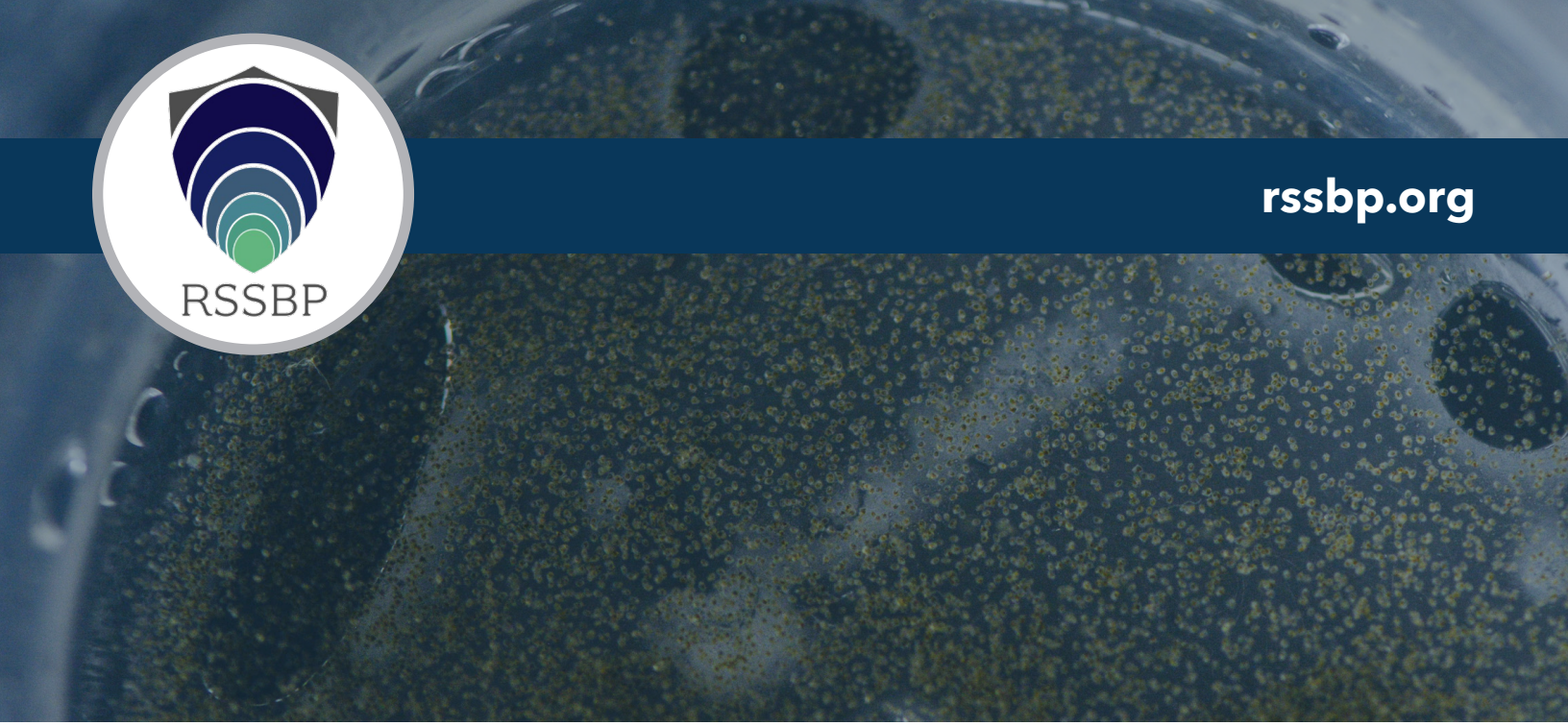

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REGIONAL SHELLFISH SEED BIOSECURITY PROGRAM (RSSBP)

HATCHERY COMPLIANCE PROGRAM GUIDE

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

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TABLE OF CONTENTS

RATIONALE

Introduction and emergence of shellfish disease 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 serving well over 1,000 nurseries and farms making interstate transfers fundamental to regional commerce and production. Although less established, the same situation is developing along the Gulf Coast, with hatchery production limiting industry growth. Each state within these regions 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 treated water in the hatchery. Based on this evidence, a collective of shellfish pathologists, researchers, shellfish growers, hatchery operators, and government regulators have developed the Regional Shellfish Seed Biosecurity Program (RSSBP) to facilitate interstate commerce in hatchery seed. Incentivizing commerce in these typically disease-free products will foster enhanced biosecurity through the broader regional industry.

REGIONAL SHELLFISH SEED BIOSECURITY PROGRAM (RSSBP)

The RSSBP is a collaboration of industry, scientists, regulators and extension using the best available science to minimize risks associated with interstate seed transfers of bivalve shellfish. The project team (Table 1.) is leading the RSSBP which provide tools to: evaluate and reduce risks of transfers; inform decision making regarding interstate seed transfer; enhance biosecurity from hatchery to farm and facilitate commerce.

The RSSBP consists of four core elements:

Regional Shellfish Health Advisory Council (Table 2.)
A team of molluscan scientists/pathologists, State regulators, extension personnel and industry members to support the RSSBP and relevant stakeholders by providing science-based advice on shellfish transfers and overseeing the hatchery certification/compliance process.

Regional Network of Shellfish Pathologists
A team of experts to improve the perspective on disease distributions and risk, expand surveillance activities in areas where data are lacking, and ensure proficiency in diagnosis to support a growing aquaculture industry. Most shellfish pathologists currently work with or are employed by state agencies to assist with shellfish management issues. The Regional Shellfish Health Advisory council invites all practicing shellfish pathologists to provide advice and guidance.

Interactive Shellfish Disease Database Mapping Tool
Provides science-based information on the distribution and abundance of shellfish pathogens along the East Coast of the United States in a manner that allows informed decisions regarding the risks of spreading or exacerbating disease from shellfish transfers. This tool is available at https://rssbp.org/shellfish-data-map/

Hatchery Compliance Program (HCP) (described in detail in this document)
Hatchery products pose the lowest disease risk due to their young age, especially those only exposed to treated water. Starting here, the Program outlines a voluntary compliance process for hatcheries to improve and validate biosecurity, reducing the need for individual batch disease certifications. State participation may require changing laws, policies or other regulations before taking advantage of this Program.

HATCHERY COMPLIANCE PROGRAM

The purpose of the RSSBP hatchery biosecurity compliance is to promote biosecurity practices in shellfish hatcheries and facilitate the process for permitting interstate commerce of biosecure bivalve shellfish seed and larvae being sold directly out of hatchery facilities. These transfers pose lower risk of disease transfer due to their young age and measures taken to prevent pathogen exposure through the hatchery rearing process. The RSSBP is designed to capitalize on this inherent higher level of biosecurity. **The Hatchery Compliance Program is voluntary and *does not* guarantee that all states or hatcheries will participate**. The Program consists of two components - a facility component and a product component, providing an opportunity for stepwise participation. The facility component ensures a satisfactory Best Management Practices (BMP) plan for minimizing disease risk is in place and is being implemented. The product component demonstrates the effectiveness of the BMP plan via product health history evaluations documenting the absence of disease and Pathogens of Concern (POCs) (Table 3.). Hatcheries can now participate in the Program as verified BMP-compliant facilities while building the required product health history. The further the hatchery is in the process, the higher the level of biosecurity reducing risk of disease transfer.
If hatcheries choose not to participate, or for some reason compliance is not achieved, the hatchery may simply continue by independently complying with the legal authority

requirements for the recipient location which may include batch health exams, zero tolerance for pathogen detection, or outright bans. Similarly, if a state does not accept compliance under this program, it may impose additional requirements or restrictions.

FACILITY ELIGIBILITY

Basic facility participation requires the pursuit of RSSBP **Best Management Practices** (BMPs) within the facility to minimize disease risk. Facilities undergo an initial review of application paperwork documenting compliance to BMPs and are then audited onsite by independent experts in the field of shellfish aquaculture production to verify BMP compliance. ***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 continue to follow RSSBP BMPs, maintain annual disease surveillance of products, submit annual renewal forms, and pass an annual on-site audit to verify compliance. In addition, the facility manager must notify the RSSBP team (info@RSSBP.org) and regulators in states where seed has been transferred under this Program of any issues that may affect compliance (e.g., a system failure, change in BMP protocols, positive disease detection). Compliance may be downgraded to maintain biosecurity which does not prohibit seed transfers but may require a return to batch testing. Reinstatement may occur pending Advisory Council review of the situation and any corrective actions implemented.

PRODUCT ELIGIBILITY

Only specific shellfish products from a BMP-Compliant Facility may be considered compliant under this Program. The Program ensures that a facility has a satisfactory BMP plan and has implemented that plan. The product component is the next layer of biosecurity to ensure products meet biosecurity standards and **demonstrate the minimal disease risk of the facility**. Eligible products must be produced and maintained on 1um filtered water or another demonstrated mechanism (e.g. pasteurization, use of well water, artificial seawater, etc.) to minimize the risk of disease introductions from the source water. ***Products reared in untreated/ambient water, such as, flow-through nurseries or brown water culture are not eligible under the RSSBP at this time.*** These two actions together imply a good level of biosecurity that should adequately protect transfers among areas with similar disease profiles even if prevalence's differ among source and recipient waters. In other situations, such as the transfer of seed from an area containing a pathogen not present in recipient waters, it may be necessary to ensure that the Pathogens of Concern (POCs) (Table 3.) are routinely absent to demonstrate the effectiveness of the BMP.

Additional product eligibility requirements include**:**

- Records of health evaluations from an independent pathology laboratory (Appendix 1). Ideally, this should cover the previous three years with a minimum of two sampling events per species, per year during the production season (6 samples over the 3-year period) demonstrating no detections of POCs. The sole exception is an acceptable level of *Perkinsus marinus* (Dermo disease) where it is ubiquitously distributed and persistent.

- The health evaluations must be performed on the largest size seed the hatchery desires to be certified for transfer under the RSSBP. Smaller seed (or larvae) will be automatically approved given that disease transfer risks are lower for smaller and younger animals and those certified passed through those smaller younger stages without carrying pathogens forward. Seed larger than that meeting health history standards will continue to require any and all testing requirements of the permitting authority for the recipient waters.

BMP-compliant facilities successful in certifying specific products will be able to label those products as RSSBP Biosecure, and all records will be available to participating regulatory agencies. This process is intended to obviate the need for shipment-by-shipment health evaluations for participating states. For products to maintain RSSBP Biosecure status the facility must continue to be BMP-Compliant and maintain annual disease surveillance on the specific products which will be verified by an annual audit of health evaluation records.

PROGRAM BENEFITS

Compliance under the RSSBP will maintain a higher level of biosecurity than individual batch health evaluations by providing a consistent standard for biosecurity, a record of biosecurity performance, and opportunities for improving biosecurity. The Program's prescribed and structured annual health surveillance will cost less than batch by batch sampling for facilities routinely transferring products outside their local waters. This will reduce the demand on the limited resources and capacity of pathology laboratories. State regulatory importation permit processes will benefit from science-based decision-making tools that allow for streamlining permit reviews, facilitating timely commerce and reducing costs to State agencies. Streamlining will be enhanced through the RSSBP's Interactive Shellfish Disease Database Mapping 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 (Table 1.) with oversight of an Advisory Council (Table 2.). The Council is comprised of molluscan scientists/pathologists, regulators, extension personnel and industry members along the East Coast of the United States with recent additions of Gulf Coast members as the Program is expanding into the Gulf Coast. 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. The Project team and Advisory Council makes the final decision of approving Facility BMP-compliance and Biosecure product compliance.

HATCHERY PARTICIPATION STEPS

1. Enrolled Facility - Hatchery facilities apply and pass facility documentation review to be enrolled (the first step towards BMP-Compliant facility status)

To become a BMP-Compliant facility, the hatchery must submit an application (Appendix 2.) providing adequate documentation that the facility description and practices are compliant with the RSSBP Best Management Practices for Minimizing Disease Risks. The documentation is reviewed by the project team and compared with the RSSBP BMPs. Facility application documentation that meets the biosecurity standards are listed as enrolled on the `Participating Hatcheries' document posted on rssbp.org, indicating they have developed an acceptable biosecurity plan for their facility. Incomplete or unclear Facility application documentation will be returned for revision.

2. BMP-Compliant Facility - Pass an annual facility audit to become a verified BMP-Compliant Facility

Enrolled facilities will be scheduled for a BMP compliance verification via an in-person facility audit. Audits are conducted by independent experts in the field (Appendix 3.) and are valid for one year, unless a breach occurs (e.g., unexpected disease is detected in a health exam). If the audit is passed, the facility status is listed as BMP-Compliant Facility. If the audit result is conditional or failed, the facility remains in the enrolled status until an audit is passed. To remain a BMP-compliant facility, a renewal form (Appendix 4.) must be submitted and an annual audit passed.

3. Biosecure Product(s) - Apply and pass a health history records audit

Shellfish products, specific to species and size, produced from a BMP-Compliant Facility may be certified under this Program. This ensures products meet biosecurity standards and **demonstrate the minimal disease risk of the products specified**.

Products must be held on water treated to eliminate pathogens (e.g., 1µm filtered water, pasteurized water, etc.). Products held in untreated water, such as, ambient water nurseries are not eligible under the RSSBP at this time (see Eligibility section for more details). Application for Biosecure product status will undergo an audit of health evaluation history records. Products must have health evaluations for three concurrent years with at least 2 health evaluations per year during the production season when pathogens are most likely. BMP-compliant facilities successful in certifying specific products will be able to label those products as RSSBP Biosecure, which obviates the need for shipment-by-shipment health evaluations in participating states. For products to maintain RSSBP Biosecure status the facility must continue to be BMP-Compliant and maintain annual disease surveillance on the specific products.

APPLICATION AND AUDITING TIMEFRAME

Interested hatchery facility managers should apply by submitting a completed application form (available at rssbp.org) to the project team via info@rssbp.org. The timeframe for new application and renewal submissions is August to October. The new facility audit timeframe is November to March. Initial facility audits will be conducted in the off-season to allow ample time to observe and discuss systems and record keeping without impacting production schedules. Subsequent annual audits will be scheduled during early production to observe the active implementation of BMPs and workflow. Follow-up audits are conducted as needed if a compliance issue arises.

FACILITY AUDIT PROTOCOL

Upon receipt of hatchery applications, the Project Team will coordinate with the facility and auditors (Appendix 3.) to find a mutually agreed upon date and time for an on-site verification of the implementation of RSSBP BMPs. The auditors are independent of the RSSBP and its stakeholders; selected to maintain consistency across facilities and remove any perceived bias. Initial audits will be conducted by at least two auditors and ideally with facilitation by a member of the project team to provide a comprehensive review of the implementation of the facility biosecurity BMPs. Annual audits in subsequent years may be conducted by an individual auditor, with or without facilitation by the project team. Auditors are provided with the pertinent facility application, product heath history summary reports for any relevant products, and a facility source water report generated by the shellfish disease database tool which identifies known pathogens of concern (POCs) for their use in completing a facility audit form (Appendix 5), which details comments related to each of the BMPs. The audit consists of a detailed walkthrough of the facility with the hatchery manager. Audits typically `follow the water' starting where the source water enters the hatchery, is treated, and how it's distributed to the other production areas. An initial audit takes close to two hours, depending on the size and complexity of the hatchery systems, with auditors asking questions and taking notes. The job of the auditor is to verify the

operational practices described in the application and ensure that hatchery practices comply with Program BMPs. Auditors are asked to submit their completed report to the project team within a week of the audit and provide a recommendation to approve, deny or conditionally approve (pending a corrective action) RSSBP facility BMP compliance. Questions or concerns with compliance are resolved through consultation with the Advisory Council and other expertise as needed. In the case of conditional approval, a brief follow-up audit visit by the facilitator and/or auditor is required to ensure the correction was made. The final decision is made by the project team with approval by the Advisory Council. If RSSBP compliance is approved, a letter of Facility BMP compliance is sent to the hatchery along with the audit report. The hatchery should provide this letter to state regulators where they wish to ship seed with a request that this designation be considered in the decision-making process.

PRODUCT AUDIT PROTOCOL

Upon receipt of applications, the Project Team collects shellfish health evaluation records directly from the independent pathology laboratories listed on the application. These records are reviewed with respect to each product requested for certification for the current prior three-year period.

RSSBP HATCHERY BEST MANAGEMENT PRACTICES (see Appendix 6. for details)

1. Water treatment to prevent pathogen exposure during early life stage cultivation should employ a series of filters to get to 1µm filtration, or demonstrate another means to minimize the risk of pathogen exposure from source water (e.g., pasteurization, well water, etc.).

2. Adequate separation is required between untreated water and treated water to avoid cross contamination including physical separation of areas, water drainage, equipment, workflow, and cleaning.

2-a. Physical separation of areas– Adult animals, i.e., broodstock, should be segregated from algal, larval, and post-set culture systems within the hatchery. If applicable, quarantine practices must be demonstrated for all non-local endemic species of broodstock.

2-b. Water drainage – Contain/divert untreated water drainage in some manner (floor drains, etc.) to avoid spilling out on the floor where it could easily come in contact with clean equipment (hoses, buckets) or be tracked throughout the facility.

2-c. Equipment – 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.

2-d. Workflow – Workflow and operational plans should be designed to prevent the introduction of raw water and contaminants from entering areas where cultivated life stages are in treated water.

2-e. Cleaning – Cleaning of water filters or other water treatment apparatus should be conducted in an area separate from treatment areas or any areas containing treated water to avoid cross contamination.

3. Records should be kept for broodstock, spawning, and maintenance of systems used to eliminate POCs.

3-a. Broodstock records must be maintained and document source location (source water), genetic background, and collection date. If applicable, quarantine practices must be documented for all non-local endemic species of broodstock.

3–b. Spawning records must be maintained that document the specific broodstock used from the broodstock records, spawn code/name, and date spawned in order to accommodate any trace back from health certification results.

3-c. Records should be kept indicating maintenance of systems to eliminate POCs from source water (e.g., filter change regimes, relative "age" of all active filters). Labels on equipment indicating maintenance are strongly recommended to alert all staff of needs.

4. Health examinations should be conducted on animals 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 Shellfish Health Advisory Council must be notified of any disease issues that come up during Program participation including any actions taken to rectify the situation.

5. All Federal, State and Local permitting requirements, such as obtaining hatchery facility permits must be followed. Non-compliance with permitting 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 *Perkinsus marinus* (the causative agent of dermo), so high that it will worsen disease locally.

Exotic broodstock–Broodstock of a species not endemic or naturalized to the region, e.g., from outside the East Coast or country.

Health Evaluation–A thorough examination of a shellfish sample by an independent pathologist (Appendix 1.) using standard methods such as histopathology, Ray's fluid thioglycollate method (RFTM) for *Perkinsus marinus* detection, and molecular diagnostics.

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.

Table 1. RSSBP PROJECT TEAM

Name	Affiliation	Email
Dave Bushek	Haskin Shellfish Research Laboratory, Rutgers University	bushek@hsrl.rutgers.edu
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Jennifer Pollack	Texas A&M University-Corpus Christi	Jennifer.Pollack@tamucc.edu
Bob Rheault	East Coast Shellfish Growers Association	bob@ecsga.org
Leslie Sturmer	University of Florida, Institute of Food and Agriculture Services	lnst@ufl.edu
William Walton	Virginia Institute of Marine Science	walton@vims.edu

TABLE 2. SHELLFISH HEALTH ADVISORY COUNCIL

The RSSBP is coordinated under the guidance of the Shellfish Health Advisory Council. The Council serves to support state regulators by providing science-based advice on shellfish transfers as well as overseeing the hatchery compliance process and best management practices.

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

*Council Co-Chairs

TABLE 3. PATHOGENS OF CONCERN (POCs)

POCs are defined as pathogens known to be harmful to health and survival of aquacultured shellfish. This list is focused on POCs on the Atlantic and Gulf Coasts of the U.S.

For RSSBP compliance, product health histories must demonstrate no detection of the following POCs with the sole exception of an acceptable level of Perkinsus marinus (Dermo disease) where it is ubiquitously distributed and persistent (light infection at < 5% prevalence).

Disease	**Pathogen**	**Host(s)**
MSX disease (multinucleated sphere X)	*Haplosporidium nelsoni*	Oysters *(primarily Crassostrea virginica)*
Dermo disease	*Perkinsus marinus*	Oysters *(primarily Crassostrea virginica)*
SSO disease (seaside organism)	*Haplosporidium costale*	Eastern Oysters *(Crassostrea virginica)*
ROD (Roseovarius)	*Roseovarius crassostreae*	Eastern Oysters *(Crassostrea virginica)*
Bonamiosis	*Bonamia ostreae*	European Flat Oysters (*Ostrea edulis*)
Bonamiosis	*Bonamia exitiosa*	Oysters
Perkinosis	*Perkinsus chesapeaki*	Clams, Oysters
QPX disease	QPX	Hard clams
Neoplasia	Neoplasia, gonadal & disseminated	Clams
Marteiliosis	*Marteilia refringens*	Flat oysters, Mussels
Grey meat disease (SAP)	*Merocystis kathae*	Sea Scallops
Oyster herpesvirus / OsHV-1	*Ostreid herpesvirus-1	Oysters

* Ostreid herpesvirus-1 (OsHV-1) is a contagious viral disease of molluscan shellfish that has impacted some regions of the West Coast of the US, and other countries, however has not been reported along the East and Gulf coasts of the US.

POC References

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Ford, S. E. 2011. **Dermo** disease of oysters caused by Perkinsus marinus (revised). ICES Identification Leaflets for Diseases and Parasites in Fish and Shellfish, No. 30. 6 pp. https://doi.org/10.17895/ices.pub.5202

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Ostreid Herpesvirus-1. USDA APHIS Information Sheet November 2021. https://www.aphis.usda.gov/sites/default/files/oshv1-info-sheet.pdf

FREQUENTLY ASKED QUESTIONS (FAQs)

- **What products are eligible under the process?**

  Shellfish products from a BMP - Compliant Facility that are maintained solely on water treated to remove pathogens (no exposure to untreated/ambient water) and meet the qualifications of the 3-year health evaluation 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 untreated/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 <u>not</u> eligible as transmissible stages of pathogens have been found associated with gametes from infected broodstock, however, 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 evaluation record for 3 consecutive years?**

  Your facility can participate in the RSSBP while building product health history. Initiate composite testing in your hatchery of the largest life stage (per species) you intend to sell and continue to batch test. Submit an application for facility BMP compliance and continue to maintain facility BMP compliance while building product health history. Include a biosecure product request when your hatchery has 3 consecutive years of reports that meet qualifications.

- **What if my hatchery wants to sell 2 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 2 mm, begin seasonal health evaluations 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 facility audit?**

  The auditors provide *a recommendation* to approve, deny or conditionally approve (pending a corrective action) facility BMP compliance.

- **When will I know the results of the facility and product audit?**

  Results of the audit will be provided via a letter approximately 2 weeks after the audit in most cases, unless further consultation is needed. The facility manager will also receive a copy of the audit report.

- **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 RSSBP team (info@RSSBP.org) and regulators in states where seed was transferred under this program. In this case, compliance may 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 facility 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. The audit process should be seen as an opportunity for dialog and finding ways to improve the biosecurity process even further.