

HAWAII ADMINISTRATIVE RULES
TITLE 4 DEPARTMENT OF AGRICULTURE
SUBTITLE 6 DIVISION OF PLANT INDUSTRY
CHAPTER 71A
PLANT AND NON-DOMESTIC ANIMAL QUARANTINE
MICROORGANISM IMPORT RULES

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Historical note: Chapter 4-71A is based substantially upon chapter 4-71, HAR, entitled "Nondomestic Animal and Microorganism Import Rules". [Eff. 7/13/81; am and comp 9/19/91; comp 2/21/92; am and comp 9/13/93; comp 1/30/95; am and comp 8/16/99]

SUBCHAPTER 1

GENERAL PROVISIONS

§4-71A-1 Objective. The board, while mindful of the benefit to the State of allowing import of microorganisms for purposes such as scientific and medical research, biotechnology and commerce, recognizes the concomitant necessity for regulating importation of microorganisms in order to protect important State interests. The objective of this chapter is to implement the requirements of chapter 150A, HRS, with respect to microorganisms by regulating the importation of specific microorganisms that are detrimental or potentially harmful to agriculture, horticulture, animal or public health, or natural resources, including native biota, or have an adverse effect on the environment as determined by the board of agriculture. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-2 Definitions. As used in the chapter:

"Advisory subcommittee" means one of the advisory subcommittees on entomology, invertebrate and aquatic biota, land vertebrates, plants, algae, bacteria, fungi, protozoa, or viruses appointed by the chairperson pursuant to section 150A-10, HRS;

"Applicant" means a person who has submitted an application for import or possession of a microorganism or both through permit or other official document authorizing import under this chapter and has paid the applicable fee;

"Board" means the board of agriculture of the department of agriculture;

"Branch" means the plant quarantine branch;

"Chief" means the chief or manager of the plant quarantine branch or a department employee designated by the chief or chairperson;

"Completed permit application" means a permit application submitted by an applicant on the form

provided by the department and which contains the required information adequate, in the chief's judgment, for review by the department, and if appropriate, by the advisory subcommittee(s), advisory committee, and board of agriculture;

"Department" means the department of agriculture;

"High risk microorganism" means a microorganism the import of which has been determined to be highly likely to cause significant harm to agriculture, horticulture, the environment, or animal or public health, in the absence of appropriate restrictions or safeguards;

"Importer" means a person who receives for transport or brings or causes to be brought to the State in any manner, any microorganism for the purpose of debarkation or entry;

"Label" means the written, printed, or graphic matter on or attached to the outside of the container of microorganisms with the required markings to cause inspection of the microorganism contained in the shipment;

"Letter of authorization" means an official document in lieu of an import permit or microbial product registration issued by the branch authorizing a specific unlisted microorganism species determined to be a low risk microorganism to enter the State;

"Low risk microorganism" means a microorganism species that is most likely already present in Hawaii, the import of which is not likely to cause additional harm to agriculture, horticulture, the environment, or animal or public health in the absence of restrictions or safeguards, or for which department-imposed restrictions other than the notification, labeling, and inspection requirements of this chapter are not likely to reduce any risks that may be associated with import of the microorganism;

"Microbial product" means a manufactured product containing known cultures of microorganisms for the purpose of bioremediation or bioaugmentation, including a product such as a microbial pesticide;

"Microorganism" means any unicellular microscopic organism including but not limited to algae, bacteria,

fungi, protozoa, and viruses;

"Moderate risk microorganism" means a microorganism the import of which has been determined to potentially cause harm to agriculture, horticulture, the environment, or animal or public health, in the absence of appropriate restrictions or safeguards;

"Nonrestricted microorganisms" means any microorganism on the list of nonrestricted microorganisms required to be maintained pursuant to section 150A-6.3 HRS;

"Permit" means a written document issued by the branch to allow the introduction and possession of a microorganism subject to permit conditions established by rule or the board;

"Permittee" means any person that has applied for and been granted a permit for the introduction and possession of a microorganism under this chapter;

"Person" means any individual, agency, firm, corporation, association, institution, or partnership or any organized group of persons whether incorporated or not;

"Recombinant DNA" means molecules that are constructed outside living cells by joining natural or synthetic deoxyribonucleic acid (DNA) segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of those described herein;

"Restricted microorganism" means any microorganism on the list of restricted microorganisms required to be maintained pursuant to section 150A-6.3 HRS;

"Registration" means the process required for import of microbial products containing certain strains of nonrestricted microorganisms;

"Select human pathogens" means species of microorganisms that present high risk to public health and which have oversight by the Centers for Disease Control and Prevention under 42 United States Code of Federal Regulations, section 72.6;

"Site inspection" means department inspection of the facility, equipment, records pertaining to the

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microorganisms imported under permit, as well as procedures to contain the microorganism;

"Unlisted microorganism" means any microorganism not on the lists of nonrestricted or restricted microorganisms or on the list of select human pathogen microorganisms required to be maintained pursuant to section 150A-6.3, HRS. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-3 Importation of microorganisms, generally. (a) The introduction into Hawaii of any microorganism shall require, at a minimum, a request for import, approval for the import in advance of shipment, and compliance with the notification, labeling, and inspection requirements of sections 4-71A-4, 4-71A-8, and 4-71A-9. Failure to comply with these requirements is sufficient cause for refusal to allow entry of the microorganism into the State.

(b) In addition to the requirements of subsection (a), import into Hawaii and possession of a microorganism is allowed only as provided below for each respective category and requires:

- (1) A written request for import pursuant to section 4-71A-4 and as provided in section 4-71A-24, for a microorganism species on the list of nonrestricted microorganisms;
- (2) A permit, for a microorganism species on the list of restricted microorganisms, Part A or Part B, as provided in sections 4-71A-4, 4-71A-7 and, as applicable, sections 4-71A-21 and 4-71A-22;
- (3) A special permit or letter of authorization, according to risk level, for an unlisted microorganism species, as provided in section 4-71A-4 and 4-71A-25;
- (4) An emergency permit, for an unlisted microorganism species or a microorganism species on the list of restricted microorganisms in an emergency or disaster situation, as provided in section 4-71A-12; and

- (5) Notification to the department of health of entry for possible department of health inspection and monitoring, for a microorganism species on the list of select human pathogens, as provided in section 4-71A-23.

(c) Importation of microbial products shall be subject to the requirements of subsection (a) and subchapter 4. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-4 Request for importation. (a) Except as otherwise provided for microbial products, a request to import a microorganism species, regardless of whether listed for import or unlisted, shall be submitted to the chief with the following information:

- (1) Importer's reason for importing the specific microorganism into the State;
 - (2) A request that the department inspect the microorganism upon arrival in the State;
 - (3) An agreement to be responsible for all costs, charges, or expenses incident to the inspection or treatment of the imported microorganisms;
 - (4) A waiver of all claims for damages incident to the inspection or the fumigation, disinfection, quarantine, or destruction of the microorganism, if any treatment is deemed necessary;
 - (5) Name, complete address, telephone, and facsimile numbers of the shipper and importer;
 - (6) Quantity, common and scientific names (genus and species names unless not yet classified) of each microorganism;
 - (7) Description of each species of microorganism including whether or not the microorganism is a recombinant DNA strain;
 - (8) Mode of transportation; and
 - (9) Approximate date of arrival.
- (b) A request to import into Hawaii and possess

a microorganism species on the restricted list, Part B, for the purposes described in section 4-71A-22(c)(1), (2) and (3), shall include, in addition to the information required in subsection (a), the following:

- (1) Description of the proposed use of the microorganism, including whether or not inoculation studies will be done;
- (2) Description and location of the facility, and description of the equipment and procedures that will be used to contain the microorganism, including a floor plan or blueprint of the facility or both that addresses:
 - (A) Design and construction;
 - (B) Work and storage areas;
 - (C) Equipment such as biosafety cabinets, autoclaves, freezers, incubators, holding tanks, generators;
 - (D) Plumbing system such as sinks, drains, effluent treatment and discharge systems;
 - (E) Air-handling system such as air conditioning, supply and exhaust air system, and types and placement of filters; and
 - (F) Biosafety procedures.
- (3) Explanation of the method for destroying and disposing of the microorganism;
- (4) Statement as to whether or not the use of the microorganism is subject to federal, county or state requirements other than the department's;
- (5) The material safety data sheet, product label, and product information sheet;
- (6) Importer's qualification and previous experience working with the requested microorganism, including documentation to confirm relevant education, employment, and previous experience; and
- (7) Any other pertinent documented information required by the chief.

(c) A request to import an unlisted microorganism or a microorganism that requires board action shall include the information required in subsections (a) and (b), as well as the following additional information:

- (1) Description of the microorganism including information on its taxonomic classification, natural habitat, geographic range or niche requirements, temperature requirements, host range, and dispersal capabilities; and
- (2) Analysis of the microorganism's potential impact on Hawaii's environment, agricultural, horticultural and aquacultural industries, and animal and human health, in the event the microorganism escapes or is released into the environment.

(d) Failure to provide the information requested and to complete the application as required in this section shall be sufficient cause for denial of the request for import. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-5 Application review. (a) Upon receipt of a completed application for import of a nonrestricted microorganism species from cultured stock or a select human pathogen microorganism species, the branch shall verify the list placement of the requested microorganism and, if appropriate under section 4-71A-24 and 4-71-23, respectively, shall give permission to import without permit, fee, or board review, subject to satisfaction of pre-entry and inspection requirements.

(b) The chief, without submitting a permit application to the board, may approve or disapprove the issuance of a permit for import of a microorganism other than one listed in section 4-71A-6(1)-(5), based on a past board decision relating to the same species and strain of microorganism if the current application presents substantially the same circumstances of importation, provided that the respective permit conditions previously established by the board shall

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apply if the permit is approved.

(c) A permit application for import of a microorganism species that was previously disapproved by the board may be resubmitted for board action as provided in section 4-71A-7 upon determination by the chief that conditions for importation are substantially different from the previously disapproved request. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-6 Permit applications requiring board action. Board action, as well as prior review by the advisory subcommittee(s) and the advisory committee on plants and animals pursuant to section 4-71A-7, are required for requests to import the following:

- (1) A microorganism species on the list of restricted microorganisms (Part A);
- (2) A microorganism species on the list of restricted microorganisms (Part B) or an unlisted microorganism if either are to be imported for purposes other than those described in subsections 4-71A-22(c)(1),(2), or (3);
- (3) A strain of a microorganism on the list of restricted microorganisms (Part B) that is likely to increase the risk level above that of a moderate risk microorganism;
- (4) An unlisted microorganism species determined by the department to be a high risk microorganism; and
- (5) Any microorganism species not from cultured stock. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-7 Processing permit applications requiring board action. (a) The applicant shall provide the chief with seven copies of the application together with information required by section 4-71A-4.

(b) The chief shall compile the information submitted by the applicant and send it to the members

of the appropriate advisory subcommittee(s) for review.

(c) The comments and recommendations of the advisory subcommittee(s) shall be compiled and sent to the advisory committee on plants and animals for review.

(d) The comments and recommendations of the advisory subcommittee(s), the advisory committee on plants and animals, including the committee's votes, and of the chief shall be compiled and submitted to the board at its regular scheduled meeting.

(e) The board shall take action to approve or disapprove the permit application.

(f) The board may impose permit conditions including but not limited to, time, place, location, use, special precautions, health requirements, and requirements for safeguarding the microorganism from escape, unauthorized release, or theft, as well as any applicable requirements of municipal, state, or federal law. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-8 Pre-entry requirements. (a) The importer is responsible for assuring that all parcels or containers of microorganisms for import are marked as follows:

- (1) Any microorganism imported into Hawaii by mail or air express as individual parcels shall be plainly and legibly marked on the outer packaging, "Live Organism" and "This Parcel May be Opened and Delayed for Agriculture Inspection. Infectious microorganisms affecting humans and animals shall be packaged and labeled or marked in accordance with the transport requirements of the U.S. Department of Transportation 49 CFR Parts 171-180 and the U.S. Department of Health and Human Services 42 CFR part 72; or
- (2) Any microorganism imported into Hawaii by means other than in subsection (a)(1), shall be accompanied by a bill of lading, waybill

or other shipping document that is plainly and legibly marked "Agriculture Inspection Required".

(b) Any microorganism imported into Hawaii by mail or any other means, shall be accompanied by an invoice, packing list or other document indicating the quantity and scientific name of each microorganism or the name of each microbial product contained in the shipment. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-9 Inspection upon entry. (a) All microorganisms shall enter the State through the port of Honolulu except that the chief may, in the chief's discretion, allow import of a microorganism through another port in order to avoid unnecessary delay and expense when the shipment has been misrouted there through no fault of the importer, provided that the department's pre-entry inspection can be adequately carried out at the alternate port.

(b) The importer or transportation company, as applicable, shall notify the chief, in writing, immediately upon arrival of the microorganism, of the arrival, giving the following information:

- (1) Waybill number;
- (2) Container number;
- (3) Name and address of the consignor;
- (4) Name and address of the consignee or the consignee's agent in the State;
- (5) Number of packages;
- (6) Description of contents of each package;
- (7) Port of entry; and
- (8) Other pertinent information determined necessary by the chief.

(c) The microorganism shall be held at the approved port of entry for inspection by the department.

(d) Upon inspection, the microorganism may be refused entry, seized, held in quarantine, disinfected, treated chemically or manually, or destroyed at the expense of the importer, as

appropriate in the department's discretion, for any of the following:

- (1) No valid permit;
- (2) No invoice or other documentation required to enter the State;
- (3) Damaged or leaking parcel; or
- (4) Shipment infested with a pest.
- (e) The importer is responsible for all costs, charges, expenses, damages, or losses incident to the inspection, treatment, disinfection, quarantine, destruction, of a microorganism, if treatment is deemed necessary. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-10 Site Inspection. (a) Site inspection and approval by the department are required before a permit is issued.

(b) The site shall be in compliance with the following:

- (1) Use, facility, equipment, procedures, and safeguards proposed and described in the import request, as approved by the board or chief; and
- (2) Permit conditions. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-11 Permits. (a) A permit for import and possession of a microorganism shall be obtained in advance of importation and shall be:

- (1) Valid for the period designated on the face of the permit; and
- (2) Nontransferable, unless otherwise specified in the permit.

(b) Where a permit for an import of a microorganism species on the restricted list, (Part B) or an unlisted moderate risk level microorganism allows for transfer or sale of the microorganism, a proposed transferee must first:

- (1) Obtain a permit for possession by

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application to the chief pursuant to sections 4-71A-4 and, if applicable, 4-71A-7;

- (2) Obtain site inspection approval; and
- (3) Demonstrate ability to comply with established permit conditions, except that the board, without requiring a permit, may allow the transfer or sale of a microorganism described in subsection (b), if the microorganism is sold as food or beverage.

(c) The provisions of this section as well as sections 4-71A-13, -14, -15, -16, -18, -19 and -20 are applicable to special permits for import and possession of unlisted microorganisms.

(d) Permits are subject to conditions as provided in subchapter 3 and, where applicable, as established by the board. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-12 Emergency permit. (a) The department may issue an emergency permit on a case-by-case basis to a state or federal agency or state university to allow import and possession of a microorganisms on the list of restricted microorganisms or an unlisted microorganism for the purpose of remediating any emergency or disaster affecting agriculture, horticulture, the environment, or animal or public health; provided that:

- (1) The board, without advisory committee review, first obtains advice from qualified persons with relevant expertise;
- (2) The board determines that import in less time than is required for issuance of a permit or special permit by the board pursuant to sections 4-71A-21, 4-71-22 and 4-71A-25, as applicable, is necessary to remediate the emergency or disaster; and
- (3) The board determines that the importer is able to meet conditions established by the board.

(b) Application for emergency permit shall be made as provided in section 4-71A-4 and shall explain the emergency circumstances warranting expedited board action. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-13 Permit amendment. (a) An importer who requests a change to a permit including permit conditions shall submit to the chief the following:

- (1) A statement requesting amendment of the permit or permit conditions;
- (2) A photocopy of the valid permit with the desired exact changes clearly indicated on the photocopy;
- (3) An explanation of the requested change or changes;
- (4) Supporting documentation; and
- (5) Any other documented information determined by the chief to be necessary.

(b) The chief may approve a minor amendment to a permit but shall refer to the board a change requiring board action, such as a request to:

- (1) Add a microorganism not approved for import by the board; or
- (2) Amend permit conditions established by the board.

(c) The chief may require an additional site inspection approval for a request to add another site to the permit or to change the responsible person named in the permit.

(d) Amendment of a permit is subject to a user fee pursuant to section 4-71A-19. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-14 Permit cancellation. The chief may cancel a permit for any of the following reasons:

- (1) Noncompliance with a permit condition;
- (2) A change in statute or administrative rule restricting or disallowing import of the

- microorganism or board action disallowing a previously allowed use of the microorganism;
- (3) A citation issued to the permittee for a violation involving import or possession of a microorganism or both; or
 - (4) Upon written request by the permittee.
[Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-15 Permit renewal. (a) A request to renew a permit shall be made within two months prior to the date of permit expiration.

(b) The importer shall submit a request to renew a permit on the renewal form provided by the department and shall include the following information:

- (1) A statement requesting renewal of the permit, listing the permit and date of expiration;
- (2) A statement verifying that the request for permit renewal is for further import of the same species of microorganisms for the same purpose and using the same facility, equipment, procedures, and safeguards previously submitted by the importer and as approved by the chief or board; and
- (3) An agreement by the importer to comply with permit conditions.

(c) The chief may require a site inspection and approval for a permit renewal that adds another site to the permit or that changes the responsible person named in the permit.

(d) The chief may disapprove a permit renewal request based on the following:

- (1) Proposed changes are made to the species of microorganisms listed on the permit;
- (2) Proposed changes are made to the use, facility, equipment, procedure, or safeguards previously submitted by the importer and as approved by the chief or board;

- (3) The importer has not, as of the date of the chief's action on the permit renewal request, deposited or paid bail with respect to any outstanding summons or citation issued to the importer; or
- (4) The importer has not paid the user fee pursuant to section 4-71A-19.
- (e) If the request for permit renewal is not applied for within 30 days after the expiration of the permit, the request for renewal shall be treated as a new import request and shall be subject to the import requirements of section 4-71A-3; and if applicable, 4-71A-7. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-16 Post-entry inspection. (a) Microorganisms imported under permit shall be subject to periodic inspection by the branch.

(b) At a post-entry inspection, the permittee shall make available for inspection the microorganism, records pertaining to the microorganism imported under permit, equipment, and facility upon request by the chief.

(c) Post-entry inspections are subject to user fees pursuant to section 4-71A-19. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-17 List amendment by order. (a) By order, the board may adopt additions to or deletions from the lists of microorganisms without regard to the notice and public hearing requirements of chapter 91, HRS; provided that thirty days or more prior to the effective date of the order, the department shall issue a press release and mail notices to the Office of Environmental Quality Control for publication and to all persons who have made a timely written request of the department for advance notice of the order or the department's rulemaking proceedings. The press release and the notice shall include:

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- (1) A statement summarizing the substance of the proposed order which may include examples of the kinds of microorganisms being added to or deleted from the lists required under section 150A-6.3, HRS;
- (2) A statement that a copy of the proposed order and the proposed exact changes will be mailed to any interested person who requests a copy upon payment in advance of costs for photocopying, preparing, and mailing the copy;
- (3) A statement as to where to obtain a copy of the proposed order and the proposed exact changes for inspection, or for pick-up after payment in full of costs for photocopying and preparing; and
- (4) A statement that the department is soliciting comments regarding the proposed order during the next thirty days, where comments may be forwarded to, and where the proposed order will be discussed.

(b) The department shall consider all oral and written comments and may incorporate the same in its review of the proposed order by the advisory committee on plants and animals in a noticed, public meeting.

(c) Upon approval by the board at a noticed, public meeting, the order to adopt additions to or deletions from the lists of microorganisms shall take effect ten days after the daily or weekly publication of statewide circulation or in separate daily or weekly publications whose combined circulation is statewide. [Eff. 11/30/01] (Auth: HRS §§150A-5.9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-18 Maximum time period for permit approvals, disapprovals, extensions, or automatic approvals. (a) Pursuant to the requirements of chapter 91, HRS, the department shall establish the following maximum time periods for the processing of permit requests after acceptance of a completed permit application and payment of applicable fees pursuant to

sections 4-71-4 and 4-71-19:

- (1) For microorganism species for which the chief is authorized to approve a permit, i.e., restricted list (Part B) microorganisms for purposes provided in Section 4-71A-22(c)(1),(2), and (3), the chief may approve or disapprove the issuance of a permit within 90 days; and
- (2) For microorganisms requiring board action as provided in section 4-71A-6, the board may approve or disapprove the issuance of a permit within 180 days.

(b) Notwithstanding the requirements of subsection (a), the maximum period of time shall be extended indefinitely in the event of a national disaster, state emergency, or union strike, which prevents the department from fulfilling application or review requirements in a timely manner.

(c) Except as provided for in subsection (b), an application request for the issuance of a permit shall be given automatic approval if action is not taken by the department within the established maximum period of time as specified in subsection (a). After the expiration of the maximum time period is brought to the attention of the department, the department shall have a reasonable amount of time to issue the permit.

(d) This section shall apply only to application requests for business or development-related permits required by law to be obtained prior to the formation, operation, or expansion of a commercial or industrial enterprise.
[Eff. 11/30/01] (Auth: HRS §§ 91-13.5, 150A-9)
(Imp: HRS §150A-6.3)

§4-71A-19 User fees. (a) The fee to process permits or permit renewals for import of an unlisted microorganism or a microorganism on the list of restricted microorganisms shall be as follows:

- (1) Five dollars per permit for a single

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shipment within one year from date of issuance or within a calendar year; or

- (2) Fifty dollars per permit for unlimited shipments within one year from date of issuance or within a calendar year.

(b) The fee to amend a permit shall be five dollars per request.

(c) The fee to process the registration of a microbial product shall be fifty dollars for unlimited shipments within two years from the date of issuance.

(d) The fee to renew registration of a microbial product shall be twenty-five dollars for unlimited shipments within one year from the date of renewal.

(e) In addition to the requirements of subsection (a), a fee for a site inspection as required in this chapter or by permit conditions shall be twenty-five dollars per inspection plus mileage reimbursement.

(f) For inspection requiring the services of personnel beyond official working hours, an additional fee shall be assessed which shall include applicable charges for overtime wages, fixed charges for personnel services, and meals if required.

(g) Permit and inspection fees may be waived by the chief for not-for-profit organizations, universities, schools, or government agencies.

(h) All fees shall be paid in full at the time of submission of the request and shall be submitted to the chief as follows:

- (1) Cash for walk-in payments only; or
- (2) Money orders, cashier's or company check made payable to the "Hawaii Department of Agriculture".

(i) All fees paid are non-refundable. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-20 Violations. Any person who violates any provision or requirement of this chapter or of any notice given pursuant thereto, shall be subject to the penalties provided for under section 150A-14, HRS.

[Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

SUBCHAPTER 2

INTRODUCTION OF MICROORGANISMS

§4-71A-21 List of restricted microorganisms, Part A. (a) The list of restricted microorganisms, Part A, is comprised of microorganisms classified as high risk microorganisms.

(b) The list of microorganisms designated as restricted, Part A, dated October 25, 2001, is located at the end of this chapter and made a part of this section.

(c) The introduction into Hawaii and possession of a microorganism on the list of restricted microorganisms, Part A, shall be by permit approved by the board pursuant to sections 4-71A-4 and 4-71A-7 and subject to permit conditions established by the board as further provided in section 4-71A-26. [Eff. 11/30/01] (Auth: HRS §§150A-5.9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-22 List of restricted microorganisms Part B. (a) The list of restricted microorganisms, Part B, is comprised of microorganisms classified as moderate risk microorganisms.

(b) The list of microorganisms designated as restricted, Part B, dated October 25, 2001, is located at the end of this chapter and made a part of this section.

(c) The introduction into Hawaii and possession of a microorganism on the list of restricted microorganisms, Part B, may be allowed by permit approved by the chief for the following purposes:

- (1) Laboratory studies, analyses, or diagnostics excluding manufacturing or production;
- (2) Plant or soil inoculation studies in a laboratory or growth chamber; or

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(3) Cultivation of algal, cyanobacterial and photosynthetic bacterial species in a closed or semi-closed system such as a photobioreactor.

(d) The introduction into Hawaii and possession of a microorganism on the list of restricted microorganisms, Part B, for purposes other than those described in subsection (c) will require a permit approved by the board pursuant to sections 4-71A-4 and 4-71A-7.

(e) If the chief determines that import of a strain of microorganism on the list of restricted microorganisms, Part B, is likely to increase the level of risk above that of a moderate risk microorganism as defined in section 4-71A-2, the request to import will require a permit approved by the board pursuant to sections 4-71A-4 and 4-71A-7.

(f) A permit issued under this section is subject to permit conditions as provided in subchapter 3. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-23 List of select human pathogens. (a) The list of microorganisms designated as select human pathogens, dated October 25, 2001, is located at the end of this chapter and made a part of this section.

(b) The introduction into Hawaii and possession of a microorganism on the list of select human pathogens is allowed without permit issued by the department subject to branch approval for the import in advance of shipment, and satisfaction of pre-entry and inspection requirements and further provided that:

- (1) The importer submits to the chief in advance of shipment a valid certificate issued by the CDC, for the movement of a species cited in Appendix A of the CDC List of Select Agents at 42 United States Code of Federal Regulations, section 72.6; or
- (2) The importer is a clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, (42 United

States Code of Federal Regulations, section 263a) that utilizes microorganisms on the list of select human pathogens for diagnostic, reference, verification, or proficiency testing purposes and is exempt from 42 United States Code of Federal Regulations, section 72.6.

(c) The branch shall notify the department of health of the entry into the State of the microorganism for the purpose of possible inspection and monitoring by the department of health. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-24 List of nonrestricted microorganisms.

(a) The list of nonrestricted microorganisms is comprised of microorganisms classified as low risk.

(b) The list of microorganisms designated as nonrestricted, dated October 25, 2001, is located at the end of this chapter and made a part of this section.

(c) Nonrestricted microorganisms imported for purposes and uses which, in the chief's judgment, are not likely to increase the level of risk above that of a low risk microorganism as defined in section 4-71A-2 may be imported into the State without a permit provided that:

- (1) The importer files a written statement with the chief on a form provided by the department, pursuant to section 4-71A-4; and the branch confirms that the microorganism requested for import is on the list of nonrestricted microorganisms and is from cultured stock; and
- (2) The microorganism meets the pre-entry and inspection requirements of section 4-71A-8 and 4-71-9, respectively.

(d) A request for import of a nonrestricted microorganism for a purpose or use that is likely to increase the level of risk above that described in subsection (a) or a request for import of a

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nonrestricted microorganism strain that is likely to increase the level of risk above that described in subsection (a) shall require a permit approved by the chief provided that the importer can comply with permit conditions in section 4-71A-27, and if applicable, section 4-71A-28.

(e) Microbial products containing microorganisms only on the list of nonrestricted microorganisms are subject to the import requirements for microbial products in subchapter 4. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-25 Unlisted microorganisms. (a) The introduction into Hawaii and possession of a microorganism not on any of the lists of microorganisms included in this chapter may be allowed based on the department's determination of the level of risk presented by the microorganism requested for import and its proposed use as provided below.

(b) An unlisted microorganism that is determined by the department to be a low risk microorganism may be allowed import by a letter of authorization issued by the chief without advisory committee review or board approval.

(c) An unlisted microorganism that is determined by the department to be a moderate risk microorganism may be allowed import by special permit approved by:

- (1) The chief without advisory committee or board approval, provided that the microorganism is for laboratory studies, diagnostics, and analyses, excluding manufacture or production; plant or soil inoculation studies in the laboratory or growth chamber; or cultivation of algal, cyanobacterial and photosynthetic bacterial species in a closed or semi-closed system such as photobioreactor; provided the importer can comply with permit conditions in section 4-71A-27, and if applicable, section 4-71A-28; or
- (2) The board, with advisory committee review,

if the microorganism is for purposes other than those listed in subsection (c)(1), provided that, the importer can comply with permit conditions established by the board.

(d) An unlisted microorganism that is determined by the department to be a high risk microorganism may be allowed import by special permit approved by the board, with advisory committee review, for purposes approved by the board, provided that the importer is able to comply with permit conditions established by the board.

(e) An unlisted microorganism imported by special permit shall be subject to the import, inspection, and standard permit requirements of subchapter 1 of this chapter.

(f) An unlisted microorganism allowed for import will be subsequently proposed for listing on the appropriate list of microorganisms based on the department's determination of the level of risk presented by the microorganism.

(g) A special permit issued under this section is subject to permit conditions established as provided in this section and in subchapter 3. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

SUBCHAPTER 3

PERMIT CONDITIONS

§4-71A-26 Permit conditions. (a) The importation and possession of a microorganism by permit shall be subject to conditions appropriate to eliminate or minimize the risks otherwise associated with the microorganism and its use.

(b) Permit conditions established by rule or by the board include, but are not limited to, restrictions as to time, place, location and use, special precautions, health requirements, and requirements for safeguarding the microorganism from escape, unauthorized release, or theft, as well as any

applicable requirements of municipal, state, or federal law.

(c) The permittee shall comply with the requirements of this chapter, chapter 150A, HRS, standard permit conditions and, if applicable, supplemental permit conditions established herein or, if the permit requires board action, with permit conditions established by the board.

(d) When an applicant whose request would not otherwise require board action is unable to comply with a permit condition established by rule, the chief in his discretion may forward the request for advisory committee review and board action. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-27 Standard permit conditions. All microorganisms allowed import through permit issued by the chief are subject to the standard permit conditions set forth below, provided that, for each permit, the identity of the microorganism or microorganisms or, alternatively, reference to an attached list of identified microorganisms to be imported, the purpose or purposes for import, permittee's name and address, site including address, and name and title of the person responsible for the particular import shall be inserted, as appropriate, in conditions (1), (2), (4) and (5), respectively:

- (1) The microorganisms, _____, shall be used for _____, a purpose approved by the chief, and shall not be sold, given, transferred or released in Hawaii, unless approved by the chief in writing;
- (2) The permittee, _____, shall be responsible and accountable for all microorganisms imported, from the time of their arrival to their final disposition;
- (3) The microorganisms are subject to the pre-entry requirements of section 4-71A-8 and the inspection requirements of section 4-

71A-9;

- (4) The microorganisms shall be safeguarded at _____, a site inspected and approved by the branch prior to importation. Removal of the microorganisms to another site shall require site inspection and prior approval by the chief;
- (5) The microorganisms shall be maintained by _____ as the responsible person or by trained or certified personnel designated by the responsible person;
- (6) The permittee shall adhere to the use, facility, equipment, procedures, and safeguards proposed and described in the permit application, as approved;
- (7) The approved site, microorganisms, and records pertaining to the microorganisms under permit shall be subject to post-entry inspections pursuant to section 4-71A-16;
- (8) The permittee shall immediately report to the chief any theft, accidental release, exposure, or disease outbreaks involving the microorganisms;
- (9) Upon completion or termination of the use of the microorganisms, the microorganisms shall be destroyed by autoclaving. In the event autoclaving is not possible, the permittee shall obtain written authorization from the chief for an appropriate alternate method of destruction;
- (10) The permittee shall submit an annual report of all the microorganisms imported for the calendar year by January 31st of the following year. The report shall include the permit number, scientific name and quantity of each microorganism species imported, and status of use of the microorganisms;
- (11) The permittee shall submit a final report on the method of destruction of the microorganism species to the chief within 30 days of completion or termination of the use

- of the microorganisms;
- (12) The permittee shall have available a procedural or safety manual at the time of inspection which identifies the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks of exposure or contamination;
 - (13) It is the responsibility of the permittee to comply with any applicable requirements of municipal, state, or federal law pertaining to the microorganisms;
 - (14) The permittee shall submit to the chief a copy of all valid licenses, permits, certificates or their equivalent required for the operation of the facility where the microorganisms are safeguarded. The permit issued by the chief may be cancelled upon revocation, suspension, or termination of any of the aforementioned documents required for operation of the facility;
 - (15) Any violation of the permit conditions may result in citation or in cancellation of the permit, or both;
 - (16) A cancelled permit is invalid and upon written notification from the chief, all microorganisms listed on the permit shall not be imported. In the event of permit cancellation, any microorganism species imported may be moved, seized, treated, quarantined, destroyed, or sent out of state at the discretion of the chief. Any expense or loss in connection therewith shall be borne by the permittee;
 - (17) The permit conditions are subject to cancellation or amendment at any time due to changes in statute or administrative rules restricting or disallowing import of the microorganisms or due to Board of Agriculture action disallowing a previously permitted use of the microorganisms; and
 - (18) The permittee shall agree in advance to

defend and indemnify the State of Hawaii, its officers, agents, and employees for any and all claims against the State of Hawaii, its officers, agents, or employees that may arise from or be attributable to any of the microorganisms that are introduced under this permit. This permit condition shall not apply to a permittee that is a federal or State of Hawaii entity or employee, provided that the state employee is a permittee in the employee's official capacity. [Eff. 11/30/01] (Auth: HRS §§150A-5.9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-28 Supplemental permit conditions. The following supplemental permit conditions are established for import of microorganism species on the list of restricted microorganisms, Part B, according to the respective import purpose or use:

- (1) For laboratory studies, diagnostics and analyses: the permittee shall comply with the Centers for Disease Control and Prevention and National Institutes of Health Biosafety Level 2 guidelines for laboratory facility, safety equipment, standard microbiological practices and special practices as found in the current edition of the *Biosafety in Microbiological and Biomedical Laboratories*; or
- (2) For plant or soil inoculation studies in a laboratory or growth chamber:
 - (A) The permittee shall collect and disinfect the runoff prior to disposal into a waste disposal system approved by the branch; and
 - (B) Upon completion or termination of the use of the restricted articles, the inoculated materials shall be destroyed or sterilized by autoclaving.
- (3) For recombinant DNA research: the permittee

- shall comply with the National Institutes of Health current biosafety level guidelines for recombinant DNA research published in and as amended in the *Federal Register*; or
- (4) For algae, cyanobacteria and photosynthetic bacteria in closed or semi-closed systems such as photobioreactors: the effluent shall be disinfected prior to discharge or routed to a waste-disposal system approved by the branch. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

SUBCHAPTER 4

INTRODUCTION OF MICROBIAL PRODUCTS

§4-71A-29 Introduction of a microbial product.

(a) The introduction into Hawaii and possession of a microbial product is allowed only as provided below.

(b) A microbial product containing only microorganisms on the list of nonrestricted microorganisms, including recombinant DNA strains determined by the department to be low risk, may only be imported into the State through a registration with the branch. A microbial product containing recombinant DNA strains of nonrestricted microorganisms other than strains determined by the department to be low risk shall require a permit for import subject to meeting the requirements of sections 4-71A-4 and, if applicable, 4-71A-7 and 4-71A-10;

(c) A microbial product containing only unlisted microorganism species determined by the department to be low risk microorganisms may be allowed import by letter of authorization subject to meeting the requirements of section 4-71A-4;

(d) A microbial product containing only one or more unlisted microorganism species other than species determined by the department to be low risk microorganism(s) may be allowed import by permit subject to meeting the requirements of sections 4-71A-

4, and if applicable, 4-71A-7 and 4-71A-10; and

(e) A microbial product containing only microorganisms on both the lists of nonrestricted and restricted microorganisms may be allowed import by permit pursuant to sections 4-71A-4, and if applicable, 4-71A-7 and 4-71A-10. [Eff. 11/30/01] Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-30 Microbial product registration. (a) A request to register a microbial product for import into the State shall be submitted to the chief on the department application form in advance of shipment, providing the information required in section 4-71A-4(a)(3),(4),(5),(7),(8) and (9), as well as the following additional information:

- (1) A request to introduce a microbial product into the State under registration;
- (2) A request that the department inspect the microbial product upon arrival in the State;
- (3) Quantity of each microbial product and scientific (genus and species) name of the microorganisms contained in each of the microbial products;
- (4) Material safety data sheet and label that includes the name, brand, or trade mark, ingredient statement, directions for use, and caution or warning statement, name and address of the manufacturer or person for whom manufactured; and
- (5) Description of the method of disposal for the microbial product.

(b) Registration is effective for one year from the date of issuance.

(c) Registration is subject to a fee pursuant to section 4-71A-19(c). [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-31 Conditions of registration. (a) Registered microbial products shall be allowed

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import for distribution, sales, or individual use.

(b) Registered microbial products shall be used in accordance with the product label.

(c) The registrant shall immediately notify the chief in writing of any changes made to the registered microbial product including to the microorganisms contained in the product, product label and use of the product. The written notification shall be submitted to chief in advance of shipment.

(d) Microbial products imported into the State are subject to pre-entry and inspection requirements pursuant to §4-71A-8 and §4-71A-9. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-32 Registration renewal. (a)

Registration of a microbial product may be renewed only when there are no changes in or to the microorganisms contained in the microbial product, product label, or the use of the product as previously registered.

(b) The chief may disapprove a request for renewal of registration for the following reasons:

- (1) Changes declared on the request for registration renewal are, in the chief's judgment, sufficiently significant to require a new registration; or
- (2) The registrant has not deposited or paid bail with respect to any summons or citation issued to the registrant as of the date of the chief's action on the request.

(c) A request to renew the registration of a microbial product shall not be made more than two months prior to the date of expiration.

(d) The registrant shall submit a written request for renewal to the chief with the following statements and information:

- (1) A request to renew registration;
- (2) A request that the department examine the microbial product upon arrival in the state;
- (3) An agreement by the registrant to

- comply with conditions of registration;
- (4) An agreement to be responsible for all costs, charges, or expenses incident to the inspection or treatment of the imported microbial products;
 - (5) A waiver of all claims for damages or losses incident to the inspection, treatment, disinfection, treatment, quarantine, or destruction of the microbial product, if necessary; and
 - (6) A statement that there are no changes in or to the microorganisms contained in the product as previously registered, product label, or use of the product.
- (e) If the request for registration renewal is not submitted within 30 days after the expiration of an existing registration, the request for registration renewal shall be treated as a new registration request and shall be subject to the import requirements and fees of sections 4-71A-19 and 4-71A-30. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-33 Cancellation of registration. The chief may cancel the registration of a microbial product for any of the following reasons:

- (1) Any violation of the conditions of registration;
- (2) A written request by the registrant to cancel registration; or
- (3) The microorganism(s) contained in the microbial product are no longer on the list of nonrestricted microorganisms. [Eff. 11/30/01] (Auth: HRS §§150A-5.9, 150A-6.3) (Imp: HRS §150A-6.3)

§4-71A-34 Import of a microbial product under trade secret claim. (a) Import of a microbial product containing a microorganism for which species identification is claimed by the product's

manufacturer or shipper to be trade secret shall be subject to special handling to assure confidentiality of the species identification of the microorganism, provided that the manufacturer or shipper and importer comply with branch procedures for notification and accommodation of a trade secret claim.

(b) Notwithstanding the assertion of a trade secret claim as described in subsection (a), the manufacturer or shipper shall disclose to the chief the scientific name or species identification of each microorganism contained in the microbial product requested for import, after which the asserted trade secret data will only be reviewed as necessary by certain persons in the branch's permit and registration review process. To maintain confidentiality, the asserted trade secret data will appear in coded form in written materials at any public meetings at which the import request is considered or in any disclosure of public records.

(c) It is the responsibility of the applicant or permittee to defend a trade secret claim if challenged and prove trade secret status. The department will treat a properly asserted trade secret claim as such and maintain confidentiality for the asserted trade secret data to the extent permitted by law or unless required to disclose the information pursuant to chapter 92F, HRS. If upon challenge, the state Office of Information Practices or a court determines that the scientific name or species identification of a microorganism contained in a microbial product is not a trade secret, subject to the outcome of any appeal, the department will disclose the data.

(d) A microbial product under trade secret claim is subject to the import requirements for microbial products described in this subject.

(e) Both a local importer as applicant and a manufacturer or shipper as co-applicant shall complete and sign an application for import under trade secret claim as provided herein and on branch forms. A trade secret claim under this section will be processed as follows:

(1) The manufacture or shipper shall notify the

chief in writing of a trade secret claim asserted as to species identification of one or more microorganisms contained in a microbial product and shall provide the product name and the name and address of the local importer;

- (2) Upon notification, the chief shall send to the manufacturer or shipper a permit application for import under trade secret claim;
- (3) The manufacturer or shipper shall list on the application the scientific name of each microorganism contained in the product, identifying which microorganisms are asserted to be trade secret protected, and shall complete and sign the application;
- (4) Prior to submitting the completed application to the branch for special handling, the manufacturer or shipper shall send to the importer a copy of the same application, first deleting species identification for those microorganisms in the product asserted to be trade secret protected; and
- (5) The importer shall complete, sign and submit the trade secret data redacted application to the department.

(f) Products containing microorganisms under trade secret claim shall not be listed on the same permit application as products for which no trade secret claim is asserted. [Eff. 11/30/01] (Auth: HRS §§150A-9, 150A-6.3) (Imp: HRS §150A-6.3)

DEPARTMENT OF AGRICULTURE

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The adoption of chapter 4-71 shall take effect ten days after filing with the Office of the Lieutenant Governor.

/s/ _____
JAMES J. NAKATANI
Chairperson,
Board of Agriculture

APPROVED:

/s/ _____
BENJAMIN J. CAYETANO
Governor
State of Hawaii

Dated: _____ 11/15/01 _____

APPROVED AS TO FORM:

Haunani Burns
Deputy Attorney General

_____ 11/20/01 _____
Filed