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Plant Quarantine Branch  
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May 8, 2009

To: Advisory Committee on Plants and Animals

From: Amy Takahashi, Microorganism Specialist  
Plant Quarantine Branch

Subject: Request to: (1) Allow the Importation of an Alga, *Porphyra yezoensis*, on the List of Restricted Microorganisms (Part B), for Cultivation, by NoriTech Hawaii, Inc.; and (2) Establish Permit Conditions for the Importation of an Alga, *Porphyra yezoensis*, on the List of Restricted Microorganisms (Part B), for Cultivation, by NoriTech Hawaii, Inc.

We have received a request from NoriTech Hawaii, Inc. to import a red marine alga, *Porphyra yezoensis*, for cultivation in land-based seawater ponds and tanks.

**COMMODITY:** Various shipments of red marine alga, *Porphyra yezoensis*, sporelings.

**SHIPPER:** NoriTech Seaweed Biotechnologies, Ltd. (NTI), 19 Habrosh Street, Savyon, 56530, Israel.

**IMPORTER:** NoriTech Hawaii, Inc. (NTH), c/o Bendet, Fidell, Sakai & Lee, 841 Bishop Street, 1500 Davies Pacific Center, Honolulu, Hawaii 96813. NTH is a subsidiary of Seaweed Bio-Technology Incorporated (SBTI), a Delaware corporation. SBTI also owns NTI, an Israeli corporation.

**CATEGORY:** *Porphyra yezoensis* is on the List of Restricted Microorganisms (Part B). Pursuant to chapter 4-71A, Hawaii Administrative Rules, the importation of *P. yezoensis* for cultivation in systems that are not in a closed or semi-closed system such as a photobioreactor requires an import permit approved by the Board of Agriculture (Board).

**PURPOSE:** *P. yezoensis* will be cultivated in land-based seawater ponds and tanks and harvested for use as an ingredient for nutraceuticals, food

supplements, animal foods, cosmetics, pharmaceuticals, sushi wraps, and dyes.

**PQB NOTES:** *P. yezoensis* was previously approved by the Board in February 1996 for laboratory use to extract a fluorescent pigment, R-Phycoerthrin. The pigment is used as a marker in medical and biotech research.

**DISCUSSION:**

- 1. Person Responsible:** Dr. Israel Levy, NTI's Chief Technology Officer, will be in charge of growing and handling *P. yezoensis*. See **Appendix C** for Dr. Levy's curriculum vitae.
- 2. Safeguard Facilities:** *P. yezoensis* sporelings will be cultivated at NTH located at the Natural Energy Laboratory of Hawaii Authority (NELHA) in Kailua-Kona, Hawaii. NTI has leased approximately 5.461 acres at NELHA. See **Appendix A** for the site location at NELHA.
- 3. Method of Disposition:** *P. yezoensis* will be cultivated in contained systems on land. All discharge is through a central discharge vault located underground in accordance with the NELHA guidelines. All ponds will be cleaned by steam after each growth cycle. A 3.5% active chlorine solution will be used once a year to clean the ponds and harvesting pipes.

**PQB NOTES:** See **Appendix I** for the letter from Mr. Jan War, NELHA Operation's Manager, regarding NoriTech's discharge of seawater from the tanks or ponds. See **Appendix H** for NELHA's Aquatic Species Health Management Program (ASHMP), Policies and Guidelines for Tenants, January 2008. The ASHMP was obtained online by the Plant Quarantine Branch (PQB) after the review by the Advisory Subcommittee on Algae.

- 4. Abstract of Organism:** The genus *Porphyra* includes more than 80 species. Most of the species are known worldwide as edible seaweed. *Porphyra* grows naturally in the upper intertidal zones in various regions of the world where cold seawater temperatures range 5- 20°C. The salinity range of *Porphyra* is 20-40 ppm. *Porphyra* is particularly abundant on cold-temperate and boreal shores of the Northern and Southern Hemisphere. *Porphyra* has a parenchimateous type thallus. Sporelings discharged from the thalli attach to a substrate where they germinate depending on favorable conditions. The *P. yezoensis* shipped by NTI has a sexual life cycle through the Conchocelis phase and an asexual life cycle by production of monospores.

The applicant states, "Porphyra is not an aggressive or opportunistic species. The dispersion life cycle (sexual or asexual) of the sporelings is very sensitive, and they cannot survive unless they are attached to substrate within a matter of hours after discharge. Since they lack cell walls during that time they are susceptible to stress conditions, including changes in salinity, dryness and excessive light.

The ecological area in which *Porphyra* can grow is the same domain as for seaweeds like *Fucus* and *Ascophyllum* (brown seaweeds). The *Fucus* and *Ascophyllum* seaweeds are so dominant in that area that the presence of the *Porphyra* does not pose any threat to them.

Since cultivation will be on land and not in the ocean, we do not expect any escape or release of any microorganism into the ocean.

The surface water temperature in the ocean around Hawaii is approximately 25°C. In the unlikely event that sporelings reach the ocean after all precautions, the high temperatures will prohibit them from growing and they will die.

In any event, the imported sporelings will be held in deep freeze (-80°C) for at least two months before shipment to Hawaii. These freezing conditions will kill the living organisms and ensure that the sporelings do not contain any biological contaminants such as epiphytes, parasites and diseases.

Thus, there should be no impact on the local environment."

The NTI/NTH cultivation systems produce *Porphyra* that is in compliance with the Food and Drug Administration's Good Manufacturing Practice standards and can be used as an ingredient in food supplements, cosmetics, animal food and nutraceutical and pharmaceutical products. PQB NOTES: See **Appendix E** for more information on *Porphyra*.

- 5. Cultivation System:** Sporelings will be grown in a wet lab that complies with the Centers for Disease Control and Prevention laboratory Biosafety Level 2. In the next step, the thalli will be cultivated in small tanks and ponds. Mature thalli will be cultivated in batches in cultivation ponds. The *Porphyra* with seawater will be routed to a chopping unit and mechanically cut into small pieces and then returned to the ponds according to a cultivation pattern. Two cutting sessions are needed for one cultivation cycle.

The NTH cultivation system is comprised of cultivation blocks each with 500 m<sup>2</sup> ponds. Each cultivation block will contain various stages of the alga as shown in Appendix B totaling 15,808m<sup>3</sup>. Total harvest should yield 180 tons of *Porphyra* annually. All ponds and tanks will be made of fiberglass, PVC or polyethylene and will stand on metal structure 20-40 cm above ground. The ponds and tanks will be covered with safety nets to protect the algal cultures from birds and foreign objects.

The harvested *Porphyra* will be rinsed thoroughly to remove salt and sand, which can be trapped between the thalli. The *Porphyra* is then dried and milled into flakes or powder, as needed, and then vacuum packed. The packaged *Porphyra* is stored in a dry, cool, and shaded area to minimize oxidation.

See **Appendix B** for the number of ponds and tanks to be used, their dimensions and the layout of cultivation blocks.

- 6. Analysis of Impact:** There is no impact to Hawaii from the introduction of *P. yezoensis* for cultivation in land based systems for the following reasons:
- a. *P. yezoensis* is not an aggressive or opportunistic alga;
  - b. Freezing the sporelings to -80°C for at least two months prior to shipping ensures that the sporelings will be shipped without epiphytes, parasites and diseases;
  - c. In the event of escape, the sporelings are not expected to survive in the Hawaiian ocean because they must attach themselves to a substrate within a matter of hours after being discharged;
  - d. The sporelings do not have cells walls during this time making them susceptible to stress conditions, including changes in salinity, dryness, and excessive lights; and
  - e. The sporelings will not grow at high temperatures at 25°C.

**PQB NOTES:** Based on the information provided on the alga and the applicant's procedures to discharge unused alga into a NELHA approved vault, the PQB recommended that only alga in the laboratory be autoclaved. Remaining alga in tanks and ponds will be routed to the underground vault for disposal as specified by the applicant. See proposed Permit Condition #12 for requirements for the cleaning of pond, tanks and harvesting pipes. The PQB requests that the Advisory Subcommittee

on Algae recommend a proper disposal method if the disposal method proposed by the applicant is not acceptable.

**7. How can we be sure that marine endoparasite, *Olpidiopsis porphyrae*, does not enter Hawaii via NTI cultures?**

NTI's Response: "The conditions which favors the outbreak of this disease are:

- a. High temperatures
- b. Low salinity
- c. Inadequate air drying of the *Porphyra* before freezing.

The NoriTech inoculum material which will be shipped to Hawaii will be treated as follows: Sporelings will be dried until reaching 20-30% moisture before freezing for 3-6 months at -60°C -80°C. Usually nori nets (in Japan & China) are dried to 30-40% moisture and freeze for 15 days at -20°C before cultivation. From the literature we know that the best treatment to avoid this disease is freezing the inoculum before cultivation (Huaiyu & Jiahai 2005. Appl. Phycol. 17(1); 51-56). Our salinity levels in Israel are around 30 ppt which is significantly higher than this in the east which are around 25 ppt which gives us another preclusion against the development of fungal or bacterial diseases.

In addition, I should mentioned that we are using fresh material coming from the freezer every year and for the last 6 years which we have been cultivating *Porphyra* we have not noticed any disease in our cultivated nori. In Hawaii we will work under quarantine conditions in the sense that all our operations will be on land and no live material will be let to escape into the surrounding environment."

See **Appendix D** for an abstract on *Olpidiopsis porphyrae* sp. nov., an endoparasite that infects commercially cultivated *P. yezoensis*.

**8. How will sporelings be shipped to Hawaii? Describe the container used to hold the alga and provide a description or photo of *P. yezoensis* when shipped to Hawaii.**

NTI's Response: "The *Porphyra yezoensis* sporelings will be shipped to Hawaii under freezing conditions in small isolation container 50cmL X 30cmW X 50cmH, with dry ice. Sporelings <0.5 mm on small net 5X5 cm (about 10,000 per net) dry and frozen will be packed inside the isolation container."

**PQB NOTES:** This request was submitted for review by the Advisory Subcommittees on Algae and Invertebrates and Aquatic Biota and the Advisory Committee on Plants and Animals (Advisory Committee). Their recommendations and comments are listed chronologically in this submittal.

**ADVISORY SUBCOMMITTEE ON ALGAE - MARCH 17, 2008:** This request was submitted to the Advisory Subcommittee on Algae to review the following: (1) importation of *P. yezoensis* for cultivation in ponds and tanks; (2) proposed permit conditions for the importation of *P. yezoensis* for cultivation in ponds and tanks; and (3) potential risk of the endoparasite, *Olpidiopsis porphyrae* sp. nov. on *P. yezoensis*.

**1. Allow the importation of an alga, *Porphyra yezoensis*, on the List of Restricted Microorganisms (Part B), for cultivation by NoriTech Hawaii, Inc.**

Mr. Kobayashi: "In Appendix A-14, the applicant seems to indicate in Item #1, "Interaction with the local ocean environment", that the sporelings are unable to survive in local waters because of the temperatures, but also states that "All species grown already exist in the ocean around Hawaii."

Also, although the applicant does not expect any escape or release of the organism, is there a reaction plan? The purpose of a reaction/remediation plan is to address unexpected escapes, releases or other unexpected events. I would be greatly concerned if there planned escapes or releases. Any thought or evaluation or release due to vandalism, theft, etc?

I'm not sure there is a potential problem, but am somewhat uncomfortable if these areas haven't been addressed. I still need to look at the issues regarding the endoparasites and hope to done soon."

NTI's Response to Mr. Kobayashi's comments:

- "1. *Porphyra yezoensis* was first identified in the North shores of Japan. Since this species is widely been used in aquaculture through Japan, China Korea and also in USA using net culture dispersed on the open ocean, *Porphyra yezoensis* was observed lately also in the USA Atlantic coast. The main thing is that the haploidic stage (the commercial [commercial] leaf stage) can survive up to 20°C temperatures. This temperatures requirements restricts the possible dispersion of this species in area where the sea the temperature is higher. The sexual microscopic stage (*Conchocelis*) can overcome higher temperatures up to 30°C, but it cannot reproduce in those temperatures. The sporelings which are the

haploidic phase cannot grow in higher temp than 20°C. The Porphyra in Hawaii is *Porphyra vietnamensis* which is warm water Porphyra, totally different in temperatures requirements that *Porphyra yezoensis*.

2. If plants escape from the ponds to the surrounding sea they will not survive because of the water relatively high temperatures which prevent their development. Also, they have to compete with other seaweeds and plants in the sea, which are stronger and more aggressive from Porphyra.
3. As we mentioned the ponds will [be] covered by nets to prevent escape of material by wind or birds.
4. In order to prevent vandalism the growing site will be surrounded by fence, and if required we will also implement other protective measure (like alarm) to prevent unauthorized access to the site."

Mr. Kobayashi's response to NTI's comments: "If I understand the NoriTech response, the original statement about all species grown already existing in the oceans around Hawaii is in error and that there is a local species which differs from the requested import item. I don't have any other comments."

Dr. Bidigare: Recommends approval.

Dr. R. Wong: Recommends approval.

Dr. Whelen: Recommends approval. "Unclear how freezing at -80°C will kill parasites or disease. It apparently doesn't kill the algae. Many organisms are preserved, not killed, by freezing."

NTI Response: "NTI provided the following articles, which suggest that freezing and drying of the inoculums helps to decrease the probability of infection with chytrid disease and other fungal pathogens:

1. Ding H. & Ma J. 2005. simultaneous infection by red rot and chytrid diseases in *Porphyra yezoensis* Ueda. J. apply. Phycol. 17:51-56. See Appendix F for the article.
2. Fugita Y. & Migita S. 1980. Death of parasitic *Pythium porhyrae* by drying and freeze-preservation of red rot infected thalli of *Porphyra yezoensis*. Bull. Fac. Fish. Nagasaki Univ. 49:11-16. PQB NOTES: A copy of this

article was not provided by the applicant and is not included in this submittal.

3. Woo J-H, Kitamura E., Myouga H. & Kamei Y. 2002. An antifungal protein from the marine bacterium *Streptomyces* sp strain AP77 is specific for *Pythium porphyrae* a causative agent of red rot disease in *Porphyra* spp. *Appl. Environ. Microbiol.* 68: 2666-2675. See **Appendix G** for the article."

Dr. Whelen's comments to NTI response:

"The articles support the NTI response below (see above); however, neither article can substantiate the NTI assertion in the application, "Freezing the sporelings to -80°C for at least two months prior to shipping ensures that the sporelings will be shipped without epiphytes, parasites and diseases." Perhaps the third article does, but it may be a bulletin versus a peer-reviewed scientific article."

Dr. Sherwood:

- "1. Please note on Page 4 of NoriTech's written documentation (Section 2: Species to be imported) that two species of *Porphyra* are proposed for importation: *P. yezoensis* and *P. haitanensis*. Details and documentation, however are only provided for the former species. Both species are currently recognized taxonomically: *P. yezoensis* is native to Japan, and *P. haitanensis* is native to China.
2. Hawaii has one recognized species of the genus *Porphyra* (*P. vietnamensis*), which is a very widespread tropical species known from multiple continents. Molecular research being completed in my laboratory at the present time indicates that we do not yet know the full story of the native diversity of this genus in Hawaii – there may in fact be multiple species here that were not recognized in the past based on morphology alone. This is a common story for this genus, which is quite cryptic to identify morphologically. However, given that we do have members of the genus in the state, and their full identity is not understood, I don't think we can assume that escaped sporelings from the culturing facility would not survive in Hawaii waters.
3. Section 7 of the NoriTech document (page 9) states that the seaweeds *Fucus* and *Ascophyllum* are so dominant in the ecological zone where *Porphyra* occurs that *Porphyra* is very unlikely to form nuisance growth. However, neither *Fucus* nor *Ascophyllum* is found in Hawaii.



4. Page 12 of the NoriTech document (Risk Analysis table) states that "All species grown already exist in the ocean around Hawaii". As I explained earlier, the only recognized species of *Porphyra* in Hawaii is *P. vietnamensis*.
5. Very little is known about the endoparasite, *Olpidiopsis porphyrae*. Other parasites in this genus have been shown to be able to infect related species of red algae, and so infection across species boundaries is known. It is not known what the effects would be on the native species of *Porphyra* if the parasites were to infect Hawaiian populations of *P. vietnamensis*. Indeed, it is not even known if the parasite already exists here naturally in *P. vietnamensis* plants."

NTI's response to Dr. Sherwood's comments:

- “1a. Our application is only for the importation of *Porphyra yezoensis*.
- 1b. The growth condition of *Porphyra yezoensis* is known. No haploidic plant ('leave') can survive 25°C which as we know it is about the ambient surface temp around Hawaii. The spores of *Porphyra* are the most vulnerable phase in the life history of the *Porphyra*, without any resistance to heat, dry, high sunlight conditions. The local *Porphyra* in Hawaii is *Porphyra vietnamensis* which can grow at higher temperatures.
- 1c. In Hawaii other seaweeds are dominant like *Ulva*, *Lyngbia*, *Padina*[,] *Sargassum*, *Acanthophora*, *Jania* and *Pterocladia* which are densely occupying the reefs and will create establishment problems for *Porphyra yezoensis*.
- 1d. *Porphyra yezoensis* is known from the Pacific Ocean around the north Japanese, China and Korean shores and it is absent from tropical areas because of the high water temperatures, such as in Hawaii.
- 1e. The endoparasite *Olpidiopsis porphyrae* is known from China and Japan which are cultivating *Porphyra* and is totally absent from NoriTech™ cultivating *Porphyra yezoensis*. The biological material which we want to import to Hawaii has been used for 8 years in our cultivation of *Porphyra* in Israel and we never encountered such a disease and we have provided information related to measures we are taking to keep preventing it.
- 2a. The conditions which favors the outbreak of this disease are:
  - a. high temperatures
  - b. Low salinity and

- c. inadequate air drying of the *Porphyra* before freezing.
- 2b. The NoriTech inoculum material which will be shipped to Hawaii will be treated as follows: Sporelings will be dried until reaching 20-30% moisture before freezing for 3-6 months at -60--80°C. conditions.
- 2c. Usually Nori nets (in Japan & China) are dried to 3-40% moisture and frozen for 15 days at -20°C before cultivation.
- 2d. From the literature we know that the best treatment to avoid this disease is freezing the inoculum before cultivation (Huaiyu & Jiahai 2005. Appl. Phycol. 17(1): 51-56).
- 2e. The salinity level in Israel are around 39 ppt which are another preclusion against the development of fungal or bacterial diseases.
- 2f. The procedure with which we treat the spores decreases to a minimum the possibility of parasites and diseases.
- 2g. As mentioned above, in 8 years of growing in Israel we did not have any case of parasites or disease.”

PQB NOTES: The article referenced in (2d). above is also found in **Appendix F** of this submittal.

Dr. Sherwood's comments to NTI's response: “I don't have any further comments, it looks good to me.”

**2. Establish permit conditions for the importation of an alga, *Porphyra yezoensis*, on the List of Restricted Microorganisms (Part B) for cultivation, by NoriTech Hawaii, Inc.**

Mr. Kobayashi: See comments above.

Dr. Bidigare: Recommends approval.

Dr. R. Wong: No recommendation.

Dr. Whelen: Recommends approval.

Dr. Sherwood: See comments above.

**3. Advisory Subcommittee on Algae comments regarding endoparasite, *Olpidiopsis porphyrae* sp. nov. on *P. yezoensis*.**

Mr. Kobayashi: No comments.

Dr. Bidigare: No comments.

Dr. R. Wong: "Measures in place appear to be adequate for addressing this organism."

Dr. Whelen: "What data show that this endoparasite is killed by freezing?"

NTI's response to Dr. Whelen's comment regarding the endoparasite is on page 7 of this submittal.

Dr. Sherwood: "Very little is known about the endoparasite, *Olpidiopsis porphyrae*. Other parasites in this genus have been shown to be able to infect related species of red algae, and so infection across species boundaries is known. It is not known what the effects would be on the native species of *Porphyra* if the parasites were to infect Hawaiian populations of *P. vietnamensis*. Indeed, it is not even known if the parasite already exists here naturally in *P. vietnamensis* plants."

NTI's response to Dr. Sherwood's comments regarding *O. porphyrae* is on pages 9-10 of this submittal.

**ADVISORY SUBCOMMITTEE ON ALGAE REVIEW - OCTOBER 14, 2008:** This request was submitted to the Advisory Subcommittee on Algae to review the potential effects from the introduction of *P. yezoensis* on the environment and the proposed permit conditions to assure that import of *P. yezoensis* presents minimal or no significant effects on the environment.

**1. If the item requested for import is accidentally released, what is the probable impact on the environment?**

Mr. Kobayashi: Probably minimal or no significant effects on the environment.

Dr. Bidigare: Dr. Bidigare is on sabbatical and is not able to respond to this question.

Dr. R. Wong: Probably minimal or no significant effects on the environment.

Dr. Whelen: Probably minimal or no significant effects on the environment.

Dr. Sherwood: Probably minimal or no significant effects on the environment.

**2. Are the proposed permit conditions sufficient to assure that the item requested for import presents probably minimal or no significant effects on the environment?**

Mr. Kobayashi: Yes.

Dr. Bidigare: Dr. Bidigare is on sabbatical and is not able to respond to this question.

Dr. R. Wong: Yes.

Dr. Whelen: Yes.

Dr. Sherwood: Yes.

**PQB NOTES:** The activity proposed under this permit application would initiate a project that uses state lands (NELHA). Under a recent Hawaii appellate court decision, that fact will require an environmental assessment (EA) under chapter 343, HRS, as a condition of permit issuance, unless the project is covered by an exemption established pursuant to rules implementing chapter 343, HRS. Sufficient answers to questions 1 and 2, above, are necessary for PQB's determination as to whether the Department's exemption from the EA (for microorganism permit for algae cultivation and production for various purposes) can properly be exercised in this instance.

**ADVISORY SUBCOMMITTEE ON ALGAE REVIEW - OCTOBER 23, 2008:**

Information on the causal agent of red rot disease on *P. yezoensis* was submitted to the Advisory Subcommittee on Algae for their review and comment. NoriTech cited three documents regarding chytrid disease and other fungal pathogens on *P. yezoensis*. NoriTech provided copies for the first two articles. The third article was not provided.

1. Ding H. & Ma J. 2005. simultaneous infection by red rot and chytrid diseases in *Porphyra yezoensis* Ueda. J. apply. Phycol. 17:51-56. See **Appendix F** for the article.
2. Woo J-H, Kitamura E., Myouga H. & Kamei Y. 2002. An antifungal protein from the marine bacterium *Streptomyces* sp strain AP77 is specific for *Pythium porphyrae* a causative agent of red rot disease in *Porphyra* spp.

Appl. Environm. Microbiol. 68: 2666-2675.” See **Appendix G** for the article.

3. Fugita Y. & Migita S. 1980. Death of parasitic *Pythium porphyrae* by drying and freeze-preservation of red rot infected thalli of *Porphyra yezoensis*. *Bull. Fac. Fish. Nagasaki Univ.* 49:11-16. PQB NOTES: A copy of this article was not provided by the applicant and is not included in this submittal.

Mr. Kobayashi: “I suppose the question that can be raised is whether or not these are the only contaminants or is this a mixture of unknowns, with limited revelation of the identity of what is truly being imported.”

Dr. Bidigare: Dr. Bidigare is on sabbatical and is not able to respond to this request.

Dr. R. Wong: No comments.

Dr. Whelen: See Dr. Whelen’s comment on Page 7 of this submittal.

Dr. Sherwood: No comments.

### **ADVISORY COMMITTEE ON PLANTS AND ANIMALS REVIEW**

**OCTOBER 31, 2008**: This request was submitted to the Advisory Committee on Plants and Animals (Advisory Committee) at its meeting on October 31, 2008, at the Plant Quarantine Branch Conference Room. The presentation and discussion are summarized as follows:

Ms. Amy Takahashi, Microorganism Specialist, Plant Quarantine Branch, referring to proposed permit conditions, recommended that Permit Condition No. 11 require that algae in the laboratory be destroyed by autoclaving. She also proposed to add Permit Condition No. 12 after Permit Condition No. 11 to require that all ponds be cleaned as described by the applicant, “All ponds shall be cleaned by steam after each growth cycle. A 3.5% active chlorine solution will be used once a year to clean the ponds and harvesting pipes.” The text from the initially proposed condition No. 12 is renumbered as No. 13 and all subsequent permit conditions are renumbered accordingly.

Advisory Committee member, Mr. Rob Hauff, asked if it was common to have the applicant not present at the Advisory Committee meeting. Ms. Takahashi stated that the shipper (applicant’s representative) in Israel had planned to attend this meeting but

cancelled at the last minute. Ms. Takahashi stated that she had informed the shipper that the request could be withdrawn and submitted to the Advisory Committee at a later date. Advisory Committee member, Dr. John McHugh stated that as an example, the soil conservation district board requires the cooperator to show up at the meeting and present their case.

Advisory Committee member, Mr. Ken Redman, referring to Permit Condition No. 1 commented that the condition requires that the microorganism shall not be transferred or released. Ms. Takahashi stated that the extract of the algae will be used as an ingredient in foods and nutraceuticals. Ms. Takahashi recommended that it be made clear that the permittee seeks to be allowed to harvest and export the algae.

Advisory Committee member, Mr. Kenneth Matsui, questioned whether this alga is significantly better than the one being mass-produced in the Orient. Mr. Matsui said he suspects that this request is for tax credit purposes, and that such requests do not have a good track record for producing long-term employment in Hawaii. Mr. Matsui said he wants to know if NoriTech is participating in a tax incentive program and whether or not the company is a subsidiary. He said that a company can invest minimal funds in a subsidiary and if there is a problem and the company declares bankruptcy, then the State is left with the problem. He added that if the company was a division, the State could turn to the parent company. Advisory Committee member, Ms. Katherine Kealoha, stated that her office (Office of Environmental Quality Control) did an initial review of NoriTech's financial background and that NoriTech is set up like a cooperative and has principal members that provided investment funds and are actually from Hawaii.

Advisory Committee Chairperson, Dr. Lyle Wong, commented that the Advisory Committee is reviewing a microorganism on the List of Restricted Microorganisms (Part B) and asked whether it was proper to raise various environmental issues and possibly recommend disapproval when regulations allow for the importation of a microorganism on the List of Restricted Microorganisms (Part B). Ms. Takahashi stated that Advisory Committee review is necessary because of the cultivation systems that will be used. Dr. Wong commented that the prior import of *P. palmata* for laboratory use is under the same Restricted B category. Mr. Matsui stated that the difference with this request is that the alga is routed to an open hole in the ground where there may be lava tubes that discharge the alga into the ocean. Mr. Matsui believes that this request carries a significantly higher risk than a petri dish or aquarium. Dr. Wong stated that the Advisory Committee is addressing the risks and asked if this submittal would be forwarded to the other Advisory Subcommittee, on Invertebrate and Aquatic Biota, for review. Mr. Hauff confirmed that the Department of Land and Natural Resources

recommends that this request be reviewed by the Advisory Subcommittee on Invertebrate and Aquatic Biota.

Mr. Matsui commented that the live spores could go through the screening process. Dr. Leonard Young, Department's Aquaculture Specialist, stated that the applicant is shipping sporelings, which include both sexes.

Advisory Committee member, Dr. John McHugh asked about the 25°C. water surface temperature. Mr. Matsui stated that the *P. yezoensis* is an intertidal species, which would require the light at higher levels because the colder water from below probably won't generate light. It was noted that the average water temperature around Hawaii is 74°F or 23.3°C. Dr. Young stated that this alga would thrive in our environment.

Mr. Redman stated that five members of the Advisory Subcommittee commented that this request probably presents minimal or no significant impact on the environment. Mr. Redman asked Dr. Young if this alga would have more than a minimal impact on the environment. Dr. Young responded that the alga would grow.

Legal Counsel, Ms. Haunani Burns, asked if the alga's survival and temperature requirement would be reviewed by the Advisory Subcommittee on Algae. Dr. Wong asked if the Advisory Subcommittee on Invertebrates and Aquatic Biota have concerns about environmental impact, is it reasonable to request that the applicant conduct an environmental assessment. Ms. Burns stated that if the Advisory Committee does not get the clear sense that the item for import fits the exemption criteria that the Advisory Subcommittee is addressing, as to probably minimal or no significant impact, then the Advisory Committee needs to seriously consider whether it is appropriate that there be an environmental assessment. Dr. Wong asked if it would be more appropriate for the Plant Quarantine Branch (PQB) rather than the Advisory Committee to ask for the environmental assessment. Ms. Burns stated that the PQB would probably take their clue from the Advisory Subcommittee, but that the Advisory Committee could make that recommendation as well. Ms. Burns noted that issues could come up at the Advisory Committee level which the Advisory Subcommittee was not aware of. She noted that information could also come up beyond the Advisory Committee and that if the information needs to be examined, the PQB would closely examine the information.

Ms. Kealoha asked if the Advisory Committee could recommend sending the request to the Advisory Subcommittee on Invertebrate and Aquatic Biota and also recommended an environmental assessment. Mr. Matsui stated that it may be better for the Advisory Subcommittee on Invertebrate and Aquatic Biota to review the request first. Mr. Matsui also stated that the Advisory Committee could request that the applicant be present at its meeting to answer questions. Mr. Redman asked if more feedback is needed from the Advisory Subcommittee on Algae. Ms. Takahashi stated that without specific

questions, the Advisory Subcommittee on Algae may not have additional comments. Mr. Redman stated that if the alga grows in Hawaii, then it may have a huge impact on the environment.

The Advisory Committee had no further discussion. The Advisory Committee unanimously approved referring this request (6 to 0) to the Advisory Subcommittee on Invertebrates and Aquatic Biota for review and requested that the applicant or its representative be present at the next meeting of the Advisory Committee. The Advisory Committee stated it would also be helpful to have a representative from the Natural Energy Laboratory of Hawaii Authority at the meeting.

**PQB NOTES:** In response to the summary above, NELHA and NTI submitted the following documents:

1. **APPENDIX J** includes NTI and NELHA's responses to the comments made by individual members of the Advisory Committee on Plants and Animals at its meeting on October 31, 2009.
2. **APPENDIX K** includes a list of permits issued by the Hawaii Department of Agriculture to NELHA tenants for various aquatic species. Mr. Jan War, Operations Manager at NELHA noted that *P. yezoensis* and *P. tenera* were previously allowed import into NELHA facility. Mr. War also noted that *P. tenera* was imported by another NELHA tenant as early as 1983.

As the issue of an environmental assessment was raised in the Advisory Committee on Plants and Animals discussion, the subject of environmental assessments is discussed at page 24 of this submittal.

#### **ADVISORY SUBCOMMITTEE ON INVERTEBRATES AND AQUATIC BIOTA**

**JANUARY 4, 2009:** As requested by the Advisory Committee on Plants and Animals, this request was submitted to the Advisory Subcommittee on Invertebrate and Aquatic Biota for their review. Their recommendation and comments are as follows:

1. **Allow the importation of an alga, *Porphyra yezoensis*, on the List of Restricted Microorganisms (Part B), for cultivation by NoriTech Hawaii, Inc.**

Dr. Eldredge: No response.

Dr. Suzumoto: "I defer to the expertise of members of the Advisory Subcommittee on Algae who have already weighed in on this issue in the affirmative, i.e., supporting



approval. Discussion by members of the Advisory Committee on Plants and Animals have raised a reasonable concern (How does NELHA specifically in this case address disposal of micro-and macro-organisms to ensure no ecological impact?) and its corollary (Is NELHA's claim of a 24-year legacy of zero impact on the environment supportable by independent verification?), both presumably addressable by proper state agencies at any time. All other concerns raised (e.g., can the imported microorganism survive temperatures above 20dC in a tank with acclimated HI macro-algae?; if endoparasites are found in shipments, can they be easily quarantined and tested for deleterious effect on indigenous macro-algae?) are best addressed by independent lab testing during the run of the program in question."

Dr. Pooley: No response.

Dr. Riggs: No response.

Mr. Thom: Recommends approval. "I do not believe an EA is necessary. Whenever possible, I believe that applicant should be present at the review."

Dr. Rossiter: No response.

Dr. Polhemus: Recommends disapproval. "I believe there to be too many unknowns in order for this organisms to be imported into the state. Until all aspects of temperature and light regimes as well as the other state concerns are addressed, this species should be not be imported.

**General:**

The applicant stated "Porphyra is not an aggressive or opportunistic species." However, the applicant does not cite or refer to any ecological information to show this species is not aggressive. It is assumed the statement may be derived from experience working with the species, but ecological data on the species would be useful to evaluate.

The applicant stated "Fucus and Ascophyllum seaweeds are so dominant in that area that the presence of the Porphyra dose not pose any threat to them." Since these species are not present in Hawaii, it is unclear what is the relevance and application to Hawaii. The applicant further states "In Hawaii other seaweeds are dominant like Ulva, Lyngbia, Padina[,] Sargassum, Acanthophora, Jania and Pterocladia which are densely occupying the reefs and will create establishment problems for Porphyra yezoensis." This statement suggests that the action of establishment is simplistic and based on the presence of other algae. Maybe Porphyra might have a disadvantage for becoming dominant, but assuming

simple competition can prevent an introduction is naïve. The applicant also does not address habitat equivalency from the native range to Hawaii. This alga may be able to survive at deeper depths than its native range and still be able to maintain the same level of photosynthesis. If the alga can survive in deeper water (meaning lower light levels), then temperatures may be in a more acceptable range to the alga. Habitat characteristics need to be considered in the potential for this organism to become established. Temperature concerns are expressed below, but light requirement for this alga should be stated with all appropriate literature citations. These light requirements should be compared to the light gradient in Hawaii.

On page 12 of the applicant's request, there is a "Risk Analysis" and under #1 it states that "all species grown already exist in the ocean round Hawaii." Although this comment was pointed out by the Subcommittee on Algae, it also demonstrates a significant mistake on part of the applicant's request. Mislabeled a species distribution may suggest other information could be incorrect. What was meant by this statement?

Also, the "Risk Analysis" does not address multiple vectors that might transfer this organism or a non-target organism. For example, what about wind borne vectors for a disease outbreak, what about algal material once it leaves the netted area, what are the facility conditions around the processing area (as stated below). Often the movement of an organism occurs in an unintended stepwise fashion. To address this issue, a thorough review of the process must occur. Please see below for questions regarding the process on the applicant's facility.

Mr. Kobayashi on the Subcommittee on Algae comment on a reaction plan. However, it is my opinion the applicant did not address the concern. It is noted that the applicant believes the algae will not survive, but if it is was to be found in the coastal environment or outside its facility, what would the applicant do to address the discovery? Mr. Kobayashi's request for a specific reaction plan to be developed is reasonable and should be addressed.

**Temperature:**

The applicant stated that "The sexual microscopic stage (*Conchocelis*) can overcome higher temperature up to 30°C, but it cannot reproduce in those temperatures." The fact that some stages of life can survive in water temperature in Hawaii may indicate a possibility of the alga adapting to Hawaiian temperatures. In addition, Hawaii has fairly deep water near shore and has a unique interface on deep photic zones that have cooler temperatures. Although

light is reduced, it may provide cooler water and high nutrients. Also, the temperatures required for growth and survival may be different. What are the physiological temperature tolerances of this alga?

The applicant state, "...surface water temperature in the ocean around Hawaii is approximately 25°C. In unlikely event that sporelings reach the ocean after all precautions, the high temperatures will prohibit them from growing and they will die." Although most Hawaiian waters are considered warm, certain regions may have water temperature more suited to this alga. Some areas may experience upwelling enough to lower the temperature or may have terrestrial influence reducing water temperatures. The applicant should compare the physiological temperature limits (not just the ideal temperatures ranges) of the organism to temperature profiles nearby NELHA (or any other location expected to hold an imported species). These profiles should encompass both temporal (ideally annual) and spatial (multiple arrays) ranges from the surface down to 100 meter water depth. In addition, the applicant should address the possibility of algal parts, not just the sporelings reaching the ocean and the risk of larger plant parts establishing.

It is noted that Dr. Young responded at the Advisory Committee meeting that he believed "...the alga would grow." I believe this comment should be addressed.

Another issue that has not been discussed is the possibility of any algae becoming slightly more temperature tolerant over time. Once the organism has been brought into the state, there are no controls over the conditions in which this species is being maintained. The temperature range of the incoming water at the NELHA facility is not discussed nor its variation due to surface environmental influence. Does the cold water supply go down occasionally possibly allowing a more temperature tolerant strain to be developed from occasional heat stress. The risk of increased thermal tolerance over time must be addressed and eliminated before this species is to be imported.

**Disease and non-targets:**

See question #5

The applicant does not address the possibility of other epiphytes on the algae. Is there reason to believe that freezing will kill everything? If it does not kill the algae, then it very well may not kill other epiphytic algae. This risk needs to be addressed.

**Process of operations/water discharge:**

I do not believe the applicant has provided enough information on the growing and processing system to address points of concern for the safe handling of the organism.

The applicant stated "Since cultivation will be on land and not in the ocean, we do not expect any escape or release of any microorganism into the ocean." This statement is overly broad and does not fully address multiple vectors and complex pathways. More information in great detail needs to be provided in order for this issue to be reviewed properly.

The applicant stated "In Hawaii we will work under quarantine conditions in the sense that all our operations will be on land and no live material will be let to escape into the surrounding environment." Where is the detailed description of the 'quarantine' operation? More detailed descriptions are needed for the disposal system and its access. I would consider untreated water dumped into the ground as releasing live material into the environment. What are the decontamination protocols for individuals and their respective clothing upon leaving the facility?

The applicant will have significant size culture facilities and part of the process is to dry the *Porphyra*. Is the process of drying done on site and within the permitted premises? What is the distance between tanks and processing? Are there opportunities for fragments to become loose on the ground? Does the drying process render the organisms inactive?

The applicant stated "As we mentioned the ponds will [be] covered by nets to prevent escape of material by wind or birds." However, what about the area around the tanks and culture ponds? Algal fragments can be on the ground around the ponds and them susceptible to be carried away by birds and rodents. How are loose fragments on the applicants parcel handled? The covering system of the facility needs to be described in more detail.

From my understanding, each pond tank will drain via PVC pipes into a concrete vault and then drain from the concrete vault into a dry well. Are they covered? Can they be drained and disinfected occasionally? Are they secured and on the applicant's parcel? Do the ponds and concrete vault have screens/ how are the screens maintained? What are the specifics of the "dry well?" The description needs to have more detail. These points may serve as unsecured points of escape through unforeseen vectors.

It is uncertain the exact discharge location for the freshwater. Is this into the municipal sewer system? Are fragments likely to be discharged into this system? If so, an evaluation of the risk associated with this discharge should be completed.

It is also noted that the applicant's parcel as shown in appendix A is extremely close to the ocean. This is of grave concern as it closes the gap for the organism to escape."

**2. Establish permit conditions for the importation of an alga, *Porphyra yezoensis*, on the List of Restricted Microorganisms (Part B) for cultivation, by NoriTech Hawaii, Inc.**

Dr. Eldredge: No response.

Dr. Suzumoto: Recommends approval.

Dr. Pooley: No response.

Dr. Riggs: No response.

Mr. Thom: Recommends approval. "All 22 established {proposed} permit conditions must be strictly complied with."

Dr. Rossiter: No response.

Dr. Polhemus: Recommends approval. "If this organism is allowed to be imported, then I submit comments on the following permit conditions.

New—I suggest adding a condition that would serve to minimize the possibility of this alga developing temperature tolerant strains. An exact temperature range should be stated for culture to minimize exposure to higher temperatures. However, the applicant should still address the above stated concerns and questions.

#2 What is the responsibility of the applicant beyond the "final disposition?" If the organisms or an associated organisms escapes based on this importation, what is the responsibility of the applicant and/or NELHA?

#9 What is the definition of "accidental release?" Does this mean an escape outside the established perimeter of the applicant's facility or an introduction into a natural environment?

#10 What are the disposal methods required under this condition? They should have been included in this application.

#12 This condition requires steam cleaning of the systems after each growth cycle, but does not address the fragments and effluent of the fragments. Does steam treatment have a 100% success for all dislodged fragments? Are the discharge of fragment after a steam cleaning a concern?

#15 This requirement should be fulfilled before importation is allowed and ideally, this requirement should be part of the application in order for the experts to review the protocols. These types of protocols stated in the application could show strength or weaknesses in the handling of the imported organisms.

Others not listed:

The permit conditions do not address the possibility of a natural event aiding in the release and dispersal of the imported organism. How would the applicant handle a tsunami or hurricane?

DLNR would be interested in assisting in future site inspections in order to help monitor the handling of all imported organisms. DLNR is responsible state agency for protecting Hawaii's ocean resources and DLNR view [views] alien species to be one of the major threats to our costal areas. A collaborative approach to site inspection would aid in the protection of our coastal resources."

**3. If the item requested for import is accidentally released, what is the probable impact on the environment?**

Dr. Eldredge: No response.

Dr. Suzumoto: Probably minimal or no significant effects on the environment.

Dr. Pooley: No response.

Dr. Riggs: No response.

Mr. Thom: Probably minimal or no significant effects on the environment.

Dr. Rossiter: No response.

Dr. Polhemus: No response.

**4. Are the proposed permit conditions sufficient to assure that the item requested for import presents probably minimal or no significant effects on the environment?**

Dr. Eldredge: No response.

Dr. Suzumoto: Yes.

Dr. Pooley: No response.

Dr. Riggs: No response.

Mr. Thom: Yes.

Dr. Rossiter: No response.

Dr. Polhemus: No. "The conditions do not address significant weather events, a specific response plan if a release occurs, or the development of temperature tolerant strains. Please see comments in question #2."

**5. Advisory Subcommittee on Algae comments regarding endoparasite, *Olpidiopsis porphyrae* sp. nov. on *P. yezoensis*.**

Dr. Eldredge: No response.

Dr. Suzumoto: "In my opinion, claims of zero-parasites/pathogen pathogen potential should be easily verifiable, and experiments conducted by, but not limited to, Waikiki Aquarium, University of Hawaii, and/or NELHA on any potential parasite found would certainly advance knowledge on the subject and yet be environmentally isolatable if NELHA containment strategies prove sound and if the state sanctions a quick research response authority should the issue arise."

Dr. Pooley: No response.

Dr. Riggs: No response.

Mr. Thom: "I believe the treatments & processing of *P. yezoensis* are sufficient to limit the endoparasite infection. Although possible, highly unlikely to create any kind of catastrophe [catastrophe]."

Dr. Rossiter: No response.

Dr. Polhemus: ““The applicant stated “...in 8 years in growing in Israel we did not have any case of parasites or disease.” Hawaii’s environment is different and the disease could show up if not already present. The real question is what is the response plan and can it spread to native populations of algae given it is not clearly host specific. Culture systems so close to the ocean may provide an incubation (whether brought with this import or already present) of the disease to spread in Hawaii. Can it spread by wind driven spray or water given it spreads by means of motile biflagellate zoospores (Woo et al, 2002)?

The applicant stated that “NTI provided the following articles, which suggest that freezing and drying of the inoculums helps to decrease the probability of infection with chytrid disease and other fungal pathogens.” This method can “reduce” the occurrence of the disease, but given the massive scale of operations so close to the ocean, can this disease infect the native *Porphyra* or other native algal species? I am not familiar with the native *Porphyra*, but if it is located within a reasonable nearby area, I would view this as high risk of transfer to native populations. How host specific is this disease?

The applicant does not address any internal pathogen or disease that this organism may potentially have. Has this been document [documented] with any *Porphyra* species?”

NTI’s response to Dr. Dan Polhemus recommendation and comments are referenced in **Appendix L** of this submittal.

**Environmental Assessment (EA):** Pursuant to a May 2008 Hawaii Intermediate Court of Appeals decision (Ohana Pale Ke Ao v. Board of Agriculture, 118 Haw. 247 (App. 2008)), the Department of Agriculture’s (Department’s) import permit process is subject to the requirements of the Hawaii Environmental Protection Act, chapter 343, Hawaii Revised Statutes (HRS). Under this decision, the requirement for an EA as a condition of the import permit or related authorization applies in those circumstances where the underlying permit activity for the importation initiates a “program or project” and where the use of state or county funds or state or county lands is involved. When those circumstances are present, an EA is required to determine whether the proposed project or program is likely to have a significant impact on the environment. However, certain activities may be eligible for “exemption” under provisions established through the Environmental Council, State Office of Environmental Quality Control (OEQC), provided that the project or program is determined to have little or no impact on the environment.



**Exemption from EA:** In September 2008, the Department obtained the concurrence of OEQC's Environmental Council for exemption from EA for those Plant Quarantine Branch import permits and related authorizations that satisfy certain criteria, including conditions to minimize risk to agriculture, horticulture, the environment, or animal or public health. The exemption from EA for non-domestic animals applies to the import of animals for various purposes according to their placement on lists maintained by the Board and subject to permit conditions appropriate to eliminate or minimize risks associated with the animal and its use. Permit conditions address matters such as health requirements, special precautions, and safeguarding from escape, theft or release. Under the exemption, purposes for importation of non-domestic animals include, but are not limited to, direct sales as food or for aquaculture production (live fish, crustaceans, etc.), pet trade (tropical fish, bird, etc.), scientific research by universities or government agencies, exhibition in municipal zoos or government-affiliated aquariums, private or commercial use. The exemptions from EA are only applicable when a project or program will probably have minimal or no significant effect on the environment. Under OEQC's rules and the Department's exemption list, exemptions are inapplicable when the cumulative impact of planned successive actions in the same place, over time, is significant, or when an action that is normally insignificant in its impact on the environment may be significant in a particularly sensitive environment.

**PQB Process for Exemption from EA.** When seeking an exemption from EA for an import request that requires the full Board review process, the Department must obtain the advice of other outside agencies or individuals having jurisdiction or expertise as to the propriety of the exemption. (Section 11-200-8(a), HAR.) The Board review process already includes recommendations and comments from the technical consultants (Advisory Subcommittee members) and the Advisory Committee on Plants and Animals (Advisory Committee). The representation of outside agencies such as the Hawaii Department of Land and Natural Resources, Hawaii Department of Health, OEQC on the Advisory Committee provide opportunity for these agencies input on the public health and environmental aspects of the import and appears to meet the consultation requirement of OEQC's rule. In addition, the input received from the Department's technical consultants on the Advisory Subcommittees, as individuals with expertise on the subject matter and the presence of individuals retired from the University of Hawaii and the Honolulu Zoo on the Advisory Committee appears to meet the consultation requirement.

Where the recommendations from the technical consultants and Advisory Committee support exemption from an EA, the Department may prepare a declaration of exemption, which includes a description of the import request, lists of consultants, consultant's recommendation and comments, and the basis for the Department's

determination of "probably minimal or no significant effect on the environment." The declaration of exemption from EA is submitted to the Board together with the import request. Where the recommendations from the technical consultants and Advisory Committee support an EA, the Department may require an EA as a prerequisite for Board review.

**PROPOSED PERMIT CONDITIONS:** The permit conditions proposed for this request are based on the permit conditions established by rules for microorganisms on the List of Restricted Microorganisms (Part B). Permit Condition No. 3 was added to make sure the sporelings were treated by freezing for two months to kill any parasite and disease. Permit Condition No.10 was added to require that the permittee comply with NELHA's requirement for effluent discharge. The following permit conditions were revised as follows:

1. The microorganisms, *Porphyra yezoensis*, shall be used for cultivation in the laboratory, ponds, and tanks, a purpose approved by the Board of Agriculture (Board), and shall not be sold, given, transferred or released in Hawaii, unless approved by the Board in writing.
2. The permittee, NoriTech Hawaii, Inc., c/o Bendet, Fidell, Sakai & Lee, 841 Bishop Street, 1500 Davies Pacific Center, Honolulu, Hawaii 96813, shall be responsible and accountable for all microorganisms imported, from the time of their arrival to their final disposition.
3. The microorganism shall be frozen at -80°C for a minimum of two months prior to shipping the microorganism to Hawaii. The sporelings shall be free from contaminants such as epiphytes, parasites, and diseases.
4. The microorganisms are subject to the pre-entry requirements of section 4-71A-8, Hawaii Administrative Rules (HAR), and the inspection requirements of section 4-71A-9, HAR.
5. The microorganisms shall be safeguarded in the laboratory and in pond and tank systems approved by the Plant Quarantine Branch (PQB), located at NoriTech Hawaii, Inc., Natural Energy Laboratory of Hawaii Authority (NELHA) in Kailua-Kona, Hawaii, 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 PQB chief.

6. The microorganisms shall be maintained by Dr. Israel Levy as the responsible person or by trained or certified personnel designated by the Dr. Israel Levy.
7. The permittee shall adhere to the use, facility, equipment, procedures, and safeguards proposed and described in the permit application, as approved.
8. 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, HAR.
9. The permittee shall immediately report to the PQB chief any theft, accidental release, exposure, or disease outbreaks involving the microorganisms.
10. The permittee shall comply with the aquaculture effluent treatment and disposal methods established by the Natural Energy Laboratory of Hawaii Authority.
11. Upon completion or termination of the use of the microorganism in the laboratory, the microorganisms shall be destroyed by autoclaving. In the event autoclaving is not possible, the permittee shall obtain written authorization from the PQB chief for an appropriate alternate method of destruction.
12. All ponds shall be cleaned by steam after each growth cycle. A 3.5% active chlorine solution will be used once a year to clean the ponds and harvesting pipes.
13. The permittee shall keep records of all the microorganisms imported from the time of the arrival to their final disposition or destruction. The record shall include the permit number under which the microorganism was imported, microorganism scientific name, date and quantity of each microorganism species imported, and status of the microorganism's use. The permittee shall make the records available to the PQB chief upon request.
14. The permittee shall submit a final report on the method of destruction of the microorganism species to the PQB chief within 30 days of completion or termination of the use of the microorganisms.
15. 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.

16. It is the responsibility of the permittee to comply with any applicable requirements of municipal, state, or federal law pertaining to the microorganisms.
17. The permittee shall submit to the PQB 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 PQB chief may be cancelled upon revocation, suspension, or termination of any of the aforementioned documents required for operation of the facility.
18. Any violation of the permit conditions may result in citation or in cancellation of the permit, or both.
19. A cancelled permit is invalid and upon written notification from the PQB 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 PQB chief. Any expense or loss in connection therewith shall be borne by the permittee.
20. 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.
21. For microorganisms in the laboratory, 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*.
22. The permittee shall agree in advance to defend and indemnify the State of Hawaii, its officers, agents, and employees for any and all claims against the State of Hawaii, its officers, agents, or employees that may arise from or be attributable to any of the microorganisms that are introduced under this permit. This permit condition shall not apply to a permittee that is a federal or State of Hawaii entity or employee, provided that the state or federal employee is a permittee in the employee's official capacity.

May we request your recommendation and comments on this request at the meeting of Advisory Committee on Plants and Animals on May 15, 2009 at the Plant Quarantine Conference Room, 1849 Auiki Street, Honolulu, Hawaii 96819.