

## 2001 SENATE BILL 421

February 5, 2002 – Introduced by Senators COWLES, BURKE and DARLING, cosponsored by Representatives FREESE, KRAWCZYK, LASSA, HAHN, SYKORA, TOWNSEND and RYBA. Referred to Committee on Health, Utilities, Veterans and Military Affairs.

1     **AN ACT** *to create* 146.61 of the statutes; **relating to:** creating a biological agent  
2             registry, requiring reporting of biological agents, requiring the exercise of  
3             rule-making authority, and providing a penalty.

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### *Analysis by the Legislative Reference Bureau*

Current federal law requires that facilities that transfer or receive certain microorganisms or toxins register with an entity that is authorized by the federal secretary of health and human services.

This bill requires the department of health and family services (DHFS) to maintain a registry of biological agents that are possessed or maintained in Wisconsin. Information in the registry is not a public record and may be released by DHFS only to the federal centers for disease control and prevention or, under specified circumstances, to a law enforcement agency. “Biological agent” is defined in the bill to mean a virus, bacterium, rickettsia, fungus, or toxin that is specified in federal regulations, or certain genetically modified microorganisms or elements. Reporting is not required if the biological agent is part of a clinical specimen that is intended for diagnosis, reference, or verification purposes, although isolates that are recovered from these specimens must be destroyed when the diagnosis is complete. The report also is not required if the biological agent is a vaccine strain or toxin that is specified in federal regulations as exempt from federal reporting requirements. DHFS must promulgate rules that specify the biological agents that are required to be listed in the registry and reported, the information required to be reported and the frequency and time limitations for the reporting, and criteria for biosafety

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standards that are consistent with federal requirements. Before promulgating the initial rules, DHFS must consult with members of an advisory committee appointed by the secretary of health and family services.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

1           **SECTION 1.** 146.61 of the statutes is created to read:

2           **146.61 Biological agent registry. (1)** In this section:

3           (a) “Biological agent” means any of the following:

4           1. A select agent that is a virus, bacterium, rickettsia, fungus, or toxin that is  
5 specified under 42 CFR 72, Appendix A.

6           2. A genetically modified microorganism or genetic element from an organism  
7 under subd. 1. that is shown to produce or encode for a factor associated with a  
8 disease.

9           3. A genetically modified microorganism or genetic element that contains  
10 nucleic acid sequences coding for a toxin under subd. 1. or its toxic subunit.

11           (b) “Law enforcement agency” has the meaning given in s. 165.77 (1) (b).

12           (c) “State agency” has the meaning given in s. 16.375 (1).

13           (d) “State epidemiologist” has the meaning given in s. 252.01 (6).

14           **(2)** The department shall maintain a registry of biological agents that are  
15 possessed or maintained in this state.

16           **(3)** After first consulting with the committee under 2001 Wisconsin Act .... (this  
17 act), section 2 (1), for initial rules, the department shall promulgate rules that do all  
18 of the following, for implementation and maintenance of the registry specified in sub.

19           (2):

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1 (a) Specify the biological agents that are required to be listed in the registry and  
2 reported under sub. (4).

3 (b) Specify the information required to be reported under sub. (4), and the  
4 frequency and time limitations for the reporting.

5 (c) Specify criteria for biosafety standards, for persons handling biological  
6 agents, that are consistent with requirements under 42 CFR 72.6 (c) (1).

7 **(4)** Except as provided in subs. (5) and (6), whoever possesses or maintains a  
8 biological agent that is specified by rule under sub. (3) (a) shall report to the  
9 department, on a form designated by the department, the information specified by  
10 rule under sub. (3) (b) in the frequency and under the time limitations specified by  
11 rule under sub. (3) (b).

12 **(5)** (a) Subsection (4) does not apply to a biological agent to which any of the  
13 following applies:

14 1. The biological agent is part of a clinical specimen that is intended for  
15 diagnostic, reference, or verification purposes. Isolates that are recovered from these  
16 clinical specimens and that are used for diagnostic purposes shall be destroyed when  
17 the diagnosis is completed.

18 2. The biological agent is a vaccine strain or a toxin that is specified as exempt  
19 under 42 CFR 72, Appendix A.

20 (b) Subsection (4) does not apply to a clinical laboratory that is certified under  
21 42 USC 263a and that uses biological agents for diagnostic, reference, verification,  
22 or proficiency testing purposes.

23 **(6)** A state agency, an authority, or a corporate entity may report to the  
24 department, as required under sub. (4), on behalf of the state agency's, authority's,  
25 or corporate entity's personnel to which sub. (4) applies.

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1           **(7)** Information submitted to or maintained in the registry under this section  
2 is confidential, is not a public record under subch. II of ch. 19, and may be released  
3 by the department only to a law enforcement agency under a communicable disease  
4 investigation or in connection with an investigation involving the release, theft, or  
5 loss of a biological agent or to the centers for disease control and prevention of the  
6 federal department of health and human services.

7           **(8)** Whoever violates this section may be required to forfeit not more than  
8 \$1,000 for the first offense and may be required to forfeit not more than \$10,000 for  
9 the 2nd or any subsequent offense within a year. Each day of continued violation  
10 constitutes a separate offense. The one-year period shall be measured by using the  
11 dates of the offenses that resulted in convictions.

**SECTION 2. Nonstatutory provisions.**

12           **(1) APPOINTMENT OF ADVISORY COMMITTEE.** The secretary of health and family  
13 services shall exercise his or her authority under section 15.04 (1) (c) of the statutes  
14 to appoint all of the following as members of an advisory committee that shall provide  
15 recommendations to the department of health and family services concerning the  
16 initial rules promulgated under section 146.61 (3) of the statutes, as created by this  
17 act:  
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19           (a) A representative of employees of the University of Wisconsin–Madison who  
20 perform research using biological agents.

21           (b) A representative of the state laboratory of hygiene.

22           (c) A representative of the department of health and family services.

23           (d) A representative of the biotechnology industry.

24           (e) The state epidemiologist, appointed under section 252.01 (6) of the statutes.

**SECTION 3. Effective date.**  
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1 (1) This act takes effect on the first day of the 10th month beginning after  
2 publication.

3 (END)