

**2001 DRAFTING REQUEST**

**Bill**

Received: 11/11/2001

Received By: kenneda

Wanted: As time permits

Identical to LRB:

For: Robert Cowles (608) 266-0484

By/Representing: Jennifer Halbur

This file may be shown to any legislator: NO

Drafter: kenneda

May Contact:

Addl. Drafters:

Subject: Health - public health

Extra Copies:

Submit via email: YES

Requester's email: Sen.Cowles@legis.state.wi.us

Carbon copy (CC:) to:

---

**Pre Topic:**

No specific pre topic given

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**Topic:**

Biological agents registry

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**Instructions:**

See Attached

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**Drafting History:**

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/P1	kenneda 11/26/2001	gilfokm 11/28/2001 rschluet 11/29/2001	jfrantze 11/29/2001	_____	lrb_docadmin 11/29/2001		
/P2	kenneda 12/28/2001	gilfokm 01/04/2002	jfrantze 01/07/2002	_____	lrb_docadmin 01/07/2002		

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/1	kenneda 01/21/2002	gilfokm 01/24/2002	jfrantze 01/25/2002	_____	lrb_docadmin 01/25/2002	lrb_docadminS&L 01/28/2002	lrb_docadmin 01/28/2002
				_____			
				_____			
				_____			

FE Sent For:

LA Intro.

<END>

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Vers.    Drafted    Reviewed    Typed    Proofed    Submitted    Jacketed    Required

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May Contact:

Addl. Drafters:

Subject: **Health - public health**

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Submit via email: **YES**

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/P1	kenneda 11/26/2001	gilfokm 11/28/2001	jfrantze 11/29/2001	_____	lrb_docadmin 11/29/2001		

~~Schluer~~  
11/29/2001

*Jo 1/7* *Jo 1/7*

FE Sent For:

1st/p2 - 12/28/01  
*KMG*  
2nd/p2 - 1/4/02  
*KMG*

**2001 DRAFTING REQUEST**

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1?	kenneda	1/11/28 Kmg	J 11/29	J 11/29			

FE Sent For:

<END>





# ROBERT L. COWLES

Wisconsin State Senator • 2nd Senate District

November 8, 2001

To: Debora Kennedy

From: Jennifer Halbur

Re: Biological Agents Registry

Senator Cowles would like a bill drafted to create a biological agents registry in Wisconsin.

I have attached a bill introduced in North Carolina that creates a registry for that state. Rob would like the same bill introduced in Wisconsin.

Please let me know if there are any problems in applying the North Carolina bill in Wisconsin or if you need any further information. I can be reached at 266-0484.

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2001

H

1

HOUSE BILL 1472\*

Short Title: Biological Agents Registry.

(Public)

Sponsors: Representatives Culpepper; Goodwin and M. Crawford.

Referred to: Judiciary II.

October 30, 2001

1 A BILL TO BE ENTITLED  
2 AN ACT DIRECTING THE DEPARTMENT OF HEALTH AND HUMAN  
3 SERVICES TO ESTABLISH A BIOLOGICAL AGENTS REGISTRY, AND  
4 IMPOSING CIVIL PENALTIES FOR VIOLATION OF REGISTRY  
5 REQUIREMENTS.

6 The General Assembly of North Carolina enacts:

7 SECTION 1. Part 1 of Article 6 of Chapter 130A of the General Statutes is  
8 amended by adding the following new section to read:

9 "§ 130A-149. Biological agents registry; rules; penalties.

10 (a) The Department shall establish and administer a program for the registration  
11 of biological agents. The biological agents registry shall identify the biological agents  
12 possessed or maintained by any laboratory, medical facility, or research facility in this  
13 State and shall contain other information required under rules adopted by the  
14 Commission. As used in this section, the term 'biological agent' means any  
15 microorganism, virus, infectious substance, or biological product that may be  
16 engineered as a result of biotechnology, or any naturally occurring or bioengineered  
17 component of any such microorganism, virus, infectious substance, or biological  
18 product capable of causing:

- 19 (1) Death, disease, or other biological malfunction in a human, an animal,  
20 a plant, or another living organism;
- 21 (2) Deterioration of food, water, equipment, supplies, or material of any  
22 kind;
- 23 (3) Deleterious alteration of the environment; or
- 24 (4) Any other risk of serious harm to the public health or safety.

25 (b) The Commission shall adopt rules for the implementation of the registry  
26 program, as follows:

- 27 (1) Determining the biological agents required to be reported under this  
28 section.

## GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 2001

1           (2) Designating specific information required to be reported including  
2           time limits for reporting, form of reports, and to whom reports shall be  
3           submitted.

4           (3) Providing for the release of information in the registry to State and  
5           federal law enforcement agencies and the United States Centers for  
6           Disease Control and Prevention pursuant to a communicable disease  
7           investigation commenced or conducted by the Department, the  
8           Commission, or other State or federal law enforcement agency having  
9           investigatory authority, or in connection with any investigation  
10           involving release, theft, or loss of biological agents.

11           (4) Establishing a system of safeguards to be followed by laboratories,  
12           medical facilities, and research facilities, including a process for the  
13           laboratories or facilities to alert appropriate authorities of unauthorized  
14           possession or attempted possession of biological agents. The rules  
15           shall designate appropriate authorities for receipt of alerts from  
16           laboratories or facilities.

17           (c) Any person having administrative authority over a laboratory, medical  
18           facility, or research facility that possesses or maintains any biological agent required to  
19           be reported shall report to the Department the information required by the Commission  
20           for inclusion in the biological agent registry.

21           (d) Except as otherwise provided in this section, information maintained in the  
22           registry pursuant to this section shall be confidential and shall not be a public record  
23           under G.S. 132-1. The Department may, in accordance with rules adopted by the  
24           Commission, release information contained in the biological agent registry for the  
25           purpose of conducting or aiding in a communicable disease investigation. The  
26           Department shall cooperate with and may share information contained in the biological  
27           agent registry with the United States Centers for Disease Control and Prevention, and  
28           state and federal law enforcement agencies in any investigation involving the release,  
29           theft, or loss of a biological agent required to be reported under this section. Release of  
30           information from the registry as authorized under this subsection shall not render the  
31           information released a public record under G.S. 132-1.

32           (e) The Department shall impose a civil penalty for violation of this section in  
33           the amount of up to one thousand dollars (\$1,000). Each day of a continuing violation  
34           shall be a separate offense. Any laboratory or facility wishing to contest a penalty shall  
35           be entitled to an administrative hearing in accordance with Chapter 150B of the General  
36           Statutes."

37           **SECTION 2.** G.S. 130A-29(c) is amended by adding the following  
38 subdivision to read:

39           "(10) Pertaining to the biological agents registry in accordance with G.S.  
40           130A-149."

41           **SECTION 3.** This act becomes effective January 1, 2002.



## House Bill 1472

### BIOLOGICAL AGENTS REGISTRY.

Bill Text: [Edition 1](#) | [Edition 2](#)

Introduced by: [Crawford, M](#); [Culpepper](#); [Goodwin](#);

P/L = Public/Local Bill | \$ = Affects Appropriations  
 \* = Bill Text Has Changed

Session: 2001 - 2002

Prime Sponsors: [William T. Culpepper, III.](#)

Fiscal Note: [Available](#)

Attributes: P \*

Date	Action
10/30/2001	H Filed
10/30/2001	H Ref To Com On Judiciary II
11/06/2001	HA Reptd Fav Com Substitute
11/06/2001	H Cal Pursuant Rule 36(b)

[\[how a law is made\]](#)

### Bill Look-Up

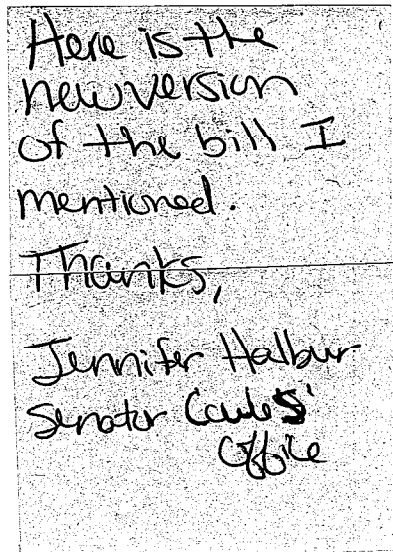
Enter a bill number to search for.

Example: Enter *s7* to search for Senate Bill 7 or *h7* to search for House Bill 7.

2001 - 2002 Session  Bill Number:

[Disclaimer](#)

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**NORTH CAROLINA GENERAL ASSEMBLY**

**LEGISLATIVE FISCAL NOTE**

**BILL NUMBER:** H1472 (Proposed Committee Substitute)

**SHORT TITLE:** Biological Agents Registry

**SPONSOR(S):** Representative Culpepper

<b>FISCAL IMPACT</b>					
	<b>Yes (x)</b>	<b>No ( )</b>	<b>No Estimate Available ( )</b>		
	<b><u>FY 2001-02</u></b>	<b><u>FY 2002-03</u></b>	<b><u>FY 2003-04</u></b>	<b><u>FY 2004-05</u></b>	<b><u>FY 2005-06</u></b>
<b>REVENUES</b>	<b>*Cannot be estimated</b>				
<b>EXPENDITURES</b>					
Division of Public Health					
LOW ESTIMATE	\$4,900*	\$7,395	\$7,617	\$7,786	\$8,081
POSITIONS:	.225	.15	.15	.15	.15
HIGH ESTIMATE	\$30,600*	\$61,918	\$63,775	\$65,688	\$67,659
POSITIONS:	1.05	1.05	1.05	1.05	1.05
<b>*Figure represents six months of program expenditures</b>					
<b>PRINCIPAL DEPARTMENT(S) &amp; PROGRAM(S) AFFECTED:</b> Division of Public Health					
<b>EFFECTIVE DATE:</b> January 1, 2002					

**BILL SUMMARY:** Amends GS 130A to require the Department of Health and Human Services to establish and administer a program for the registration of biological agents. The Commission for Health Services shall adopt rules for the implementation of the registry, which includes determining the agents to be reported, designating the specific information to be maintained, providing for the release of information in the registry to State and Federal law enforcement agencies, and establishing a system of safeguards to be followed by laboratories and other entities. The information collected shall be confidentially maintained and the Department shall only release information according to the rules adopted by the Commission. The Department shall impose a civil penalty for willful and knowing violation of this act, of \$1,000 per day for each day of violation.

**ASSUMPTIONS AND METHODOLOGY:**

Included is a high and low estimate for the budget. For the low estimation, it is anticipated that the development and subsequent maintenance of the registry may be completed by a portion of two positions: an Office Assistant V and a Medical Laboratory Supervisor II. It is estimated for the first three months that 20% of the Office Assistant V's time will be spent on the creation of the registry/database, contacting the laboratories and other persons who may possess biological agents, and developing internal procedures for the tracking of select agents. It is estimated that this staff person's time for maintenance of the registry will decrease to 15% for support and further refining the registry during the last three months of FY02. It is anticipated that a Medical Laboratory Supervisor II will spend 5% of their time managing the development of the registry. For the purpose of this fiscal analysis, the midpoints of the position pay grades were used for calculations. Beginning in FY03, it is estimated that the clerical staff time needed for maintenance of the registry will further reduce to 10% of an Office Assist V's time and will continue at 5% of a Medical Laboratory Supervisor II's time.

LOW						HIGH					
Expenses	FY01-02	FY02-03	FY03-04	FY04-05	FY05-06	Expenses	FY01-02	FY02-03	FY03-04	FY04-05	FY05-06
Pay Grade 61 Office Assistant V	3 months @ 20% and 3 months @ 15% \$2,925	\$3,445	\$3,549	\$3,655	\$3,765	Pay Grade 72 - Laboratory Specialist	\$28,125	\$57,938	\$59,676	\$61,466	\$63,310
Pay Grade 74 Medical Laboratory Supervisor II	5% of time for 6 months \$1,475	\$2,950	\$3,039	\$3,130	\$3,224	Pay Grade 74 Medical Laboratory Supervisor II	5% of time for 6 months \$1475	\$2,950	\$3,039	\$3,130	\$3,224
Supplies/Miscellaneous	\$500	\$1,000	\$1,030	\$1,061	\$1,093	Supplies	\$1,000	\$1,030	\$1,061	\$1,093	\$1,126
<b>Total</b>	<b>\$4,900</b>	<b>\$7,395</b>	<b>\$7,617</b>	<b>\$7,846</b>	<b>\$8,081</b>	<b>Total</b>	<b>\$30,600</b>	<b>\$61,918</b>	<b>\$63,775</b>	<b>\$65,688</b>	<b>\$67,659</b>

For the high estimate, it is proposed that it will take a full time position at a program manager level to develop the database, contact the laboratories and entities that will become subject to this legislation, create the internal policies for this registry and to fully develop a secure database (as prescribed by the legislation). For the purpose of fiscal analysis, a full time pay grade 72 position has been used. The 5% of a manager's time is consistent with the low estimate.

It is estimated that 50 – 75 laboratories and entities will be reporting. Language in the Proposed Committee Substitute has broadened the definition of those required to report; therefore, this range may be low. Estimates for the amount to be collected from laboratories/persons for noncompliance are unavailable at this time. In addition, the Department will utilize a computer and software for the registry which it has available. The

fiscal analysis includes office supplies and postage for the first fiscal year at \$500 and subsequent years at \$1000 in addition to the staffing needs.

The legislation is effective January 1, 2002; therefore, the first year of the fiscal analysis is based on six months of operation and the additional years include 12 months. The calculations are based on a 3% inflationary increase.

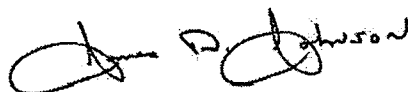
The Department has indicated they can absorb these program expenses within existing budget.

**TECHNICAL CONSIDERATIONS:**

**FISCAL RESEARCH DIVISION 733-4910**

**PREPARED BY:** Lisa Hollowell

**APPROVED BY:** James D. Johnson

A handwritten signature in black ink, appearing to read "James D. Johnson", is written over the printed name.

**DATE:** November 6, 2001

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2001

H

2

HOUSE BILL 1472\*  
Committee Substitute Favorable 11/6/01

Short Title: Biological Agents Registry. (Public)  
Sponsors:  
Referred to:

October 30, 2001

A BILL TO BE ENTITLED  
AN ACT DIRECTING THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO  
ESTABLISH A BIOLOGICAL AGENTS REGISTRY, AND IMPOSING CIVIL  
PENALTIES FOR VIOLATION OF REGISTRY REQUIREMENTS.

The General Assembly of North Carolina enacts:

**SECTION 1.** Part 1 of Article 6 of Chapter 130A  
of the General Statutes is amended by adding the following new  
section to read:

**"§ 130A-149. Biological agents registry; rules;  
penalties.**

(a) The Department shall establish and  
administer a program for the registration of biological agents.  
The biological agents registry shall identify the biological  
agents possessed and maintained by any person in this State and  
shall contain other information required under rules adopted by  
the Commission.

(b) The following definitions apply in this  
section:

(1) 'Biological agent' means:

- a. Any select agent that is a  
microorganism, virus, bacterium, fungus,  
rickettsia, or toxin listed in Appendix A of  
Part 72 of Title 42 of the Code of Federal  
Regulations.
- b. Any genetically modified  
microorganisms or genetic elements from an  
organism on Appendix A of Part 72 of Title 42  
of the Code of Federal Regulations, shown to  
produce or encode for a factor associated with  
a disease.
- c. Any genetically modified  
microorganisms or genetic elements that  
contain nucleic acid sequences coding for any  
of the toxins listed on Appendix A of Part 72  
of Title 42 of the Code of Federal  
Regulations, or their toxic submits.

(2) 'Person' means any association,  
business, corporation, facility, firm, individual,  
institution of higher education, organization,  
partnership, society, State agency, or other legal  
entity.

(c) The Commission shall adopt rules for the  
implementation of the registry program, as follows:

(1) Determining and listing the biological



agents required to be reported under this section.

- (2) Designating persons required to make reports and specific information required to be reported including time limits for reporting, form of reports, and to whom reports shall be submitted.
- (3) Providing for the release of information in the registry to State and federal law enforcement agencies and the United States Centers for Disease Control and Prevention pursuant to a communicable disease investigation commenced or conducted by the Department, the Commission, or other state or federal law enforcement agency having investigatory authority, or in connection with any investigation involving release, theft, or loss of biological agents.
- (4) Establishing a system of safeguards that requires persons possessing and maintaining biological agents subject to this section to comply with the same federal standards that apply to persons registered to possess the same agents under federal law.
- (5) Establishing a process for persons that possess and maintain biological agents to alert appropriate authorities of unauthorized possession or attempted possession of biological agents. The rules shall designate appropriate authorities for receipt of alerts from these persons.

(d) Any person that possesses and maintains any biological agent required to be reported under this section shall report to the Department the information required by the Commission for inclusion in the biological agent registry.

(e) Except as otherwise provided in this section, information prepared for or maintained in the registry under this section shall be confidential and shall not be a public record under G.S. 132-1. The Department may, in accordance with rules adopted by the Commission, release information contained in the biological agent registry for the purpose of conducting or aiding in a communicable disease investigation. The Department shall cooperate with and may share information contained in the biological agent registry with the United States Centers for Disease Control and Prevention, and state and federal law enforcement agencies in any investigation involving the release, theft, or loss of a biological agent required to be reported under this section. Release of information from the registry as authorized under this subsection shall not render the information released a public record under G.S. 132-1. Release of information from the registry as authorized under this subsection also shall not render the information prepared for or maintained in the registry a public record under G.S. 132-1.

(f) The Department shall impose a civil penalty for a willful or knowing violation of this section in the amount of up to one thousand dollars (\$1,000). Each day of a continuing violation shall be a separate offense. Any person wishing to contest a penalty shall be entitled to an administrative hearing in accordance with Chapter 150B of the General Statutes."

**SECTION 2.** G.S. 130A-29(c) is amended by adding

the following subdivision to read:

"(10) Pertaining to the biological agents  
registry in accordance with G.S. 130A-149."

**SECTION 3.** This act becomes effective January 1,  
2002.

## TELEPHONE DRAFTING INSTRUCTIONS

Drafting instructions received by Debora Kennedy.

DATE: 11/26/01  
CONVERSATION WITH: Jennifer Halber  
OF: Counsel's office  
TELEPHONE NO: 6-0484  
REGARDING LRB # OR DRAFT TOPIC: 4234 - Biol. agents registry

### INSTRUCTIONS:

- ① Is it necessary to require procedures by rule for "alerting authorities"? No; delete
- ② Present draft? Yes
- ③ Make regular misdemeanor for viol., rather than admin for future? Yes



King

D-NOTE

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

Sen. Cat.

1 AN ACT ~~relating to~~; relating to: creating a biological agent registry, requiring the exercise  
2 of rule-making authority, and providing a penalty.

*Analysis by the Legislative Reference Bureau*

This is a preliminary draft. An analysis will be provided for a later version.

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

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

4 146.61 Biological agent registry. (1) In this section:

5 (a) "Biological agent" means any of the following:

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

8 2. A genetically modified microorganism or genetic element from an organism  
9 under ~~par. (a)~~ that is shown to produce or encode for a factor associated with a  
10 disease.

subd. 1.

subd. 1.

1 3. A genetically modified microorganism or genetic element that contains  
2 nucleic acid sequences coding for a ~~toxin~~ toxin under ~~part (a)~~ or its toxic subunit.

3 (b) "Law enforcement agency" has the meaning given in s. 165.77 (1) (b).

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

that do all of the following

6 (3) The department shall promulgate ~~all of the following~~ rules for  
7 implementation and maintenance of the registry specified in sub. (2):

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

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

12 (c) Specify ~~the~~ criteria for biosafety standards for persons handling biological  
13 agents that are consistent with requirements under 42 CFR 72.6 (c) (1).

14 (4) Whoever possesses or maintains a biological agent that is specified by rule  
15 under sub. (3) (a) shall report to the department, on a form designated by the  
16 department, the information specified by rule under sub. (3) (b) in the frequency and  
17 under the time limitations specified by rule under sub. (3) (b).

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

24 (6) Whoever violates this section may be required to forfeit not more than  
25 ~~for~~ for the first offense and may be required to forfeit not more than ~~for~~ for

\$1,000

\$10,000

*subsequent*

1 the 2nd or any ~~subsequent~~ offense within a year. Each day of continued violation constitutes  
2 a separate offense. The one-year period shall be measured by using the dates of the  
3 offenses that resulted in convictions.

4

(END)

D. NOTE

**DRAFTER'S NOTE**  
**FROM THE**  
**LEGISLATIVE REFERENCE BUREAU**

LRB-4234/fdn <sup>pl</sup>

DAK:j....  
*mg*

To Jennifer Halbur:

I have not specified an effective date for this bill, but it needs at least a 9-month delayed effective date, in order to provide time for promulgation of the rules. It would be possible for DHFS to promulgate emergency rules within a shorter time, without requiring a finding of emergency, if you wish.

Please review carefully the penalty provision; I have made it applicable to a violation of s. ~~146.62~~ *but you may wish to narrow it considerably. Please review the penalty amounts*

Please do not hesitate to let me know if you need further assistance with this bill.

*146.61(4)  
or (5)*

Debora A. Kennedy  
Managing Attorney  
Phone: (608) 266-0137  
E-mail: debora.kennedy@legis.state.wi.us

**DRAFTER'S NOTE**  
**FROM THE**  
**LEGISLATIVE REFERENCE BUREAU**

LRB-4234/P1dn  
DAK:kmg:jf

November 29, 2001

To Jennifer Halbur:

I have not specified an effective date for this bill, but it needs at least a 9-month delayed effective date, in order to provide time for promulgation of the rules. It would be possible for DHFS to promulgate emergency rules within a shorter time, without requiring a finding of emergency, if you wish.

Please review carefully the penalty provision; I have made it applicable to a violation of s. 146.61 (4) or (5). Please review the penalty amounts.

Please do not hesitate to let me know if you need further assistance with this bill.

Debra A. Kennedy  
Managing Attorney  
Phone: (608) 266-0137  
E-mail: [debra.kennedy@legis.state.wi.us](mailto:debra.kennedy@legis.state.wi.us)





# ROBERT L. COWLES

Wisconsin State Senator • 2nd Senate District

December 13, 2001

To: Debora Kennedy

From: Jennifer Halbur

Re: LRB 4234/P1dn relating to the creation of a biological registry

Senator Cowles would like to include the creation of an advisory group in this bill. The purpose of the group would be to provide recommendations to DHFS relating to items (a) (b) and (c) listed under 146.61 (3). The group should consist of one representative from each of following populations: UW researchers, the State Laboratory of Hygiene, the Department of Health and Family Services and the Biotechnology companies. The members of the advisory group should be appointed by the State Epidemiologist for Communicable Diseases.

✓ The Senator would like to exempt archived species from the reporting requirements. Therefore, any lab that has archived biological agent species would not have to report those species to the DHFS. *See later memo*

✓ The penalty amounts in the bill can remain as you have them for now.

✓ Please provide a 9 month delayed effective date for the bill.

Please let me know you have any questions or need any further information from me.  
Phone: 266-0484



# ROBERT L. COWLES

Wisconsin State Senator • 2nd Senate District

December 19, 2001

To: Debora Kennedy  
From: Jennifer Halbur  
Re: Biological Agents Registry

I have attached a list of exemptions that Senator Cowles would like to include in the Biological Agents Registry bill.

In the last memo that I sent to you regarding modifications to the draft, I listed "archived species," as something that should be exempt. The attached sheet addresses this issue as well under A. 4.

Part B on the attached sheet relating to "authorized registering agencies" makes reference to 42 CFR Pt. 72.6 (C). It is my understanding that this refers to "corporations." I am not sure if a different term would have to be used in our bill to ensure Universities are included.

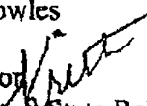
Please let me know if you have any questions or need further information from me. I can be reached at 266-0484.

UNIVERSITY OF  
**WISCONSIN**  
M A D I S O N

VIA FACSIMILE

December 18, 2001

TO: Senator Rob Cowles

FROM: Kristi V. Thorson   
Assistant Director, State Relations

RE: Biological Agents Registry

Thank you for welcoming the University of Wisconsin-Madison's comments on your proposed legislation, the biological agents registry bill (LRB 4234). We appreciate the opportunity to make suggestions that we hope will reinforce and strengthen the intent of your bill while avoiding unintended implications that might jeopardize important basic research, medical applications or commercial activities. The following comments reflect suggestions made by various faculty and staff representing our College of Agriculture and Life Sciences, School of Veterinary Medicine, Graduate School, State Lab of Hygiene, Safety Department and others.

**A. Exemptions**

**Suggestion:** Include language to permit exemptions compatible with those allowed under 42 CFR Pt. 72.6 (h). They include:

1. If the agent is part of a clinical specimen intended for diagnostic, reference or verification purposes. Isolates recovered from such specimens must be destroyed after diagnosis is complete.
2. If the agent is a toxin with an LD50 for vertebrates of more than 100ng per kg body weight and is used for medical or biomedical research.
3. The agent is an exempted strain. (This usually means a non-virulent strain or "vaccine" strain.)
4. Certain clinical laboratories (such as the State Lab of Hygiene) can possess agents for diagnosis and reference purposes.

**Rationale:** To test for certain organisms, labs must have positive controls to ensure that the test is working properly.

**B. Authorized registering agencies**

**Suggestion:** Include language authorizing state agencies and corporate entities to register with the department on behalf of their personnel. Such a provision would be consistent with 42 CFR Pt. 72.6 (c).

Office of the Chancellor

Memo to Senator Cowles re. LRB 4234

December 18, 2001

Page 2

**Rationale:** This would greatly facilitate registration by large organizations (universities, biotech companies, medical units) operating in the state. This approach is consistent with the current policy employed by the Center for Disease Control.

I hope these comments are useful. In so far as the proposed legislation parallels federal policy and adopts federal standards it should not introduce significant hardships for the University and our faculty and staff.

Associate Dean Tim Mulcahy from the Graduate School and I look forward to discussing this bill with you and Jennifer tomorrow afternoon.

CC: Tim Mulcahy



D-NOTE

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

requiring reporting of biological agents,

1 AN ACT <sup>Gen. Cat.</sup> to create 146.61 of the statutes; relating to: creating a biological agent  
2 registry, requiring the exercise of rule-making authority, and providing a  
3 penalty.

*Analysis by the Legislative Reference Bureau*

This is a preliminary draft. An analysis will be provided for a later version.

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

4 SECTION 1. 146.61 of the statutes is created to read:  
5 146.61 Biological agent registry. (1) In this section:  
6 (a) "Biological agent" means any of the following:  
7 1. A select agent that is a virus, bacterium, rickettsia, fungus, or toxin that is  
8 specified under 42 CFR 72, Appendix A.  
9 2. A genetically modified microorganism or genetic element from an organism  
10 under subd. 1. that is shown to produce or encode for a factor associated with a  
11 disease.

consulting

After first consulting with the committee under sub. (7),

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

INSERT 2-3

3 (b) "Law enforcement agency" has the meaning given in s. 165.77 (1) (b).

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

6 (3) The department shall promulgate rules that do all of the following, for  
7 implementation and maintenance of the registry specified in sub. (2):

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

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

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

14 (4) <sup>Except as provided under subs. (5) and (6),</sup> Whoever possesses or maintains a biological agent that is specified by rule  
15 under sub. (3) (a) shall report to the department, on a form designated by the  
16 department, the information specified by rule under sub. (3) (b) in the frequency and  
17 under the time limitations specified by rule under sub. (3) (b).

INSERT 2-17

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

24 (9) Whoever violates this section may be required to forfeit not more than  
25 \$1,000 for the first offense and may be required to forfeit not more than \$10,000 for

9

1 the 2nd or any subsequent offense within a year. Each day of continued violation  
2 constitutes a separate offense. The one-year period shall be measured by using the  
3 dates of the offenses that resulted in convictions.

INSERT  
3-3

4 (END)

D-NOTE

(INSERT 2-3)

✓

(c) "State agency" has the meaning given in s.

16.375(1). ✓

(d) "State epidemiologist" has the meaning given

in s. 252.01(6). ✓



INSERT 2-17

(B) (a) (5) Subsection (4) does <sup>not</sup> apply to a biological agent

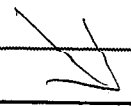
to which any of the following applies:

1. ~~If~~ the biological agent is part of a clinical specimen that is intended for diagnostic, reference, or verification purposes. <sup>Isolates</sup> ~~Isolates~~ that are recovered from these ~~chemical~~ <sup>clinical</sup> specimens and that are used for diagnostic purposes shall be destroyed when the diagnosis is completed.

2. ~~If~~ the <sup>biological</sup> agent is a vaccine strain or a toxin that is specified as exempt under

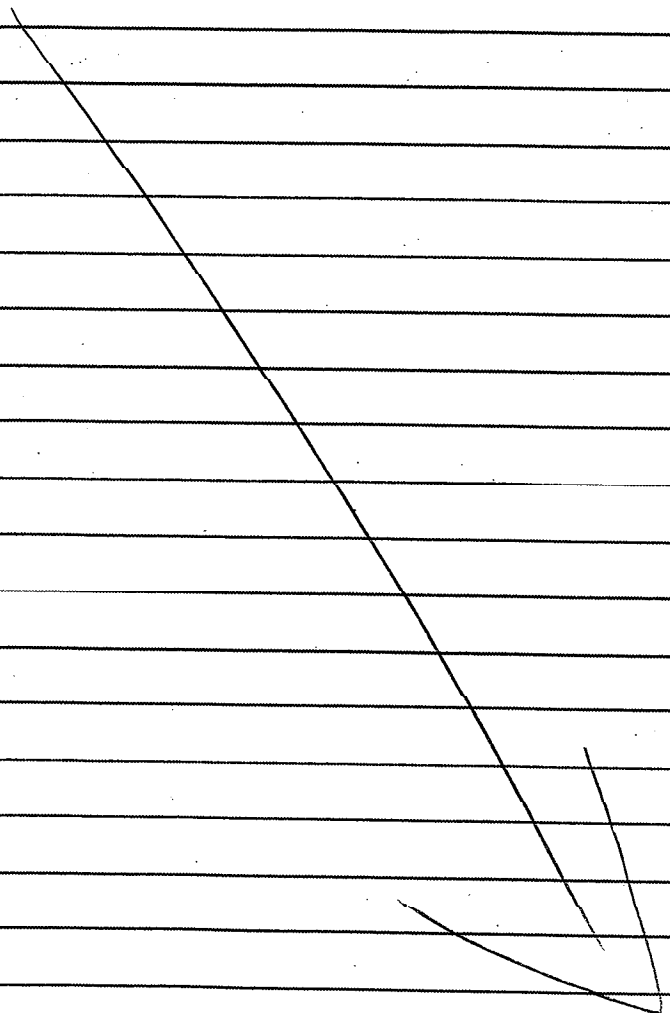
42 CFR 72, Appendix A.

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



13  
(6)

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



(B)  
(7)

The state epidemiologist shall appoint all of the following as members of an advisory committee, which shall provide recommendations to the department concerning the rules promulgated under sub. (3):

(a) A representative of employees of the University of Wisconsin - Madison who perform research using biological agents.

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

(c) A representative of the department.

(d) A representative of the biotechnology industry.

END  
INSERT 2-17

Nonstat File Sequence: **FFF** LRB \_\_\_\_\_ / \_\_\_\_\_

**EFFECTIVE DATE**

- 1. In the component bar: For the action phrase, execute: ... create → action: → \*NS: → effdate  
For the text, execute: ..... create → text: → \*NS: → effdateA
- 2. Nonstatutory subunits are numbered automatically. Fill in the SECTION # or subsection # only if a "frozen" number is needed.

**SECTION #** \_\_\_\_\_ . **Effective date.**

10th

( #1 ) ( ) ..... This act takes effect on the first day of the 10th month beginning after publication.

- 1. In the component bar: For the action phrase, execute: ... create → action: → \*NS: → effdateE  
For the text, execute: ..... create → text: → \*NS: → effdate
- 2. Nonstatutory subunits are numbered automatically. Fill in the SECTION # or subsection # only if a "frozen" number is needed.

**SECTION #** \_\_\_\_\_ . **Effective dates;** .....

..... This act takes effect on the day after publication, except as follows:  
( #1 ) ( ) ..... The treatment of sections ..... of the statutes takes effect on .....

- 1. In the component bar: For the budget action phrase, execute:..create → action: → \*NS: → 94XX  
For the text, execute: ..... create → text: → \*NS: → effdate
- 2. Nonstatutory subunits are numbered automatically. Fill in the SECTION # or subsection # only if a "frozen" number is needed. Below, for the budget, fill in the 9400 department code.

**SECTION 94** \_\_\_\_\_ . **Effective dates;** .....

( #1 ) ( ) ..... The treatment of sections ..... of the statutes takes effect on .....

**DRAFTER'S NOTE**  
**FROM THE**  
**LEGISLATIVE REFERENCE BUREAU**

LRB-4234/P2dn

DAK ~~WLL~~ jf

new  
D-NOTE  
✓  
KMG

Jennifer:

✓  
1. Please review s. 146.61 (5) (a) 2.; instead of using the language proposed, I referred to the exemptions listed in Appendix A of 42 CFR 72.6; these are the same as the language proposed.

2. I have drafted s. 146.61 (6) very similarly to the language proposed (please note that I have defined "state agency" and that I have included an authority in the provision). However, the provision does not appear to me to be "consistent" with 42 CFR 72.6 (c), which appears to permit the secretary of the federal department of health and human services to authorize a state agency or private entity to register facilities in lieu of having the registration performed by the federal government. In addition, 42 CFR 72.6 (c) permits the authorization only if the secretary determines that the registering entity's criteria meets with certain federal requirements.

Please let me know when you would like the draft to be in introducible form.

Debora A. Kennedy  
Managing Attorney  
Phone: (608) 266-0137  
E-mail: debora.kennedy@legis.state.wi.us

→ 3. Please review s. 146.61 (7); I am not sure if this is what you want. Usually, the secretary of an agency appoints such a committee. Is the state epidemiologist supposed to be a member, in addition to the DHFS representative? Is this committee to exist only for purposes of the initial rules promulgation (in which case, the provision should be non-statutory), or beyond that time? ✓

**DRAFTER'S NOTE**  
**FROM THE**  
**LEGISLATIVE REFERENCE BUREAU**

LRB-4234/P2dn  
DAK:kmg:jf

January 7, 2002

Jennifer:

1. Please review s. 146.61 (5) (a) 2.; instead of using the language proposed, I referred to the exemptions listed in Appendix A of 42 CFR 72; these are the same as the language proposed.
2. I have drafted s. 146.61 (6) very similarly to the language proposed (please note that I have defined "state agency" and that I have included an authority in the provision. However, the provision does not appear to me to be "consistent" with 42 CFR 72.6 (c), which appears to permit the secretary of the federal department of health and human services to authorize a state agency or private entity to register facilities in lieu of having the registration performed by the federal government. In addition, 42 CFR 72.6 (c) permits the authorization only if the secretary determines that the registering entity's criteria meets with certain federal requirements.
3. Please review s. 146.61 (7); I am not sure if this is what you want. Usually, the secretary of an agency appoints such a committee. Is the state epidemiologist supposed to be a member, in addition to the DHFS representative? Is this committee to exist only for purposes of the initial rules promulgation (in which case, the provision should be nonstatutory), or beyond that time?

Please let me know when you would like the draft to be in introducible form.

Debora A. Kennedy  
Managing Attorney  
Phone: (608) 266-0137  
E-mail: debora.kennedy@legis.state.wi.us



**ROBERT L. COWLES**

Wisconsin State Senator • 2nd Senate District

January 15, 2002

To: Debora Kennedy, Managing Attorney

From: Jennifer Halbur

Re: LRB 4234/P2dn; Relating to a Biological Agents Registry

Please modify s. 164.61(7) of the draft to eliminate the state epidemiologist as the appointee of the advisory committee members. Instead, have the Secretary of the Department of Health and Family Services appoint the committee. Please add to the members of the committee, the state epidemiologist.

The advisory committee should exist for purposes of the initial rules promulgation.

After the above changes are made, please send us a copy of the draft in introducible form.

Please call if you need any further information: 266-0484.



SOON - In edit 1/20 ✓

State of Wisconsin  
2001 - 2002 LEGISLATURE

LRB-4234/P2  
DAK:kmg:jf

~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

Sen. Cost.

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.

*Analysis by the Legislative Reference Bureau*

~~This is a preliminary draft. An analysis will be provided for a later version.~~

INSERT  
A

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

4 SECTION 1. 146.61 of the statutes is created to read:  
5 **146.61 Biological agent registry.** (1) In this section:  
6 (a) "Biological agent" means any of the following:  
7 1. A select agent that is a virus, bacterium, rickettsia, fungus, or toxin that is  
8 specified under 42 CFR 72, Appendix A.  
9 2. A genetically modified microorganism or genetic element from an organism  
10 under subd. 1. that is shown to produce or encode for a factor associated with a  
11 disease.



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

3           (b) "Law enforcement agency" has the meaning given in s. 165.77 (1) (b).

4           (c) "State agency" has the meaning given in s. 16.375 (1).

5           (d) "State epidemiologist" has the meaning given in s. 252.01 (6).

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

*2001 Wisconsin Act ... (this act),  
Section (2) (1) for initial rules*

*AUTO  
REF  
CKA*

8           (3) After first consulting with the committee under ~~s. 165.77~~, the department  
9 shall promulgate rules that do all of the following, for implementation and  
10 maintenance of the registry specified in sub. (2):

*auto ref. "KB"*

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

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

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

17           (4) Except as provided in subs. (5) and (6), whoever possesses or maintains a  
18 biological agent that is specified by rule under sub. (3) (a) shall report to the  
19 department, on a form designated by the department, the information specified by  
20 rule under sub. (3) (b) in the frequency and under the time limitations specified by  
21 rule under sub. (3) (b).

22           (5) (a) Subsection (4) does not apply to a biological agent to which any of the  
23 following applies:

24           1. The biological agent is part of a clinical specimen that is intended for  
25 diagnostic, reference, or verification purposes. Isolates that are recovered from these

1 clinical specimens and that are used for diagnostic purposes shall be destroyed when  
2 the diagnosis is completed.

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

5 (b) Subsection (4) does not apply to a clinical laboratory that is certified under  
6 42 USC 263a and that uses biological agents for diagnostic, reference, verification,  
7 or proficiency testing purposes.

**APPOINTMENT OF ADVISORY COMMITTEE.**

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

SECTION 4. Nonstatutory Provisions.

*of health and family services*

11 (1) The state epidemiologist shall appoint all of the following as members of an

12 advisory committee, which shall provide recommendations to the department

13 concerning the rules promulgated under ~~sub. (4)~~:

14 (a) A representative of employees of the University of Wisconsin-Madison who  
15 perform research using biological agents.

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

17 (c) A representative of the department.

18 (d) A representative of the biotechnology industry.

19 (e) Information submitted to or maintained in the registry under this section

20 is confidential, is not a public record under subch. II of ch. 19, and may be released

21 by the department only to the centers for disease control and prevention of the

22 federal department of health and human services or to a law enforcement agency

23 under a communicable disease investigation or in connection with an investigation

24 involving the release, theft, or loss of a biological agent.

AUTO REF "KA"

MOVE THIS TO P. 4, after l. 5

change all components to nonstat.

# auto ref. "KB"

NO 11

initial

Secretary of the department of health and family services shall exercise his or her authority

under section 15.04 (1)(c) of the statutes to

section 252.01 (6) of the statutes.

7

to the centers for disease control and prevention of the federal department of health and human services or to a law enforcement agency

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

6 **SECTION 2. Effective date.**

7 (1) This act takes effect on the first day of the 10th month beginning after  
8 publication.

9 (END)

INSERT MATERIAL FROM p. 3 HERE

2001-2002 DRAFTING INSERT  
FROM THE  
LEGISLATIVE REFERENCE BUREAU

LRB-4234/lins  
DAK:kmg:jf

INSERT A

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

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 under specified circumstances. "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 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.

**Basford, Sarah**

---

**From:** Halbur, Jennifer  
**Sent:** Monday, January 28, 2002 4:46 PM  
**To:** LRB.Legal

Hi,

I need LRB 4234/1 to be jacketed for the Senate. Please send it to Senator Cowles Office 123 South. I also need LRB 3345/1 to be jacketed for the Senate.

Thank you!

Jennifer Halbur  
Policy Advisor  
Office of State Senator Robert Cowles  
2nd Senate District  
(608)266-0484  
Jennifer.Halbur@legis.state.wi.us