

107TH CONGRESS  
1ST SESSION

# S. 1706

To provide for the enhanced control of biological agents and toxins.

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IN THE SENATE OF THE UNITED STATES

NOVEMBER 15, 2001

Mr. HARKIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To provide for the enhanced control of biological agents and toxins.

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 “Bioweapons Control  
5 and Tracking Act of 2001”.

6 **SEC. 2. REGULATION OF BIOLOGICAL AGENTS AND TOXINS.**

7 (a) BIOLOGICAL AGENTS PROVISIONS OF THE  
8 ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT  
9 OF 1996; CODIFICATION IN THE PUBLIC HEALTH SERV-  
10 ICE ACT, WITH AMENDMENTS.—

1           (1) PUBLIC HEALTH SERVICE ACT.—Subpart 1  
2           of part F of title III of the Public Health Service  
3           Act (42 U.S.C. 262 et seq.) is amended by inserting  
4           after section 351 the following:

5   **“SEC. 351A. ENHANCED CONTROL OF BIOLOGICAL AGENTS**  
6                                   **AND TOXINS.**

7           “(a) REGULATORY CONTROL OF BIOLOGICAL  
8   AGENTS AND TOXINS.—

9                           “(1) LIST OF BIOLOGICAL AGENTS AND TOX-  
10   INS.—

11                           “(A) IN GENERAL.—The Secretary shall by  
12                           regulation establish and maintain a list of each  
13                           biological agent and each toxin that has the po-  
14                           tential to pose a severe threat to public health  
15                           and safety.

16                           “(B) CRITERIA.—In determining whether  
17                           to include an agent or toxin on the list under  
18                           subparagraph (A), the Secretary shall—

19                                   “(i) consider—

20   “(I) the effect on human health  
21   of exposure to the agent or toxin;

22   “(II) the degree of contagious-  
23   ness of the agent or toxin and the  
24   methods by which the agent or toxin  
25   is transferred to humans;

1                   “(III) the availability and effec-  
2                   tiveness of immunizations to prevent  
3                   and treatments for any illness result-  
4                   ing from infection by the agent or  
5                   toxin; and

6                   “(IV) any other criteria that the  
7                   Secretary considers appropriate; and

8                   “(ii) consult with appropriate Federal  
9                   departments and agencies, and with sci-  
10                  entific experts representing appropriate  
11                  professional groups.

12                  “(2) BIENNIAL REVIEW.—The Secretary shall  
13                  review the list under paragraph (1) biennially, or  
14                  more often, and republish the list as necessary to in-  
15                  corporate revisions to protect the public health and  
16                  safety.

17                  “(b) REGULATION OF POSSESSION, USE, AND  
18                  TRANSFER OF LISTED BIOLOGICAL AGENTS AND TOX-  
19                  INS.—The Secretary shall by regulation provide for—

20                  “(1) the establishment and enforcement of safe-  
21                  ty standards and procedures for the possession, use  
22                  and transfer of biological agents and toxins listed  
23                  pursuant to subsection (a)(1), including measures to  
24                  ensure—

1           “(A) proper training and appropriate skills  
2           to handle such agents and toxins; and

3           “(B) proper laboratory facilities to contain  
4           and dispose of such agents and toxins;

5           “(2) the establishment and enforcement of safe-  
6           guards and security standards and procedures to  
7           prevent access to such agents and toxins for use in  
8           domestic or international terrorism or for any other  
9           criminal purpose;

10          “(3) the establishment of procedures to protect  
11          the public safety in the event of a violation of the  
12          safety procedures established under paragraph (1) or  
13          the safeguards established under paragraph (2); and

14          “(4) appropriate availability of biological agents  
15          and toxins for research, education, and other legiti-  
16          mate purposes.

17          “(c) REGISTRATION AND TRACEABILITY MECHA-  
18          NISMS; DATABASE.—Regulations under subsection (b)  
19          shall require registration of the possession, use, and trans-  
20          fer of biological agents and toxins listed pursuant to sub-  
21          section (a)(1), and such registration shall include informa-  
22          tion available to the registered persons regarding the char-  
23          acterization of such biological agents and toxins to facili-  
24          tate their identification and traceability. The Secretary

1 shall maintain a national database of the location of such  
2 agents and toxins, with their characterizations.

3 “(d) SECURITY AND SAFEGUARDS.—

4 “(1) IN GENERAL.—In carrying out paragraphs  
5 (2) and (3) of subsection (b), the Secretary shall es-  
6 tablish appropriate security requirements for persons  
7 possessing, using, or transferring biological agents  
8 and toxins listed pursuant to subsection (a)(1), and  
9 shall ensure compliance with such requirements as a  
10 condition of registration under regulations issued  
11 under subsection (c). In developing such require-  
12 ments the Secretary shall consult with the Attorney  
13 General and appropriate security experts.

14 “(2) RESTRICTED PERSONS.—Regulations  
15 issued under subsection (b) shall include  
16 provisions—

17 “(A) to restrict access to biological agents  
18 and toxins listed pursuant to subsection (a)(1)  
19 only to those individuals who need to handle or  
20 use such agents or toxins; and

21 “(B) to provide for prompt screening of  
22 such persons using criminal, immigration, and  
23 national security databases available to the  
24 Federal Government to identify persons who

1           are restricted persons, as defined in section  
2           175b of title 18, United States Code.

3           “(e) INSPECTIONS.—The Secretary shall have the au-  
4           thority to inspect persons subject to regulations under  
5           subsection (b) to ensure their compliance with such regu-  
6           lations.

7           “(f) EXEMPTIONS.—The Secretary may establish ex-  
8           emptions from the applicability of provisions of regulations  
9           under subsection (b) if the Secretary determines that the  
10          exemptions are consistent with protecting the public  
11          health and safety. Any exemption from registration under  
12          subsection (c) shall be based on transience of possession  
13          or on the lack of utility of the agent or toxin for use as  
14          a weapon, and shall be consistent with maintaining a com-  
15          plete database under such subsection (c).

16          “(g) DISCLOSURE OF INFORMATION.—

17                 “(1) IN GENERAL.—Any information in the  
18                 possession of any Federal agency that identifies a  
19                 person, or the geographic location of a person, who  
20                 is registered pursuant to regulations under this sec-  
21                 tion (including regulations promulgated before the  
22                 effective date of this subsection), and any site-spe-  
23                 cific information relating to the type, quantity, or  
24                 identity of a biological agent or toxin listed pursuant  
25                 to subsection (a)(1) or the site-specific security

1 mechanisms in place to protect such agents and tox-  
2 ins, shall not be disclosed under section 552(a) of  
3 title 5, United States Code.

4 “(2) DISCLOSURES FOR PUBLIC HEALTH AND  
5 SAFETY; CONGRESS.—Nothing in this section may be  
6 construed as preventing the head of any Federal  
7 agency—

8 “(A) from making disclosures of informa-  
9 tion described in paragraph (1) for purposes of  
10 protecting the public health and safety; or

11 “(B) from making disclosures of such in-  
12 formation to any committee or subcommittee of  
13 Congress with appropriate jurisdiction upon re-  
14 quest.

15 “(h) CIVIL PENALTY.—In addition to any other pen-  
16 alties that may apply under law, any person who violates  
17 any provision of regulations under subsection (b) shall be  
18 subject to the United States for a civil penalty in an  
19 amount not exceeding \$250,000 in the case of an indi-  
20 vidual and \$500,000 in the case of any other person.

21 “(i) DEFINITIONS.—For purposes of this section, the  
22 terms ‘biological agent’ and ‘toxin’ have the meanings  
23 given such terms in section 178 of title 18, United States  
24 Code.”.

25 (2) RELATION TO OTHER LAWS.—

1           (A) RULE OF CONSTRUCTION.—Regula-  
 2           tions promulgated by the Secretary of Health  
 3           and Human Services under section 511 of the  
 4           Antiterrorism and Effective Death Penalty Act  
 5           of 1998 are deemed to have been promulgated  
 6           under section 351A of the Public Health Serv-  
 7           ice Act, as added by paragraph (1) of this sub-  
 8           section. Such regulations, including the list  
 9           under subsection (d)(1) of such section 511,  
 10          that were in effect on the day before the date  
 11          of the enactment of this Act remain in effect  
 12          until modified by the Secretary.

13          (B) CONFORMING AMENDMENT.—Sub-  
 14          sections (d), (e), (f), and (g) of section 511 of  
 15          the Antiterrorism and Effective Death Penalty  
 16          Act of 1996 (42 U.S.C. 262 note) are repealed.

17          (3) REGULATIONS REGARDING REGISTRA-  
 18          TION.—

19               (A) DATE CERTAIN FOR PROMULGATION;  
 20               EFFECTIVE DATE REGARDING CRIMINAL AND  
 21               CIVIL PENALTIES.—Not later than 30 days  
 22               after the date of the enactment of this Act, the  
 23               Secretary of Health and Human Services shall  
 24               promulgate an interim final rule for carrying  
 25               out section 351A(c) of the Public Health Serv-

1 ice Act, as added by paragraph (1) of this sub-  
2 section. Such interim final rule takes effect 60  
3 days after the date on which such rule is pro-  
4 mulgated for purposes of—

5 (i) section 175B (b) and (c) of title  
6 18, United States Code (relating to crimi-  
7 nal penalties, as added by subsection (b) of  
8 this section; and

9 (ii) section 351(h) of the Public  
10 Health Service Act (relating to civil pen-  
11 alties).

12 (B) SUBMISSION OF REGISTRATION APPLI-  
13 CATIONS.—A person who, as of the date of the  
14 interim final rule promulgated under subpara-  
15 graph (A), is in possession of a biological agent  
16 or toxin listed pursuant to section 351A(a) of  
17 the Public Health Service Act, as added by  
18 paragraph (1) of this subsection, shall in ac-  
19 cordance with such interim final rule, submit an  
20 application for a registration to possess such  
21 agent or toxin not later than 30 days after the  
22 date on which such rule is promulgated.

23 (4) EFFECTIVE DATE REGARDING DISCLOSURE  
24 OF INFORMATION.—Subsection (g) of section 351A  
25 of the Public Health Service Act, as added by para-

1 graph (1) of this subsection, is deemed to have  
2 taken effect on the effective date of the  
3 Antiterrorism and Effective Death Penalty Act of  
4 1996.

5 (b) SELECT AGENTS.—

6 (1) IN GENERAL.—Section 175b of title 18,  
7 United States Code, as added by section 817 of Pub-  
8 lic Law 107–56, is amended—

9 (A) by striking “(a)” and inserting  
10 “(a)(1)”;

11 (B) by transferring subsection (c) from the  
12 current placement of the subsection and insert-  
13 ing the subsection before subsection (b).

14 (C) by striking “(c)” and inserting “(2)”;

15 (D) by redesignating subsection (b) as sub-  
16 section (d); and

17 (E) by inserting before subsection (d) as so  
18 redesignated) the following subsections:

19 “(b) UNREGISTERED FOR POSSESSION OR TRANS-  
20 FER.—Whoever knowingly possesses or transfers a select  
21 agent for which such person has not obtained a registra-  
22 tion required by a regulation issued under section 351A(c)  
23 of the Public Health Service Act shall be fined under this  
24 title, or imprisoned for not more than 5 years, or both.

1       “(c) TRANSFER TO UNREGISTERED PERSON.—Who-  
2 ever knowingly transfers a select agent to a person who  
3 has not obtained a registration required by a regulation  
4 issued under subsection (c) of section 351A of the Public  
5 Health Service Act shall be fined under this title, or impris-  
6 oned for not more than 5 years, or both.”.

7       (c) REPORT TO CONGRESS.—Not later than 1 year  
8 after the date of the enactment of this Act, the Secretary  
9 of Health and Human Services, after consultation with  
10 other appropriate Federal agencies, shall submit to Con-  
11 gress a report that—

12           (1) describes the extent to which there has been  
13 compliance by governmental and private entities  
14 with applicable regulations under section 351A of  
15 the Public Health Service Act (as added by sub-  
16 section (a)(1));

17           (2) describes the actions taken by the date of  
18 the report and future plans of the Secretary for up-  
19 dating the list of biological agents and toxins under  
20 such section 351A;

21           (3) describes the actions taken by the date of  
22 the report and future plans of the Secretary for de-  
23 termining compliance with regulations under such  
24 section 351A and for taking appropriate enforce-  
25 ment actions; and

1           (4) provides any recommendations of the Sec-  
2           retary for administrative or legislative initiatives re-  
3           garding such section 351A.

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