RSSBP
Regional Shellfish Seed Biosecurity Program

REGIONAL SHELLFISH SEED BIOSECURITY PROGRAM (RSSBP)- HATCHERY COMPLIANCE

A collaboration of Industry, Scientists, Regulators and Extension – using the best available science to minimize risks associated with interstate seed transfers of bivalve shellfish

December 14, 2021

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PROJECT TEAM

David Bushek, Haskin Shellfish Research Laboratory, Rutgers University, bushek@hsrl.rutgers.edu
Ryan Carnegie, Virginia Institute of Marine Science, carnegie@vims.edu
Lisa Calvo, Rutgers University & NJ Sea Grant Consortium, lcalvo@hsrl.rutgers.edu
Lori Gustafson, USDA APHIS Veterinary Services, Lori.L.Gustafson@aphis.usda.gov
Karen Hudson, Virginia Institute of Marine Science, khudson@vims.edu
Lucas Marxen, Rutgers University, ljmarxen@njaes.rutgers.edu
Robert Rheault, East Coast Shellfish Growers Association, bob@ecsga.org

CONTACTS

David Bushek (bushek@hsrl.rutgers.edu), Ryan Carnegie (carnegie@vims.edu)

RATIONALE

Introduction and emergence of shellfish diseases is a concern for shellfish farmers, commercial harvesters, and resource managers worldwide. History reveals abundant examples of devastating impacts of disease on shellfish populations and shellfish farms. Often, the spread of disease has been associated with the transfer of shellfish stocks. Hence, it is imperative that transfers of shellfish from one area to another are done only after careful consideration of disease transfer risks. It is important to understand the health status of the stock destined for transfer, as well as the relevant history and current status of disease within receiving and sending areas.

The growth of shellfish aquaculture on the East Coast of the U.S. has long relied on the hatchery production of seed. There are approximately 50 hatcheries along the East Coast and interstate transfers are fundamental to regional commerce and production. Each state within the region has policies or regulations regarding seed importations. Most require health evaluation and careful review of each shipment batch proposed for importation. This process is time consuming and costly. Research continues to demonstrate that there is little risk of disease transfer associated with young/small seed that has been maintained on filtered water in the hatchery. Based on this evidence, a collective of shellfish pathologists, researchers, shellfish growers, hatchery operators, and government regulators have been working to develop tools and a program to facilitate interstate commerce in hatchery seed, in the belief that incentivizing commerce in these typically disease-free products will foster enhanced biosecurity through the broader regional industry.

REGIONAL SHELLFISH SEED BIOSECURITY PROGRAM

The purpose of the Regional Shellfish Seed Biosecurity Program (RSSBP) is to facilitate the process for permitting interstate commerce of biosecure bivalve shellfish seed and larvae being sold directly out of hatchery facilities. These transfers typically pose minimal risk of disease transfer due to their young age and the high level of water filtration maintained through much of the hatchery rearing process. The RSSBP is designed to capitalize on this inherent higher level of biosecurity. The Program is voluntary and *does not* guarantee that all states or hatcheries will participate. Hatcheries that are compliant under this program will be able to ship product into participating states via a streamlined permitting process, which obviates the need for shipment by shipment health evaluations. Enhanced biosecurity will be achieved via hatchery compliance with the RSSBP Best Management Practices (BMPs) for minimizing disease risks and demonstration of the absence or acceptable levels of pathogens of concern (POC) in seed and larval products through a series of past and ongoing health evaluations conducted across the production season. If hatcheries choose not to participate, or for some reason compliance is not achieved, the hatchery may simply continue with the status quo of batch health evaluation of products for sale and distribution as required by legal authority for the recipient location. Similarly, if a state does not participate or accept compliance under this program, the process remains whatever the state requirements may be for importing seed.

BENEFITS

Compliance under the RSSBP will maintain a higher level of biosecurity than that provided by the haphazard status quo batch health evaluation process. The Program's prescribed structured annual health surveillance will cost less than batch by batch sampling and be less taxing on limited resources of pathology laboratories. State regulatory importation permit processes will be streamlined for compliant hatcheries, facilitating timely commerce and reducing costs to State agencies. Streamlining

will be enhanced through the RSSBP's Shellfish Disease Database tool, developed alongside this Program effort. The database will serve as the central repository for disease monitoring data and Program paperwork. Importantly, the Program will foster confidence of both State regulators and shellfish farmers that importations occurring under the program pose minimal risks of disease transfer. **Central to the RSSBP is the belief that compliance with importation regulations will be enhanced if the process for approval is streamlined and the costs are reduced.**

ADMINISTRATION

The Program is currently administered by the grant project team (page 1) with oversight of an Advisory Council (Table 1). The Council is comprised of the project team and additional molluscan scientists/pathologists, regulators, extension personnel and industry members along the East Coast of the United States. The Council's role is to thoroughly vet the RSSBP elements, including eligibility, BMPs, and the verification process, and ensure that the RSSBP provides a reasonable and effective effort to reduce risk and improve biosecurity of shellfish seed transfers.

PROCESS

Interested hatcheries fill out an application and submit to the project team. The project team confirms species and seed size eligibility by reviewing the three-year health history of the facility. If eligible, the project team coordinates an audit of the facility. The auditors are neutral, respected experts in the field selected to maintain consistency across facilities and remove any perceived bias. The audit team performs an on-site inspection of the hatchery to verify the implementation of Program BMPs. The audit team reports back to the project team, providing a recommendation to approve, deny or conditionally approve (pending a corrective action) RSSBP compliance. Questions or concerns with compliance are resolved through consultation with the Advisory Council and other expertise as needed. The 2020-21 pilot program is developing the administrative process details, including determination of an audit team.

ELIGIBILITY

Eligibility is based on a demonstration that the hatchery follows RSSBP prescribed best management practices (BMPs) and has no history of disease concerns. To be eligible, a hatchery must have records of health evaluations from an approved laboratory for the previous three years with a minimum two sampling events per year during the production season (6 samples over the 3-year period) demonstrating no POC detections, or acceptable levels for like-to-like transfer areas. The health evaluations must be performed on the size seed that the hatchery desires to be certified for interstate, or in some instances within state transfer, under the RSSBP. Seed (or larvae) smaller than the largest seed meeting health history standards will be automatically approved given that disease transfer risks are lower for smaller and younger animals. Seed larger than that meeting health history standards will not be approved and will require batch testing prior to transfer until a history of acceptable health evaluations can be documented for that size class. Once a hatchery is compliant under RSSBP, annual health evaluations must be continued with a minimum of two sampling events per year across the production season and any POC occurrence requires immediate notification to the Project team and regulators in states where seed has been transferred under the Program. Health histories will be used in combination with RSSBP BMP criteria and desired distribution locations to inform hatchery compliance approvals. *Hatcheries working with exotic broodstock species (non-native) are not eligible under the RSSBP.*

Once a hatchery is compliant under the RSSBP, the hatchery must meet the following conditions to continue to operate under the RSSBP:

- Follow RSSBP BMPs.
- Continue to maintain annual disease surveillance by approved diagnostic laboratories.
- Pass an annual audit demonstrating compliance with RSSBP BMPs.
- Notify the Project team and regulators in states where seed has been transferred under this Program of any POC occurrence.

SHELLFISH DISEASE DATABASE TOOL (Regional Shellfish Biosecurity Surveillance Map)

The purpose of this application tool is to provide information on the distribution and abundance of shellfish pathogens along the East Coast of the U.S. in a manner that allows informed decisions concerning the risks of spreading or exacerbating disease from shellfish transfers. A working version of the tool, which is still in development, can be accessed at:
https://mosaic.njaes.rutgers.edu/rssbp-database/.

COMPLIANCE LEVELS

The program will determine hatchery RSSBP compliance for one of two levels: Level 1, with regional like-to-like pathogen status transfers allowed, or a more stringent Level 2, with East Coast-wide transfer allowed. This determination will be based on hatchery interest and risk evaluation based on history of POC detections and hatchery practices.

Level 1 - For regional transfers between areas of like pathogen status. Hatcheries demonstrate active employment of RSSBP BMPs (described below) to reduce risks of disease acquisition and transfer. Health records demonstrate continued compliance with POC acceptance levels (Table 2) for transfers to areas of like pathogen status. The RSSBP Shellfish Disease Database tool can be used to determine the pathogen status of an area.

Level 2 – For East Coast-wide transfers. In addition to meeting Level 1 requirements, Level 2 hatchery health records demonstrate absence of POCs over past three years and best management practices demonstrating exceptional control that greatly reduces potential disease acquisition within the hatchery.

RSSBP HATCHERY BEST MANAGEMENT PRACTICES

1) Adult animals, i.e., broodstock, should be segregated from algal, larval, and post-set culture systems within the hatchery and nursery areas.

2) Algal, larval and post set systems should be adequately separated from areas with use of unfiltered water and animals previously exposed to unfiltered water, to avoid splashing and cross contamination.

3) Water filtration for early life stage cultivation should employ a series of filters to get to 1µm filtration, or another means to minimize the risk of disease introductions from source water must be demonstrated (e.g., pasteurization, well water, etc.).

4) Cleaning of water filters should be conducted in an area separate from areas where animals are held and cultivated to avoid cross contamination.

5) Records and/or labels should be kept indicating maintenance of systems to eliminate POCs from source water (e.g., filter change regimes, relative "age" of all active filters).

6) Demonstrated workflow and operational plans should prevent the introduction of raw water and contaminants from entering areas where cultivated life stages are in filtered water.

7) Equipment should be assigned to specific operational areas (e.g., containers used to transport adult animals, should be used only for such tasks) or effectively sanitized between uses when shared.

8) Health examinations should be conducted on seed experiencing unexplained, atypical mortality and records kept. This maintains the Program's ability to stay alert to possible emerging pathogens as well as POCs. The Advisory Council must be notified of any disease issues that come up during Program participation including any actions taken to rectify the situation.

9) Broodstock records must be maintained and document source location (source water), genetic background, and collection date.

10) Spawning records must be maintained that document broodstock used, spawn code/name, and date spawned in order to accommodate any trace back from health evaluation results.

11) If applicable, quarantine practices must be demonstrated and documented for all non-local endemic species of broodstock.

12) All state permitting requirements such as hatchery facility permits must be followed. Non-compliance with state requirements will result in removal of the hatchery from the RSSBP.

DEFINITIONS

Biosecurity—A set of measures designed to reduce the risk of introduction, establishment and spread of pathogenic agents to, from, or within a farm. Biosecurity is maintained in part through good farm management, avoiding overcrowding and keeping stress on animals low. An important additional means is to ensure transferred seed does not carry exotic pathogens or levels of established pathogens, like dermo, so high that it will worsen disease locally.

Health Evaluation—A thorough examination of a shellfish sample using standard methods such as histopathology, Ray's fluid thioglycollate method (RFTM) and molecular diagnostics by an approved pathologist.

Like-to-Like Pathogen Status—Pathogen status of the origin and destination waters being the same. This information can be found using the Shellfish Disease Database tool--a web-based portal documenting pathogen distributions of molluscan shellfish. It's important to note there are other considerations when moving shellfish such as broodstock genetics and environment (salinity, temperature) that aren't directly addressed in this Program but should be considered.

Non-local broodstock—Endemic species of broodstock from regions or areas with different pathogen profiles. This includes in-state and out-of-state endemic species. Non-local broodstock should be held in quarantine and follow all applicable state regulations.

Exotic broodstock—Broodstock of a species not endemic or naturalized to the East Coast, from outside the East Coast or country.

Advisory Council—The Council is made up of regulators, pathologists, industry and extension specialists representative of multiple States along the East Coast of the U.S.

ADVISORY COUNCIL MEMBERS

Table 1. 2021 Advisory Council membership

Name	Affiliation	State	Area
Debbie Bouchard	University Maine	ME	Pathology
*Ryan Carnegie	Virginia Institute Marine Science	VA	Pathology
*Dave Bushek	Rutgers University	NJ	Pathology
Lisa Calvo	Rutgers University	NJ	Extension
Karen Hudson	Virginia Institute Marine Science	VA	Extension
Tal Ben-Horin	North Carolina State	NC	Extension
Marcy Nelson	Maine Department Marine Resources	ME	Regulatory
Rebecca Thur	MD Department Natural Resources	MD	Regulatory
Bob Rheault	East Coast Shellfish Growers	RI	Industry
Mike Congrove	Oyster Seed Holdings	VA	Industry
Julie Davis	Lady's Island Oysters	SC	Industry
Lori Gustafson	USDA APHIS VS	Federal	Regulatory
Carolina Borque	Louisiana Department Fish and Wildlife	LA	Regulatory

*Council Co-Chairs

PATHOGENS OF CONCERN (POC)

Table 1. Pathogens known to be harmful to health and survival of aquacultured shellfish on the East Coast of the U.S.

Pathogen	Host(s)	Tolerance for Level 1 Compliance
MSX	Oysters	No detection
Dermo	Oysters	Light infection, < 5% prevalence
SSO	Oysters	No detection
ROD	Oysters	No detection
Bonamia ostreae	Oysters	No detection
Bonamia exitiosa	Oysters	No detection
OsHV-1	Oysters	No detection
Perkinsus chesapeaki	Clams, Oysters	No detection
QPX	Hard clams	No detection
Neoplasia, gonadal & disseminated	Clams	No detection
Marteilia refringens	Flat oysters, Mussels	No detection
Merocystis kathae	Sea Scallops	No detection

FREQUENTLY ASKED QUESTIONS (FAQs)

- **What products are eligible under the process?**
  Shellfish products from a hatchery that are maintained solely on filtered water (no exposure to ambient water) and meet the qualifications of the 3-year health history. Note: testing is recommended on the largest size product for commerce because that will cover all earlier life stages/sizes.

- **What products are <u>not</u> eligible under this process?**
  Any shellfish product that has been deployed in an ambient water environment. For example, broodstock from a field location or seed oysters from an ambient water nursery system are <u>not</u> eligible. Gametes are not eligible as transmissible stages of pathogens have been found associated with gametes from infected broodstock. These are typically washed away in the hatchery following the first water change of larvae. Gametes may be batch certified for use or used following appropriate quarantine protocols to ensure no pathogens are transferred to receiving waters.

- **What if my hatchery doesn't have a health history record for 3 consecutive years?**
  Initiate composite testing in your hatchery of the largest life stage (per species) you intend to sell and continue to batch test. Apply when your hatchery has 3 consecutive years of reports that meet qualifications for the level of interest.

- **What if my hatchery wants to sell 5 mm seed but my health evaluation history is on 1 mm seed?**
  The largest size health evaluation applies for all products of smaller size so in this case all products smaller than 1 mm are covered by the current health history. If no health history records exist on a larger size, in this case 5 mm, begin seasonal pathology screens of the larger seed to get the required health history. Batch evaluations would be required for the larger sizes only until the 3-year record criteria is met.

- **What are the possible outcomes of the audit?**
  The auditors provide a recommendation to approve, deny or conditionally approve (pending a corrective action) RSSBP compliance.

- **When will I know the results of the audit?**
  Results of the audit will be provided approximately 2 weeks after the audit in most cases, unless further consultation is needed.

- **What happens if my hatchery is operating under the RSSBP and a disease issue comes up during the season?**
  Under the program, any disease issue must be immediately reported to the project team and regulators in states where seed was transferred under this program. In this case, compliance will be temporarily suspended and batch health evaluation testing of products for commerce will be utilized. Regaining approved status will be decided on a case-by-case basis with consultation from the Advisory Council.

- **What if my hatchery doesn't pass the audit –does this count against me?**
  No. This program is not intended to negatively impact industry commerce. Not all hatchery facilities will have the ability to comply with the BMPs and in those cases, facilities simply continue the batch heath evaluations of products for commerce when needed.

HATCHERY APPLICATION OVERVIEW

APPLICATION PROCESS

- Hatchery completes the application, which includes a three-year (2 samples per year) record of seed health evaluations.
- The application is submitted to the Project Team (page 1).
- The Project Team will confirm Program eligibility by reviewing the health history and coordinate an audit team to visit the hatchery.
- The audit team will verify the implementation of the Program BMPs as described in the application and report back to the Project Team with a recommendation of compliance – approval, conditional approval (pending a corrective action), or denial.

APPLICATION (INFORMATION REQUESTED)

1. Contact information.
2. Physical location and source water (list specific body of water for hatchery and nursery if applicable).
3. General information about operation.
    - Years in operation.
    - Water treatment for broodstock, algae, larvae, and post set cultivation systems.
    - Description origin of broodstock (local, non-local, non-native), holding systems, and wastewater.
    - Species cultivated.
    - Compliance with required state permits (yes/no.)
4. Seed and other products for which RSSBP compliance is requested (by species, life stage, and size).
5. Brief descriptions of how the hatchery complies with the RSSBP BMPs.
6. Demonstration of health evaluation history (3 years with 2 samples per year).

    Note: health history is only <u>required</u> for life stage(s)/ sizes desired for RSSBP compliance, not all life stages/sizes in the hatchery. Seed smaller than that approved under RSSBP will automatically be covered. For instance, a clean health history for 4 mm seed will cover seed less than or equal to 4 mm. Seed larger will require additional health evaluations.
7. Permission to retrieve all shellfish health examination records from the pathology laboratory of record. This permission must be granted. Record confidentiality will be maintained by audit team and Advisory Council.
8. Signature and date.

AUDIT OVERVIEW

The goal of the audit is to provide 3rd party verification the hatchery is complying with the RSSBP Best Management Practices.

- Upon receipt of a hatchery's application for RSSBP compliance, the Project Team (page 1) will collect the shellfish health records from the pathologist and verify hatchery eligibility for species, Level and size.

- The Project Team will then coordinate auditors and provide them with the application, eligibility, and source water report (generated by the shellfish disease database tool). The audit team will be comprised of at least two auditors. Auditors will be recognized experts having experience with shellfish aquaculture that have no conflicting business or regulatory affiliations.

- The audit team will arrange to visit the hatchery and conduct an in-person audit of the BMPs. Cost of auditor travel is covered by grant funds for the pilot program and will need to be revisited moving forward. The audit team will be responsible for verifying the operational practices described in the application and ensuring that hatchery practices comply with Program BMPs.

- The project team will review the audit report and recommendation and consult with the Advisory Council if there are any concerns. If RSSBP compliance is approved, a letter of program compliance will be sent to the hatchery. The hatchery should provide this letter to state regulators where the hatchery wishes to ship seed with a request that this designation be considered in the decision-making process.
- To maintain compliance under the program, the hatchery must continue to implement Program BMPs and health evaluations (at least 2 per season), and pass an annual audit.