PERMIT PROCESS
REVIEW COMMITTEE
REPORT

SUBMITTED TO:
RUSSELL KOKUBUN, CHAIRMAN
BOARD OF AGRICULTURE

SEPTEMBER 25, 2013
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University of Hawai‘i (UH) researchers conducting scientific and medical research who require the importation of microorganisms must comply with Hawaii Department of Agriculture (HDOA) Hawaii Administrative Rules relating to plant and non-domestic animal quarantine, specifically the Microorganism Import Rules (see Attachment A). These rules 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.

Moreover, additional requirements are mandated dependent on the particular category of the microorganism species, the risk level it poses, and whether its introduction is related to an emergency or disaster situation.

The Hawaii Administrative Rules were developed by the HDOA to implement the requirements of Chapter 150A, HRS (see Attachment B). There are cogent reasons for the legislation and administrative rules, as the imported microorganisms could be potentially harmful to Hawai‘i’s agriculture, environment, and public health. For example, an invasive seaweed approved for importation for a research project was released from the laboratory and currently plagues Kane‘ohe Bay. On the other hand, research conducted on imported microorganisms can be beneficial. To illustrate, understanding the molecular genetic characteristics of the pineapple heart rot pathogen led to the most probable source of inoculum and the prevention of subsequent introduction of infected plant materials into the state of Hawai‘i. In addition, rapid identification of other pests and pathogens has led to pest management strategies that have saved the livelihood of farmers and prevented the devastation of native forests.

For many years, researchers have voiced their dissatisfaction with the permitting process, citing the excessive time and effort required to receive a permit. Because their work is generally supported by grant funds awarded for a specified period, often two to three years, delays in receiving the permit curtail the time to conduct the research, which results in a host of negative consequences. Some researchers claim they have been waiting for three or more years for permit approval; received approval past the mid-point in their grant period, which jeopardized their work and standing with the funding agency; and/or were forced to sub-contract work to other universities, which exported funds and jobs that could have remained in Hawai‘i. Students’ research and training have also been affected, resulting in delays in graduation and the availability of the next generation of scientists for STEM positions.
The problems with the permitting process were discussed at the Board of Agriculture (BOA) meeting conducted on April 26, 2011. The Board approved the motion that the HDOA would work in partnership with the University of Hawai‘i to conduct discussions and determine how the permit process could be streamlined and improved. Chairperson Russell Kokubun appointed Dr. Sylvia Yuen, ex-officio member of the Board and then interim dean of the UH College of Tropical Agriculture and Human Resources, to facilitate the committee. Dr. Gary Ostrander, then vice chancellor for Research and Graduate Education at UH-Manoa, endorsed the formation of the Permit Review Process Committee (hereinafter referred to as the Committee) and identified the UH representatives who should serve on the Committee.

The Committee consisted of the following members:

- Dr. Anne Alvarez, professor, Department of Plant and Environmental Protection Sciences, College of Tropical Agriculture and Human Resources (CTAHR), UHM
- Ms. Eleanor Low, research compliance officer, Biosafety, Office of the Vice Chancellor for Research and Graduate Education, UHM
- Mr. Alton Miyasaka, aquatic biologist, Hawai‘i Department of Land and Natural Resources, Division of Aquatics Resources
- Dr. Vivek Nerurkar, professor, chair, Department of Tropical Medicine and Medical Microbiology and Director JABSOM Biocontainment Facility, JABSOM, UHM
- Ms. Carol Okada, branch manager, Plant Quarantine Branch, Department of Agriculture
- Ms. Amy Takahashi, microorganism specialist, Plant Quarantine Branch, Department of Agriculture
- Dr. Chris Whelen, laboratory director, State Laboratories Division, Hawai‘i Department of Health
- Dr. Sam Wilson, post-doctoral candidate with Dr. Dave Karl at the Center for Microbial Oceanography Research and Education (C-MORE), UHM
- Dr. Sylvia Yuen, interim dean and director, CTAHR, UHM (note: Dr. Yuen currently serves as special assistant to the president, UH)

The Committee convened its first meeting in June 2011 and worked on its charge for the next 14 months. The aim of the Committee was to propose a permit process that

- is more efficient in implementing procedures
- is timely
- meets federal and state requirements
- meets biological logic
- safeguards Hawai‘i’s plant, animal, and public health
- allows for new knowledge and discovery, and
- is transparent.
A draft report was prepared and highlights of the report were shared at two meetings (conducted on April 12 and 13, 2012) with University of Hawai'i researchers. Relevant comments and concerns from the researchers were incorporated into the present report. Dr. Yuen also briefed the deans of the John A. Burns School of Medicine (JABSOM), College of Natural Sciences (CNS), and College of Tropical Agriculture and Human Resources (CTAHR) on the work of the Committee.

As the report was nearing completion, an incident occurred which raised questions regarding the security and physical containment of microorganisms at the university’s Kaka‘ako campus. This incident prompted the HDOA to scrutinize permits and permit conditions relating to JABSOM and the requirements for laboratory containment. Because the outcome of the inquiry had the potential to affect the Permit Process Review Committee’s work and recommendations, the Committee’s formal proceedings were recessed. However, activities related to the Committee’s charge continued during this period. For example, meetings were held with UH and JABSOM representatives to resolve the aforementioned issue and with HDOA staff to resolve problems with longstanding applications so that they could be approved. Further, briefings were provided to new Interim Vice Chancellor for Research Brian Taylor, new Assistant Vice Chancellor for Research Compliance John Galland, and Interim UH President David Lassner. All of the aforementioned expressed their commitment to supporting the Committee’s work. The Kaka‘ako campus incident has been resolved, and because the outcome did not have significant impact on the Committee’s work, the Committee reconvened to complete its report.

This report presents the findings of the Committee, which are presented below in three sections:

- Current Permit Review Procedures and Problem Areas
- Proposed Changes to Permit Review Procedures
- Recommendations
Currently, permit review procedures and problem areas

**Current Permit Review Procedures**

The instructions disseminated by the University of Hawai‘i to researchers regarding the requirements for biological commodities transport, use, and possession can be found in Attachment C. A revision of this document which is presently pending review and approval by the Institutional Biosafety Committee (IBC) is contained in Attachment D. A description of the current microorganism permit process utilized by the HDOA and a diagram of the permit process are presented below.

Microorganisms include algae, bacteria, fungi, protozoa, and viruses. All microorganisms are restricted entry into Hawai‘i and require either

- a permit approved by the Board of Agriculture (BOA) or by the Plant Quarantine Branch (PQB) chief, Hawaii Department of Agriculture; or
- a letter approved by the PQB chief.

Microbial products (products containing a microorganism) may be allowed entry through registration approved by the HDOA.

The requirement for an environmental assessment (EA) as a condition for a permit or other related approvals is limited to those circumstances where the importation involves the initiation of a “project or program” and where the use of public funds or lands is involved. Certain activities may be eligible for “exemption” under provisions established through the Environmental Council if the project or program is determined to have little or no impact on the environment. Factors for consideration including the underlying use of the microorganism and whether the microorganism has previously been imported would be relevant to any determination as to whether or not an applicant was proposing to initiate a program or project. It is the technical consultants’ (i.e., Advisory Subcommittee members’) assessments and recommendations regarding a particular import application that the HDOA most relies on. Should a request be determined appropriate for exemption, the HDOA will prepare a declaration of exemption. Should a request be determined appropriate for an EA, the applicant’s request may require full review by the Advisory Subcommittee (AS), Advisory Committee on Plants and Animals (ACPA), and the Board of Agriculture.

The microorganism import requirement for permit and other related approvals is based on the microorganism’s placement on one of the lists in the Microorganism Import Rules, Chapter 4-71A, Hawaii Administrative Rules, and its proposed use.
Upon receiving a completed application, the PQB verifies the list placement of the requested microorganism and, if appropriate, gives permission to import the microorganism or routes the request for BOA action.

**Table of Lists of Microorganisms and Import Requirements**

<table>
<thead>
<tr>
<th>MICROORGANISMS BY LISTS</th>
<th>APPLICATION APPROVED BY PQB CHIEF</th>
<th>APPLICATIONS APPROVED BY BOA ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Restricted Microorganisms</td>
<td>Letter without fee or BOA review.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Permit approved by the PQB chief for a purpose or use that is likely to increase the level of risk above the status of low; or a microorganism strain that is likely to increase the level of risk above the status of low.</td>
<td></td>
</tr>
<tr>
<td>Restricted B Microorganisms</td>
<td>*Permit for laboratory studies, analyses, diagnostics, excluding manufacturing or production.</td>
<td>*Permit for purposes not approved by PQB chief.</td>
</tr>
<tr>
<td></td>
<td>*Permit for plant or soil studies in the laboratory or growth chamber.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Permit for cultivation of algae or cyanobacterial and photosynthetic bacterial species in a closed or semi-closed system such as a photobioreactor.</td>
<td></td>
</tr>
<tr>
<td>Restricted A Microorganisms</td>
<td>Applications are not subject to PQB chief approval.</td>
<td>*Permit approved by the BOA for any purpose.</td>
</tr>
<tr>
<td>Selected Human Pathogens</td>
<td>Letter without fee or BOA review provided that the importer is a clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 and imports microorganisms for proficiency testing exempt by federal regulations.</td>
<td>*Permit approved by the BOA if the applicant cannot meet the requirements for a letter.</td>
</tr>
<tr>
<td>Unlisted Microorganisms</td>
<td>Advisory Subcommittee review to recommend level of risk associated with the microorganism and its proposed use.</td>
<td>Advisory Subcommittee review to recommend level of risk associated with the microorganism and its proposed use.</td>
</tr>
<tr>
<td></td>
<td>A low-risk import requires a letter</td>
<td>A moderate-risk import for</td>
</tr>
<tr>
<td>High-risk import</td>
<td>Moderate-risk import</td>
<td>Subject to $50.00 fee.</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Requires a *permit approved by the BOA.</td>
<td>Requires a *permit approved by the PQB chief for purposes listed above for Restricted B microorganisms.</td>
<td>Purposes not approved by the PQB chief requires a *permit approved by the BOA.</td>
</tr>
</tbody>
</table>

*Permit fee is $150.00 for a single-shipment permit or $500.00 for a multi-shipment permit. Permits are valid for one year from the date of issuance or one calendar year based on the request.

Processing applications requiring BOA action: The PQB chief compiles the information submitted by the applicant and sends it to the following:

**Advisory Subcommittee(s).** Comments and recommendations of the Advisory Subcommittee(s) are compiled and sent to the public meeting of the Advisory Committee on Plants and Animals.

**Advisory Committee on Plants and Animals.** Comments and recommendations of the Advisory Subcommittee(s) and Advisory Committee on Plants and Animals, including the committees’ votes, and of the PQB chief are compiled and submitted to the BOA.

**Board of Agriculture.** The BOA takes action to approve or disapprove the permit application. The BOA may impose permit conditions including but not limited to time, place, location, use, special precautions health requirements, and escape, unauthorized release, or theft, as well as any federal law.

All microorganism requests must be submitted using Form PQ-7, Permit Application for Restricted Commodities Into Hawaii. The addendum to the application is required for unlisted microorganisms and for microorganisms on the List of Restricted Microorganisms (Parts A and B). For microbial products, Form PQ-MP must be completed.

Site inspection and approval are required prior to issuance of a permit. The site inspection fee of $25.00 plus mileage reimbursement may be waived by the PQB chief for research by not-for-profit organizations, universities, or government agencies, or for exhibition in municipal zoos or government-affiliated aquariums.

With the implementation of the proposed changes, the timeframe goal for processing microorganisms may be revised as follows:

- Letter by PQB chief: 2 weeks
- Permit by PQB chief: 6–8 weeks
- Permit by BOA: 3 months
The Committee identified bottlenecks in the current permit review procedures which prolonged the time of the review and the eventual decision to approve or not approve the application. These bottlenecks were clustered into the following 10 problem areas:

1. **There is insufficient staff to handle the workload.** The downturn in the State’s economy resulted in a lowering of State agency budgets and a reduction of HDOA personnel. Consequently, there is only one HDOA staff member with responsibility for overseeing all of the applications relating to the importation of microorganisms to Hawai‘i. The heavy workload—which includes responsibilities such as reviewing each application for completeness and conducting clerical tasks, training, and site inspections—requires additional support to complete assignments in a timely manner. In addition, considerable time and effort is spent preparing for the defense of applications during hearings, which should be the responsibility of the well-informed applicant.

2. **Communication regarding the application process is inadequate.** Researchers filing an application do not have complete or convenient access to information (e.g., resources, examples, contacts, and FAQs) on the import permit process to efficiently prepare an application.

3. **Technology is needed to improve the application process.** The import permit application process for researchers is presently paper based and inefficient. This results in longer processing times, less accessibility to important information, and difficulty in tracking applications.

4. **Review committees need more members and procedural changes to operate more efficiently.** The Advisory Subcommittees and the Advisory Committee on Plants and Animals review applications to make recommendations to the Plant Quarantine Branch or the Board of Agriculture. The small number of reviewers creates problems when members are not available, are not timely in responding, or lack sufficient expertise in the technical subject area. Moreover, present operating procedures sometimes create delays which can be avoided.

The Board of Agriculture evaluates the findings and recommendations from the HDOA staff, including reports from the Advisory Subcommittee(s) and the Advisory Committee on Plants and Animals, and is the ultimate authority to approve/not approve an application to import microorganisms. The BOA generally meets monthly, but if a quorum of members is not present, approval of permit applications must be carried over to the next meeting, when again a quorum may not be present.
5. **The fast-track approval process for high-priority projects is not widely shared.** There are some projects of great importance that require immediate action, and the current permit procedures include a mechanism to fast-track these high-priority projects. However, the opportunity and procedures relating to the faster review are not well known among the research community.

6. **Grouping applications for permits is needed to reduce duplication and speed up the approval process.** The time required for multiple laboratory inspections and permit reviews for microorganisms to be studied in laboratories that already meet biosecurity and plant-protection quarantine standards is redundant and greatly lengthens the permit approval process. Moreover, permit requests at the species level results in hundreds of applications, each of which must be reviewed, approved, and monitored. This results in a tremendous workload for both researchers and the HDOA.

7. **The requirement for annual or semi-annual reports on most permits is burdensome.** Some researchers have thousands of strains of microorganisms, some tagged with a permit that requires a separate annual report. There are also older strains whose permit requirements mandate semi-annual reports. The numerous reports are extremely burdensome to researchers who must also submit federal reports and state permits to the HDOA, which must then review and process the reports.

8. **The time granted for a state permit for some microbial pathogens is too short.** State permits are valid for only one year from date of issuance or for one calendar year. This time period is too short and creates more work for everyone when yearly renewal permits must be filed by researchers and reviewed by the HDOA. In contrast, federal permits for plant pathogens are granted for a two-year period.

9. **The list of microorganisms maintained by the HDOA is outdated.** The present list of microorganisms was developed in 2001 or earlier and is outdated. It does not reflect changes to taxonomy that occur as research is conducted over time and organisms are reclassified and renamed. In addition, it does not accurately portray microorganisms that are high-risk for the state from a microbiological point of view. Many organisms on the list are already widely prevalent in Hawai‘i, are not easily transmissible, or will not survive in Hawai‘i’s environment. When an accurate list of high-risk microorganisms is not available, it is difficult for researchers to import microorganisms of low risk to Hawai‘i because the species may not be listed. Under the current system, when an organism is not on the list, it automatically requires review by HDOA, which includes review by the Plant Quarantine Branch and the Advisory Subcommittees to determine the risk level associated with the microorganism and its proposed use even though the microorganism may have little to no effect on the environment.
10. **There is no entity that presently provides oversight of the permit review process.** Continuing oversight of the permitting process is necessary to sustain the collaborative working relationship between the HDOA and UH, to address new problems and issues as they arise, and to provide ongoing quality improvement.
PROPOSED CHANGES TO PERMIT REVIEW PROCEDURES

Much of the Committee’s deliberations were spent identifying what could be done to develop a permit-review process that safeguarded Hawai‘i’s agriculture, environment, and public health but was more efficient and timely than current procedures. Given that the present system was established to meet federal and State requirements, as well as on court mandates resulting from lawsuits, it was not feasible to devise a completely new set of review procedures. Rather, the Committee focused on resolving the problems that slowed the permit review process. The table below presents the bottlenecks in the procedures—which were identified in the previous section—and how these problems could be overcome. Note that where possible, the Committee has worked with the UH and HDOA to proactively deal with certain problems, rather than waiting for them to be addressed at the completion and submission of its report. The proactive actions taken by UH and HDOA are also presented in the following table.

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>RESOLUTION</th>
</tr>
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</table>
| 1. There is insufficient staff to handle the workload. The downturn in the State’s economy resulted in a lowering of State agency budgets and a reduction of HDOA personnel. Consequently, there is only one HDOA staff member with responsibility for overseeing all of the applications relating to the importation of microorganisms to Hawai‘i. The heavy workload—which includes responsibilities such as reviewing each application for completeness and conducting clerical tasks, training, and site inspections—requires additional support to complete assignments in a timely manner. In addition, considerable time and effort is spent preparing for the defense of applications during hearings, which should be the responsibility of the well-informed applicant. | **Action Taken:** **UH**
- Vice Chancellor Gary Ostrander approved the assignment of Ms. Eleanor Low, UH-Manoa research compliance officer, to assist with the processing of permit applications filed by University researchers. She presently allocates 50 percent of her time to the aforementioned responsibility, which includes assisting the University to implement the actions recommended in this report. She also works closely with HDOA permit administrators to assist with needed tasks to reduce the time HDOA currently spends with researchers on their applications and preparing reports for public and BOA hearings. Heretofore, although some assistance was provided, there was no officially assigned UH staff member devoted to permit-related responsibilities. Ms. Low is familiar with the permit procedures and has experience in briefing researchers on how to complete permit applications and prepare for site inspections. |
### Recommendations:

#### HDOA

- Assign technicians or other staff to assist the HDOA permit specialists, including the microorganism specialist, in routine clerical duties such as data entering, scanning, copying, and other tasks. In addition, rotate HDOA inspectors into the specialist pool and cross-train them to provide assistance to the permit specialists, including the microorganism specialist.

- Reorganize the Plant Quarantine Branch to create an additional microorganism specialist position. The two microorganism specialists can assume different primary responsibilities and provide back-up services for each other. One reorganizational possibility might be the assignment of animal, human, and medically important pathogens to one specialist, and plant pathogens to the other specialist, recognizing that assignment of zoonotic and overlap agents will always be challenging.

#### Communication regarding the application process is inadequate.

Researchers filing an application do not have complete or convenient access to information (e.g., resources, examples, contacts, and FAQs) on the import permit process to efficiently prepare an application.

#### Recommendation:

#### UH

- Develop a pre-proposal/application process to facilitate researchers’ ability to efficiently prepare an application for review prior to submission to the HDOA. The process should be developed in collaboration with the HDOA, with annual reviews and updates for continuous improvement. The permit application process should be widely shared with the UH community using strategies such as the following:
  - regularly scheduled announcements to deans, department chairs, and faculty;
  - informational packets to new faculty;
  - postings on a dedicated website; and
3. Technology is needed to improve the application process. The import permit application process for researchers is presently paper-based and inefficient. This results in longer processing times, less accessibility to important information, and difficulty in tracking applications.

**Action Taken:**

**UH**

- Vice Chancellor Gary Ostrander allocated an IT position to the UHM Office of Research Compliance to assist in the development of an electronic-based system for HDOA microorganism permit applications as recommended below.

**Recommendation:**

**UH**

- Develop and establish an IT-based system, ideally using reusable code, to develop applications for submission to the HDOA. The following are examples of desirable attributes of the system:
  - is secure;
  - allows for electronic approvals;
  - has ability to track applications throughout the review process;
  - contains samples of successful and unsuccessful applications;
  - stores information and data securely that individual researchers can use to populate their new applications and reports;
  - provides links to application form and resources;
  - is written in user-friendly terms; that is, will allow non-UH importers, with proper safeguards, to also use the system; and
  - includes dictionary of terminology and agencies.

It is imperative that the IT-system be developed in collaboration with the HDOA. Pilot testing and user training are crucial for acceptance and successful
4. **Review committees need more members and procedural changes to operate more efficiently.** The Advisory Subcommittees and the Advisory Committee on Plants and Animals review applications to make recommendations to the Plant Quarantine Branch or the Board of Agriculture. The small number of reviewers creates problems when members are not available, are not timely in responding, or lack sufficient expertise in the technical subject area. Moreover, present operating procedures sometimes create delays which can be avoided.

### Action Taken:

#### HDOA

- Supported HB 2429 HD1, which allows ex-officio members of the BOA to designate a representative for board meetings. The bill was approved by the 2012 Hawaii State Legislature and signed into law by the governor. This measure will allow matters requiring BOA approval to be acted on in a timely manner by increasing the probability of achieving quorum at board meetings.

#### Recommendations:

**UH**

- Assign the UH Research Compliance Officer, in collaboration with the HDOA, to periodically review the need for Advisory Subcommittee and Advisory Committee on Plants and Animals members and identify individuals qualified and willing to serve. The list of scientists should be transmitted to the HDOA for review and submittal to the BOA chairperson who has the authority to approve and appoint the experts who will serve.

**HDOA and UH**

- Review the operating procedures of the SA and ACPA, and revise them as necessary to create efficiencies. This includes:
  - using updated technology, such as web conferencing, to make it easier for members to participate in meetings even if they are out of state;
  - involving the applicant in a meeting with
reviewers to respond to questions and concerns regarding the proposed project, which will reduce the back-and-forth communication between parties that lengthens the period of review;

- instructing researchers to attach the UH Institutional Biosafety Committee (IBC) and, if applicable, the Institutional Animal Care and Use Committee (IACUC) reports to their permit applications. Redacted minutes of the meeting in which the application was discussed and a listing of IBC/IACUC members and their areas of expertise should be obtained from the UH Office of Compliance and attached to the application. Third-party certifications, if any, and federal agency certificates or registrations should also accompany permit request applications, as they provide other sources of validation and support by scientists that the application should be approved.

- Scheduling pre-set meeting dates and times for the SA and ACPA to discuss and approve applications. This will reduce the time spent scheduling meetings and provide researchers with a more predictable timeline for the approval of their applications.

5. The fast-track approval process for high-priority projects is not widely shared. There are some projects of great importance that require immediate action, and the current permit procedures include a mechanism to fast-track these high-priority projects. However, the opportunity and procedures relating to the faster review are not well known among the research community.

**Recommendations:**

**UH**

- Review the criteria for high-priority projects with HDOA to ensure they are well defined to clearly differentiate the projects that require immediate attention.

- Develop an application form or procedures to request fast-track approval of permit requests, which includes the principal investigator’s contact information and the need for the priority review.

- Work with the research community to determine how HDOA fee charges for fast-tracking applications should be covered, especially for researchers whose work requires multiple permits.
and/or repeated importation of several different microorganisms.

- Make information regarding fast-tracking permit applications widely accessible to all researchers.
- Assist researchers to complete fast-track applications as quickly as possible and work with the HDOA to move these applications quickly through the review process.

| 6. Grouping applications for permits is needed to reduce duplication and speed up the approval process. The time required for multiple laboratory inspections and permit reviews for microorganisms to be studied in laboratories that already meet biosecurity and plant protection quarantine standards is redundant and greatly lengthens the permit approval process. Moreover, permit requests at the species level result in hundreds of applications, each of which must be reviewed, approved, and monitored. This results in a tremendous workload for both researchers and the HDOA. |
| Recommendations: |
| HDOA |
| - Assess the number of permits presently required and develop strategies to reduce those that are excessive and burdensome to researchers (e.g., ascertaining whether it is possible to approve permitting all species within a genus except those already established to be of high risk). The redundancy of inspections might be addressed by granting approval to compliant laboratories for all microorganisms within the larger taxonomic groups that are basically handled using the same general protocols. |
| - Determine whether laboratory inspections can be scheduled to include a cluster of permits involving laboratories using similar protocols. Permits for certain types of research should be evaluated by standards common to all similar laboratories. |
| - Allow a researcher holding an HDOA permit to assume responsibility for another researcher who wants to use the permittee’s microorganisms, provided that the microorganisms are used for the same purpose and under the same protocols as specified on the permit and that work is done in a laboratory listed in the conditions of the permit with regular inspections by HDOA. It should be underscored that the researcher who holds the permit is responsible for the conduct of the personnel and work in the laboratory and that any violations of the permit could result in citation and/or cancellation of the permit. |
| - Adjust the requirements needed to pass a
laboratory inspection to the level of invasiveness and risk of the organism to be handled, since risks for different types of organisms (e.g., non-pathogens, environmental bacteria, plant pathogens, animal and human pathogens) are different.

7. The requirement for annual or semi-annual reports on most permits is burdensome. Some researchers have thousands of strains of microorganisms, some tagged with a permit that requires a separate annual report. There are also older strains whose permit requirements mandate semi-annual reports. The numerous reports are extremely burdensome to researchers who must also submit federal reports and state permits to the HDOA, which must then review and process the reports.

**Recommendations:**

**UH**

- Entertain requests from researchers to consolidate imported microorganisms they work with into a single possession and use permit that states the specific action sought and why it is necessary. After a scientific review of requests, those deemed justified should be formally submitted to the HDOA for consideration and further action. This will initiate a series of required actions which must be completed before report requirements can be changed.

**HDOA**

- Work collaboratively with UH to reduce the reporting requirements of conforming researchers while maintaining the integrity of the permit system.
- Conduct actions needed to change report requirements for relevant permits.

The establishment of new reporting requirements will necessitate changes to HDOA rules and BOA-required actions. The consolidation of a number of old import permits for a researcher into one possession permit requires

- a request from UH to consolidate all the imported microorganisms into a single possession and use permit,
- a public notice and hearing conducted by the HDOA, and
- approval of the consolidation by the BOA.

Changing the requirement for semi-annual reporting will
require the BOA to revise the permit conditions because the reporting requirement was established by the BOA. For new import requests to the Board, HDOA currently recommends to the Board that the permit conditions require researchers to maintain reports; however, researchers must be able to submit the reports to HDOA upon request.

### 8. The time granted for a state permit for some microbial pathogens is too short.

State permits are valid for only one year from date of issuance or for one calendar year. This time period is too short and creates more work for everyone when yearly renewal permits must be filed by researchers and reviewed by HDOA. In contrast, federal permits for plant pathogens are granted for a two-year period.

**Recommendations:**

**UH**

- Formally request a lengthening of the permit period (e.g., from 1 to 2 years) for plant pathogens from the HDOA. The above action should reduce the number of applications and renewals submitted and reduce the workload for all relevant parties.

**HDOA**

- Implement actions to change the time period granted for permits requesting the importation of microorganisms.

Changing the period of time granted for a state permit requires changes to HDOA regulations, which presently include

- a request from within the agency or from the UH or other external group;
- HDOA developing rulemaking changes and recommendations which integrate feedback from UH;
- HDOA posting public notice, conducting public hearing, and preparing recommendations to the BOA; and
- BOA taking action to approve or not approve changes to time periods for permits.
9. The list of microorganisms maintained by the HDOA is outdated. The present list of microorganisms was developed in 2001 or earlier and is outdated. It does not reflect changes to taxonomy that occur as research is conducted over time and organisms are reclassified and renamed. In addition, it does not accurately portray microorganisms that are high-risk for the state from a microbiological point of view. Many organisms on the list are already widely prevalent in Hawai‘i, are not easily transmissible, or will not survive in Hawai‘i’s environment. When an accurate list of high-risk microorganisms is not available, it is difficult for researchers to import microorganisms of low risk to Hawai‘i because the species may not be listed. Under the current system, when an organism is not on the list, it automatically requires review by HDOA to include review by the Plant Quarantine Branch and the Advisory Subcommittees to determine the risk level associated with the microorganism and its proposed use even though the microorganism may have little to no effect on the environment.

Recommendations:

UH

- Convene a committee which includes representatives from the HDOA and the HDOH to initiate the revision of the current list of microorganisms and to update the list as necessary into the future. The list and proposed changes should then be transmitted to the HDOA for further review and approval. This should be done on a set schedule (e.g., annually) to avoid the list becoming outdated.

HDOA

- Work with legal counsel from the Office of the Attorney General to develop a legally defensible process to update the list of microorganisms without going through the rule-making process.

Making list changes currently requires actions by the Advisory Subcommittee(s), Advisory Committee, and BOA; public hearing and comments; additional comments by the BOA; approval by the governor; publication in the newspaper; and enactment into law. However, rule changes (e.g., DLNR rule changes) can be built into the process by stating in the rule that the list will be changed at specified time periods (e.g., every two years) so the proposed changes are routine with set conditions. Changes can then be enacted, as long as the HDOA, with support from its scientific advisors, provides a cogent rationale for the actions taken to the BOA on a regular schedule. The latter set of actions is what is recommended for HDOA.

10. There is no entity that presently provides oversight of the permit review process. Continuing oversight of the permitting process is necessary.

Recommendation:

HDOA

- Establish a Permit Review Task Force consisting of
to sustain the collaborative working relationship between the HDOA and UH, to address new problems and issues as they arise, and to provide ongoing quality improvement.

six individuals:
- two appointed by the BOA chairperson,
- one appointed by the director of the Department of Health,
- one appointed by the director of the Department of Land and Natural Resources,
- two appointed by the UHM vice chancellor for Research, of which one will be a faculty member who represents the research community, and
- one from commercial importers of microorganisms appointed by the BOA chairperson.

The Task Force should be charged with overseeing the permit review process, including resolving problems and continuously improving the application and issuance of permits for microorganisms.
RECOMMENDATIONS

The aim of the present Committee was to improve the permit review process so that applications for the importation of microorganisms are reviewed quickly and efficiently and approval does not result in harm to Hawai‘i’s flora, fauna, environment, and people. The Committee recognizes that improvement will require procedural changes by both the UH and HDOA. It will also require the UH and HDOA to work collaboratively and, in some respects, to integrate their operating systems so that applications and actions relating to them can move and be tracked seamlessly from one agency to the other. The following recommendations will effect changes that will lead to the desired outcome:

Recommendations for UH

1. Continue to dedicate a staff member (presently allocated at 0.50 FTE) to permit review responsibilities, including assisting UH researchers through the process, working collaboratively with the HDOA on permit issues, and continuously improving permit processes and procedures.

2. Develop a pre-application process within the UH to assist researchers to efficiently file permit applications with a high probability of securing approval. The process should be transparent and widely shared within the University community.

3. Develop, in collaboration with the HDOA, an IT-based application process which will improve accountability and efficiency. User feedback, pilot testing, and training are necessary components in the development and implementation of the new electronic system.

4. Assign the UH Research Compliance Officer the task of working with the HDOA to periodically review the need for members for the Advisory Subcommittee and Advisory Committee on Plants and Animals and solicit individuals to serve on those groups.

5. Review the criteria, develop an application form and procedures, and determine an equitable fee structure for “high-priority” projects. The results of these actions should be widely shared with the University’s research community.

6. Review lists of microorganisms and update lists as necessary on a set schedule. Transmit the updated lists to the HDOA for further review and approval.

7. Work with the HDOA to assess the number of permits presently required and develop strategies to reduce those that are excessive and burdensome to researchers as well as to the HDOA.
Recommendations for the HDOA

1. Assign technicians and cross-train inspectors who can be rotated into the specialist pool to provide assistance to permit specialists. Reorganize the Plan Quarantine Branch to create an additional microorganism specialist position.

2. Maintain ongoing communication with the UH research compliance officer regarding the information and actions needed to quickly and efficiently process permit applications successfully.

3. Work collaboratively with UH on developing an IT-based application and permit review process which is integrated with the HDOA online systems.

4. Partner with UH to review the operating procedures of the Advisory Subcommittee and Advisory Committee on Plants and Animals to determine how they can be modified to create efficiency and reduce reviewing time without sacrificing quality and safety standards.

5. Work with UH to expedite the processing of “high-priority” projects.

6. Upon request by UH, initiate proposed changes—including modifying rules, conducting public hearings, and securing BOA approvals—that will allow for (a) the consolidation of import permits; (b) changes to semi-annual reporting; (c) changes to time period granted for plant pathogen permits, and (d) updates to the list of microorganisms without the rule-making process.

7. Oversee the Permit Review Task Force to ensure it is fulfilling its mandate and continuously improving the permit application system. This includes addressing issues that are beyond the scope of the present Committee and other issues that may arise in the future which require the attention and collaborative work of all parties to resolve.
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Subchapter 2 Introduction of

Microorganisms

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Subchapter 4 Introduction of Microbial Products

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

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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 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)
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.

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(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
§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 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

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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 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 microorganism 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.

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(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

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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 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.
§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

(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 71A-21

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
(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 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,

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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-26
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 71A-28

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
§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-71A-30, 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 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

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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 manufacture 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)

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DEPARTMENT OF AGRICULTURE

Chapter 4-71A, Hawaii Administrative Rules, on the Summary Page dated October 25, 2001, was adopted on October 25, 2001, following public hearings held on October 1, 2001, October 3, 2001, and October 5, 2001 after public notice was given in the Honolulu Star-Bulletin and the Midweek on August 27, 2001.

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

CHAPTER 150A
CHAPTER 150A
PLANT AND NON-DOMESTIC ANIMAL QUARANTINE
AND MICROORGANISM IMPORT

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PART I. GENERAL PROVISIONS

[§150A-1] Short title. This chapter may be cited as the "Hawaii Plant Quarantine Law". [L 1973, c 69, pt of §1]

§150A-2 Definitions. As used in this chapter the term:

"Aggregate bulk freight" means manmade, unpackaged, pre-processed, inspected and certified, homogenous particulate material, without mark or count, that is usually free-flowing and bought and sold by weight or volume, such as clean sand, gravel, crushed stone, slag, recycled concrete, and geosynthetic aggregates.

"Algae" means any plant containing chlorophyll, which lacks true roots, stems, and leaves, and typically inhabits moist habitats, except those algae on or in humans or animals in Hawaii and those in or on processed foods, beverages, or pharmaceuticals.

"Animal" means any invertebrate or vertebrate species of the animal kingdom including but not limited to mammal, bird, fish, reptile, mollusk, crustacean, insect, mite, and nematode, other than common domestic animal such as dog and cat.

"Bacteria" means any prokaryotic or archaeobacterial organism, except those bacteria on or in humans or animals in Hawaii, and those in or on processed foods, beverages, or pharmaceuticals.

"Board" means the board of agriculture.

"Cement bulk freight" means unpackaged, homogenous cement, without mark or count, that is usually free-flowing and bought and sold by weight or volume.

"Chairperson" means the chairperson of the board of agriculture, or the chairperson's duly authorized agents.

"Coal bulk freight" means unpackaged, homogenous coal, without mark or count, that is usually free-flowing, bought and sold by weight or volume, and used as a fuel.

"Department" means the department of agriculture.

"Freight" means nonpassenger goods, cargo, or lading, transported for pay.

"Fungus" means all nonchlorophyll-bearing thallophytes, except those fungi on or in humans or animals in Hawaii, and those on or in processed foods, beverages, or pharmaceuticals.

"Import" means shipment to the State from any point outside of the State.

"Insect" means an invertebrate animal belonging to the class Insecta, including beetle, bug, fly, and other arthropods, such as spider, mite, tick, centipede, and wood louse.
"Inspect" means to examine material to ascertain the presence or absence of quarantine pests and to otherwise determine compliance with the provisions of this chapter or any rule adopted under this chapter.

"Inspector" means any employee or official of the department authorized by the board to administer and enforce the provisions of this law.

"Label" means the written, printed, or graphic matter upon the container of any article as pertaining to plant quarantine laws and regulations.

"Liquid bulk freight" means unpackaged, homogenous liquid goods, without mark or count, that are usually free-flowing and bought and sold by weight or volume, such as oil, or other complex mixture of petroleum hydrocarbons, bituminous liquids such as asphalt, gasoline, and fuel oils.

"Microbial product" means any product manufactured with known cultures of microorganisms for the purpose of bioremediation or bioaugmentation, including products such as microbial pesticides.

"Microorganism" means any unicellular microscopic organism including but not limited to algae, bacteria, fungi, protozoa, and viruses.

"Net weight" means the gross weight of the freight minus the container weight, if any.

"Passed" means the clearance status for entry given an article for import after inspection or quarantine requirements have been met.

"Pest" means any animal, insect, disease agent or other organism in any stage of development that is detrimental or potentially harmful to agriculture, or horticulture, or animal or public health, or natural resources including native biota or has an adverse effect on the environment as determined by the board.

"Protozoa" means any nonphotosynthetic eukaryotic organisms, either unicellular or composed of a group of more or less identical cells, generally motile by means of appendages or movements of the cell itself at some or all stages of their life cycle, except those protozoa on or in humans or animals in Hawaii, and those in or on processed foods, beverages, or pharmaceuticals.

"Soil" means that part of the upper layer of earth in which plants can grow; this material may or may not contain organic matter and includes such planting media as deteriorated peat, except clean coral, sand, pottery and industrial clay, volcanic cinders and other similar soil-free material.

"Unlisted microorganism" means any microorganism not on the lists of nonrestricted or restricted microorganisms or on the list of select human pathogen microorganisms.
"Vehicle" means any automobile, truck, tractor and similar equipment.
"Virus" means any or a class of noncellular submicroscopic obligate parasite, chiefly nucleoprotein in composition but often reducible to crystalline form, except those viruses on or in humans, or animals in Hawaii, and those on or in processed foods, beverages, or pharmaceuticals. [L 1973, c 69, pt of §1; gen ch 1985; am L 1990, c 243, §1; am L 1991, c 104, §1; gen ch 1993; am L 1995, c 193, §1; am L 1996, c 153, §2; am L 1997, c 63, §1; am L 1999, c 177, §2; am L 2000, c 211, §2; am L Sp 2008, c 3, §2; am L 2010, c 173, §3]

[§150A-3] Delegation of duties. All authority vested in the board or chairperson by virtue of this chapter may with like force and effect be exercised by such employees of the department as the board or chairperson may from time to time designate for the purpose. [L 1973, c 69, pt of §1; gen ch 1993]

§150A-4 Effect on department of land and natural resources and the department of health. Nothing in this chapter shall be construed to amend or alter the functions, duties, and powers of the department of land and natural resources and the department of health relative to chapters 171, 183D, 187A, 197, 321, and 328. [L 1973, c 69, pt of §1; am L 1987, c 230, §4 and c 283, §16]

§150A-4.5 Pest inspection, quarantine, and eradication fund. (a) There is established in the state treasury the pest inspection, quarantine, and eradication fund, into which shall be deposited:

(1) Legislative appropriations for biosecurity and inspection, quarantine, and eradication services;

(2) Service fees, charges, and penalties collected under section 150A-5.3;

(3) Fees imposed for services pursuant to this chapter or rules adopted under this chapter;

(4) Fines for violations of this chapter;

(5) Federal funds received for biosecurity, pest inspection, control, management, quarantine, and eradication programs;

(6) Grants and gifts;
(7) All interest earned or accrued on moneys deposited in the fund; and

(8) Any other moneys made available to the fund.

(b) The moneys in the pest inspection, quarantine, and eradication fund shall be expended by the department for the operation of biosecurity and pest inspection, quarantine, eradication, and monitoring programs; the electronic importer manifest program; related facilities; the execution of emergency remedial measures when pests are detected in the course of inspection and quarantine activities by the department; training of inspectors; education of the agricultural industry, permit and certificate holders, and the general public as to import requirements; and for any other purposes deemed necessary to carry out the purposes of this chapter. In addition, the moneys shall be expended to facilitate the processing and issuance of permits and microorganism import documents and for the operations, activities, and monitoring of permitted and certified plants, animals, and microorganisms. [L Sp 2007, c 9, pt of §1; am L 2008, c 236, §5; am L 2010, c 173, §4; am L 2012, c 127, §2]
PART II. REGULATION OF IMPORTATION

§150A-5 Conditions of importation. The importation into the State of any of the following articles, viz., nursery-stock, tree, shrub, herb, vine, cut-flower, cutting, graft, scion, bud, seed, leaf, root, or rhizome; nut, fruit, or vegetable; grain, cereal, or legume in the natural or raw state; moss, hay, straw, dry-grass, or other forage; unmanufactured log, limb, or timber, or any other plant-growth or plant-product, unprocessed or in the raw state; soil; microorganisms; live bird, reptile, nematode, insect, or any other animal in any stage of development (that is in addition to the so-called domestic animal, the quarantine of which is provided for in chapter 142); box, vehicle, baggage, or any other container in which such articles have been transported or any packing material used in connection therewith shall be made in the manner hereinafter set forth:

(1) Notification of arrival. Any person who receives for transport or brings or causes to be brought to the State as freight, air freight, baggage, or otherwise, for the purpose of debarkation or entry therein, or as ship's stores, any of the foregoing articles, shall, immediately upon the arrival thereof, notify the department, in writing, of the arrival, giving the waybill number, container number, name and address of the consignor, name and address of the consignee or the consignee's agent in the State, marks, number of packages, description of contents of each package, port at which laden, and any other information that may be necessary to locate or identify the same, and shall hold such articles at the pier, airport, or any other place where they are first received or discharged, in such a manner that they will not spread or be likely to spread any infestation or infection of insects or diseases that may be present until inspection and examination can be made by the inspector to determine whether or not any article, or any portion thereof, is infested or infected with or contains any pest. The department may adopt rules to require identification of specific articles on negotiable and non-negotiable warehouse receipts, bills of lading, or other documents of title for inspection of pests. In addition, the department shall adopt rules to designate restricted articles that shall require:

(A) A permit from the department in advance of importation; or
(B) A department letter of authorization or registration in advance of importation.
The restricted articles shall include but not be limited to certain microorganisms or living insects. Failure to obtain the permit, letter of authorization, or registration in advance is a violation of this section;

(2) Individual passengers, officers, and crew.

(A) It shall be the responsibility of the transportation company to distribute, prior to the debarkation of passengers and baggage, the State of Hawaii plant and animal declaration form to each passenger, officer, and crew member of any aircraft or vessel originating in the continental United States or its possessions or from any other area not under the jurisdiction of the appropriate federal agency in order that the passenger, officer, or crew member can comply with the directions and requirements appearing thereon. All passengers, officers, and crew members, whether or not they are bringing or causing to be brought for entry into the State the articles listed on the form, shall complete the declaration, except that one adult member of a family may complete the declaration for other family members. Any person who defaces the declaration form required under this section, gives false information, fails to declare restricted articles in the person's possession or baggage, or fails to declare in cargo manifests is in violation of this section;

(B) Completed forms shall be collected by the transportation company and be delivered, immediately upon arrival, to the inspector at the first airport or seaport of arrival. Failure to distribute or collect declaration forms or to immediately deliver completed forms is a violation of this section; and

(C) It shall be the responsibility of the officers and crew of an aircraft or vessel originating in the continental United States or its possessions or from any other area not under the jurisdiction of the appropriate federal agency to immediately report all sightings of any plants and animals to the plant quarantine branch. Failure to comply with this requirement is a violation of this section;
(3) Plant and animal declaration form. The form shall include directions for declaring domestic and other animals cited in chapter 142, in addition to the articles enumerated in this chapter;

(4) Labels. Each container in which any of the above-mentioned articles are imported into the State shall be plainly and legibly marked, in a conspicuous manner and place, with the name and address of the shipper or owner forwarding or shipping the same, the name or mark of the person to whom the same is forwarded or shipped or the person's agent, the name of the country, state, or territory and locality wherein where the product was grown or produced, and a statement of the contents of the container. Upon failure to comply with this paragraph, the importer or carrier is in violation of this section;

(5) Authority to inspect. Whenever the inspector has good cause to believe that the provisions of this chapter are being violated, the inspector may:

(A) Enter and inspect any aircraft, vessel, or other carrier at any time after its arrival within the boundaries of the State, whether offshore, at the pier, or at the airport, for the purpose of determining whether any of the articles or pests enumerated in this chapter or rules adopted thereto, is present;

(B) Enter into or upon any pier, warehouse, airport, or any other place in the State where any of the above-mentioned articles are moved or stored, for the purpose of ascertaining, by inspection and examination, whether or not any of the articles is infested or infected with any pest or disease or contaminated with soil or contains prohibited plants or animals; and

(C) Inspect any baggage or personal effects of disembarking passengers, officers, and crew members on aircraft or vessels arriving in the State to ascertain if they contain any of the articles or pests enumerated in this chapter. No baggage or other personal effects of the passengers or crew members shall be released until the baggage or effects have been passed.

Baggage or cargo inspection shall be made at the discretion of the inspector, on the pier, vessel, or aircraft or in any quarantine or inspection area.
Whenever the inspector has good cause to believe that the provisions of this chapter are being violated, the inspector may require that any box, package, suitcase, or any other container carried as ship's stores, cargo, or otherwise by any vessel or aircraft moving between the continental United States and Hawaii or between the Hawaiian Islands, be opened for inspection to determine whether any article or pest prohibited by this chapter or by rules adopted pursuant thereto is present. It is a violation of this section if any prohibited article or any pest or any plant, fruit, or vegetable infested with plant pests is found;

(6) Request for importation and inspection. In addition to requirements of the United States customs authorities concerning invoices or other formalities incident to importations into the State, the importer shall be required to file a written statement with the department, signed by the importer or the importer’s agent, setting forth the importer's desire to import certain of the above-mentioned articles into the State and:

(A) Giving the following additional information:
   (i) The kind (scientific name), quantity, and description;
   (ii) The locality where same were grown or produced;
   (iii) Certification that all animals to be imported are the progeny of captive populations or have been held in captivity for a period of one year immediately prior to importation or have been specifically approved for importation by the board;
   (iv) The port from which the same were last shipped;
   (v) The name of the shipper; and
   (vi) The name of the consignee; and

(B) Containing:
   (i) A request that the department, by its duly authorized agent, examine the articles described;
   (ii) An agreement by the importer to be responsible for all costs, charges, or expenses; and
   (iii) A waiver of all claims for damages incident to the inspection or the fumigation, disinfection, quarantine, or destruction of the articles, or any of them, as hereinafter provided, if any treatment is deemed necessary.
Failure or refusal to file a statement, including the agreement and waiver, is a violation of this section and may, in the discretion of the department, be sufficient cause for refusing to permit the entry of the articles into the State;

(7) Place of inspection. If, in the judgment of the inspector, it is deemed necessary or advisable to move any of the above-mentioned articles, or any portion thereof, to a place more suitable for inspection than the pier, airport, or any other place where they are first received or discharged, the inspector is authorized to do so. All costs and expenses incident to the movement and transportation of the articles to such place shall be borne by the importer or the importer's agent. If the importer, importer's agent, or transportation company requests inspection of sealed containers of the above-mentioned articles at locations other than where the articles are first received or discharged and the department determines that inspection at such place is appropriate, the department may require payment of costs necessitated by these inspections, including overtime costs;

(8) Disinfection or quarantine. If, upon inspection, any article received or brought into the State for the purpose of debarkation or entry therein is found to be infested or infected or there is reasonable cause to presume that it is infested or infected and the infestation or infection can, in the judgment of the inspector, be eradicated, a treatment shall be given such article. The treatment shall be at the expense of the owner or the owner's agent, and the treatment shall be as prescribed by the department. The article shall be held in quarantine at the expense of the owner or the owner's agent at a satisfactory place approved by the department for a sufficient length of time to determine that eradication has been accomplished. If the infestation or infection is of such nature or extent that it cannot be effectively and completely eradicated, or if it is a potentially destructive pest or it is not widespread in the State, or after treatment it is determined that the infestation or infection is not completely eradicated, or if the owner or the owner's agent refuses to allow the article to be treated or to be responsible for the cost of treatment and quarantine, the article, or any portion thereof, together with all packing and containers, may, at the discretion of the inspector, be destroyed or sent out of the State at the expense of the owner or the owner's agent. Such destruction or exclusion shall not be made the basis of a claim against the department or the inspector for damage or loss incurred;
(9) Disposition. Upon completion of inspection, either at the time of arrival or at any time thereafter should any article be held for inspection, treatment, or quarantine, the inspector shall affix to the article or the container or to the delivery order in a conspicuous place thereon, a tag, label, or stamp to indicate that the article has been inspected and passed. This action shall constitute a permit to bring the article into the State; and

(10) Ports of entry. None of the articles mentioned in this section shall be allowed entry into the State except through the airports and seaports in the State designated and approved by the board. [L 1973, c 69, pt of §1; am L 1974, c 232, §1; am L 1977, c 114, §2; am L 1980, c 265, §2; am L 1985, c 133, §1; gen ch 1985; am L 1990, c 243, §2; am L 1992, c 229, §3; am L 2000, c 211, §3; am L 2005, c 64, §2]

§150A-5.3 Inspection, quarantine, and eradication service fee and charge. (a) There is imposed a fee for the inspection, quarantine, and eradication of invasive species contained in any freight, including marine commercial container shipment, air freight, or any other means of transporting freight, foreign or domestic, but not including aggregate bulk freight, cement bulk freight, coal bulk freight, or liquid bulk freight, that is brought into the State. The transportation company shall bill the fee to the person responsible for paying the freight charges to the transportation company within fifteen days of the delivery of the freight. The fee shall be paid by the person responsible for paying the freight charges to the transportation company within forty-five days of receipt of the bill. The transportation company shall collect the fee from the person responsible and forward the payment to the department at the port of disembarkation within forty-five days of receipt of the fee; provided that the transportation company shall not be liable for any fee that is not paid by the person responsible for paying the freight charges to the transportation company.

The department shall deposit the fee into the pest inspection, quarantine, and eradication fund under section 150A-4.5.

(b) The fee shall be assessed and collected on the net weight of the imported freight computed on the basis of 75 cents for every one thousand pounds of freight, or part thereof, brought into the State. [L Sp 2007, c 9, pt of §1; am L 2008, c 16, §4; am L Sp 2008, c 3, §3; am L 2010, c 173, §5; am L 2011, c 36, §1]
§150A-5.4 Failure to pay or remit the inspection, quarantine, and eradication service fee; fines. (a) The following fines shall be imposed for failure to pay, bill, or remit the inspection, quarantine, and eradication service fee as provided for in section 150A-5.3:

(1) A person responsible for paying the freight charges to the transportation company who fails to pay the fee; or

(2) A transportation company that fails to:

(A) Bill the fee, within fifteen days of the delivery of the freight, to the person responsible for paying the freight charges to the transportation company; or

(B) Remit the fee to the department within forty-five days of collecting the fee from the person responsible for paying the freight charges to the transportation company,

shall pay a fine of two times the amount of the inspection, quarantine, and eradication service fee or $50, whichever is higher.

(b) All fines shall be paid to the department and deposited into the pest inspection, quarantine, and eradication fund under section 150A-4.5. [L 2010, c 173, §2]

§150A-5.5 What constitutes importation. (a) The landing of any article for the purpose of inspection or quarantine shall not be construed to give the article any status or the owner any right incident to articles which have actually been passed and allowed into the State.

(b) In legal effect, articles landed for the purpose of inspection or quarantine shall be construed to be still outside the State seeking entry, and shall not, in whole or in part, be considered suitable for entry into the State unless a tag, label, or stamp has been affixed to the article, its container, or its delivery order by the inspector as provided in section 150A-5(9), except that articles quarantined in the biocontrol containment facilities of the department or of other government agencies engaged in joint projects with the department may be released upon issuance of a permit approved by the board.

(c) Notwithstanding subsections (a) and (b), the import of articles in violation of this chapter or rules adopted under this chapter may subject the importer to penalty although the articles have not been passed for entry. [L 1985, c 133, §4; am L 1990, c 243, §3; am L 1996, c 153, §3]
Exceptions to the right to import. Nothing in this chapter shall permit the importation of any animal or article if the same, or any of them, has, by rule of the department been prohibited. [L 1985, c 133, §5]

§150A-6 Soil, plants, animals, etc., importation or possession prohibited. No person shall transport, receive for transport, or cause to be transported to the State, for the purpose of debarkation or entry thereinto, any of the following:

1. Soil; provided that limited quantities of soil may be imported into the State for experimental or other scientific purposes under permit with conditions prescribed by the department;

2. Rocks, plants, plant products, or any article with soil adhering thereto;

3. Any live snake, flying fox, fruit bat, Gila monster, injurious insect, or eels of the order Anguilliformes, or any other animal, plant, or microorganism in any stage of development that is detrimental or potentially harmful to agriculture, horticulture, animal or public health, or natural resources, including native biota, or has an adverse effect on the environment as determined by the board, except, as provided in this chapter and provided that, notwithstanding the list of animals prohibited entry into the State, the department may bring into and maintain in the State four live, sterile brown tree snakes of the male sex for the purpose of research or training of snake detector dogs, and, further, that a government agency may bring into and maintain in the State not more than two live, nonvenomous snakes of the male sex solely for the purpose of exhibition in a government zoo, but only after:

   A. The board is presented with satisfactory evidence that the sex of the snakes was established to be male prior to the shipment; and

   B. The board gives written approval conditioned upon such terms as the board may deem necessary, which terms shall include measures to assure the prevention of escape, continuing supervision and control by the board with respect to any department import under this paragraph, and the manner in which the snakes shall be disposed of or destroyed.
In case of the death of one or more snakes, the department or government agency may import and maintain replacements subject to the conditions described in this paragraph; and

(4) Any live or dead honey bees, or used bee equipment that is not certified by the department to be free of pests; provided that nothing in this paragraph shall be construed to prohibit the importation of bee semen. [L 1973, c 69, pt of §1; am L 1974, c 232, §2; am L 1985, c 133, §2 and c 179, §2; am L 1990, c 243, §4; am L 1994, c 48, §1; am L 1996, c 153, §4; am L 1997, c 63, §2; am L 1998, c 10, §1, c 28, §1, and c 244, §1; am L 1999, c 21, §1 and c 177, §3; am L 2000, c 211, §4; am L 2003, c 10, §1]

§150A-6.1 Plant import. (a) The board shall maintain a list of restricted plants that require a permit for entry into the State. Restricted plants or any portion thereof shall not be imported into the State without a permit issued pursuant to rules.

(b) The department shall designate, by rule, as restricted plants, specific plants that may be detrimental or potentially harmful to agriculture, horticulture, the environment, or animal or public health, or that spread or may be likely to spread an infestation or infection of an insect, pest, or disease that is detrimental or potentially harmful to agriculture, horticulture, the environment, or animal or public health. In addition, plant species designated by rule as noxious weeds are designated as restricted plants.

(c) The department may regulate or prohibit the sale of specific plants on the list of restricted plants by rule.

(d) Noxious weeds may be imported only for research, by permit, and shall not be offered for sale or sold in the State.

(e) No person shall import, offer for sale, or sell within the State any plant or propagative portion of Salvinia molesta or Salvinia minima and Pistia stratiotes. [L 2000, c 211, pt of §1; am L 2003, c 85, §9; am L 2004, c 10, §16; am L 2008, c 40, §2]

§150A-6.2 Animal import. (a) The board shall maintain:

(1) A list of conditionally approved animals that require a permit for import into the State;

(2) A list of restricted animals that require a permit for both import into the State and possession; and

(3) A list of animals that are prohibited entry into the State.
(b) The board shall adopt rules, pursuant to chapter 91, to establish an advisory committee of no fewer than three members with applicable expertise in vertebrate biology to identify whether an animal is a prohibited hybrid animal when the department suspects that the lineage of the animal is not as stated by the owner or on other official documents.

(c) Animals on the lists of conditionally approved and restricted animals shall be imported only by permit. Any animal that is not on the lists of conditionally approved, restricted, or prohibited animals shall be prohibited until the board's review and determination for placement on one of these lists; provided that the department may issue a special permit on a case-by-case basis for the importation and possession of an animal that is not on the lists of prohibited, restricted, or conditionally approved animals, for the purpose of remediating medical emergencies or agricultural or ecological disasters, or conducting medical or scientific research in a manner that the animal will not be detrimental to agriculture, the environment, or humans, if the importer of the animal can meet permit requirements as determined by the board; and provided further that the department may issue a short-term special permit on a case-by-case basis not to exceed ninety days for the importation and possession of an animal that is not on the lists of prohibited, restricted, or conditionally approved animals for the purpose of filming, performance, or exhibition, if the importer of the animal can meet permit and bonding requirements as determined by the board. [L 2000, c 211, pt of §1]

§150A-6.3 Microorganism import.  (a) The board shall maintain:

(1) A list of nonrestricted microorganisms allowed entry into the State without a permit;

(2) A list of restricted microorganisms that require a permit for import into the State and possession; and

(3) A list of microorganisms that are select human pathogens allowed entry into the State without a permit but that require the department to notify the department of health of entry for the purpose of possible department of health inspection and monitoring.

Import of a microorganism on these lists, as well as import of any unlisted microorganism, shall be subject to the notification, labeling, and inspection requirements of section 150A-5, and is allowed only as provided herein.
(b) Import of a microorganism on the restricted list of microorganisms shall be by permit issued pursuant to rules and subject to conditions established by rules; provided that, if the department in its discretion determines that import of a microorganism on the restricted list or the microorganism's proposed use presents a high risk to agriculture, horticulture, the environment, or animal or public health, the import request shall be subject to advisory committee review and board approval, including a determination that the importer is able to comply with conditions established by the board, before a permit may be issued.

(c) Import and possession of an unlisted microorganism may be allowed based on the department's determination of the level of risk presented by the import, including its proposed use, to agriculture, horticulture, the environment, or animal or public health. Import shall be either by letter of authorization or special permit issued by the department, without advisory committee review or board approval, or, alternatively, by special permit issued by the department subsequent to advisory committee review and board approval, according to risk level as provided by rule; provided that in the latter instance the importer is able to comply with conditions established by the board.

(d) 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 microorganism on the list of restricted microorganisms or an unlisted microorganism for the purpose of remediating any emergency or disaster affecting agriculture, horticulture, the environment, animal or public health, or for emergency preparedness; 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 special permit under subsections (b) and (c) as applicable, is necessary to remediate the emergency or disaster; and

3. The importer is able to meet conditions established by the board.

(e) Microbial products may be imported as follows:

1. Microbial products containing certain strains of microorganisms on the nonrestricted list of microorganisms, as identified by rule, may enter the State without a permit but shall not be imported without a registration issued pursuant to
rules. Import of an unregistered microbial product required to be registered with the department is a violation of this section; and

(2) Import of microbial products other than those products required to be registered pursuant to paragraph (1) shall be by permit or letter of authorization, as provided in subsections (b) and (c) as applicable.

(f) The requirements of this section other than the notification, labeling, and inspection requirements of section 150A-5 shall not apply to import of microorganisms by the following:

(1) The state department of health or Tripler Army Medical Center for their laboratories; provided that the department of health shall develop and implement within its laboratories a mechanism for coordinated oversight and inventory control of microorganisms imported for its laboratories and implement internal procedures to assure proper biosafety containment and laboratory practices commensurate with microorganism risk levels; and

(2) A laboratory certified under the Clinical Laboratories Improvement Amendments of 1988 (42 U.S.C. 263 et seq.); provided that the certified laboratory is registered with the department pursuant to rules and imports microorganisms that are applicable to the category of examinations or procedures for which the foregoing certification was approved.

The department of health and Tripler Army Medical Center may transfer any such imported microorganisms between their respective laboratories without approval from the department of agriculture, but with notification to the department of agriculture prior to the transfer; provided that transfer of such imported microorganisms from the department of health, Tripler Army Medical Center, or a laboratory certified and registered as described in paragraph (2) to other entities in the State shall require prior approval from the department of agriculture in the form of a letter of authorization or a permit for possession.

(g) The board may amend conditions in permits, letters of authorization, and registrations, or cancel permits, letters of authorization, and registrations, as necessary, if the board determines that the classification of the microorganism being imported or the conditions attendant to the microorganism's import and use must be changed due to newly discovered risks to agriculture, horticulture, the environment, or animal or public
§150A-6.4 Permit and other import document issuance; requirements. Except as otherwise provided in this part, all permits, letters of authorization, or registrations referenced in sections 150A-6 through 150A-6.3 shall be issued pursuant to rules. Any violation of conditions listed on the permits, letters of authorization, or registrations shall be a violation of this chapter. [L 2000, c 211, pt of §1; am L 2002, c 61, §3]

§150A-6.5 Animals; prohibition against possession, etc.; exception. No person shall possess, propagate, sell, transfer, or harbor any animal included on the list of prohibited animals maintained by the board, except upon a determination that the species:

(1) Was initially permitted entry and later prohibited entry into the State; or

(2) Was continually prohibited but unlawfully introduced and is currently established in the State; and

(3) Is not significantly harmful to agriculture, horticulture, or animal or public health, and the environment.

Under the circumstances described in this [section], the board may permit possession of the individual animal through its registration with the department while still prohibiting the same species of animal from importation, propagation, transfer, and sale. [L 2000, c 211, pt of §1]

§150A-6.6 Import lists amendment. Without regard to the notice and public hearing requirements of chapter 91, the board may adopt rules to make additions to or deletions from the lists required to be maintained in sections 150A-6.1 through 150A-6.3; provided that the board shall adopt rules pursuant to chapter 91 to establish methods to obtain public input and notify the public of additions to or deletions from the lists required under sections 150A-6.1 through 150A-6.3. [L 2000, c 211, pt of §1]

§150A-6.7 REPEALED. L 2010, c 173, §10.

§150A-7 Disposition. (a) It is a violation of sections 150A-5 and 150A-6 to bring into the State contrary to those sections any plant, plant product, animal, microorganism, or any article infested with pests or contaminated with soil and the
same shall be refused admittance and may, in the discretion of the inspector, be seized and treated, destroyed, or excluded at the expense of the owner or the owner's agent.

(b) It is a violation of this part to bring to or possess in the State any living creature that is prohibited or restricted, without a permit issued by the department, except as expressly provided in this part. The creature shall constitute contraband and shall be seized immediately upon discovery, whenever found, and be destroyed, donated to a government zoo, or sent out of the State, at the discretion of the department. Any expense or loss in connection therewith shall be borne by the owner or the owner's agent.

(c) Whenever any living creature introduced or admitted under rules of the department escapes, or is found to be free from confinement, the department may confiscate or capture it and any progeny at the expense of the owner. The department may destroy the creature, donate it to a government zoo, or send it out of the State after five days at the discretion of the department. Any expense or loss in connection therewith shall be borne by the owner or the owner's agent. [L 1973, c 69, pt of §1; am L 1985, c 133, §3; am L 1990, c 243, §5; am L 1992, c 229, §4; am L 1998, c 10, §2; am L 1999, c 177, §4; am L 2000, c 211, §5]

§150A-7.5 User fees. Fees may be assessed for the processing and issuance of permits issued by the department under this part, for inspections related to permit conditions, and for the registration of microbial products containing certain strains of microorganisms, as established by rule. [L 1996, c 153, §1; am L 1999, c 177, §5; am L 2000, c 211, §6]

§[150A-7.6] Processing fees for importation and possession requests. (a) There is imposed a fee for the processing of requests for the importation or possession of plants, animals, or soil that require a permit, or for the importation or possession of microorganisms that require a permit, letter of authorization, or registration under this chapter. The fee shall be paid in full at the time the request is submitted.

(b) The fees collected under this section shall be deposited into the pest inspection, quarantine, and eradication fund established under section 150A-4.5.

(c) The fees to process requests for importation and possession shall be as follows:

(1) $20 for a permit for a single shipment of restricted plants;
(2) $100 for a permit for unlimited number of shipments of restricted plants, as provided by permit, occurring within one year of the date of issuance;

(3) $20 for a permit for a single shipment of conditionally approved animals;

(4) $100 for a permit for up to an unlimited number of shipments of conditionally approved animals, as provided by permit, occurring within one year of the date of issuance;

(5) $50 for a permit for a single shipment of restricted animals that require permits for both importation and possession;

(6) $200 for a permit for up to an unlimited number of shipments of restricted animals that require permits for importation and possession, as provided by permit, occurring within one year of the date of issuance;

(7) $100 for a special permit for an unlisted animal in an emergency or disaster situation or for conducting medical or scientific research;

(8) $500 for a short-term special permit for an unlisted animal for a film production, performance, or exhibition;

(9) $2500 for a permit for plants, animals, or microorganisms that require a rule amendment to change a listing maintained by the board pursuant to section 150A-6.1, 150A-6.2, or 150A-6.3, to allow importation or possession of the organism or to otherwise accommodate the request for import or possession;

(10) $150 for a permit for a single shipment of listed or unlisted microorganisms that require permits for importation and possession;

(11) $500 for a permit for up to an unlimited number of shipments of listed or unlisted microorganisms that require a permit for importation or possession, as provided by permit, occurring within one year of the date of issuance or within a specified calendar year;

(12) $50 for a letter of authorization for import of unlisted microorganisms;
(13) $100 for an emergency permit of an unlisted microorganism or a microorganism on the list of restricted microorganisms in an emergency or disaster situation;

(14) $150 for registration to import a microbial product; and

(15) $150 for registration of a laboratory described in section 150A-6.3(f)(2).

(d) In addition to any fee under subsection (c), a fee of $250 shall be charged for the expedited processing of a permit, letter of authorization, or registration application. Expedited processing shall take no more than thirty days and shall not be available for a permit for importation or possession of plants, animals, or microorganisms that require:

(1) An amendment to rules to change the listing of the organism;

(2) Board approval; or

(3) Review as to the requirements of chapter 343. [L 2010, c 172, §2]

§150A-8 Transporting in State. Flora and fauna specified by rules and regulations of the department shall not be moved from one island to another island within the State or from one locality to another on the same island except by a permit issued by the department. [L 1973, c 69, pt of §1; am L 1974, c 232, §3; am L 1977, c 114, §3]

§150A-9 Rules and regulations. The department shall have the authority to carry out and effectuate the purposes of this chapter by rules and regulations. [L 1973, c 69, pt of §1]

§150A-9.5 Interim rules. (a) The department shall have the power, subject to the provisions of this section, to establish, implement, and enforce interim rules governing the transporting of flora and fauna into and within the State. Such rules shall not be subject to chapter 91.

(b) An interim rule may be adopted in the event that the importation or movement of any flora or fauna, in the absence of effective rules, creates a situation dangerous to the public health and safety or to the ecological health of flora or fauna present in the State which is so immediate in nature as to constitute an emergency. No interim rule shall be adopted
without such a finding by the advisory committee on plants and animals created under section 150A-10.

(c) Interim rules adopted by the department pursuant to this section shall be effective as stated by such rules; provided that:

1. Any interim rule shall be published at least once statewide within twelve days of issuance; and

2. No interim rule shall be effective for more than one year.

(d) Any person may appeal the reasonableness of any interim rule or determination of the advisory committee to the circuit court. [L 1977, c 114, §1; am L 1999, c 177, §6; am L 2000, c 211, §7; am L 2003, c 85, §10; am L 2004, c 10, §16]

§150A-10 Advisory committee on plants and animals. There shall be an advisory committee on plants and animals composed of the chairperson of the board or the chairperson's representative who shall be chairperson of the committee, the chairperson of the board of land and natural resources, the director of the office of environmental quality control, the director of department of health or their designees, and five other members, with expertise in plants, animals, or microorganisms, and who, by virtue of their vocation or avocation, also are thoroughly conversant with modern ecological principles and the variety of problems involved in the adequate protection of our natural resources. The latter five members shall be chosen by the chairperson. The committee shall advise and assist the department in developing or revising laws and regulations to carry out and effectuate the purposes of this chapter and in advising the department in problems relating to the introduction, confinement, or release of plants, animals, and microorganisms.

The chairperson may create ad hoc or permanent subcommittees, as needed. [L 1973, c 69, pt of §1; gen ch 1985; am L 1990, c 243, §6; gen ch 1993]

[$§150A-11$] Enforcement. Inspectors shall enforce the provisions of this chapter and related rules promulgated by the department.

Inspectors shall be provided with suitable badges or insignia of office by the department, and shall have power to serve and execute warrants in all matters relating to the quarantine laws, to issue a citation for any violation of this chapter and related rules, and to seize contraband articles throughout the State. [L 1985, c 133, §6]
Entry of private property for enforcement. Whenever any member of the department of agriculture deems it necessary for the protection of animal or public health, agriculture, or the environment, to enter any land, building, vessel or aircraft for the purpose of seizing, capturing, confiscating or removing any living creature that is prohibited or restricted and without a permit, the member may make complaint to the district judge in whose circuit the alleged violation is occurring, and the district judge may thereupon issue a warrant, directed to any police officer of the circuit, commanding the police officer to take sufficient aid, and being accompanied by the member of the department, to go to the place described in the complaint, and to seize, capture, confiscate or remove, under directions of the member, the prohibited or restricted creature. [L 1992, c 229, §2]

Citation and summons. There shall be printed a form of citation and summons for use in citing violators warning the person to appear and answer the charge against the person at a certain place and at a time within seven days after the citation. The citation and summons shall be so designed to include all necessary information to make it valid and legal within the laws and rules of the State. The form and contents of such citation and summons shall be adopted or prescribed by the district courts. In every case when a citation and summons is issued, the original of the same shall be given to the accused; provided that the district courts may prescribe the issuance to the accused of a carbon copy of the citation and summons and provide for the disposition of the original and any other copies. Every citation and summons shall be consecutively numbered and each carbon copy shall bear the number of its original. [L 1985, c 133, §7]

Administration of oath. When a complaint is made to any prosecuting officer of the violation of the provisions of this chapter or the rules promulgated and adopted pursuant thereto, the inspector who issued the citation and summons shall subscribe to the complaint under oath. [L 1985, c 133, §8]

Penalty. (a) Any person who violates any provision of this chapter other than sections 150A-5, 150A-6(3), and 150A-6(4) or who violates any rule adopted under this chapter other than those rules involving an animal that is prohibited or a plant, animal, or microorganism that is restricted, without a
permit, shall be guilty of a misdemeanor and fined not less than $100. The provisions of section 706-640 notwithstanding, the maximum fine shall be $10,000. For a second offense committed within five years of a prior offense, the person or organization shall be fined not less than $500 and not more than $25,000.

(b) Any person who violates section 150A-5 shall be guilty of a petty misdemeanor and fined not less than $50 and not more than $5,000. For a second offense committed within five years of a prior offense, the person may be fined not less than $250 and not more than $15,000.

(c) Any person who:

(1) Violates section 150A-6(3) or 150A-6(4), or owns or intentionally transports, possesses, harbors, transfers, or causes the importation of any snake or other prohibited animal seized under section 150A-7(b), or whose violation involves an animal that is prohibited or a plant, animal, or microorganism that is restricted, without a permit, shall be guilty of a misdemeanor and subject to a fine of not less than $5,000, but not more than $20,000;

(2) Intentionally transports, harbors, or imports with the intent to propagate, sell, or release any animal that is prohibited or any plant, animal, or microorganism that is restricted, without a permit, shall be guilty of a class C felony and subject to a fine of not less than $50,000, but not more than $200,000; or

(3) Intentionally imports, possesses, harbors, transfers, or transports, including through interisland or intraisland movement, with the intent to propagate, sell, or release, any pest designated by statute or rule, unless otherwise allowed by law, shall be guilty of a class C felony and subject to a fine of not less than $50,000, but not more than $200,000.

(d) Whenever a court sentences a person or organization pursuant to subsection (a) or (c) for an offense which has resulted in the escape or establishment of any pest and caused the department to initiate a program to capture, control, or eradicate that pest, the court shall also require that the person or organization pay to the state general fund an amount of money to be determined in the discretion of the court upon advice of the department, based upon the cost of the development and implementation of the program.

(e) The department may, at its discretion, refuse entry, confiscate, or destroy any prohibited articles or restricted articles that are brought into the State without a permit issued
by the department, or order the return of any plant, fruit, vegetable, or any other article infested with pests to its place of origin or otherwise dispose of it or such part thereof as may be necessary to comply with this chapter. Any expense or loss in connection therewith shall be borne by the owner or the owner's agent.

(f) Any person or organization that voluntarily surrenders any prohibited animal or any restricted plant, animal, or microorganism without a permit issued by the department, prior to the initiation of any seizure action by the department, shall be exempt from the penalties of this section.

(g) For purposes of this section, "intent to propagate" shall be presumed when the person in question is found to possess, transport, harbor, or import:

1. Any two or more animal specimens of the opposite sex that are prohibited or restricted, without a permit, or are a pest designated by statute or rule;

2. Any three or more animal specimens of either sex that are prohibited or restricted, without a permit, or are a pest designated by statute or rule;

3. Any plant or microorganism having the inherent capability to reproduce and that is restricted, without a permit; or

4. Any specimen that is in the process of reproduction. [L 1985, c 133, §9; am L 1990, c 243, §7; am L 1991, c 104, §2; am L 1992, c 229, §5; am L 1998, c 222, §1; am L 2000, c 211, §§8 to 10; am L 2008, c 101, §2; am L 2010, c 128, §2]

§150A-15 Failure to obey summons. Any person who fails to appear at the place and time specified in the citation and summons issued to that person by the inspector upon the person's citation for violation of the quarantine laws or rules shall be guilty of a misdemeanor and, on conviction, fined not more than $500 or imprisoned not more than six months, or both.

If any person fails to comply with a citation and summons issued to the person, the inspector shall cause a complaint to be entered against the person and secure the issuance of a warrant for that person's arrest.

When a complaint is made to any prosecuting officer of the violation of any quarantine law or any rule promulgated thereunder, the inspector who issued the complaint and summons shall subscribe to it under oath. [L 1985, c 133, §10; gen ch 1985]
PART III. NURSERY STOCK EXPORT SHIPMENTS

§150A-21 Certification for shipment. The department may certify as to the pest condition or post treatment of shipments when officially required. Fees may be charged for certificates in certain instances and shall be deposited into the pest inspection, quarantine, and eradication fund. [L 1977, c 114, pt of §4; am L 2010, c 173, §6]

[$§150A-22$] Responsibility for treatment. Any treatment of nursery stock which may be required under the provisions of law shall be at the risk and at the expense of the owner or persons in charge or in possession thereof at the time of treatment, unless otherwise provided. [L 1977, c 114, pt of §4]

§150A-23 Nursery stock certificate. The department may issue and authorize the use of nursery stock certificates by any shipper complying with its regulation for nursery inspection. Shipments accompanied by these certificates may move to other localities within the county or to other counties without inspection at destination. Nursery stock certificates may be issued for interstate shipments. Fees may be charged for nursery certification and shall be deposited into the pest inspection, quarantine, and eradication fund. Nursery stock certificates shall not be altered or misused.

The department may revoke or suspend the right to use any nursery stock certificate which is issued to any person who fails to comply with requirements for use of the certificate. [L 1977, c 114, pt of §4; am L 2010, c 173, §7]
§150A-31 Certificate for shipment. The department may certify as to the pest condition of honey bee shipments when health certificates are officially required. Fees to cover the department's certification costs may be charged for health certificates as provided by rule and shall be deposited into the pest inspection, quarantine, and eradication fund. Health certificates shall not be altered or misused. [L 1996, c 111, §1; am L 2010, c 173, §8]
PART V. CERTIFIED IMPORTERS OF MICROORGANISMS

§150A-41 Microorganism import. (a) Notwithstanding the permit requirements of sections 150A-5 and 150A-6.3, the board may issue a certificate to an importer of microorganisms authorizing import and possession of microorganisms on the list of restricted microorganisms or unlisted microorganisms referenced in section 150A-6.3; provided that:

(1) The import and possession is for medical or scientific purposes;

(2) The microorganisms are contained in a laboratory or other contained system approved by the department;

(3) The microorganisms are used in a manner that will not be detrimental to agriculture, horticulture, the environment, animals, or humans; and

(4) The importer is able to meet requirements established by the board, as further verified through site inspection by the department.

(b) Import by a certified importer of microorganisms other than those listed in the importer's certificate or for uses other than specified for each type of microorganism listed in the certificate shall be pursuant to section 150A-6.3.

(c) A certified importer importing pursuant to certificate shall comply with the provisions of part II other than the permit requirement, as applicable, in particular, the notification, labeling, and inspection requirements of section 150A-5. [L 1999, c 177, pt of §1; am L 2000, c 211, §11]

§150A-42 Certificate. (a) An importer requesting a certificate under this part shall complete and submit an application to the department providing information as required by rule.

(b) Fees may be assessed for the processing and issuance of a certificate and for inspections related to the certificate, as established by rule and shall be deposited into the pest inspection, quarantine, and eradication fund. Fees may vary according to the type of certification issued and the costs incurred for inspections.

(c) A certificate issued under this part shall be valid for no more than two years from date of issuance. A certified importer may reapply for certification pursuant to subsection (a). [L 1999, c 177, pt of §1; am L 2010, c 173, §9]
[§150A-43] Suspension or revocation of certificate. Any certificate issued pursuant to this part may be suspended or revoked by the department, after hearing, for violation of any certificate requirement or condition or any provision of this chapter or rule adopted under this part. Any order made by the department for the suspension or revocation of a certificate shall be in writing and shall set forth the reasons for the suspension or revocation. The action of the department in suspending or revoking a certificate may be reviewed in the manner provided in chapter 91. [L 1999, c 177, pt of §1]

[§150A-44] Summary suspension. Notwithstanding any law to the contrary, the department may cause the immediate suspension of an importer's certificate, subject to subsequent notice and hearing or other adequate procedures, upon the department's determination that there is an impending danger of escape or release of, or contamination from or exposure to microorganisms imported pursuant to certificate so as to present a threat to public health or safety, animal health, agriculture, horticulture, or the environment, or in the event of a medical emergency or agricultural or ecological disaster resulting from escape or release of, or contamination from or exposure to microorganisms imported pursuant to certificate.

The department may order the summary suspension of the certificate for a period not to exceed twenty days. The order of suspension shall be served upon the certified importer at the same time as the notice of hearing for further suspension or revocation and the hearing shall be scheduled prior to the expiration of the order of suspension. The period of suspension prior to the hearing shall not be extended beyond twenty days except upon the request of the importer for a reasonable continuance to adequately prepare the importer's defense. Any attempt by the importer to continue the certified activity while the certificate has been summarily suspended shall of itself be sufficient to warrant a permanent revocation of the certificate and shall subject the importer to all penalties prescribed by this chapter or any rule or order of the department. [L 1999, c 177, pt of §1]

[§150A-45] Emergency remediation. In conjunction with summary suspension of an importer's certificate, upon the department's determination that there is an impending danger of escape or release of, or contamination from or exposure to microorganisms imported pursuant to certificate so as to present a threat to public health or safety, animal health, agriculture, horticulture, or the environment, or in the event of a medical
emergency or agricultural or ecological disaster resulting from escape or release of, or contamination from or exposure to microorganisms imported pursuant to certificate, the department may, at the expense of the importer, seize, quarantine, remediate, condemn, or destroy the imported microorganisms, or any contaminated material, containment equipment, and laboratory or other contained system approved by the department, as the department in its discretion determines is necessary to address the threat, emergency, or disaster. [L 1999, c 177, pt of §1]

[§150A-46] Conditions of importation under certification. (a) A certificate issued to an importer under this part is nontransferable.

(b) Every importer issued a certificate shall comply with the requirements of the certificate.

(c) Any department employee or authorized representative may enter the premises under certification at any reasonable time to examine and inspect any microorganism, records, laboratory or other contained system approved by the department, equipment, procedures, manuals, and other related materials pertaining to the microorganism imported pursuant to certificate, and may conduct tests, collect samples, or perform any other duty for the purpose of carrying out and effectuating the purposes of this chapter. [L 1999, c 177, pt of §1]

[§150A-47] Penalties. In addition to penalties that may be applicable under section 150A-14, certified importers are subject to penalties as follows:

(1) A certified importer who violates any of the foregoing sections in this part shall be guilty of a petty misdemeanor and, notwithstanding section 706-640, shall be subject to a fine of not less than $1,000 and not more than $10,000; and

(2) A certified importer who intentionally imports a microorganism not allowed by the importer's certification with the intent to propagate, sell, or release the microorganism shall be guilty of a class C felony and, notwithstanding section 706-640, shall be subject to a fine of not less than $50,000 but not more than $500,000. [L 1999, c 177, pt of §1]

[PART VI.] BIOSECURITY PROGRAM

§150A-51 Biosecurity program; establishment. The department shall establish a biosecurity program authorized under this chapter that shall interface with other relevant state law; provided that the biosecurity program is not inconsistent with federal law. [L 2008, c 236, pt of §2]

§150A-52 Objectives of biosecurity program. The objectives of the biosecurity program shall be to:

(1) Establish a multi-dimensional system to prevent the entry into the State and interisland movement of pests and prohibited or restricted organisms without a permit; and

(2) Respond effectively to eradicate, control, reduce, and suppress incipient pest populations and established pests and seize and dispose of prohibited or restricted organisms without a permit. [L 2008, c 236, pt of §2]

§150A-53 General actions to achieve objectives. To achieve the objectives of the biosecurity program, the department shall plan for and, within available legislative appropriations, implement the following:

(1) Work with government agencies and agricultural commodity exporters of other states and countries to establish pre-entry inspection programs under which inbound cargo into the State is inspected at the ports of departure or other points outside the State;

(2) Establish, operate, or participate in operating port-of-entry facilities where multiple government agencies may inspect, quarantine, fumigate, disinfect, destroy, or exclude as appropriate, articles that may harbor pests or exclude articles that are prohibited or restricted without a permit, with the goals of:

(A) Performing inspections in an efficient, effective, and expeditious manner for the government agencies involved and for cargo owners, carriers, and importers; and

(B) Providing for the proper and safe storage and handling of cargo, especially agricultural and food commodities, awaiting inspection;
(3) Develop, implement, and coordinate post-entry measures to eradicate, control, reduce, and suppress pests and, as appropriate, eradicate or seize and dispose of prohibited or restricted organisms without a permit that have entered the State;

(4) Collaborate with relevant government agencies, agricultural commodity importers, and other persons to examine and develop joint integrated systems to better implement the biosecurity program;

(5) Improve cargo inspection capabilities and methods, including enhancement of the content and submission requirements for cargo manifests and agricultural commodity ownership and movement certificates;

(6) Promote the production of agricultural commodities in the State to reduce cargo shipments of imported commodities into the State; and

(7) Provide public education on the negative effects of pests and prohibited or restricted organisms without a permit, to the environment and economy of the State. [L 2008, c 236, pt of §2]

§150A-54 Biosecurity program; charges; costs. (a) The department shall set and impose charges for the inspection, quarantine, and eradication of pests in accordance with this chapter and chapter 141. The department shall deposit the charges into the pest inspection, quarantine, and eradication fund established pursuant to section 150A-4.5.

(b) The department shall set the charges at amounts intended to generate revenues that, when combined with federal and other funds, are sufficient to pay for the operating and maintenance cost of the program and debt service on bonds issued to fund facilities constructed for the program. [L 2008, c 236, pt of §2]

§150A-55 Federal and other funds. The department shall place high priority on seeking and applying for federal and other funds for the biosecurity program. [L 2008, c 236, pt of §2]

§150A-56 Schedule of appropriations and expenditures for program. (a) By January 1, 2009, the department shall prepare a schedule of proposed annual appropriations for the biosecurity program for the ensuing six fiscal years that represents the department's realistic expectation as to the amounts necessary to
effectively operate the program, yet remain within the constraints of projected state revenue growth.

(b) By January 1 of each fiscal year thereafter, the department shall update the schedule to include the following information, as applicable, for the immediate past fiscal year, current fiscal year, and ensuing five fiscal years:

1. The proposed appropriations submitted or to be submitted by the department to the governor for the biosecurity program;

2. The proposed appropriations submitted or to be submitted by the governor to the legislature in the executive or supplemental budget;

3. The actual appropriations by the legislature; and

4. The actual expenditures.

(c) The department shall submit each required schedule to the legislature no later than twenty days prior to the convening of each regular session of the legislature.

(d) The department may submit with each schedule a narrative commenting on the effects of any variance between the actual expenditure for the biosecurity program during a fiscal year and proposed appropriation submitted by the department to the governor for that fiscal year. [L 2008, c 236, pt of §2]

[§150A-57] Annual report. The department shall submit an annual report on the biosecurity program to the legislature no later than twenty days prior to the convening of each regular session of the legislature. The schedule required under section 150A-56 shall be included in the pertinent annual report. [L 2008, c 236, pt of §2]
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University of Hawaii Requirements for Biological Commodities
Transport, Use and Possession

I. OVERVIEW OF FEDERAL AND STATE MANDATES

Federal mandates, International Air Transportation Association (IATA) and Department of Transportation (DOT) require any person transporting hazardous materials to comply with 49 CFR Parts 100 to 185.

State mandates, Hawaii Administrative Rules Title 4 Department of Agriculture require all individuals who wish to import and possess microorganisms in the State of Hawaii to obtain an importation permit and to comply with HAR Chapter 71A Microorganism Import Rules and permit conditions of each individual permit.

II. COMPLIANCE REQUIREMENTS

TRAINING

The Animal Welfare and Biosafety Program Compliance Office requires all UH Personnel to complete Transport Awareness training if they will

- Prepare biological materials for shipment
- Marking and Labeling of packages
- Prepare shipping documentation
- Accept/receive packages (Importation)
- Supervise the transport of packages

Initial training is required and must be retaken within 24 months of the previous training. Training includes State of Hawaii Department of Agriculture Importation regulations overview, shipper’s responsibilities and provides necessary guidelines and references to ensure compliance with dangerous goods transportation.

APPROVALS

Importing Biological Commodities

Biological commodities imported into the State of Hawai‘i require at minimum a University Authorization (BSP2 form). A state or federal permit or a letter of authorization is required for any microorganism importation. All American Type Tissue Culture Collection (ATCC) requests will require a letter of exception from HDOA.

University Authorization to Import Biological Materials

Please follow these steps to obtain University authorization:
   Older versions of the BSP2 form are no longer accepted
2. Include with your BSP2 Authorization request;  
   a. Date of Annual Biosafety Training  
   b. Date of Transport Awareness Training. Training is provided at the Laulima Worksite "Transportation of Infectious and Biological Substances Training"  
   c. Copy of your Federal and/or State Permit or License (HDOA, CDC, USDA, Department of Commerce). See below for information regarding obtaining a permit or letter of authorization.
3. Submit to uhpermit@hawaii.edu or fax to 956-2265.

We are not responsible for documentation submitted to other email addresses or fax numbers. Only the Biological Materials Transfer Specialist or the AWBP Director may sign and approve any biological commodities transfer documents at the University of Hawaii.

Note: Biological commodities derived from animals, plants, or that have been genetically modified/engineered imported into the State of Hawaii from the UK and other foreign countries may require an APHIS/USDA permit. Prior to obtaining a BSP2 authorization from the University Compliance Office, researchers should contact the office to determine if a permit is necessary.

State Hawaii Department of Agriculture (HDOA) Permit, Letter of Authorization or Exception

HDOA Permit:

- Restricted Microorganisms Part A  
- Restricted Microorganisms Part B  

HDOA Letter of Authorization:

- NR listed “Nonrestricted” Microorganisms  

HDOA Letter of Exception:

- American Type Tissue Culture
University of Hawaii Requirements for Biological Commodities
Transport, Use and Possession


To obtain a Hawai’i Department of Agriculture (HDOA) permit, letter of authorization or exception to import biological commodities, contact Permit Compliance at uhpermit@hawaii.edu or 956-8420. The State of Hawai’i permit process may be lengthy depending on the type of request; all applicants should consider submitting their permit applications to the Permit Compliance at least one year prior to the date needed.

FORMS

- BSP2 UH Authorization
- HDOA PQ-7 application form
- HDOA PQ-7 application instructions

OTHER PERMITS & LICENSES

Centers for Disease Control (CDC) Etiologic Agent Import Permit Program
A CDC import permit is generally required for any infectious agent known or suspected to cause disease in humans. Visit the Centers for Disease Control Etiologic. CDC import permits are required for entry into the United States.

Further Information may be obtained by calling CDC at (404) 718-2077 or visiting the website: http://www.cdc.gov/od/eaipp/importApplication/

United States Department of Agriculture (USDA/APHIS)

A USDA permit may be required for movement of materials within the United States:

- Tissue culture materials and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origins
- Imported veterinary biological products
- Importation, interstate movement, or release of a genetically-engineered organism
- Plant and plant products imported into the United States
- Transit through and interstate movement within the United States of:
  - Plant pests (plant feeding insects, mite’s snails, slugs, and plant pathogens)
  - Biological control organisms of plant pests and weeds, parasitic plants, and federally-listed noxious weeds under regulatory authorities

Further information may be obtained by calling the USDA/APHIS at (301) 734-7834 or visiting the website: www.aphis.usda.gov/vs.

Select Agents

Individuals wishing to import select agents and toxins must be registered with CDC’s Select Agent Program in accordance with 42 CFR Part 73 (Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule) for the select agent(s) and toxin(s) listed on the import permit application. Also, In accordance with 42 CFR Part 73.16(a), an APHIS/CDC Form 2 must be completed and submitted to the CDC Select Agent Program and granted approval prior to the shipment of the select agents or toxins under the import permit. Contact the UH Select Agent Program Coordinator at (808) 956-8420 or by email: lowelean@hawaii.edu.

Exports of Infectious Materials

The export of a wide variety of etiologic agents of human, plant, and animal diseases may require a license from the Department of Commerce. Information may be obtained by calling the Department of Commerce Bureau of Export Administration at 202-482-4811 or through the internet at: www.bis.doc.gov/Licensing/
University of Hawaii Requirements for Biological Commodities
Transport, Use and Possession

III. FAQ’s

Question 1 Why do I still need to obtain HDOA and UH approval for microorganisms on the HDOA Nonrestricted List?
Hawaii Department of Agriculture requires a written request for import of any microorganism on the list of “nonrestricted microorganism.” The written request is in the form of a PQ-7 submitted through the UH Permit Compliance. (see Hawaii Administrative Rules (HAR) 4-71A-4, 4-71A-24)

Question 2 What is a Nonrestricted list microorganism?
HAR 4-71A-24(a) defines nonrestricted microorganism as microorganisms classified as low risk.

Question 3 Can I send in the HDOA permit application directly to Department of Agriculture?
No. HDOA has delegated initial responsibility of permit application oversight to UH Animal Welfare and Biosafety Program’s Permit Compliance section. Permittee’s work with the program’s coordinator to ensure all documentation needed by HDOA has been completed. Applications are submitted by UH on behalf of the applicant.

Permit Compliance Contact Information:

Eleanor W. Low, M.S., RBP (ABSA)
Biosafety Officer
Animal Welfare and Biosafety Program
University of Hawaii at Manoa
1960 East-West Road, Biomed T110E
Honolulu, HI 96822
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ATTACHMENT D

BIOLOGICAL COMMODITIES TRANSPORT, USE AND POSSESSION AT THE UNIVERSITY OF HAWAI‘I
Biological Commodities Transport, Use and Possession at the University of Hawaii
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PURPOSE

The Biological Commodities Transfer Program was implemented in 2007 to ensure that all University of Hawaii researchers, staff and students comply with state and federal regulations governing the movement of biological materials.

OVERVIEW OF FEDERAL AND STATE MANDATES

I. Federal mandates, International Air Transportation Association (IATA) and Department of Transportation (DCT) require any person transporting hazardous materials to comply with 49 CFR Parts 100 to 185.

State mandates, Hawaii Administrative Rules Title 4 Department of Agriculture require all individuals who wish to import and possess microorganisms in the State of Hawaii to obtain an importation permit and to comply with HAR Chapter 71A Microorganism Import Rules and permit conditions of each individual permit.

PROGRAM REVIEW

An annual review of the operating polices and procedures will be conducted to ensure compliance with current state and federal regulations. Annual auditing of records will be conducted to ensure accuracy and completeness of all records relating to biological commodities transport, use and possession for UH researchers.

GOALS/OBJECTIVES

1. Provide training on
   o State and Federal regulations and University Polices and Procedures related to the import, export, transfer or possession of biological commodities
   o Procedures required to obtain UH approval, HDOA and any applicable federal permits
   o How to prepare documentation for UH, HDOA, CDC and or USDA/APHIS and obtain approval prior to transfer
   o How to properly prepare biological commodities for shipment
2. Provide guidance and act as liaison between the UH researcher and State and Federal agencies.
3. Assess and monitor biological commodities transfers and laboratories which have imported biological commodities to ensure compliance with all applicable Federal and State regulations
4. Monitor and maintain accurate database of all Biological commodities in current possession at the UH facilities.

MEETING GOALS/OBJECTIVES

I. TRAINING

1. Transport of Biological and Infectious Substance Transport Awareness. The Animal Welfare and Biosafety Program Compliance Office requires all UH Personnel to complete Transport Awareness training if they will
   - Prepare biological materials for shipment
   - Marking and Labeling of packages
   - Prepare shipping documentation
   - Accept/receive packages (Importation)
   - Supervise the transport of packages
   Initial training is required and must be retaken within 12 months of the previous training. Training includes State of Hawaii Department of Agriculture Importation regulations overview, shipper’s responsibilities and provides necessary guidelines and references to ensure compliance with dangerous goods transportation.
   Transport Awareness training can be completed online at https://laulima.hawaii.edu/autoenroll/?tibs-permits

2. General Biosafety
   In addition to Transport Awareness Training, UH researchers, laboratory staff and students working with biological commodities are required to complete an initial in-classroom training, as well as an online refresher annually. To schedule classroom training, contact Biosafety Program Training Coordinator Mr. Stephen Case at stevec@hawaii.edu.
   Refresher training may be completed online at https://laulima.hawaii.edu/autoenroll/?uh_biosafety

3. UH Category A shipper (Also known as UH SA Program Unit 4)
   Transfer of any Infectious Materials classified by the International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) as a Category A, Infectious Substance including select agents and toxins requires completion of in-classroom training. A refresher must be
completed annually. To schedule an in classroom training, contact Ms. Eleanor Low at lowelean@hawaii.edu.

4. Bloodborne Pathogens
This is a mandatory course designed for all University of Hawaii research staff that may come into contact with human fluids and other biological materials including cell lines. Bloodborne pathogen training is required when there is an occupational exposure to blood or other potentially infectious materials OSHA 1910.1030(a). Provided in classroom interactive setting as required by OSHA (1910.1030(g)(2)).
To schedule classroom training, contact Biosafety Program Training Coordinator Mr. Stephen Case at stevec@hawaii.edu.

II. APPROVALS & DOCUMENTATION
1. Importing Biological Commodities

Biological commodities imported into the State of Hawai‘i require at minimum a University Authorization (BSP2 form). A state or federal permit or a letter of authorization is required for any microorganism importation. All American Type Tissue Culture Collection (ATCC) requests will require a letter of exception from HDOA. Outlined below are the steps to obtain approval for importing biological materials.

A. University Authorization to Import Biological Materials

a. Complete a BSP2 Form
2. (http://manoa.hawaii.edu/ovcrge/pdf/BSP2new.pdf)
3. Include with the BSP2 Authorization request;
   i. Date of Annual Biosafety Training
   ii. Date of Transport Awareness Training. Training is provided at the Laulima Worksite “Transportation of Infectious and Biological Substances Training”
   iii. Copy of your Federal and/or State Permit or License (HDOA, CDC, USDA, Department of Commerce). See below for information regarding obtaining a permit or letter of authorization.
   b. Submit to uhpermit@hawaii.edu or fax to 956-2265.

Approvals are generally granted within 48 hours of receipt except on holidays, furloughs and non business days.
Only the Biological Materials Transfer Program coordinator or the AWBP Director may sign and approve any biological commodities transfer documents at the University of Hawaii.

Biological commodities derived from animals, plants, or that have been genetically modified/engineered imported into the State of Hawaii from the UK and other foreign countries may require an APHIS/USDA permit. Prior to obtaining a BSP2 authorization from the Biological Materials Transfer Program, researchers should contact to determine if a permit is necessary.

B. State Hawaii Department of Agriculture (HDOA) Permit, Letter of Authorization or Exception

Generally, importation of microorganisms will require a State of Hawaii Department of Agriculture Import Permit. Permits expire one year from the date of issue and must be renewed for continued approval.

All Hawaii Department of Agriculture (HDOA) permit, letter of authorization or exception requests must go through the UH Biological Commodities Transfer Specialist, at uhpermit@hawaii.edu or 956-8420.

A fee may be required for the permit. See link
http://hdoa.hawaii.gov/pi/pq/import-program/pq-non-domestic-animal-and-microorganism-lists/ or

http://hdoa.hawaii.gov/pi/pq/import-program/plant-quarantine-application-for-permits/

List of Microorganisms by restriction can be found at the links below;

HDOA Permit:

- Restricted Microorganisms Part A (High Risk) (*Minimum of 6 months to a year to obtain Permit*)

- Restricted Microorganisms Part B (Moderate Risk) (*Minimum of 3 months to one year to obtain Permit*)

HDOA Letter of Authorization (*Minimum of 30 days to 3 months to obtain Authorization*):
• NR listed “Nonrestricted” Microorganisms (Low Risk)

HDOA Letter of Exception (Minimum of 30 days to 3 months to obtain Exception):

• American Type Tissue Culture
  http://www.atcc.org/AboutATCC/ComplianceFormsAndRegulatoryPermits/tabid/714/Default.aspx

C. OTHER PERMITS & LICENSES

Centers for Disease Control (CDC) Etiologic Agent Import Permit Program

A CDC import permit is generally required for any infectious agent known or suspected to cause disease in humans. Visit the Centers for Disease Control Etiologic. CDC import permits are required for entry into the United States.

Further Information may be obtained by calling CDC at (404) 718-2077 or visiting the website: http://www.cdc.gov/od/eaipp/importApplication/

United States Department of Agriculture (USDA/APHIS)

A USDA permit may be required for movement of materials within the United States:

• Tissue culture materials and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origins
• Imported veterinary biological products
• Importation, interstate movement, or release of a genetically-engineered organism
• Plant and plant products imported into the United States
• Transit through and interstate movement within the United States of:
  o Plant pests (plant feeding insects, mite's snails, slugs, and plant pathogens)
  o Biological control organisms of plant pests and weeds, parasitic plants, and federally-listed noxious weeds under regulatory authorities

Further information may be obtained by calling the USDA/APHIS at (301) 734-7834 or visiting the website: www.aphis.usda.gov/vs.
D. SELECT AGENTS AND TOXINS

Individuals wishing to import select agents and toxins must be registered with CDC’s Select Agent Program in accordance with 42 CFR Part 73 (Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule) for the select agent(s) and toxin(s) listed on the import permit application. Also, in accordance with 42 CFR Part 73.16(a), an APHIS/CDC Form 2 must be completed and submitted to the CDC Select Agent Program and granted approval prior to the shipment of the select agents or toxins under the import permit. Contact the UH Select Agent Program Coordinator at (808) 956-8420 or by email: lowelean@hawaii.edu.

E. EXPORTS OF BIOLOGICAL MATERIALS

The export of a wide variety of etiologic agents of human, plant, and animal diseases may require a license from the Department of Commerce. Information may be obtained by calling the Department of Commerce Bureau of Export Administration at 202-482-4811 or through the Internet at: www.bis.doc.gov/Licensing/

F. UH APPROVALS

Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC) and Human Studies Program approvals may be required for the Biological Materials transfer. It is the responsibility of the Principal Investigator to ensure all UH approvals have been completed prior to requesting the transfer.

III. INVENTORY

The Centers for Disease Control and Prevention (CDC) and United States Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS) Select Agent Program regulate the importation, possession, and use of microorganism’s nation-wide. The Hawaii Department of Agriculture (HDOA) enforces similar regulations along with the issuance of importation permits for the possession and use of microorganisms in the State of Hawaii.

The UH Laboratory Inventory Declaration (UH LID) form has been developed to enable the UH Biosafety Program to improve accountability and documentation of the numerous campus laboratory inventories possessing, using and storing microorganism. The inventory declaration forms are to be completed annually and submitted to the Animal Welfare and Biosafety Program Biological Materials Transfer Specialist. Databases are maintained for all biological materials approved for import, possession or transfer. Final disposition of any biological materials must be documented. Refer to
University of Hawaii Mānoa Laboratory Decommissioning Policy (M2.400) for complete close out of a laboratory.

Any researcher who possess, transfers or uses Category A, Infectious Materials, Select agents and toxins must maintain accurate records, which include:
1) Inventory Log
2) Training Records
3) Dangerous Goods Declaration Shipping Papers
4) Current annually updated Biosafety and Biosecurity Plans

IV. INSPECTIONS
Laboratory Inspections of laboratories for Principal Investigators who have obtained import permits and UH approvals for importation, transfer or possession of biological materials may be conducted on an annual basis to ensure compliance with permit conditions.

FORMS
- BSP2 UH Authorization
- HDOA PQ-7 application form
- HDOA PQ-7 application instructions
- UH Laboratory Inventory Declaration (UHLID) Form
PROCUREMENT PROCESS FLOW CHARTS

Biological Commodities Procurement Process - Import

- Have you completed General Biosafety Training?
  - Yes
  - No: Contact Steve Case at stevec@hawaii.edu
- Have you completed Transport Awareness Training?
  - Yes: Contact Eleanor Law at uhpermit@hawaii.edu
  - No: Contact Eleanor Law at uhpermit@hawaii.edu
- Is this an import request?
  - Yes: Follow Export/Shipping Flow Chart
  - No: Is this an Export/Shipping Request?
- Import of DNA, Tissue, Plant/Animal/Human Parts, Environmental Sample, Serum or other fluids
- Is it Recombinant?
  - Yes: Submit BSFP request to uhpermit@hawaii.edu
  - No: Is the microorganism on the RA, AIL list?
    - Yes: Submit BSFP request to uhpermit@hawaii.edu
    - No: Is the microorganism on the RA, AIL list?
      - Yes: Submit BSFP request to uhpermit@hawaii.edu
      - No: On the NR list? and PI has approved for UH NR list?
        - Yes: Contact Eleanor Law lovenstein@hawaii.edu/Permit (PO), BSFP, IRC approval and Lab Inspection Required.
        - No: Contact Eleanor Law lovenstein@hawaii.edu/Permit (PO), BSFP, IRC approval and Lab Inspection Required.