

Honolulu, Hawaii

Feb 17, 2006

RE: H.B. No. 563
H.D. 1

Honorable Calvin K.Y. Say
Speaker, House of Representatives
Twenty-Third State Legislature
Regular Session of 2006
State of Hawaii

Sir:

Your Committee on Judiciary, to which was referred H.B. No. 563 entitled:

"A BILL FOR AN ACT RELATING TO MICROORGANISM IMPORT,"

begs leave to report as follows:

The purpose of this bill is to clarify processes for the importation of microorganisms necessary for medical and scientific uses by repealing the Microorganism Import Certification Program in part V of Chapter 150A, Hawaii Revised Statutes.

The Department of Agriculture (DOA) testified in support of this bill. The University of Hawaii (UH), Hawaii Science & Technology Council, and a concerned individual opposed this measure. Two concerned individuals provided comments.

DOA has indicated that current statutory and administrative rule provisions provide a better process for importing microorganisms than the certification program repealed by this bill. During the hearing on this bill, however, your Committee was informed that DOA and biotechnology researchers who had testified in opposition to this measure had devised a workable alternative that might streamline importation of microorganisms for research purposes. In lieu of the laboratory certification program repealed by this bill, a new provision would authorize laboratories conducting research under a federal grant award or an award from an non-federal funding agency approved by DOA to import microorganisms through means other than the current permitting

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process. Decision-making was deferred to allow interested parties to propose language satisfactory to all concerned. The amended draft for this bill now reflects this agreed-to revision.

DOA provided your Committee a Justification Sheet dated February 2, 2006. As in the justification sheet attached to the original bill in 2005, the revised justification sheet expressed concerns that the laboratory certification program repealed by this bill vests "discretion to determine whether the risk level for a desired microorganism species would not exceed the certified importer laboratory's containment capability" with the laboratory itself, not DOA.

The revised justification sheet adds the following explanation of the recently proposed revisions to this bill:

Federal grant awards provide assurance that the grantee's research meets federal requirements such as compliance with the: (1) Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), which is intended to provide protection against misuse of federally regulated microorganisms; (2) national institutes of health guidelines involving DNA molecules for research involving certain federally regulated microorganisms and recombinant DNA molecules; (3) nuclear regulatory commission standards and regulations; (4) occupational health and safety standards issued by the occupational health and safety administration; (5) bloodborne pathogens; and (6) federal, state, and local health and safety standards to minimize employees' risk of injury or illness. As for non-federal funding sources, board approval of the funding source would be required before such award grantees would be eligible for exemption from the import permit requirement. Regardless of the funding source, department approval of the grantee's institutional biosafety committee would be a prerequisite for this exemption. Under this proposed amendment, all but certain microorganisms of particular concern to the department, as determined by rule, could be imported by qualified grantees without a permit.

Accordingly, your Committee has amended this bill by:

- (1) Establishing conditions under which the importation of microorganisms for laboratory research under a federal grant award or award from a non-federal funding agency



approved by DOA is exempt from microorganism importation requirements;

- (2) Requiring prior approval from DOA for microorganisms imported under the new exemption from importation requirements to be transferred to other entities in the state;
- (3) Changing the effective date to July 1, 2020, to encourage further discussion; and
- (4) Making technical, nonsubstantive changes for style, clarity, and consistency.

As affirmed by the record of votes of the members of your Committee on Judiciary that is attached to this report, your Committee is in accord with the intent and purpose of H.B. No. 563, as amended herein, and recommends that it be referred to the Committee on Finance in the form attached hereto as H.B. No. 563, H.D. 1.

Respectfully submitted on
behalf of the members of the
Committee on Judiciary,


Sylvia Luke, Chair



