subsection (a) shall take effect 60 days
23 after the date on which the rule is promulgated, including
24 for purposes of—

1 (1) section 175(b)(1) of title 18, United States
2 Code (relating to criminal penalties), as added by
3 this Act; and

4 (2) section 511(g) of the Antiterrorism and Ef-
5 fective Death Penalty Act of 1996 (relating to civil
6 penalties), as added by this Act.

7 **SEC. 4. REGISTRATION OF BIOLOGICAL AGENTS AND TOX-**
8 **INS.**

9 In the case of a research facility that, as of the date
10 of enactment of this Act, is in possession of a biological
11 agent or toxin that is listed pursuant to section 511(d)
12 of the Antiterrorism and Effective Death Penalty Act of
13 1996, as amended by this Act, that research facility shall,
14 in accordance with the interim final rule promulgated
15 under section 3, submit an application for certification
16 under section 511(f) of the Antiterrorism and Effective
17 Death Penalty Act of 1996, not later than 30 days after
18 the date on which the rule is promulgated.

○