

JAN 18 2008

A BILL FOR AN ACT

RELATING TO HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. The legislature finds that research in the
2 fields of biotechnology, including biological agents, human
3 pathogens, and toxins, have become more prevalent over the past
4 decade because of widespread bioterrorism concerns. As a result
5 of those concerns, biotechnology research is a well-funded field
6 that is growing rapidly throughout the United States.

7 However, similar to other advanced technologies,
8 biotechnology research comes with potential risks to people,
9 property, and the environment. The substances that are used in
10 biotechnology research laboratories are often very dangerous,
11 hazardous, or environmentally destructive. Improper handling of
12 those substances could potentially result in serious bodily
13 injury or even the loss of life.

14 Unfortunately, the potential catastrophes associated with
15 biotechnology research are closer to home than most people think
16 for two reasons. One reason is that the field of biotechnology
17 research is largely unregulated and there is no widespread use



1 of uniform rules or safeguards. The second reason is that the
2 biotechnological research is being conducted at major
3 universities located in large urban centers.

4 In Hawaii, the University of Hawaii at Manoa and the
5 department of agriculture have conducted research related to
6 microorganisms and human pathogens, such as the avian, West
7 Nile, and dengue flu viruses, for many years. Upon the receipt
8 of grants to conduct biotechnological research from the National
9 Institutes of Health, the University of Hawaii at Manoa
10 established an institutional biosafety committee, as required by
11 the grants, to oversee its research activities. Unfortunately,
12 the institutional biosafety committee failed to maintain
13 compliance with the reporting guidelines required by the
14 National Institutes of Health and the department of agriculture.
15 Furthermore, an ineffective recordkeeping system at the
16 department of agriculture prevented the location and inventory
17 of hundreds of microbes and viruses from being properly recorded
18 after they were properly imported to Hawaii for research
19 purposes by permit.

20 To reduce the risk of potential catastrophes, but still
21 engage in biotechnology research that would benefit the people
22 of Hawaii, a health and safety program needs to be established



1 that would enable biotechnology research laboratories to operate
2 in a safe and reasonable manner. A health and safety program,
3 along with an accompanying oversight committee, would ensure
4 that biotechnology research laboratories in Hawaii would use an
5 approved set of uniform rules, policies, practices, and
6 procedures when engaging in their research activities. The
7 health and safety program and oversight committee would regulate
8 and sanction, if necessary, any violations or unapproved
9 practices by the research laboratories. The legislature
10 believes that this Act will allow advanced biotechnology
11 research to take place in Hawaii in a manner that provides for
12 satisfactory safeguards, which will serve to protect the
13 citizens and visitors of Hawaii from the potential dangers
14 associated with biological agents, human pathogens, and toxins.

15 SECTION 2. Chapter 321, Hawaii Revised Statutes, is
16 amended by adding a new part to be appropriately designated and
17 to read as follows:

18 "PART . BIOTECHNOLOGY RESEARCH

19 §321-A Definitions. For purposes of this part, the
20 following terms shall have the following meanings:

21 "Biological agent" means any naturally occurring,
22 bioengineered, or genetically altered or synthesized



1 microorganism (including bacteria, virus, fungus, and protozoa),
2 or infectious substance or vector, or component of any such
3 microorganism or infectious substance capable of:

- 4 (1) Causing death, disease, or other physiological change
5 in a human, an animal, a plant, or other living
6 organism;
- 7 (2) Causing deterioration of food, water, equipment,
8 supplies, or material of any kind; or
- 9 (3) Having a deleterious effect on the environment.

10 "Biosafety level two laboratory" means a laboratory that is
11 designed, equipped, or operated as a level two biosafety
12 laboratory as defined by the United States National Institutes
13 of Health Guidelines for research involving recombinant
14 deoxyribonucleic acid molecules.

15 "Biosafety level three laboratory" means a laboratory that
16 is designed, equipped, or operated as a level three biosafety
17 laboratory as defined by the United States National Institutes
18 of Health Guidelines for research involving recombinant
19 deoxyribonucleic acid molecules.

20 "Biosafety level four laboratory" means a laboratory that
21 is designed, equipped, or operated as a biosafety level four
22 laboratory as defined by the United States National Institutes



1 of Health Guidelines for research involving recombinant
2 deoxyribonucleic acid molecules.

3 "Department" means the department of health.

4 "Director" means the director of health.

5 "Facility" means a building or combination of buildings
6 under common control and ownership containing one or more
7 laboratories subject to this part.

8 "Human pathogen" means an infectious or biological agent
9 that causes disease or illness to its human host.

10 "Laboratory" means a room or rooms used primarily for
11 biological research, development, non-routine testing, or
12 experimentation activity, or any room or rooms where vertebrate
13 animals are contained under animal biosafety levels described in
14 the National Institutes of Health Guidelines. The term
15 "laboratory" also includes all enclosed areas with a laboratory
16 containment area, including any rooms, closets, facilities,
17 freezers, refrigerators, or incubators where biological agents
18 are stored, fermented, grown, proliferated, or colonized.

19 "Principal investigator" means the individual who is
20 designated by a research sponsor to direct a biological research
21 project or program the research sponsor conducts at a level two
22 or level three biosafety laboratory, and who is responsible to



1 the research sponsor for the scientific and technical direction
2 of that project or program.

3 "Research sponsor" means any state, corporation, authority,
4 individual, trust, firm, joint stock company, limited liability
5 company, partnership, research group, task force, university
6 program, association, or entity or any group thereof, any group
7 of persons, and any agency or political subdivision of the State
8 of Hawaii, the federal government or any other government,
9 subdivision, agent or agency thereof, which operates or proposes
10 to operate a level two or level three biosafety laboratory in
11 Hawaii.

12 "Toxin" means any toxic material or product of plants,
13 animals, microorganisms (including bacteria, virus, fungus,
14 rickettsia, or protozoa), protein, infectious substance, or a
15 recombinant or synthesized molecule, whatever its origin or
16 method of production. Toxin includes:

- 17 (1) Any poisonous substance or biological product that may
18 be engineered as a result of biotechnology produced by
19 a living organism; or
20 (2) Any poisonous isomer or biological product, homolog,
21 or derivative of such substance.



1 §321-B Establishment of a health and safety program for
2 biological research laboratories. (a) There shall be
3 established within the department, a health and safety program
4 for level two and level three biological research laboratories
5 in Hawaii.

6 (b) The health and safety program shall provide standards
7 for the location, operation, and maintenance of biological
8 research laboratories, including oversight, to protect the
9 safety of laboratory workers, the public, and the environment
10 from controlled biological agents, human pathogens, and toxins.

11 (c) The health and safety program shall provide standards
12 for the transportation, relocation, shipment, delivery,
13 conveyance, and receipt of biological agents, human pathogens,
14 agents, and toxins.

15 (d) The health and safety program shall provide for
16 procedures that would allow the department to order any level
17 two or level three biosafety laboratory to immediately cease and
18 desist work on a project and lock down or refrain from any
19 activity that the department determines could cause immediate or
20 irreparable injury or damage.



1 (e) The health and safety program shall be administered by
2 the Hawaii biosafety committee, which shall be appointed by the
3 director.

4 §321-C Criteria for laboratory location. (a) The
5 department shall adopt rules in accordance with chapter 91 for
6 the implementation of the health and safety program that
7 establish the criteria for determining appropriate locations for
8 the building or facility that contains a laboratory, including
9 whether a laboratory may be created within an existing building.
10 At a minimum, the criteria shall:

11 (1) Provide that sites shall not:

12 (A) Be within a flood plain;

13 (B) Be within eight hundred yards of property whose
14 regular use could endanger the site due to fire
15 or explosion;

16 (C) Be near an area of traffic congestion that might
17 impede emergency access for evacuation; or

18 (D) Endanger motorists or pedestrians.

19 (2) Provide that sites shall have sufficient land
20 available to provide for a reasonable buffer around
21 the buildings that shall be no less than one hundred
22 and fifty unobstructed feet in each direction; and



- 1 (3) Address the:
- 2 (A) Proximity of wetlands, waterways, and water
- 3 bodies;
- 4 (B) Relationship of the site to groundwater
- 5 elevation;
- 6 (C) Nature and extent of residential areas and
- 7 schools in proximity to the site;
- 8 (D) Availability and suitability of access roads to
- 9 the site, including the ability of first
- 10 responders to access the site in an emergency;
- 11 (E) Potential for adverse public health and safety
- 12 impacts;
- 13 (F) Potential impact of increased traffic volume on
- 14 adjacent roads; and
- 15 (G) Potential threat of terrorist attack or
- 16 infiltration of the building.
- 17 (b) The department shall set forth procedures, consistent
- 18 with this part, for the submission, review, and approval of
- 19 permit and construction applications and the issuance and
- 20 renewal of permit and construction applications; provided that:



1 permits may be issued that contain conditions or restrictions
2 that serve and protect public health and safety; provided
3 further that:

4 (1) Applications for a permit or renewal of a permit shall
5 be acted upon within sixty-days of the submission of a
6 completed application. The department shall not be
7 obligated to review incomplete applications. If, at
8 the conclusion of the sixty-day period, the review of
9 the application is not complete, the department may
10 issue to a research sponsor a provisional permit if
11 the application is complete and the research sponsor
12 has established substantial compliance with this part.
13 A provisional permit shall not exceed one hundred and
14 twenty days in duration and shall not be renewed or
15 extended;

16 (2) To the extent that the permit application may require
17 the submission or review of trade secret information,
18 the research sponsor may submit the information under
19 seal. Department officers and employees shall be
20 prohibited from disclosing trade secret information
21 submitted under seal pursuant to this part to any
22 third party and the information shall be used by the



1 department and its staff for no purpose other than the
2 permitting process. Reckless or intentional
3 disclosure of trade secret information submitted under
4 seal shall be a misdemeanor;

5 (3) The denial of a permit application may be appealed;
6 and

7 (4) Prior to issuance of any permit for a level three
8 biosafety laboratory under this part, the department
9 shall hold, with sixty-days notice to the public of
10 the application and its contents, a public hearing on
11 the application with a reasonable opportunity for
12 public comment on whether the application should be
13 granted.

14 **§321-D Hawaii biosafety committee; established.** (a)

15 There is established the Hawaii biosafety committee to assist in
16 administering or overseeing biological laboratories and
17 facilities operating under this part. The Hawaii biosafety
18 committee shall be composed of scientific and community
19 representatives appointed by the director from lists of
20 potential members submitted to the department by community and
21 neighborhood organizations, universities, colleges, and public
22 interest organizations located within Hawaii. The biosafety



1 committee shall consist of ten members, including one salaried
2 executive director who shall be selected by the director for a
3 term of four years.

4 (b) Members shall be appointed for a term of two years and
5 may only be removed for cause. Members shall have no financial,
6 professional, familial, or business relationship with the
7 regulated research sponsors, their affiliates, subsidiaries,
8 employees, contractors, subcontractors, investors, or founders.
9 Members appointed to fill vacancies shall serve for a full term.
10 Each member of the biosafety committee shall be eligible for
11 reappointment for up to three consecutive terms. Members of the
12 biosafety committee shall serve without compensation but their
13 reasonable costs and expenses, including travel expenses, shall
14 be reimbursed by the department.

15 (c) The biosafety committee shall periodically report to
16 the department and provide technical assistance, review of the
17 effectiveness of applicable statutes and rules, and advise or
18 deliberate as needed about technical issues arising out of
19 permits and applications derived from this part.

20 (d) The biosafety committee shall consider policy changes
21 and possible amendments to applicable statutes and rules. The
22 committee shall also seek to improve how the laboratories and



1 facilities operate, how the laboratories and facilities handle
2 biological agents, human pathogens, and toxins, and the delivery
3 or transportation of biological agents, human pathogens, and
4 toxins.

5 (e) The biosafety committee shall meet monthly or with
6 sufficient frequency to assure its ability to carry out its
7 duties and responsibilities.

8 **§321-E Institutional biosafety committees; established.**

9 (a) A research sponsor that holds a permit issued pursuant to
10 this part, shall have an institutional biosafety committee for
11 each laboratory or facility to ensure the safety of the public
12 and conformance with this part.

13 (b) Composition of an institutional biosafety committee
14 shall include at least two community representatives who have no
15 financial, professional, familial, or business relationship in
16 or with the regulated research sponsor, its affiliates or
17 subsidiaries, employees, contractors, sub-contractors, or
18 investors. Community representatives shall be selected by joint
19 approval of the department and neighborhood organizations
20 representing the communities or community where the laboratory
21 or facility is located. Community representatives shall be
22 individuals whose principal residence is within three miles of



1 the laboratory or facility, and whose principal residence has
2 been within three miles of the laboratory or facility for at
3 least the immediately preceding two years before their selection
4 to an institutional biosafety committee.

5 (c) Each institutional biosafety committee shall report to
6 the Hawaii biosafety committee. An institutional biosafety
7 committee shall meet at least four times a year and at other
8 times as specified by the Hawaii biosafety committee, or as
9 requested by a member of an institutional biosafety committee.
10 Except for executive sessions, meetings of an institutional
11 biosafety committee and all of its subcommittees shall be open
12 to the public.

13 (d) Each institutional biosafety committee shall file an
14 annual report with the Hawaii biosafety committee. The report
15 shall include, at a minimum, complete copies of all
16 institutional biosafety committee minutes for the preceding
17 reporting period, certification that the laboratory or facility
18 is in compliance with this part, a report on any quality
19 assurance and quality improvement efforts made during the
20 period, a complete roster of current institutional biosafety
21 committee members, and an update of any information relative to
22 the permit application. To the extent institutional biosafety



1 committee minutes contain information that jeopardizes trade
2 secret information, the Hawaii biosafety committee shall develop
3 procedures for assuring confidentiality of that information.
4 Institutional biosafety committee minutes shall, at a minimum,
5 conform to National Institutes of Health, Office of
6 Biotechnology Activities-issued guidance concerning the
7 preparation of, and public access to, minutes of institutional
8 biosafety committee meetings.

9 **§321-F Permit fees.** The department is authorized to
10 establish fees for the issuance and renewal of permits, which
11 may vary according to the type of use and scale of activity
12 being conducted. All fees shall be directly related to the
13 costs incurred by the department or the Hawaii biosafety
14 committee for any issuance of permits, the inspection of
15 laboratories, and any other costs associated with implementation
16 of this part. Full payment of the fees shall be a condition for
17 the granting or renewal of any permit.

18 **§321-G Research pre-approval requirement.** (a) Any
19 research sponsor operating or proposing to operate a biological
20 laboratory or laboratories, or any research sponsor conducting
21 or proposing to conduct any biological research at level two or
22 level three biosafety laboratories, shall obtain a permit from



1 the Hawaii biosafety committee. The permittee shall ensure that
2 all persons in the laboratories comply with the requirements set
3 forth in this part and the rules issued pursuant to this part.

4 (b) Each permit application shall include the following:

5 (1) Name and location of the research sponsor;

6 (2) The location and biosafety level rating or ratings for
7 each laboratory that will operate under the permit;

8 (3) Roster, biographical information, and contact
9 information of the institutional biosafety committee
10 indicating the chair and community members;

11 (4) Name, title, and contact information of each of the
12 following:

13 (A) A health officer responsible for the health of
14 the laboratory or facility, known as the health
15 officer;

16 (B) An officer responsible for biological safety at
17 the laboratory or facility, known as the
18 biological safety officer; and

19 (C) An official responsible for the overall operation
20 of the laboratory or facility, known as the
21 responsible official;



- 1 (5) Project information including, but not limited to, the
2 title and a description of the project, the grant
3 identification number or other unique institutional
4 identifier number, the principal investigator, and all
5 biological agents, human pathogens, and toxins used
6 for each project or program;
- 7 (6) Procedures and policies relating to laboratory safety
8 including, but not limited to, research, training,
9 security, laboratory inspections, transportation,
10 waste disposal, commissioning, decommissioning,
11 decontamination, termination of work with biological
12 agents, human pathogens, and toxins, training of all
13 employees, visitors, or students, and first responder
14 plans with evacuation and emergency response;
- 15 (7) Other information as required by the Hawaii biosafety
16 committee and rules under this part; and
- 17 (8) Any incident in which the research sponsor, any of its
18 officers, employees, or any other person who will work
19 in the laboratory was found to have violated, or was
20 sanctioned for violating, any law, rule, or ordinance
21 regulating the environment, health, safety, public
22 disclosure, or the truthfulness of statements.



1 **§321-H Suspension of permit.** If the director becomes
2 aware of credible evidence that an activity at a facility
3 licensed for, or seeking a license for, operation under this
4 part is likely to pose a significant and imminent threat to
5 human health or to the environment or cause substantial property
6 damage, the director may find that immediate closure of the
7 facility is required to avert the danger and may order all
8 research and related activity at that facility be suspended
9 until the director finds that the threat is resolved. If the
10 research sponsor believes the director's finding to have been
11 unwarranted, the research sponsor may seek reversal of the
12 decision by a clear and convincing standard.

13 **§321-I Reporting requirements.** (a) The licensed research
14 sponsor shall, within twenty-four hours, report to the Hawaii
15 biosafety committee any incident in which there was human
16 exposure to a biological agent, human pathogen, or toxin, and a
17 reasonable likelihood of exposure, including all incidents
18 resulting in actual or recommended prophylactic quarantine or
19 drug use.

20 (b) A research sponsor shall report any release or spread
21 of a biological agent, human pathogen, or toxin, and the
22 reasonable likelihood of a release or spread, outside the



1 primary containment area of a biosafety laboratory to the
2 department as soon as possible and in no case more than twenty-
3 four hours after the event. The report shall also be provided
4 to the Hawaii biosafety committee.

5 (c) The facility or laboratory shall also provide the
6 institutional biosafety committee with a detailed report of all
7 incidents, accidents, and other events that cause, or are
8 suspected to have caused, an illness, bodily injury, or death to
9 the public within seventy-two hours of the incident, accident,
10 or event.

11 (d) On an annual basis, the facility or laboratory shall
12 provide the Hawaii biosafety committee with an independent
13 certification from a third party for all biosafety cabinets,
14 autoclaves, tissue digesters, incubators, centrifuges, and all
15 other major laboratory equipment.

16 **§321-J Laboratory employee training.** Each facility with a
17 laboratory defined under this part shall have and implement a
18 plan to provide adequate training for the proper handling of
19 biological agents, human pathogens, and toxins that might be
20 present therein. Employee training shall include, but not be
21 limited to, decontamination methods, personnel safety
22 precautions and work habits, early warning disease surveillance,



1 accident response actions and notifications, access control and
2 monitoring, personnel management, inventory and accountability,
3 information security, and the transport of biological agents,
4 human pathogens, and toxins. Each facility shall provide a
5 training plan to its institutional biosafety committee and to
6 the Hawaii biosafety committee for approval and shall update the
7 plan annually, or as necessary. The training plan shall ensure
8 that all laboratory staff, facility workers, and researchers,
9 including the principal investigator for each facility, are
10 trained adequately. The principal investigator shall
11 participate in the creation and implementation of the training
12 plan. No individual other than a local, state, or federal
13 government representative with authorized access for regulatory
14 compliance for investigative purposes may enter the biosafety
15 laboratory located within a facility without first completing
16 the facility's training plan.

17 **§321-K Waste management plan.** Each facility operating
18 under this part shall implement a waste management and
19 decontamination plan submitted to and approved in advance as a
20 condition of permitting by the Hawaii biosafety committee.

21 **§321-L Emergency response plan.** A facility operating
22 under this part shall develop an emergency response plan, in



1 conjunction with local and state officials that address security
2 threats and releases involving the spread of biological agents,
3 human pathogens, and toxins. The emergency response plan shall
4 comply with local, state, and federal plans already in
5 existence. The plan shall address events such as severe
6 weather, earthquakes, power outages, power line breaks,
7 terrorism, and other natural, accidental, or intentional
8 emergencies. The emergency response plan, at a minimum, shall
9 address the following:

- 10 (1) Particular hazards associated with specific biological
11 agents, human pathogens, and toxins located at the
12 facility or its laboratories;
- 13 (2) Personnel roles, lines of authority, training, and
14 communication;
- 15 (3) Emergency assessment and prevention;
- 16 (4) Site security and control;
- 17 (5) Evacuation routes and procedures;
- 18 (6) Decontamination;
- 19 (7) Emergency medical treatment and first-aid;
- 20 (8) Emergency alerting and response procedures;
- 21 (9) Personal protective and emergency equipment;
- 22 (10) Regulatory scheduled preparedness exercises;



1 (11) Critique of response and follow-up subsequent to an
2 incident; and

3 (12) Communication to the public and the local news media.

4 **§321-M Inspections.** The Hawaii biosafety committee may
5 review all documentation relating to the operations of the
6 facility and any laboratories therein, and to conduct a physical
7 inspection of any facility or laboratory, with or without prior
8 notice, so long as the inspection is conducted at a reasonable
9 time under the circumstances and in a manner that maintains the
10 protection of the laboratories involved. Failure to provide any
11 requested documentation or access to a laboratory for the
12 purpose of inspection shall result in a fine and the immediate
13 suspension or restriction of a research sponsor's permit to
14 operate. A failure to provide requested documentation or access
15 to a laboratory for the purpose of inspection for a period
16 exceeding seven days shall result in suspension of the facility
17 or laboratory permit to operate at least until the failure has
18 been rectified.

19 **§321-N Prohibited research projects.** (a) Every level
20 two, level three, and level four biosafety laboratory or
21 facility in the State of Hawaii is prohibited from conducting



1 research or research projects that are reasonably likely to
2 result in the following:

3 (1) Harm to human health, human habitat, agriculture, or
4 the breeding or raising of livestock;

5 (2) Render an immunization ineffective or lessen immunity
6 in humans, animals, or plants;

7 (3) Confer to a biological agent, human pathogen, or toxin
8 resistance of clinically or agriculturally useful
9 prophylaxes or therapeutics against that biological
10 agent, human pathogen, or toxin;

11 (4) Enhance the virulence of a biological agent, human
12 pathogen, or toxin, or render a nonpathogen virulent;

13 (5) Enhance the ease of transmission of a biological
14 agent, human pathogen, or toxin from human to human,
15 animal to animal, or animal to human;

16 (6) Enable the evasion of diagnostic or detection
17 modalities;

18 (7) Alter the host range or vector of a biological agent,
19 human pathogen, or toxin;

20 (8) Enhance the susceptibility of a host population; or

21 (9) Create a novel biological agent, human pathogen, or
22 toxin, or revitalize an eradicated, inactive, dormant,



1 or extinct biological agent, human pathogen, or toxin
2 that is harmful to humans, human habitat, agriculture,
3 or livestock.

4 (b) A principal investigator may seek an exemption to the
5 prohibitions listed in subsection (a) for a specific research
6 project by submitting to the Hawaii biosafety committee, in
7 advance, a written request that specifies in detail the precise
8 research to be carried out, the purpose and need for the
9 exemption, the names of all research sponsors for the research
10 that will be subject to the exemption, the unavailability of
11 alternative means of conducting the research, a clear
12 explanation of any special risks involved in the research or
13 project, and any extraordinary safeguards and precautions that
14 would need to be implemented. The Hawaii biosafety committee
15 may only permit an exemption to the prohibitions listed in
16 subsection (a) on a case by case basis. The Hawaii biosafety
17 committee may not issue a blanket exemption to any particular
18 principal investigator or research sponsor, nor may the Hawaii
19 biosafety committee issue a blanket exemption for a particular
20 type of research project. Any exemption permitted under this
21 part shall be updated and resubmitted to the Hawaii biosafety
22 committee annually for review and reconsideration. Research or



1 projects that are subject to the prohibitions described in
2 subsection (a) shall not be exempted solely on the basis that
3 the research or project has dual purposes or uses, some of which
4 may not violate subsection (a).

5 **§321-0 Notice to employees of biosafety laboratories or**

6 **facilities.** (a) A copy of this part and the rules adopted
7 pursuant to this part shall be distributed to all employees,
8 students, and any other person who has regular access to any
9 portion of a facility or laboratory permitted under this part.

10 All entities permitted pursuant to this part shall have a system
11 for reporting health and safety violations, including a method
12 to report in an anonymous manner to the department and a method
13 to report in an anonymous manner to the institutional biosafety
14 committee.

15 (b) No person shall be required to conduct scientific
16 research, experimentation, study, or take other action in a
17 laboratory that violates any provision of this part or permits
18 issued hereunder or has reasonable potential to adversely affect
19 public or employee health and safety. No person or employer
20 shall discharge, refuse to hire, discipline, retaliate, or take
21 any adverse action against any employee, applicant, or other
22 person because the employee, applicant, or other person



1 discloses, or threatens to disclose, an activity, policy, or
2 practice that the person reasonably believes is in violation of
3 this part. In addition to any other remedy provided by law, an
4 employee, researcher, or student aggrieved by a violation of
5 this subsection, within two years, may file a complaint with the
6 attorney general, who, after a proper investigation, may bring
7 an action in the name of the State of Hawaii against the
8 facility alleged to have violated this part. If the attorney
9 general declines to bring an action based on the complaint
10 filed, the attorney general shall expeditiously provide notice
11 of decline to the grievant. The aggrieved employee, researcher,
12 or student, within one year after the notice, may institute a
13 civil action. Any party to the action shall be entitled to
14 trial by jury. Remedies available in common law tort actions
15 shall be available to prevailing parties, in addition to any
16 legal or equitable relief. The court, in addition to issuing a
17 restraining order or injunction, may order the reinstatement of
18 an employee's, researcher's, or student's position. In
19 addition, compensation of three times the lost wages, or other
20 remuneration, and interest for liquidated damages shall be paid
21 by the facility to the employee, researcher, or student, plus
22 reasonable costs and attorneys' fees.



1 §321-P Fines, civil penalties, and revocation of permits.

2 (a) The intentional or reckless violation of any conditional
3 restriction of a permit or any provision of this part shall
4 subject the violator to conviction of a misdemeanor with a fine
5 not to exceed \$5,000. Each violation shall constitute a
6 separate and distinct offense. Any false statement contained in
7 an application for a permit under this part, or in any report
8 required under this part, shall constitute a violation.

9 (b) Any violation of this part at the laboratory or of any
10 condition or restriction on a laboratory permit, may result in
11 the suspension of the research sponsor's permit to operate one
12 or more laboratories for a period of not less than one year,
13 permanent revocation of the permit, and assessment of a civil
14 penalty against the research sponsor not to exceed \$300,000.
15 Where the violation was caused by the reckless or intentional
16 conduct of the research sponsor, or agent thereof, the
17 suspension of the research sponsor's permit to operate the
18 laboratory where the violation occurred for a period of not less
19 than one year and assessment of a \$300,000 civil penalty shall
20 be the minimum sanction. Each violation shall constitute a
21 separate and distinct ground for sanction under this part.



1 (c) Any violation of this part at the laboratory or of a
 2 condition or restriction on a laboratory permit, that is
 3 preceded by two prior violations, shall result in revocation of
 4 all the research sponsor's permits to operate any level two or
 5 level three biosafety laboratory for a period of two years. The
 6 research sponsor shall also be precluded from obtaining any
 7 additional permits to operate any level two or level three
 8 biosafety laboratory for a period of two years thereafter."

9 SECTION 3. In codifying the new sections added by
 10 section 2 of this Act, the revisor of statutes shall substitute
 11 appropriate section numbers for the letters used in designating
 12 the new sections in this Act.

13 SECTION 4. This Act shall take effect on July 1, 2008.
 14

INTRODUCED BY: Mike Gabbard

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Report Title:

Health and Safety Program; Biological Research Laboratory;
Biotechnology

Description:

Establishes a health and safety program within the department of health and an oversight committee for biological research laboratories and facilities that study and contain biological agents, human pathogens, or toxins in Hawaii.

