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Potential Introduction Pathways of Ostreid Herpesvirus-1 (OsHV-1) in the United States

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Summary: There are several plausible pathways of Ostreid Herpesvirus-1 (OsHV-1) transmission to susceptible shellfish populations in the United States (U.S.) as a result of introductions from exporting countries as well as movement of virus within the U.S.

Potential import pathways of introduction: Ballast water or ship fouling have been associated with introductions of invasive aquatic animal pathogens and species and have been implicated in the introduction of OsHV-1 in other countries. Imported live shellfish and frozen uncooked seafoods have been identified as pathways of aquatic disease introduction. The exposure risks associated with these pathways are affected by the volume and countries of origin of imported live shellfish and product, the distribution pathways post-port of entry (coastal vs. inland destinations), and handling of live shellfish (e.g., purging, freshening) and disposition pathways of waste shellfish and shells. Information on these factors in the U.S. are largely unknown.

Potential domestic pathways of introduction and spread: Domestically, areas of the West coast where OsHV-1 has been detected are associated with greater likelihoods of introduction and spread of OsHV-1 virus to susceptible cultured and wild shellfish populations via all plausible pathways compared to areas of the West Coast where OSHV-1 has not been detected, and along the East and Gulf coasts, Alaska and Hawaii. A reliable quantitative estimate of the likelihood of OsHV-1 transmission via each pathway is not possible because there are significant data and knowledge gaps.

BACKGROUND

Distribution:

Ostreid herpesvirus-1 (OSHV-1) is a contagious viral disease of molluscan shellfish with a wide host range (**Table 1**) [1]. The disease is most often associated with high mortality Pacific Oyster Mortality Syndrome (POMS) or Summer Seed Mortality (SSM) outbreaks in Pacific oyster (*Crassostrea gigas*), and most published reports and research focus on the disease in this species. The reference strain (OsHV-1; GenBank # AY509253) was initially sequenced in 1995 in France [1, 2], followed by identification and characterization by Segarra et al 2010 of an OsHV-1 genotype microvariant (OsHV-1 µVar) in France in 2008-2009 [1, 3-8].

Additional OsHV-1 microvariants and variants, and at least two closely related virus genotypes, have been detected globally, including in the United States (U.S.)(**Table 1**) [1, 3, 4, 9-11]. OsHV-1 microvariants are defined by the OIE in the *Manual of Diagnostic Tests for Aquatic Animals* [2] in accordance with Segarra et al 2010 [8], as closely related to OsHV-1 µVar, and having specific genetic sequence variations relative to the reference strain. OsHV-1 variants differ genetically from the reference strain, but do not contain the specific sequence variations associated with microvariants. The term "variant" has been used in the literature to collectively refer to the OsHV-1 reference strain and all microvariants and variants. This document will follow that terminology. Any

OsHV-1 variant can cause species variable infection and disease. There are no vaccines or treatments available for this disease.

In the U.S., an OsHV-1 variant has been identified as a cause of Pacific oyster larvae mortalities in Tomales Bay, California since 2001 [12-15], and was subsequently detected in five other cultured shellfish (Eastern oyster, European flat oyster, Kumamoto oyster, Manila clam, Mediterranean mussel) [16], and in Inner Bay and Outer Bay. In addition, a variant was detected in San Diego Bay in 2018 [12, 14, 17]. No detections of OsHV-1 variants in other areas of the West Coast, along the East and Gulf coasts, and in Alaska and Hawaii, have been reported. [1, 14]. In Mexico, a variant has been detected in cultured Pacific oyster and native mangrove oyster (*C. corteziensis*) in the Gulf of California [18, 19]. To date, OsHV-1 has not been reported in cultured or wild shellfish in Canada [1]. However, there is limited published surveillance data available, and it is unknown how much surveillance is conducted in susceptible populations in North America. Consequently, the actual distribution of OsHV-1 in the U.S., Canada, and Mexico is relatively unknown.

In the U.S. susceptible shellfish are present in all coastal waters (**Table 2**) [20-22]. Shellfish are cultured in twenty-two states along the East, Gulf and West coasts including Alaska and Hawaii (**Table 2**) [20-22]. The U.S. imports live fresh and chilled susceptible shellfish and frozen and processed shellfish products from at least 11 countries with reported OsHV-1 presence (**Tables 4 – 10).** However, it is unknown if importing countries that have not reported OsHV-1 conduct routine surveillance for the pathogen, so it is possible that additional countries exporting shellfish and shellfish products to the U.S. may also have undetected OsHV-1 in susceptible populations.

United States Regulations

Currently (2020), OsHV-1 is not listed as notifiable by the World Organisation for Animal Health (OIE), and is not in the U.S. list of Notifiable Diseases and Conditions [2, 23]. However, it is proposed to be notifiable in the U.S. National List of Reportable Animals Diseases (NLRAD). The U.S. Department of Agriculture (USDA) does not have regulations or restrictions in place regarding the importation of live shellfish. The U.S. Fish and Wildlife Service (USFWS) regulates trade of live shellfish; however some live shellfish and shellfish products are exempt if they are for human or animal consumption and the species is not listed as injurious [24], endangered, threatened [25], or Convention in International Trade in Endangered Species (CITES) listed [26]. Individual states variably regulate importation and inter- and intra-state movement of wild and cultured shellfish for aquaculture and consumption (**Table 3)**[4]. West coast states, Alaska and Hawaii require disease freedom testing for OsHV-1, while East and Gulf coast states generally do not require testing.

The National Shellfish Sanitation Program (NSSP) is a collaborative program under which the U.S. Food and Drug Administration (FDA) works with the states, the Interstate Shellfish Sanitation Conference, and industry to assure the safety of domestic and imported shellfish intended for human consumption [27]. Domestic and foreign processing establishments are required to follow FDA food safety guidelines. General processing sanitation requirements include ensuring safety of the water used to produce ice or that contacts food and food contact surfaces, and storage and handling protocols to prevent cross-contamination of shellfish and product. In the U.S., sewage and waste water, solid waste disposal, and other disposition pathways are required to meet Federal and State laws and regulations [27, 28]. Additional requirements for importation include inspections of seafood importers, evaluations of filers of seafood products, and foreign country program assessments [29]. Aquatic pathogen surveillance testing is not performed on raw shellfish, shellfish products, processing equipment, or solid and liquid processing waste streams [27] [30, 31]. In March 2018, the FDA published proposed determination (FDA-2018-N-0810) which would allow importation of live, fresh, or fresh-frozen shellfish for consumption from the European Union [32, 33]. Similarly, New Zealand worked with the FDA to establish a memorandum of understanding to allow for importation of live shellfish.

Management of ballast water discharge via ballast water treatment and exchange (BWTE) is regulated federally (U.S. Environmental Protection Agency; U.S. Coast Guard), and at the state level. Ballast water discharges are required to meet International Maritime Organization (IMO) ballast water management Convention D-2 standards for allowable concentrations of living organisms and microorganisms considered “indicators problematic for ballast water” [34-36]. The regulations do not contain stipulations regarding viruses. Vessels that do not discharge ballast water, discharge only to shore side facilities or to water that presents little threat (public drinking water) are not required to install a ballast water treatment system (BWTS) [37]. Vessels operating in only one Captain of the Port (COPT) Zone are exempted from ballast water exchange reporting and recordkeeping requirements [37]. COPT Zones are administrative, are not established using ecological or biological bases, and may not be appropriate boundaries for addressing invasive species [36]. The efficacy of BWTE is estimated to range from 50 percent to 90 percent [36, 38-40]. Data reporting BWTE efficacy on viruses are lacking. The lack of efficacy data has been suggested to be due to lowering of the concentration of viruses present in ballast water below the limits of detection of currently available assays by treatment methods [36, 41].

Epidemiology

Transmission occurs horizontally via ingestion of virus in water or attached to vectors (plankton, organic materials) [3, 42-44], and direct contact [1, 2, 42, 43]. Vertical transmission is suspected, but has not been confirmed [1, 3]. Water is considered a mechanical transmission vector. OsHV-1 virus enters the water column when infected shellfish shed large quantities of virus during disease outbreaks, and when subclinically infected adult shellfish periodically shed virus. Latently infected adult Pacific oysters intermittently shed virus [1, 3, 16, 43, 45, 46].

Clinical signs in Pacific oysters are most common in larvae, develop 3 to 4 days after spawning, and are nonspecific (gaping, slow closure of valves, slow growth, reduced feeding, weak circular swimming, loss of ability to swim) [1-3, 42]. Highest mortality (40 percent – 100 percent) occurs peracutely and up to 10 days in larvae, spat and juvenile oysters [42, 44] [2, 44, 46]. In Pacific oysters greater than 1 year of age, clinical signs may be inapparent or limited to gill erosions [42]. Virus has been detected in apparently healthy adult Pacific oysters suggesting latent or subclinical infection [2, 3, 42]. Mortality rates in other shellfish species are variable (**Table 1**).

Recommendations regarding diagnostic test suitability for surveillance and diagnosis are described in the World Organisation for Animal Health (OIE) *Manual of Diagnostic Tests for Aquatic Animals* [2]. Diagnostic tests include histopathology, transmission electron microscopy, polymerase chain reaction (PCR) assays [47], and in situ hybridization [2, 3]. Virus isolation and culture, antibody-based diagnostics, and serological assays are not available. In the U.S., diagnostic testing is available at some state laboratories (**Table 9**) and the USDA Animal and Plant Health Inspections Services' National Veterinary Services Laboratory.

Pathogenicity appears to be multifactorial and modulated by environmental factors, husbandry practices, co-infection with other pathogenic agents, proximity of susceptible and infected cultured and wild shellfish populations, host and viral factors [1, 2, 42, 44, 48, 49]. Similar to other herpesviruses, OsHV-1 is capable of latent or inapparent infection, followed by reactivation and replication when a sum of host and environmental factors occur [1, 3]. Seasonal and local environmental conditions vary globally [1, 50]; with disease occurring in late spring-summer in northern countries (i.e. the U.K., Ireland); in the spring in central European countries; and in winter-spring in Australia and New Zealand [49, 51, 52]. In California, mortalities typically occur during late-spring-summer [12-14]. High rates of virus detection in water and shellfish occur in shallow, sheltered lagoons and inland facilities [1, 52], and may be linked to greater water temperature fluctuations, low tidal currents, and decreased water circulation occurring in these areas [1, 44, 49].

Disease outbreaks occur when water temperatures fluctuate rapidly or reach a regionally variable threshold [1, 2, 17, 46, 50, 52], and may be related to changes in water physical and chemical properties [1, 53, 54], changes in shellfish physiology [50, 52, 55, 56], and virus survival at different temperatures [57]. An optimal thermal window (16^{o}C – 24^{o}C (60.8^{o}F – 75.2^{o}F)) may exist for viral replication in the host [1, 12]. In California, temperatures in excess of 24^{o}C (75.2^{o}F) precede mortalities.

Host factors likely include species susceptibility, age, growth rate, immune responses, and genetics [1, 58]**.** Pacific oysters appear more susceptible to infection than other shellfish species, and probability of mortality is greatest in small life stages under one year of age (larvae, spat, juveniles) [1, 12, 17, 50]. Differences in Pacific oyster genetics (stocks or family lines) appear to influence survival [4, 59, 60] [12].

Husbandry factors associated with disease development include handling of oysters during periods of high environmental risk, high stocking density, the proximity between susceptible and infected shellfish populations (cultured and wild), culture system type, fouling of culture structures, and biosecurity gaps. Lower mortality rates have been reported in Pacific oysters planted in the fall versus the spring (standard industry planting time) [13]. Lower mortality rates have been observed in Pacific oysters cultured on ropes versus baskets or trays and are attributed to stocking density and water circulation associated with the respective culture systems [43] [56].

Disease prevention and control measures should include identification of infected and susceptible cultured and wild shellfish populations [1], placing hatcheries and nurseries onshore or offshore areas not proximate to infected shellfish populations or water currents that pass through them [1, 52, 55], regulation of shellfish importation and movement (global, regional, local) [1, 42], sourcing seed shellfish from certified disease free hatcheries and wild seed from disease free locations [3, 4, 17, 43, 44, 46, 48], implementation of Food Safety Plans, business risk management plans, standard operating procedures, and biosafety protocols [1], and use of surveillance and monitoring plans to monitor domestic and wild shellfish populations [1]. Breeding for genetic resistance to OsHV-1 has increased survival of Pacific oysters in France and Australia [4, 59, 60], and, in California, lower mortality rates were observed in WA-1 Pacific oyster stock [12]. It is unknown if selection for survival to one variant infers survival to infection by the reference virus or other variants [4]. Use of triploid Pacific oysters has been suggested as a means to decrease mortality [1, 59, 60]. Rearing practice modifications include delaying or changing spat planting times to avoid environmental conditions conducive to OsHV-1 [1, 13, 61, 62]. Raising the height of rearing structures in intertidal zones and seawater column to control the water temperature, hydrodynamics, and immersion time has been successful in decreasing disease development in Pacific oysters [56]. Confinement operations may consider filtration of sea water ($\geq$5 µm), disinfection (Virkon-S (1 percent v/v x 15 minutes); sodium hydroxide (20 g/L-1 x 10 min); iodine (0.1 percent x 5 min); formalin (10 percent v/v x 30 min), and use of virus inactivation methods (water aging x 48 hours; heating water (50^{o}C (122^{o}F) x 5 min; ultraviolet irradiation x 254 nm) [1, 44, 56, 63]. Equipment and personal protective equipment should be site specific and cleaned and disinfected between uses if not discarded. Control of fouling stationary equipment in open water may be beneficial [1]. In event of an outbreak or detection, confinement facilities should destroy infected stock, disinfect water and equipment, and fallow the site [1, 64].

SUMMARY OF POTENTIAL ENTRY AND EXPOSURE PATHWAYS FROM FOREIGN COUNTRIES

Ballast water, ship fouling and movement in water:
The epidemiology associated with observed OsHV-1 spread among shellfish populations, and results of natural transmission studies, strongly implicate water as a mechanical transmission vector for virus suspended in the water column or attached to organic matter and plankton, and swimming or rafting infected shellfish larvae [1, 3, 16, 43, 45, 46, 63]. Ballast water and ship fouling have been associated with introductions of invasive aquatic animal species and pathogens, followed by dispersal via the water column, tides, and currents [38, 39, 65]. Ballast water and ship fouling have been implicated in the introduction of OSHV-1 to areas free of the disease in Australia [43].

Shellfish imported for aquaculture purposes:
Shellfish are infrequently imported for use in aquaculture in the U.S. From 2016 to 2019, one shipment of oyster seed (28,580 liters; species not identified; destinations

unknown) were imported from Canada into the U.S. (**Table 3**). No juvenile or adult shellfish were imported for use in aquaculture during this period. OsHV-1 may be introduced via this import pathway depending on what species of shellfish are imported, the source countries, and whether the importing states require OsHV-1 freedom testing.

Imported live shellfish and shellfish products for human consumption:

Importation of live shellfish, and frozen uncooked seafood have been identified as pathways of introduction of aquatic diseases [43, 66]. Data summarized for the years 2016 through 2019 indicate the U.S. imported multiple species of farmed and non-farmed live fresh and chilled shellfish, and raw frozen and processed shellfish products for human consumption from countries with reported OsHV-1 presence (Australia, China, France, Ireland, Italy, Korea, Mexico, the Netherlands, New Zealand, Portugal, Spain, and the U.K.) (**Tables 4**). In addition, the FDA recently finalized a molluscan shellfish equivalence determination for Spain and the Netherlands, allowing shellfish imports from these OsHV-1 positive countries.

Countries exporting live shellfish and shellfish products to the U.S. are required to meet FDA requirements for processing; however, imported live shellfish and shellfish products are not tested for presence of aquatic disease pathogens during processing or prior to movement, export, or sale [29, 67, 68]. OsHV-1 virus remains viable at temperatures used to transport and store live shellfish; therefore, it is highly likely that OsHV-1 infected food-sized Pacific oysters and other susceptible shellfish are exported to the U.S. from countries with reported OsHV-1 presence. Cooked, smoked and preserved oyster and shellfish products are prepared at temperatures exceeding those published for OsHV-1 virus inactivation (50^{o}C (122^{o}F)) (**Table 10**). However, specific inactivation efficacy studies of these methods have not been published for OsHV-1. The exposure risk is difficult to quantify because there is lack of knowledge regarding the destination of imported shellfish once they pass through ports of entry, and lack of information regarding the prevalence of OsHV-1 or quantity of virus present in imported shellfish or shellfish products. Once imported live shellfish and shellfish products enter the U.S, the potential exposure pathways of disease introduction to naïve domestic cultured and wild shellfish populations include purging and freshening (live shellfish) and processing and waste streams (live and processed shellfish) described below.

SUMMARY OF DOMESTIC TRANSMISSION PATHWAYS

Ballast water, ship fouling, and movement in water:

Because water has been implicated as a mechanical transmission vector for virus suspended in the water column or attached to organic matter and plankton, as well as swimming or rafting infected shellfish larvae [1, 3, 16, 43, 45, 46, 63], transmission of virus along the West Coast of the United States is a likely domestic pathway of spread between infected and naïve shellfish populations. Likewise, movement of virus in ballast water and ship fouling, followed by dispersal via the water column, tides, and currents is another plausible pathway of spread along the US West coast [38, 39, 65].

Movement of domestic shellfish for aquaculture purposes:

All coastal states regulate importation, and inter- and intra-state movements of shellfish for aquaculture purposes; however, variability in movement permitting and disease freedom requirements exists (**Table 3**)[4], possibly resulting in introduction of OsHV-1 infected shellfish to areas where the disease is not known to be present. A lack of local, regional, or national surveillance, including access to the results of industry testing, limit capability to fully assess OsHV-1 presence/absence geographically or within susceptible shellfish populations. OsHV-1 appears endemic in specific areas in California [12, 13, 16]; therefore it is highly plausible that resident populations of infected shellfish in these areas may serve as sources of virus that will be dispersed via water to adjacent areas of the West coast.

Domestic shellfish for human consumption:

The risks of OsHV-1 introduction to naïve shellfish populations posed by domestically sourced live Pacific oysters, shellfish, or processed shellfish products, are regionally variable and affected by the storage, distribution, processing, consumption, and disposal pathways. Movement and distribution of domestically reared live shellfish to commercial markets is not regulated as strictly as movement of shellfish intended for aquaculture, but is subject to FDA, NSSP, FDA, and some state regulations (**Table 9**); however, there is limited accessible data available to evaluate such movements [69]. The exposure risk is difficult to quantify because there is lack of knowledge regarding the prevalence of OsHV-1 or quantity of virus present in domestic shellfish or shellfish products sourced from or produced in areas where OsHV-1 is reported.

Exposure of susceptible shellfish via wet storage:

Live domestically reared shellfish are often temporarily held in offshore or onshore wet storage after harvesting for purging and to increase the salt content of the shellfish [27, 70]. Operators must comply with the NSSP Guide for the Control of Molluscan Shellfish under FDA purview to maintain the sanitary quality of the stored shellfish [27]. Some states also regulate wet storage (**Table 9**). Commingling of shellfish harvested from different areas is restricted, and there are requirements regarding facility structure, water quality and treatment, holding temperatures, icing; and record keeping [27]. Microbial pathogen control guidelines are specific to zoonotic bacterial pathogens. It is unlikely that imported live shellfish are held in domestic wet storage facilities. The risk of exposure posed by wet storage is dependent on the location of the facilities in proximity to infected and susceptible shellfish, state regulations regarding movements of shellfish intended for food, the source and disposition pathways of the water used, and the pre- and post-water treatment methods. The risk of exposure is greatest in areas of the West coast where OsHV-1 is present. Offshore facilities pose a plausibly greater risk due to their location in the ocean. In areas of the West coast, along the East and Gulf coasts, and in Alaska and Hawaii where OsHV-1 surveillance and/or state regulations requiring OsHV-1 disease freedom testing prior to movement of shellfish has not resulted in detections of virus. Consequently, it is unlikely that this wet storage pathway from these populations has occurred.

TRANSMISSION PATHWAYS ASSOCIATED WITH SHELLFISH

PROCESSING AND HANDLING

Exposure of susceptible shellfish via freshening:
Retail and live markets may freshen live domestically sourced and imported shellfish prior to sale by immersion in a tank of artificial seawater or brined freshwater, or by running artificial seawater or brined water over the shellfish for several days. Shellfish may also be stored on ice or at or below 5ºC (41ºF). Holding tank water and ice melt are likely disposed of via municipal wastewater systems; however, it is possible that commercial entities located near coastlines dispose of water and ice melt into the ocean or adjacent waterways. Exposure is plausible in any coastal location where imported shellfish or shellfish sourced from OsHV-1 affected areas of the US may be freshened prior to sale to consumers.

Exposure of susceptible shellfish via purging (draining, depuration):
Purging (draining, depuration) is practiced by some consumers to remove sand and grit, and reduce microbial contaminants [71]. Use of tap water to make saltwater solutions for purging is recommended; however, domestically sourced and imported live shellfish purchased in coastal areas may be placed in the ocean or adjacent water sources for this purpose. Some states have regulations discouraging this practice; however, consumer compliance and enforcement rates of such regulations are generally unknown. Exposure via this pathway is plausible wherever infected regionally sourced or imported live shellfish may be sold for human consumption.

Exposure of susceptible shellfish via domestic processing:
In areas of the West coast where OsHV-1 is present, locally sourced and imported infected shellfish likely enter food processing pathways. In areas of the West coast where OsHV-1 is not present, along the East and Gulf coasts, and in Alaska and Hawaii, imported infected shellfish may enter food production pathways. The exposure risk posed by this pathway likely is affected by the volumes of infected shellfish that are processed, the prevalence of OsHV-1 in infected shellfish, the efficacy of the liquid and solid waste stream treatments and disposal pathways, and the proximity of processing facilities to susceptible shellfish populations.

Exposure of susceptible shellfish via disposition of waste shellfish, shellfish products and consumption waste:
Approximately 40 percent of commercial seafood is discarded as waste. Landfills are the most common waste disposal pathways and monitor groundwater for microbial contamination [72-74]; however, it is unknown how the methods used are associated with the presence of aquatic animal pathogens. Wild animals and birds that forage on landfills may function as fomites or transmission vectors. There are knowledge gaps regarding the quantity of waste shellfish or shellfish product used as bait or discarded by consumers into compost piles, coastal waterways, or other pathways that may allow introduction of OsHV-1 to susceptible populations. If discarded waste is capable of contaminating ground water or is placed into waters adjacent to the ocean, it is plausible that virus will reach susceptible shellfish populations via movement of water. This exposure pathway is plausible in any

coastal area where imported infected shellfish and shellfish product may enter waste disposal pathways; the potential for exposure on the West coast is greatest where OsHV-1 virus may also be present in locally sourced, processed, and consumed shellfish.

Exposure of susceptible shellfish via disposition of shells:

OsHV-1 virus is present in the soft tissues of shellfish, not in shell constituents; however, shells from improperly shucked shellfish might retain tissues containing enough virus to pose an exposure risk. According to the literature, disposition of shells typically includes collection by solid waste companies (37 percent), disposal into the sea (25 percent), and use as compost, animal feed constituents or other uses (38 percent) [43]. Oyster shells from commercial entities (restaurants, grocery stores) are likely disposed of via landfills; however, it is plausible that commercial entities located near coastlines could dispose of shells into the ocean or natural waterways. Shells disposed of by consumers likely enter landfills; however, disposal of shells into the ocean or natural waterways is plausible. Use of shells in the U.S. for raw materials, animal feeds, or sources of calcium carbonate ($CaCO_3$) is generally unknown [43]**.** This exposure pathway is plausible in any coastal area where shells from imported infected shellfish may enter waste disposal pathways; the potential for exposure on the West coast is greatest where OsHV-1 virus may also be present in locally sourced shellfish.

POTENTIAL IMPACTS

The effect that introductions of indigenous or exotic (i.e., variants not indigenous to the U.S.) OsHV-1 might have on U.S. shellfish aquaculture depends on a) virulence of the introduced variants; b) the susceptibility of shellfish species present in the area; c) the location that the introductions occur. There are few studies of comparative pathogenicity, virulence and susceptibility among shellfish species to different OsHV-1 variants that meet the OIE requirements for natural infection [2]. Burge et al 2020 demonstrated susceptibility of U.S. Pacific oysters to OsHV-1 variants from other countries, and that high mortalities can occur (90 percent, French variant; 97.5 percent, Australian variant)[75]. A second study demonstrated differential susceptibility of oyster species to U.S. OsHV-1 variants in the field, and among oyster species and families of U.S. Pacific oysters to OsHV-1 variants from other countries in the laboratory [15]. Delmotte et al 2020 demonstrated that some oyster genotypes are more susceptible to certain OsHV-1 variants than others under field conditions [76].

The short-term impacts associated with introduction of OsHV-1 to naïve U.S. local or regional shellfish industries has been demonstrated. The emergence of OsHV-1 in Tomales Bay, California resulted in doubling of summertime mortality rates of juvenile Pacific oysters and loss of farms in that area, or movement of farms to other embayments. Cultured and wild Pacific oyster and other susceptible shellfish populations are present along the West coast from California to Alaska. Due to the endemic presence of OsHV-1 in specific areas of the West Coast, and the potential for movement of OsHV-1 virus via water, it is plausible that OsHV-1 will eventually spread along the West Coast, with associated local and regional economic effects. Exposure to exotic OsHV-1 variants also plausibly could occur via pathways described in this document.

Local and regional economic consequences of OsHV-1 introduction to naïve areas of the U.S. West Coast Pacific oyster industry is unknown, but may be significant [22]. The West Coast shellfish industry primarily cultivates Pacific oysters [21, 77]. In 2013, the West Coast industry was comprised of approximately 300 commercial shellfish farms and 5 major private hatcheries, employed approximately 3,800 people, and annually contributed over USD $270 million to the regional economy [21, 77]. An economic impact report published in 2013 stated that in 2010, Washington state shellfish aquaculture spent approximately $100 million USD in the state economy, was responsible for approximately 1,900 direct and 801 indirect jobs, and generated an estimated $77 million USD in labor income [77]. The California shellfish aquaculture industry contributed approximately $12 million USD to the state economy, generating an estimated 200 direct and 80 indirect jobs, and $10 million USD in labor income[77]. This study did not assess the economic impacts for Oregon.

Introduction of endemic or exotic OsHV-1 to the East and/or Gulf Coasts where naïve susceptible wild and/or cultured shellfish are present could result in consequences similar to those associated with OsHV-1 emergence and establishment in Tomales Bay. Pacific oyster are not cultivated on the East Coast, however, OsHV-1 susceptible species, including the Eastern oyster, are present; therefore, the consequences of introduction of OsHV-1 to this region would likely be economically impactful [78]. Approximately 1000 farms are located in all East Coast states excluding Delaware [79]. Economic data relative to shellfish aquaculture is not readily accessible for many of these states. In 2012, the total economic impact of shellfish aquaculture (hard clams and oysters) in Virginia was 925 jobs, approximately $81 million USD in output, $27 million USD in income, and $3.6 million USD in taxes. Oyster aquaculture contributed approximately 23 percent of output ($19.7 million USD), 25 percent of jobs (232 jobs), 37 percent of income ($10 million USD), and 33 percent of taxes ($1.2 million USD)[80]. Economic data for shellfish aquaculture is not readily accessible for many states along the Gulf Coast. In 2016, the Gulf states produced more shellfish by volume than any other region in the nation [22], and sources state that 80 percent to 90 percent of Eastern oyster production occurs in the Gulf of Mexico; therefore, the consequences of introduction of OsHV-1 to this region could be economically impactful [78]. Presently there have been no detections of OsHV-1 on the East or Gulf Coasts.

Volumes of shellfish exported by the U.S., including species susceptible to OsHV-1, are summarized in **Tables 11 to 15**. In 2019, the U.S. exported 177,388 kg of *Haliotis* ssp. abalone products (live and prepared product); 2,903,539 kg of live clams and clam products; 277,037 kg of live, fresh or chilled *Mytillus* spp., *Perna* spp mussels; 5,977,712 kg of *Pecten* spp., *Chlamys* spp., and other scallops spp. product (live and prepared) [69]. The impacts that OsHV-1 may have on U.S. exports of consumable shellfish products are difficult to assess. Currently, OsHV-1 is not a disease of concern to the European Union [81], and the only country that requires testing for OsHV-1 is

Canada (oyster seed specifically) [82].

REFERENCES

1. Rodgers, C., et al., *A literature review as an aid to identify strategies for mitigating ostreid herpesvirus 1 in Crassostrea gigas hatchery and nursery systems.* Reviews in Aquaculture, 2019. **11**(3): p. 565-585.

2. (OIE), W.O.f.A.H., *Manual of Diagnostic Tests for Aquatic Animals*. 7th Edition ed. 2018.

3. Mandas, D. and F. Salati, *Ostreid herpesvirus: A pathogen of oysters.* Virology: Research & Reviews, 2017. **1**(2): p. 1-5.

4. Divilov, K., et al., *First evaluation of resistance to both a California OsHV-1 variant and a French OsHV-1 microvariant in Pacific oysters.* BMC genetics, 2019. **20**(1): p. 1-9.

5. Abbadi, M., et al., *Identification of a newly described OsHV-1 µvar from the North Adriatic Sea (Italy).* The Journal of general virology, 2018. **99**(5): p. 693.

6. Burioli, E., M. Prearo, and M. Houssin, *Complete genome sequence of Ostreid herpesvirus type 1 µVar isolated during mortality events in the Pacific oyster Crassostrea gigas in France and Ireland.* Virology, 2017. **509**: p. 239-251.

7. Renault, T., et al., *Analysis of clinical ostreid herpesvirus 1 (Malacoherpesviridae) specimens by sequencing amplified fragments from three virus genome areas.* Journal of virology, 2012. **86**(10): p. 5942-5947.

8. Paul-Pont, I., N.K. Dhand, and R.J. Whittington, *Spatial distribution of mortality in Pacific oysters Crassostrea gigas: reflection on mechanisms of OsHV-1 transmission.* Diseases of Aquatic Organisms, 2013. **105**(2): p. 127-138.

9. Savin, K.W., et al., *A neurotropic herpesvirus infecting the gastropod, abalone, shares ancestry with oyster herpesvirus and a herpesvirus associated with the amphioxus genome.* Virology journal, 2010. **7**(1): p. 308.

10. Ren, W., et al., *Complete genome sequence of acute viral necrosis virus associated with massive mortality outbreaks in the Chinese scallop, Chlamys farreri.* Virology journal, 2013. **10**(1): p. 1-7.

11. Xia, J., et al., *Complete genome sequence of Ostreid herpesvirus-1 associated with mortalities of Scapharca broughtonii broodstocks.* Virology journal, 2015. **12**(1): p. 110.

12. Burge, C.A., F.J. Griffin, and C.S. Friedman, *Mortality and herpesvirus infections of the Pacific oyster Crassostrea gigas in Tomales Bay, California, USA.* Diseases of aquatic organisms, 2006. **72**(1): p. 31-43.

13. Burge, C.A., et al., *Summer seed mortality of the Pacific oyster, Crassostrea gigas Thunberg grown in Tomales Bay, California, USA: the influence of oyster stock, planting time, pathogens, and environmental stressors.* Journal of Shellfish Research, 2007. **26**(1): p. 163-

172.

14. Friedman, C.S., et al., *Herpes virus in juvenile Pacific oysters Crassostrea gigas from Tomales Bay, California, coincides with summer mortality episodes.* Diseases of aquatic organisms, 2005. **63**(1): p. 33-41.

15. Burge, C.A., R.E. Strenge, and C.S. Friedman, *Detection of the oyster herpesvirus in commercial bivalves in northern California, USA: conventional and quantitative PCR.* Diseases of Aquatic Organisms, 2011. **94**(2): p. 107-116.

16. Renault, T., et al., *Ostreid herpesvirus 1 infection among Pacific oyster (Crassostrea gigas) spat: relevance of water temperature to virus replication and circulation prior to the onset of mortality.* Appl. Environ. Microbiol., 2014. **80**(17): p. 5419-5426.

17. Grijalva-Chon, J., et al., *Detection of a new OsHV-1 DNA strain in the healthy Pacific oyster, Crassostrea gigas Thunberg, from the Gulf of California.* J. Fish Dis, 2013. **36**(11): p. 965-968.

18. Martínez-García, M.F., et al., *OsHV-1 and notifiable protozoa in healthy Crassostrea corteziensis cultured in two distant areas of the Gulf of California.* Latin american journal of aquatic research, 2017. **45**(4): p. 699-707.

19. FAO. *National Aquaculture Sector Overview*. Available from: http://www.fao.org/fishery/countrysector/naso_usa/en.

20. NASS, *2018 Census of Aquaculture*. 2019.

21. NOAA. *National Shellfish Initiative*. National Oceanic and Atmospheric Administration]. Available from: https://www.fisheries.noaa.gov/content/national-shellfish-initiative.

22. Office, G.P., *Code of Federal Regulation Title 50 Chapter I Subchapter B Part 16 Injurious Wildlife*, U.S.F.a.W. Service, Editor. 2020.

23. Office, G.P., *Code of Federal Regulation Title 50 Chapter I Subchapter B Part 17 Endangered and Threatened Wildlife and Plants*, U.S.F.a.W. Service, Editor. 2020.

24. *Importing and Exporting Shellfish and Fishery Products*. Available from: https://www.fws.gov/le/pdf/import-export-shellfish-fishery-products-fact-sheet.pdf.

25. (FDA), U.S.F.a.D.A., *National Shellfish Sanitation Program (NSSP): Guide for the Control of Mulluscan Shellfish 2017 Revision.* 2017.

26. FDA, *FDA Food Safety Modernization Act (FSMA).* 2007.

27. FDA. *Imported Seafood Safety Program*. Available from: https://www.fda.gov/food/importing-food-products-united-states/imported-seafood-safety-program.
28. Burkhardt, K., *Water Pollution from Slaughterhouses*. 2018, Environmental Integrity Project.

29. Bustillo-Lecompte, C. and M. Mehrvar, *Slaughterhouse wastewater: treatment, management and resource recovery.* Physico-chemical wastewater treatment and resource recovery, 2017: p. 153-174.

30. Gottlieb, S., *Statement from FDA Commissioner Scott Gottlieb, M.D., on effort to help bolster U.S. shellfish market by taking mutually beneficial steps to resume shellfish trade with the EU*, Food and Drug Adminstration, Editor. 2018.

31. Food and Drug Adminstration, *FDA Publishes Proposed Determination that European Union's Shellfish Safety Program is Equivalent to U.S. System*, Food and Drug Adminstration, Editor. 2018.

32. Office, G.P., *Code of Federal Regulation Title 46 Chapter I Subchapter Q Part 162 Subpart 162.060 Ballast Water Management Systems*, U.S.C. Guard, Editor. 2020.

33. Braynard, K. *12/2/2016: Marine Safety Center issues Ballast Water Managment System (BWMS) type-approval certificate to Aptimarin AS*. 2016; Available from: https://mariners.coastguard.dodlive.mil/2016/12/02/marine-safety-center-issues-ballast-water-management-system-bwms-type-approval-certificate-optimarin-as/.

34. Kim, Y., et al., *Metagenomic investigation of viral communities in ballast water.* Environmental science & technology, 2015. **49**(14): p. 8396-8407.

35. Guard, U.C., *Standards for living organisms in ships' ballast water discharged in US waters.* Federal Register, 2012. **77**: p. 17254-17320.

36. Hines, A., et al., *Biological invasions of cold-water coastal ecosystems: ballast-mediated introductions in Port Valdez/Prince William Sound, Alaska.* Final Report to Regional Citizens Advisory Council of Prince William Sound, 2000. **340**.

37. Gray, D.K., et al., *Efficacy of open-ocean ballast water exchange as a means of preventing invertebrate invasions between freshwater ports.* Limnology and Oceanography, 2007. **52**(6): p. 2386-2397.

38. Ren, J., *Technology selection for ballast water treatment by multi-stakeholders: a multi-attribute decision analysis approach based on the combined weights and extension theory.* Chemosphere, 2018. **191**: p. 747-760.

39. Hwang, J., et al., *High diversity and potential translocation of DNA viruses in ballast water.* Marine pollution bulletin, 2018. **137**: p. 449-455.

40. Health, E.P.o.A. and Welfare, *Scientific Opinion on the increased mortality events in Pacific oysters, Crassostrea gigas.* EFSA Journal, 2010. **8**(11): p. 1894.

41. Whittington, R.J., et al., *Counting the dead to determine the source and transmission of the marine herpesvirus OsHV-1 in Crassostrea gigas.* Veterinary research, 2018. **49**(1): p. 34.

42. Evans, O., I. Paul-Pont, and R.J. Whittington, *Detection of ostreid herpesvirus 1 microvariant DNA in aquatic invertebrate species, sediment and other samples collected from the Georges River estuary, New South Wales, Australia.* Diseases of aquatic organisms, 2017. **122**(3): p. 247-255.

43. Paul-Pont, I., et al., *Experimental infections of Pacific oyster Crassostrea gigas using the*

Australian ostreid herpesvirus-1 (OsHV-1) µVar strain. Diseases of aquatic organisms, 2015. **113**(2): p. 137-147.

44. Whittington, R.J., et al., *Long-term temporal and spatial patterns of Ostreid herpesvirus 1 (OsHV-1) infection and mortality in sentinel Pacific oyster spat (Crassostrea gigas) inform farm management.* Aquaculture, 2019. **513**: p. 734395.

45. Qiu, L., et al., *Detection and quantification of shrimp hemocyte iridescent virus by TaqMan probe based real-time PCR.* Journal of invertebrate pathology, 2018. **154**: p. 95-101.

46. Fuhrmann, M., et al., *The impacts of ostreid herpesvirus 1 microvariants on Pacific oyster aquaculture in the Northern and Southern Hemispheres since 2008.* REVUE SCIENTIFIQUE ET TECHNIQUE-OFFICE INTERNATIONAL DES EPIZOOTIES, 2019. **38**(2): p. 491-509.

47. de Kantzow, M., et al., *Effect of water temperature on mortality of Pacific oysters Crassostrea gigas associated with microvariant ostreid herpesvirus 1 (OsHV-1 µVar).* Aquaculture Environment Interactions, 2016. **8**: p. 419-428.

48. Solomieu, V.B., T. Renault, and M.-A. Travers, *Mass mortality in bivalves and the intricate case of the Pacific oyster, Crassostrea gigas.* Journal of invertebrate pathology, 2015. **131**: p. 2-10.

49. Pernet, F., et al., *Mass mortalities of Pacific oysters Crassostrea gigas reflect infectious diseases and vary with farming practices in the Mediterranean Thau lagoon, France.* Aquaculture Environment Interactions, 2012. **2**(3): p. 215-237.

50. Moreau, P., et al., *Pesticides and ostreid herpesvirus 1 infection in the Pacific oyster, Crassostrea gigas.* PLoS One, 2015. **10**(6): p. e0130628.

51. Fuhrmann, M., et al., *Metabolism of the Pacific oyster, Crassostrea gigas, is influenced by salinity and modulates survival to the Ostreid herpesvirus OsHV-1.* Biology open, 2018. **7**(2).

52. Paul-Pont, I., et al., *Descriptive epidemiology of mass mortality due to Ostreid herpesvirus-1 (OsHV-1) in commercially farmed Pacific oysters (Crassostrea gigas) in the Hawkesbury River estuary, Australia.* Aquaculture, 2014. **422**: p. 146-159.

53. Whittington, R.J., et al., *Further observations on the influence of husbandry practices on OsHV-1 µVar mortality in Pacific oysters Crassostrea gigas: age, cultivation structures and growing height.* Aquaculture, 2015. **438**: p. 82-97.

54. Martenot, C., et al., *Virulence of Ostreid herpesvirus 1 µVar in sea water at 16 C and 25 C.* Aquaculture, 2015. **439**: p. 1-6.

55. Castinel, A., et al., *OSHV-1 mortalities in Pacific oysters in Australia and New Zealand: the farmer's story.* Cawhthron Institute, Report No, 2015. **2567**.

56. Dégremont, L., *Evidence of herpesvirus (OsHV-1) resistance in juvenile Crassostrea gigas selected for high resistance to the summer mortality phenomenon.* Aquaculture, 2011. **317**(1-4): p. 94-98.

57. Degremont, L., M. Nourry, and E. Maurouard, *Mass selection for survival and resistance to OsHV-1 infection in Crassostrea gigas spat in field conditions: response to selection after four generations.* Aquaculture, 2015. **446**: p. 111-121.

58. Dégremont, L., et al., *Relative importance of family, site, and field placement timing on survival, growth, and yield of hatchery-produced Pacific oyster spat (Crassostrea gigas).* Aquaculture, 2005. **249**(1-4): p. 213-229.

59. Carrasco, N., et al., *A production calendar based on water temperature, spat size, and husbandry practices reduce OsHV-1 μvar impact on cultured Pacific oyster Crassostrea gigas in the Ebro Delta (Catalonia), Mediterranean coast of Spain.* Frontiers in Physiology, 2017. **8**: p. 125.

60. Evans, O., et al., *Transmission of Ostreid herpesvirus-1 microvariant in seawater: Detection of viral DNA in seawater, filter retentates, filter membranes and sentinel Crassostrea gigas spat in upwellers.* Aquaculture, 2017. **473**: p. 456-467.

61. Pernet, F., et al., *Infectious diseases in oyster aquaculture require a new integrated approach.* Philosophical Transactions of the Royal Society B: Biological Sciences, 2016. **371**(1689): p. 20150213.

62. Pughiuc, D., *Invasive species: Ballast water battles.* Seaways, March, 2010: p. 5-7.

63. Scott-Orr, H., B. Jones, and N. Bhatia, *Uncooked prawn imports: effectiveness of biosecurity controls.* 2017.

64. (FDA), U.S.F.a.D.A., *Code of Federal REgulations (CFR) Title 21, Subchapter B - Food for Human Consumption; Part 123 Fish and Fishery Products*. 2019.

65. Administration, U.S.F.a.d. *Food Safety Modernization Act and Animal Food*. 2011 [cited 2019 October 10]; Available from: https://www.fda.gov/animal-veterinary/animal-food-feeds/food-safety-modernization-act-and-animal-food.

66. Commission, U.S.I.T. *Dataweb*. Available from: www.dataweb.usitc.gov.

67. Department, E.S., *Wet Storage of Live Aquatic Animals*. Maricopa County Arizona.

68. Shen, X., et al., *Efficacy of Vibrio parahaemolyticus depuration in oysters (Crassostrea gigas).* Food microbiology, 2019. **79**: p. 35-40.

69. Agency, E.P. *Landfill Effluent Guidelines*. Available from: https://www.epa.gov/eg/landfills-effluent-guidelines.

70. Agency, U.S.E.P., *Municipal Solid Waste Landfills*. 2018.

71. Office, G.P., *Code of Fegeral Regulations Title 40 Chapter I Subchapter N Part 445 Landfills Point Source Category*, E.P. Agency, Editor. 2020.

72. Marston, A., *Senior Staff Veterinary Medical Officer, Live Animla Imports and Exports, Aquaculture Specialist*. 2020.

73. Economics, N., *Inc. The economic impact of shellfish aquaculture in Washington, Oregon, and California*. 2013, Report to the Pacific Shellfish Institute. Available from http://www ….

74. Tunnell, J.W., *Shellfish of the Gulf of Mexico*, in *Habitats and biota of the Gulf of Mexico: before the Deepwater Horizon oil spill*. 2017, Springer. p. 769-839.

75. Flimlin, G., et al., *Best management practices for the East Coast shellfish aquaculture industry.* 2010.

76. Murray, T.J. and K. Hudson, *Economic Activity Associated with Shellfish Aquaculture in Virginia–2012.* 2013.

77. Burge, C.A., et al., *First comparison of French and Australian OsHV-1 µvars by bath exposure.* Diseases of aquatic organisms, 2020. **138**: p. 137-144.

78. Delmotte, J., et al., *Contribution of Viral Genomic Diversity to Oyster Susceptibility in the Pacific Oyster Mortality Syndrome.* Frontiers in Microbiology, 2020. **11**: p. 1579.

79. Friedman, C.S., et al., *Unraveling concordant and varying responses of oyster species to Ostreid Herpesvirus 1 variants.* Science of The Total Environment, 2020. **739**: p. 139752.

TABLES

Table 1: Chronological history of reported OsHV-1 detection in shellfish species [1]

	Common name	Life stage	Mortality	OsHV-1, variants and related viruses as reported in the literature	Country	Year of Detection	Reference
Ostrea edulis	European flat oyster	Larvae, spat	Yes (high)	Herpes-like OsHV-1 uvar	France USA	1994 2011	[83] [16]
Ruditapes (Venerupis) philippinarum	Manila clam	Larvae	Yes (high)	OsHV-1 uvar	France USA	1997 2011	[83] [16]
Ruditapes decussatus	Grooved carpet shell	Larvae	Yes (high)	OsHV-1 uvar	France	1998	[84]
Crassostrea gigas	Pacific oyster	All stages	Yes (high)	OsHV-1 (reference virus; AY509253)	France China	2000 2007	[85, 86]
Crassostrea gigas	Pacific oyster	All stages	Yes (high)	OsHV-1 uvar (GenBank HQ842610.1) OsHV-1 uvar Δ9 OsHV-1 uvar Δ15 And other undescribed OsHV-1 uvar	France Ireland England Spain Italy Australia New Zealand Korea Netherlands United States Korea Sweden Norway	2008 2009 2010 2010 2010 2010 2010 2011 2011 2011 2012 2014 2014 2017	[16] [87] [42] [88] [89] [90] [91] [7] [92] [93] [94] [95] [96] [97] [19]
Pecten maximus	French scallop	Larvae	Yes (high)	OsHV-1 uvar	France	2000	[84]
Chalmys farrier	Chinese scallop	Adult	Yes (high)	Acute Viral Necrosis Virus (AVNA) GenBank GQ153938*	China	2001-2013	[10, 98]
Halitosis spp.	Wild abalone	Not reported	Yes	OsHV-1 related herpesvirus	Australia	2005	[9]
Crassostrea hongkongensis	Hong Kong oyster	Not reported	No	OsHV-1 uvar	China	2007-2013	[98]
Meretrix meretrix	Asiatic hard clam	Not reported	No	OsHV-1 uvar	China	2009-2013	[98]
Donax trunculus	Wedge clam	Not reported	No	OsHV-1 uvar (GenBank HQ842610.1)	France	2010	[99]
Mytilus edulis	Blue mussel	Not reported	No	OsHV-1 uvar (GenBank HQ842610.1)	France	2010	[99]
Mytilus galloprovincialis	Mediterranean mussel	Not reported	No	OsHV-1 uvar (GenBank HQ842610.1)	France USA	2010 2011	[99] [16]
Crassostrea virginica	Eastern oyster	Adult	Yes (52%)	OsHV-1 uvar	USA	1970 2011	[16]
Crassostrea sikamea	Kumamoto oyster	Not reported	Not reported	OSHV-1 uvar	USA	2011	[16]
Crassostrea angulata	Portuguese oyster	Adult	Yes (50-70%)	OsHV-1 uvar (GenBank HQ842610.1)	Portugal	2011	[100]

Patinopecten yessoensis	Yesso scallop	Not reported	No	OsHV-1 uvar	China	2011-2013	[98]
Scapharca broughtonii	Blood clam	Adult	Yes (high)	OsHV-1-SB GenBank KP412538	China	2012	[11]
Saccostrea glomerata	Sydney rock oyster	Not reported	No	OsHV-1 uvar	Australia	2012-2013	[44]
Anadara trapezia	Sydney cockle	Not reported	No	OsHV-1 uvar	Australia	2012-2013	[44]
Mytilus spp.	Mussel spp.	Not reported	No	OsHV-1 uvar	Australia	2012-2013	[44]
Trichomya hirsuta	Hairy mussel	Not reported	No	OsHV-1 uvar	Australia	2012-2013	[44]
Crassostrea corteziensis	Mangrove oyster	Not reported	No	OsHV-1 uvar	Mexico	2017	[19]

Table 2: Shellfish species commercially produced, recreationally harvested, or present in United States coastal waters [20, 22, 101, 102].

Common Name	Genus species	Location	Population status
Abalone spp.*	*Halitosis spp*	West Coast, Hawaii	Commercial, restoration, enhancement
Butter clam	*Saxidomus gigantea*	West Coast	Noted as present
Gaper clam	*Tresus spp.*	West Coast	Noted as present
Geoduck clam	*Panopea generosa*	West Coast, Alaska	Commercial
Hard clam (northern quahog)	*Mercenaria mercenaria*	East Coast, Gulf Coast	Commercial, Resident
Pacific littleneck clams	*Leukoma staminea*	West Coast, Alaska	Commercial
Manila clam*	*(Ruditapes (Venerupis) philippinarum*	West Coast, Hawaii	Commercial
Pacific razor clam	*Siliqua patula*	West Coast	Noted as present
Pismo clam	*Tivela stultorum*	West Coast	Noted as present
Atlantic razor (Jacknife) clam	*Ensis directus*	East Coast	Resident
Soft-shelled clam	*Mya arenaria*	East Coast (Northeast)	Commercial, Resident
Surf clam	*Spisula solidissima*	East Coast	
Bay mussel	*Mytilus trossulus*	West Coast, Alaska East Coast (Northeast)	Commercial, Resident
Blue mussels	*Mytilus edulis*	West Coast, Alaska East Coast (Northeast)	Commercial, Resident
Mediterranean mussels*	*Mytilus galloprovincialis*	West Coast	Commercial
Ribbed mussel	*Geukensia demissa*	East Coast	Resident
Eastern Oyster*	*Crassostrea virginica*	West Coast, East Coast Gulf coast	Commercial
European Flat Oyster*	*Ostrea edulis*	West Coast, Alaska	Commercial
Kumamoto oyster*	*Crassostrea sikamea*	West Coast, Alaska, Hawaii	Commercial
Olympia Oyster	*Ostrea conchaphila*	West Coast, Alaska	Commercial, restoration
Pacific Oyster*	*Crassostrea gigas*	West Coast, Alaska, Hawaii, East coast	Commercial, enhancement
Bay scallops	*Argopectin irradians*	East coast	Commercial, Resident

*susceptible to OsHV-1

Table 3: Summary of states with shellfish aquaculture. Information pertaining to regulation of inter- or intra-state movement of oyster seed, larvae, spat or broodstock are included based on availability of the data. Specific requirements regarding OsHV-1 is noted if available [20-22]

States	Number of Farms	Permitting, Regulation and Disease Monitoring Information
Alabama	3	Only native oyster species (Eastern oyster) may be used for aquaculture. Other data not readily available
Alaska	22	Intrastate movement: Requires a valid seed source approval and a disease history for the source facility and specific stock. Imported shellfish require import certification and disease testing. Imported oysters must be derived from commercial cultures located on the Pacific coast through three or more generations, and the disease history or inspection indicates no incidence of nonindigenous disease. https://pcsga.org/wprs/wp-content/uploads/2013/04/State-Shellfish-Health-Info-and-Contacts.pdf http://www.adfg.alaska.gov/FedAidPDFs/RIR.5J.2014.04.pdf
California	20	Propagation: Only approved species. Importation: Written permission is required. Shellfish are subject to inspection and must be disease and parasite free. Wild aquatics may be taken for aquaculture in accordance with specific regulations. OsHV-1 is listed as a pathogen that is monitored and investigated. https://nrm.dfg.ca.gov https://wildlife.ca.gov/Conservation/Laboratories/Shellfish-Health
Connecticut	26	Importation requires approval. Disease testing is required.
Florida	115	Culture: Only indigenous shellfish are allowed. Diploid shellfish other than hard clams must originate from broodstock sourced from the respective coast where culture will occur. Imported shellfish or gametes require diagnostic testing from an accredited laboratory and a Certificate of Veterinary Inspection. OsHV-1 is not on the required disease freedom list. https://www.fdacs.gov/content/download/64045/file/BMP_Rule_and_Manual_FINAL.pdf
Georgia	1	All commercial shellfish seed must originate in certified hatcheries or nurseries. Imported shellfish seed: A Certificate of Health that includes specific criteria is required. Shipments may be subject to visual inspection. https://coastalgadnr.org/sites/default/files/crd/pdf/shellfish_briefing.pdf?utm_campaign=&utm_content=&utm_medium=email&utm_source=govdelivery&utm_term
Hawaii	6	Permit to Import Restricted Commodities is required http://hdoa.hawaii.gov/ai/files/2013/03/Permits-and-Regulatory-Requirements-For-Aquaculture-in-Hawaii-2011-Final.pdf
Idaho	1	Data not readily available
Louisiana	28	Data not readily available
Maine	54	Shellfish seed or stock procured from Maine hatcheries can be placed on any LPA site. Seed from other area requires a permit. Movement of Eastern and European oysters requires a permit. Disease testing may be required. https://www.maine.gov/dmr/aquaculture/forms/documents/GrowingshellfishandotherspeciesonLPAsites.pdf
Maryland	30	Data not readily available
Massachusetts	157	Non-indigenous and invasive species strictly prohibited. Shellfish must be tested and found free of known diseases or come from approved sources. Approval is based on the disease history of the source and pathogen/parasite testing of broodstock and seed. https://www.mass.gov/media/5166/download
New Hampshire	18	Data not readily available
New Jersey	37	Imports: Health certificates are required unless written authorization is given from the State Veterinarian. Animals must be free of particular infectious, contagious or communicable diseases or known exposures within 30 days of shipment per AFS Blue Book procedures. https://www.jerseyseafood.nj.gov/aquacultureamp.pdf
New York	18	Specific species are authorized for culture. For more information contact the Bureau of Marine Resources. http://www.dec.ny.gov/permits/96310.html
North Carolina	35	Data not readily available
Ohio	2	Data not readily available
Oregon	15	Importation: An import permit is required to import oysters. A health certificate, certification of inspection and a declaration of disease freedom are required. Intrastate movement: A permit is required https://pcsga.org/wprs/wp-content/uploads/2013/04/State-Shellfish-Health-Info-and-Contacts.pdf

Rhode Island	25	Non-endemic species are prohibited. All shipments of shellfish must be approved. Permits are required. http://www.dem.ri.gov/pubs/regs/regs/agric/aquacult14.pdf
South Carolina	7	Data not readily available
Virginia	152	Importation: Hard clam seed from the Pacific coast is prohibited. Hard clam seed from South Carolina and Florida must meet genetic requirements and be certified free of shellfish pathogens by an approved shellfish pathologist. Eastern oysters must be certified free of disease. Other species must be approved and originate from approved states and waters. https://www.vims.edu/GreyLit/VIMS/mrr95-2ocr.pdf
Washington	112	Importation: Permits, disease testing, and health certification are required. Testing for OsHV-1 is required. https://wdfw.wa.gov/sites/default/files/202001/wdfw_shellfish_import_guidelines_2020.pdf https://pcsga.org/wprs/wp-content/uploads/2013/04/State-Shellfish-Health-Info-and-Contacts.pdf
Total	884	

Table 4: Volume of live oysters, oyster products,, and oyster seed imported to the United States from 2016 to 2019 [69].

Oysters (species not identified) Farmed, Live, Fresh or Chilled (except seed oysters)				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	1,573,367 (39%)	1,526,742 (34%)	1,842,918 (41%)	1,843,055 (40%)
No reports of OsHV-1	2,438,626 (61%)	2,997,490 (66%)	2,603,959 (59%)	2,789,426 (60%)
Annual total volume	4,011,993	4,524,232	4,446,877	4,632,481
Oysters (species not identified) Not Farmed, Live, Fresh or Chilled (except seed oysters)				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	181,196 (40%)	100,366 (32%)	119,122 (47%)	63,410 (37%)
No reports of OsHV-1	275,031 (60%)	214,390 (68%)	133,836 (53%)	110,267 (63%)
Annual total volume	456,227	314,756	252,958	173,677
Oysters (species not identified) Farmed, Other than Live, Fresh or Chilled (except seed oysters)				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	2,185 (<1%)	13 (<1%)	0	0
No reports of OsHV-1	1,543,794 (99.9%)	374,909 (99.9%)	210,117 (100%)	92,973 (100%)
Annual total volume	1,545,979	374,922	210,117	92,973
Oysters (species not identified) Not Farmed, Other than Live, Fresh or Chilled (except seed oysters)				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	58,778 (11%)	56,403 (18%)	32 (<1%)	34 (<1%)
No reports of OsHV-1	497,377 (89%)	260,748 (82%)	175,058 (99.9%)	149,421 (99.9%)
Annual total volume	556,155	317,151	175,090	149,455
Oysters (species not identified) Frozen and Products				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	4,029,153 (74%)	3,978,748 (61%)	5,404,543 (63%)	2,407,933 (41%)
No reports of OsHV-1	1,379,533 (26%)	2,576,509 (39%)	3,225,010 (37%)	3,479,369 (59%)
Annual total volume	5,408,686	6,555,257	8,629,553	5,887,302
Seed Oysters, Live, Fresh or Chilled				
Country status	Volume of imported product (liters; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	0	0	0	0
No reports of OsHV-1	0	0	0	28,580 (100%)
Annual total volume	0	0	0	28,580

Table 5: Shellfish products imported to the United States from countries that have reported presence of OhHV-1. *excluding seed oysters.

Shellfish Products	Country exporting to the United States										
	Australia	China	France	Ireland	Italy	Mexico	New Zealand	Netherlands	Portugal	Spain	UK
Abalone (Haliotis spp.) live, fresh or chilled	x	x				x					
Abalone (Haliotis spp.) prepared or preserved	x	x				x	x				
Abalone (species not identified), frozen	x	x				x					
Abalone (species not identified), products	x										
Clams, live, fresh or chilled (except geoducks)						x					
Clam products (except geoducks)		x		x		x	x	x	x	x	
Oysters, farmed, live, fresh or chilled*			x			x	x				
Oysters, not farmed, live, fresh or chilled*		x				x	x				
Oysters, farmed and not farmed, other than live, fresh or chilled		x		x		x	x				
Oyster products		x				x	x	x			
Mussels (Mytilus spp., Perna spp.) farmed, live fresh or chilled					x	x	x				
Mussels (Mytilus spp., Perna spp.) not farmed, live fresh or chilled		x					x			x	
Mussel (Mytilus spp., Perna spp.) products		x		x	x	x	x	x	x	x	x
Mussel (species not defined) products		x	x		x		x	x	x	x	x
Scallops (Pecten spp., Chlamys spp, Placopecten spp), live, fresh or chilled		x				x				x	
Scallops (Pecten spp., Chlamys spp, Placopecten spp) product	x	x				x				x	

Scallops (species not identified) product		x	x						x		

Table 6: Processed oyster products and associated production method

Shucked raw oysters	Raw oysters are washed prior to shucking, removed from their shells, washed again, graded, and rinsed or soaked in chilled seawater prior to draining and packaging. Wholesale packaging may contain seawater.
Frozen oysters	Are processed as described for shucked oysters, followed by freezing at -34°C to -45°C (-31 to -49°F) for 50 to 60 minutes (air-blast freezer), 30 to 40 minutes (spiral freezer), or 15 to 20 minutes (belt freezer). Frozen oysters are immersed in 0°C to 5°C (32°F to 41°F) water for glazing, packaged, and stored at -25°C (13°F).
Canned smoked oysters	Are smoked at 100°C to 120°C (212°F to 248°F) for 10 to 20 minutes. Meats are canned in edible vegetable oil heated to 100°C (212°F). The can is vacuum-sealed, heated to an internal temperature greater than 60°C (140° F), then rapid water-cooled (35°C (95°F)).
Canned boiled oysters	Brine steam-opened or fresh shucked oysters are used. Oyster meats and brine are placed into cans, vacuum-sealed, and processed as described for canned smoked oysters.
Dried oysters	Are typically prepared using steam-opened (110°C (230°F] x 7 to 10 minutes) meats washed in 2 percent to 3 percent salt brine or seawater. Meats are steam-treated (80°C (176°F) x 5 minutes) then placed in the sun to dry for 4 to 7 days, or dried in a hot-air dryer (27-38°C (80.6°F to 100.4°F) x 1 to 2 hours, increased to 60° C (140° F). Meats are coated with oyster extract several times during the drying process. Packaged product is stored at -20° C (-4° F) prior to shipment.
Salt-fermented oysters	Fresh shucked oysters are placed in jars with 10 percent to 20 percent table salt and spices, followed by temperature-dependent fermentation for 3 to 10 days.

Table 7: Volume of live *Haliotis* spp. abalone, and abalone products imported to the United States from 2016 to 2019 [69].

Abalone (Haliotis spp.) Live, Fresh or Chilled				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	4,363 (26%)	1,527 (3%)	10,539 (22%)	17,962 (25%)
No reports of OsHV-1	12,703 (74%)	45,669 (97%)	37,784 (78%)	54,435 (75%)
Annual total volume	17,066	47,196	48,313	72,397
Abalone (*Haliotis* spp) prepared or preserved				
Has reported OsHV-1	110,032 (74%)	118,894 (77%)	179,670 (65%)	194,354 (66%)
No reports of OsHV-1	38,388 (26%)	36,005 (23%)	43,540 (16%)	67,547 (23%)
Annual total volume	148,420	154,899	276,239	295,428
Abalone (species not identified) Product				
Has reported OsHV-1	177,884 (41%)	125,300 (37%)	160,461 (56%)	143,975 (69%)
No reports of OsHV-1	257,679 (59%)	215,566 (63%)	123,701 (44%)	64,085 (31%)
Annual total volume	435,563	340,866	284,162	208,060

Table 8: Volume of live clams and clam products imported to the United States from 2016 to 2019 [69].

Clams (species not identified, does not include geoducks) Live, Fresh or Chilled				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	1,049,610 (34%)	947,531 (33%)	948,034 (36%)	1,008,104 (42%)
No reports of OsHV-1	2,044,426 (66%)	1,890,423 (67%)	1,695,353 (64%)	1,412,899 (58%)
Annual total volume	3,094,036	2,837,954	2,643,387	2,421,003
Clams (species not identified, does not include geoducks) Frozen and Products (except geoducks)				
Has reported OsHV-1	2,045,163 (94%)	250,982 (11%)	452,001 (16%)	276,000 (9%)
No reports of OsHV-1	138,448 (6%)	2,113,574 (89%)	2,430,935 (84%)	2,653,068 (91%)
Annual total volume	2,183,611	2,364,556	2,882,936	2,929,068

Table 9: Volume of live mussels and mussel products imported to the United States from 2016 to 2019 [69].

Mussels (*Mytilus* spp., *Perna* spp.) Farmed, Live, Fresh or Chilled				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	54,699 (< 1%)	98,548 (1%)	37,614 (<1%)	37,567 (<1%)
No reports of OsHV-1	13,397,136 (99.9%)	13,010,897 (99%)	12,902,485 (99.9%)	13,057,595 (100%)
Annual total volume	13,451,835	13,109,445	12,940,099	13,095,162
Mussels (*Mytilus* spp., *Perna* spp.) Not Farmed, Live, Fresh or Chilled				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	245,512 (77%)	176,686 (89%)	72,136 (93%)	3,924 (18%)
No reports of OsHV-1	74,015 (23%)	21,630 (11%)	5,152 (7%)	18,205 (82%)
Annual total volume	319,527	198,316	77,288	22,129
Mussels (*Mytilus* spp., *Perna* spp.) Products				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	0	9,762,255 (65%)	6,410,792 (55%)	8,188,367 (51%)
No reports of OsHV-1	0	5,293,541 (35%)	5,330,741 (45%)	7,965,614 (49%)
Annual total volume	0	15,293,541	5,330,741	7,965,614
Mussels (species not identified) Products				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	1,041,747 (12%)	884,009 (12%)	912,940 (15%)	914,663 (14%)
No reports of OsHV-1	7,453,297 (88%)	6,634,273 (88%)	5,296,297 (85%)	5,582,946 (86%)
Annual total volume	8,495,044	7,518,282	6,209,237	6,497,609

Table 10: Volume of live *Pecten* spp., *Chlamys* spp., *Placopecten* spp. and Queen scallops and scallop products imported to the United States from 2016 to 2019 [69].

Scallops (*Pecten* spp., *Chlamys* spp, *Placopecten* spp. and Queen scallops) Live, Fresh or Chilled				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	10,898,791 (54%)	2,457,816 (56%)	1,916,814 (65%)	530,739 (24%)
No reports of OsHV-1	9,280,374 (46%)	1,957,992 (44%)	1,010,374 (35%)	1,727,045 (76%)
Annual total volume	20,179,165	4,415,808	2,927,188	2,257,784
Scallops (Pecten spp., Chlamys spp, Placopecten spp. and Queen scallops) Products				
Country status	Volume of imported product (kilograms; percentage of total import volume)			
	2016	2017	2018	2019
Has reported OsHV-1	50,561 (2%)	56,585 (3%)	1,707,458 (45%)	581,664 (19%)
No reports of OsHV-1	2,192,459 (98%)	2,184,524 (97%)	2,100,561 (55%)	2,424,669 (81%)
Annual total volume	2,243,020	2,241,112	3,813,816	3,006,333

Table 11: Volume of live *Haliotis* spp. abalone and abalone products exported from the U.S. from 2016 to 2019 [69].

Product	Volume of Product Exported (kilograms)			
	2016	2017	2018	2019
Abalone (*Haliotis* spp.) Live, Fresh or Chilled	574,387	280,303	34,905	40,441
Abalone (*Haliotis spp*.) Prepared or Preserved	494,846	45,713	55,560	136,947
Abalone (species not defined) Products	0	31,189	50,123	80,042
Total Volume Exported	990,976	357,205	140,588	257,430

Table 12: Volume of live clam and clam products exported from the United States from 2016 to 2019 [69].

Product	Volume of Product Exported (kilograms)			
	2016	2017	2018	2019
Clams, Live, Fresh or Chilled	654,470	725,378	626,522	639,581
Clams Products	1,154,519	2,580,150	2,540,567	2,263,958
Total Volume Exported	1,811,005	3,307,545	3,169,107	2,905,558

Table 13: Volume of live *Mytilus* spp. and *Perna* spp. mussels and mussel products exported from the United States from 2016 to 2019 [69].

Product	Volume of Product Exported (kilograms)			
	2016	2017	2018	2019
Mussels (*Mytilus* spp., *Perna* spp.) Farmed, Live, Fresh or Chilled	60,690	349,772	218,908	85,283
Mussels (*Mytilus* spp., *Perna* spp.) Not Farmed, Live, Fresh or Chilled	223,508	206,620	133,062	191,754
Mussels, Prepared or Preserved	288,456	325,604	247,030	540,808
Total Volume Exported	572,654	881,996	599,000	817,845

Table 14: Volume of live Pecten spp., Chlamys spp., Placopecten spp and Queen scallops exported from the United States from 2016 to 2019 [69].

Product	Volume of Product Exported (kilograms)			
	2016	2017	2018	2019
Scallops (*Pecten* spp., *Chlamys* spp., *Placopecten* spp. and Queen scallops), Live, Fresh or Chilled	1,897,099	1,498,204	930,390	994,295
Scallop Products	6,326,095	6,041,779	5,359,580	4,983,417
Total Volume Exported	8,223,194	7,539,983	6,289,830	5,977,712

Table 15: Volume of live oysters (species not identified) and oyster products exported from the United States from 2016 to 2019 [69].

Product	Volume of Product Exported (kilograms)			
	2016	2017	2018	2019
Oysters, Live. Fresh or Chilled	3,042,417	2,925,150	2,971,823	2,863,224
Oysters, Frozen	0	309,092	424,825	337,381
	479,597	182,864	84,393	196,027
Total Volume Exported	3,522,014	3,417,106	3,481,041	3,396,632

Table 16: Volume of seed oysters (species not identified) exported from the United States from 2016 to 2019[69].

Product	Volume of Product Exported (liters)			
	2016	2017	2018	2019
Seed Oysters, Live, Fresh or Chilled	33,359	94,079	85,663	143,339

Table References

1. Rodgers, C., et al., *A literature review as an aid to identify strategies for mitigating ostreid herpesvirus 1 in Crassostrea gigas hatchery and nursery systems.* Reviews in Aquaculture, 2019. **11**(3): p. 565-585.
2. (OIE), W.O.f.A.H., *Manual of Diagnostic Tests for Aquatic Animals*. 7th Edition ed. 2018.
3. Mandas, D. and F. Salati, *Ostreid herpesvirus: A pathogen of oysters.* Virology: Research & Reviews, 2017. **1**(2): p. 1-5.
4. Divilov, K., et al., *First evaluation of resistance to both a California OsHV-1 variant and a French OsHV-1 microvariant in Pacific oysters.* BMC genetics, 2019. **20**(1): p. 1-9.
5. Abbadi, M., et al., *Identification of a newly described OsHV-1 µvar from the North Adriatic Sea (Italy).* The Journal of general virology, 2018. **99**(5): p. 693.
6. Burioli, E., M. Prearo, and M. Houssin, *Complete genome sequence of Ostreid herpesvirus type 1 µVar isolated during mortality events in the Pacific oyster Crassostrea gigas in France and Ireland.* Virology, 2017. **509**: p. 239-251.
7. Renault, T., et al., *Analysis of clinical ostreid herpesvirus 1 (Malacoherpesviridae) specimens by sequencing amplified fragments from three virus genome areas.* Journal of virology, 2012. **86**(10): p. 5942-5947.
8. Segarra, A., *P epin JF, Arzul I, Morga B, Faury N, Renault T, Detection and description of a particular ostreid herpesvirus 1 genotype associated with massive mortality outbreaks of Pacific oysters, Crassostrea gigas.* France in, 2008: p. 92-99.
9. Savin, K.W., et al., *A neurotropic herpesvirus infecting the gastropod, abalone, shares ancestry with oyster herpesvirus and a herpesvirus associated with the amphioxus genome.* Virology journal, 2010. **7**(1): p. 308.
10. Ren, W., et al., *Complete genome sequence of acute viral necrosis virus associated with massive mortality outbreaks in the Chinese scallop, Chlamys farreri.* Virology journal, 2013. **10**(1): p. 1-7.
11. Xia, J., et al., *Complete genome sequence of Ostreid herpesvirus-1 associated with mortalities of Scapharca broughtonii broodstocks.* Virology journal, 2015. **12**(1): p. 110.
12. Burge, C.A., F.J. Griffin, and C.S. Friedman, *Mortality and herpesvirus infections of the Pacific oyster Crassostrea gigas in Tomales Bay, California, USA.* Diseases of aquatic organisms, 2006. **72**(1): p. 31-43.
13. Burge, C.A., et al., *Summer seed mortality of the Pacific oyster, Crassostrea gigas Thunberg grown in Tomales Bay, California, USA: the influence of oyster stock, planting time, pathogens, and environmental stressors.* Journal of Shellfish Research, 2007. **26**(1): p. 163-172.
14. Friedman, C.S., et al., *Herpes virus in juvenile Pacific oysters Crassostrea gigas from Tomales Bay, California, coincides with summer mortality episodes.* Diseases of aquatic organisms, 2005. **63**(1): p. 33-41.
15. Friedman, C.S., et al., *Unraveling concordant and varying responses of oyster species to Ostreid Herpesvirus 1 variants.* Science of The Total Environment, 2020. **739**: p. 139752.
16. Burge, C.A., R.E. Strenge, and C.S. Friedman, *Detection of the oyster herpesvirus in commercial bivalves in northern California, USA: conventional and quantitative PCR.* Diseases of Aquatic Organisms, 2011. **94**(2): p. 107-116.
17. Renault, T., et al., *Ostreid herpesvirus 1 infection among Pacific oyster (Crassostrea gigas) spat: relevance of water temperature to virus replication and circulation prior to the onset of mortality.* Appl. Environ. Microbiol., 2014. **80**(17): p. 5419-5426.
18. Grijalva-Chon, J., et al., *Detection of a new OsHV-1 DNA strain in the healthy Pacific oyster, Crassostrea gigas Thunberg, from the Gulf of California.* J. Fish Dis, 2013. **36**(11): p. 965-968.
19. Martínez-García, M.F., et al., *OsHV-1 and notifiable protozoa in healthy Crassostrea corteziensis cultured in two distant areas of the Gulf of California.* Latin american journal of aquatic research, 2017. **45**(4): p. 699-707.

20. FAO. *National Aquaculture Sector Overview*. Available from: http://www.fao.org/fishery/countrysector/naso_usa/en.
21. NASS, *2018 Census of Aquaculture*. 2019.
22. NOAA. *National Shellfish Initiative*. National Oceanic and Atmospheric Administration]. Available from: https://www.fisheries.noaa.gov/content/national-shellfish-initiative.
23. USDA-APHIS, *U.S. National List of Reportable Animal Diseases (NLRAD) Framework*. 2016.
24. Office, G.P., *Code of Federal Regulation Title 50 Chapter I Subchapter B Part 16 Injurious Wildlife*, U.S.F.a.W. Service, Editor. 2020.
25. Office, G.P., *Code of Federal Regulation Title 50 Chapter I Subchapter B Part 17 Endangered and Threatened Wildlife and Plants*, U.S.F.a.W. Service, Editor. 2020.
26. *Importing and Exporting Shellfish and Fishery Products*. Available from: https://www.fws.gov/le/pdf/import-export-shellfish-fishery-products-fact-sheet.pdf.
27. (FDA), U.S.F.a.D.A., *National Shellfish Sanitation Program (NSSP): Guide for the Control of Mulluscan Shellfish 2017 Revision.* 2017.
28. FDA, *FDA Food Safety Modernization Act (FSMA).* 2007.
29. FDA. *Imported Seafood Safety Program*. Available from: https://www.fda.gov/food/importing-food-products-united-states/imported-seafood-safety-program.
30. Burkhardt, K., *Water Pollution from Slaughterhouses*. 2018, Environmental Integrity Project.
31. Bustillo-Lecompte, C. and M. Mehrvar, *Slaughterhouse wastewater: treatment, management and resource recovery.* Physico-chemical wastewater treatment and resource recovery, 2017: p. 153-174.
32. Gottlieb, S., *Statement from FDA Commissioner Scott Gottlieb, M.D., on effort to help bolster U.S. shellfish market by taking mutually beneficial steps to resume shellfish trade with the EU*, Food and Drug Adminstration, Editor. 2018.
33. Food and Drug Adminstration, *FDA Publishes Proposed Determination that European Union's Shellfish Safety Program is Equivalent to U.S. System*, Food and Drug Adminstration, Editor. 2018.
34. Office, G.P., *Code of Federal Regulation Title 46 Chapter I Subchapter Q Part 162 Subpart 162.060 Ballast Water Management Systems*, U.S.C. Guard, Editor. 2020.
35. Braynard, K. *12/2/2016: Marine Safety Center issues Ballast Water Managment System (BWMS) type-approval certificate to Aptimarin AS*. 2016; Available from: https://mariners.coastguard.dodlive.mil/2016/12/02/marine-safety-center-issues-ballast-water-management-system-bwms-type-approval-certificate-optimarin-as/.
36. Kim, Y., et al., *Metagenomic investigation of viral communities in ballast water.* Environmental science & technology, 2015. **49**(14): p. 8396-8407.
37. Guard, U.C., *Standards for living organisms in ships' ballast water discharged in US waters.* Federal Register, 2012. **77**: p. 17254-17320.
38. Hines, A., et al., *Biological invasions of cold-water coastal ecosystems: ballast-mediated introductions in Port Valdez/Prince William Sound, Alaska.* Final Report to Regional Citizens Advisory Council of Prince William Sound, 2000. **340**.
39. Gray, D.K., et al., *Efficacy of open-ocean ballast water exchange as a means of preventing invertebrate invasions between freshwater ports.* Limnology and Oceanography, 2007. **52**(6): p. 2386-2397.
40. Ren, J., *Technology selection for ballast water treatment by multi-stakeholders: a multi-attribute decision analysis approach based on the combined weights and extension theory.* Chemosphere, 2018. **191**: p. 747-760.
41. Hwang, J., et al., *High diversity and potential translocation of DNA viruses in ballast water.* Marine pollution bulletin, 2018. **137**: p. 449-455.
42. Health, E.P.o.A. and Welfare, *Scientific Opinion on the increased mortality events in Pacific oysters, Crassostrea gigas.* EFSA Journal, 2010. **8**(11): p. 1894.
43. Whittington, R.J., et al., *Counting the dead to determine the source and transmission of the*

marine herpesvirus OsHV-1 in Crassostrea gigas. Veterinary research, 2018. **49**(1): p. 34.
44. Evans, O., I. Paul-Pont, and R.J. Whittington, *Detection of ostreid herpesvirus 1 microvariant DNA in aquatic invertebrate species, sediment and other samples collected from the Georges River estuary, New South Wales, Australia.* Diseases of aquatic organisms, 2017. **122**(3): p. 247-255.
45. Paul-Pont, I., et al., *Experimental infections of Pacific oyster Crassostrea gigas using the Australian ostreid herpesvirus-1 (OsHV-1) µVar strain.* Diseases of aquatic organisms, 2015. **113**(2): p. 137-147.
46. Whittington, R.J., et al., *Long-term temporal and spatial patterns of Ostreid herpesvirus 1 (OsHV-1) infection and mortality in sentinel Pacific oyster spat (Crassostrea gigas) inform farm management.* Aquaculture, 2019. **513**: p. 734395.
47. Qiu, L., et al., *Detection and quantification of shrimp hemocyte iridescent virus by TaqMan probe based real-time PCR.* Journal of invertebrate pathology, 2018. **154**: p. 95-101.
48. Fuhrmann, M., et al., *The impacts of ostreid herpesvirus 1 microvariants on Pacific oyster aquaculture in the Northern and Southern Hemispheres since 2008.* REVUE SCIENTIFIQUE ET TECHNIQUE-OFFICE INTERNATIONAL DES EPIZOOTIES, 2019. **38**(2): p. 491-509.
49. Paul-Pont, I, N.K. Dhand, and R.J. Whittington, *Spatial distribution of mortality in Pacific oysters Crassostrea gigas: reflection on mechanisms of OsHV-1 transmission.* Diseases of Aquatic Organisms, 2013. **105**(2): p. 127-138.
50. de Kantzow, M., et al., *Effect of water temperature on mortality of Pacific oysters Crassostrea gigas associated with microvariant ostreid herpesvirus 1 (OsHV-1 µVar).* Aquaculture Environment Interactions, 2016. **8**: p. 419-428.
51. Solomieu, V.B., T. Renault, and M.-A. Travers, *Mass mortality in bivalves and the intricate case of the Pacific oyster, Crassostrea gigas.* Journal of invertebrate pathology, 2015. **131**: p. 2-10.
52. Pernet, F., et al., *Mass mortalities of Pacific oysters Crassostrea gigas reflect infectious diseases and vary with farming practices in the Mediterranean Thau lagoon, France.* Aquaculture Environment Interactions, 2012. **2**(3): p. 215-237.
53. Moreau, P., et al., *Pesticides and ostreid herpesvirus 1 infection in the Pacific oyster, Crassostrea gigas.* PLoS One, 2015. **10**(6): p. e0130628.
54. Fuhrmann, M., et al., *Metabolism of the Pacific oyster, Crassostrea gigas, is influenced by salinity and modulates survival to the Ostreid herpesvirus OsHV-1.* Biology open, 2018. **7**(2).
55. Paul-Pont, I., et al., *Descriptive epidemiology of mass mortality due to Ostreid herpesvirus-1 (OsHV-1) in commercially farmed Pacific oysters (Crassostrea gigas) in the Hawkesbury River estuary, Australia.* Aquaculture, 2014. **422**: p. 146-159.
56. Whittington, R.J., et al., *Further observations on the influence of husbandry practices on OsHV-1 µVar mortality in Pacific oysters Crassostrea gigas: age, cultivation structures and growing height.* Aquaculture, 2015. **438**: p. 82-97.
57. Martenot, C., et al., *Virulence of Ostreid herpesvirus 1 µVar in sea water at 16 C and 25 C.* Aquaculture, 2015. **439**: p. 1-6.
58. Castinel, A., et al., *OSHV-1 mortalities in Pacific oysters in Australia and New Zealand: the farmer's story.* Cawhthron Institute, Report No, 2015. **2567**.
59. Dégremont, L., *Evidence of herpesvirus (OsHV-1) resistance in juvenile Crassostrea gigas selected for high resistance to the summer mortality phenomenon.* Aquaculture, 2011. **317**(1-4): p. 94-98.
60. Degremont, L., M. Nourry, and E. Maurouard, *Mass selection for survival and resistance to OsHV-1 infection in Crassostrea gigas spat in field conditions: response to selection after four generations.* Aquaculture, 2015. **446**: p. 111-121.
61. Dégremont, L., et al., *Relative importance of family, site, and field placement timing on survival, growth, and yield of hatchery-produced Pacific oyster spat (Crassostrea gigas).* Aquaculture, 2005. **249**(1-4): p. 213-229.
62. Carrasco, N., et al., *A production calendar based on water temperature, spat size, and*

husbandry practices reduce OsHV-1 μvar impact on cultured Pacific oyster Crassostrea gigas in the Ebro Delta (Catalonia), Mediterranean coast of Spain. Frontiers in Physiology, 2017. **8**: p. 125.
63. Evans, O., et al., *Transmission of Ostreid herpesvirus-1 microvariant in seawater: Detection of viral DNA in seawater, filter retentates, filter membranes and sentinel Crassostrea gigas spat in upwellers.* Aquaculture, 2017. **473**: p. 456-467.
64. Pernet, F., et al., *Infectious diseases in oyster aquaculture require a new integrated approach.* Philosophical Transactions of the Royal Society B: Biological Sciences, 2016. **371**(1689): p. 20150213.
65. Pughiuc, D., *Invasive species: Ballast water battles.* Seaways, March, 2010: p. 5-7.
66. Scott-Orr, H., B. Jones, and N. Bhatia, *Uncooked prawn imports: effectiveness of biosecurity controls.* 2017.
67. (FDA), U.S.F.a.D.A., *Code of Federal REgulations (CFR) Title 21, Subchapter B - Food for Human Consumption; Part 123 Fish and Fishery Products*. 2019.
68. Administration, U.S.F.a.d. *Food Safety Modernization Act and Animal Food*. 2011 [cited 2019 October 10]; Available from: https://www.fda.gov/animal-veterinary/animal-food-feeds/food-safety-modernization-act-and-animal-food.
69. Commission, U.S.I.T. *Dataweb*. Available from: www.dataweb.usitc.gov.
70. Department, E.S., *Wet Storage of Live Aquatic Animals*. Maricopa County Arizona.
71. Shen, X., et al., *Efficacy of Vibrio parahaemolyticus depuration in oysters (Crassostrea gigas).* Food microbiology, 2019. **79**: p. 35-40.
72. Agency, E.P. *Landfill Effluent Guidelines*. Available from: https://www.epa.gov/eg/landfills-effluent-guidelines.
73. Agency, U.S.E.P., *Municipal Solid Waste Landfills*. 2018.
74. Office, G.P., *Code of Fegeral Regulations Title 40 Chapter I Subchapter N Part 445 Landfills Point Source Category*, E.P. Agency, Editor. 2020.
75. Burge, C.A., et al., *First comparison of French and Australian OsHV-1 μvars by bath exposure.* Diseases of aquatic organisms, 2020. **138**: p. 137-144.
76. Delmotte, J., et al., *Contribution of Viral Genomic Diversity to Oyster Susceptibility in the Pacific Oyster Mortality Syndrome.* Frontiers in Microbiology, 2020. **11**: p. 1579.
77. Economics, N., *Inc. The economic impact of shellfish aquaculture in Washington, Oregon, and California*. 2013, Report to the Pacific Shellfish Institute. Available from http://www ….
78. Tunnell, J.W., *Shellfish of the Gulf of Mexico*, in *Habitats and biota of the Gulf of Mexico: before the Deepwater Horizon oil spill*. 2017, Springer. p. 769-839.
79. Flimlin, G., et al., *Best management practices for the East Coast shellfish aquaculture industry.* 2010.
80. Murray, T.J. and K. Hudson, *Economic Activity Associated with Shellfish Aquaculture in Virginia–2012.* 2013.
81. Hartman, K.
82. Marston, A., *Senior Staff Veterinary Medical Officer, Live Animla Imports and Exports, Aquaculture Specialist*. 2020.
83. Renault, T., *A review of mortality outbreaks in the Pacific oyster, Crassostrea gigas, reported since 2008 in various European Union Member States and the related implementation of Council Directive 2006/88/EC.* OIE Bulletin, 2011. **3**: p. 51-52.
84. Arzul, I., et al., *Evidence for interspecies transmission of oyster herpesvirus in marine bivalves.* Journal of General Virology, 2001. **82**(4): p. 865-870.
85. Arzul, I., et al., *Detection of oyster herpesvirus DNA and proteins in asymptomatic Crassostrea gigas adults.* Virus research, 2002. **84**(1-2): p. 151-160.
86. Davison, A.J., et al., *A novel class of herpesvirus with bivalve hosts.* Journal of General Virology, 2005. **86**(1): p. 41-53.
87. Boklund, A., et al., *The European Food Safety Authority (EFSA) Panel on Animal Health and*

Welfare. Epidemiological analyses of African swine fever in the European Union (November 2017 until November 2018). EFSA Journal, 2018. **16**(11): p. e05494.
88. Lynch, S., et al., *A previously undescribed ostreid herpes virus 1 (OsHV-1) genotype detected in the pacific oyster, Crassostrea gigas, in Ireland.* Parasitology, 2012. **139**(12): p. 1526-1532.
89. Roque, A., et al., *First report of OsHV-1 microvar in Pacific oyster (Crassostrea gigas) cultured in Spain.* Aquaculture, 2012. **324**: p. 303-306.
90. Dundon, W.G., et al., *Detection of Type 1 Ostreid Herpes variant (OsHV-1 μvar) with no associated mortality in French-origin Pacific cupped oyster Crassostrea gigas farmed in Italy.* Aquaculture, 2011. **314**(1-4): p. 49-52.
91. Jenkins, C., et al., *Identification and characterisation of an ostreid herpesvirus-1 microvariant (OsHV-1 μ-var) in Crassostrea gigas (Pacific oysters) in Australia.* Diseases of Aquatic Organisms, 2013. **105**(2): p. 109-126.
92. Hwang, J., et al., *Ostreid herpesvirus 1 infection in farmed Pacific oyster larvae Crassostrea gigas (Thunberg) in Korea.* Journal of Fish Diseases, 2013. **36**(11): p. 969-972.
93. Gittenberger, A., M. Voorbergen-Laarman, and M. Engelsma, *Ostreid herpesvirus Os HV-1 μVar in Pacific oysters Crassostrea gigas (Thunberg 1793) of the Wadden Sea, a UNESCO world heritage site.* Journal of fish diseases, 2016. **39**(1): p. 105-109.
94. Jee, B.Y., et al., *Detection of Ostreid Herpesvirus 1 from adult Pacific oysters Crassostrea gigas cultured in Korea.* Fisheries and aquatic sciences, 2013. **16**(2): p. 131-135.
95. Mortensen, S., et al., *Summer mortalities and detection of ostreid herpesvirus microvariant in Pacific oyster Crassostrea gigas in Sweden and Norway.* Diseases of Aquatic Organisms, 2016. **117**(3): p. 171-176.
96. Martenot, C., et al., *Detection of different variants of Ostreid Herpesvirus 1 in the Pacific oyster, Crassostrea gigas between 2008 and 2010.* Virus research, 2011. **160**(1-2): p. 25-31.
97. Martenot, C., et al., *Detection of undescribed ostreid herpesvirus 1 (OsHV-1) specimens from Pacific oyster, Crassostrea gigas.* Journal of invertebrate pathology, 2015. **132**: p. 182-189.
98. Bai, C., et al., *Emerging and endemic types of Ostreid herpesvirus 1 were detected in bivalves in China.* Journal of invertebrate pathology, 2015. **124**: p. 98-106.
99. Garcia, C., et al., *Descriptions of Mikrocytos veneroïdes n. sp. and Mikrocytos donaxi n. sp.(Ascetosporea: Mikrocytida: Mikrocytiidae), detected during important mortality events of the wedge clam Donax trunculus Linnaeus (Veneroida: Donacidae), in France between 2008 and 2011.* Parasites & vectors, 2018. **11**(1): p. 119.
100. Batista, F.M., et al., *Sequence variation in ostreid herpesvirus 1 microvar isolates detected in dying and asymptomatic Crassostrea angulata adults in the Iberian Peninsula: Insights into viral origin and spread.* Aquaculture, 2015. **435**: p. 43-51.
101. Institute, P.S. *Shellfish Aquaculture: Learn More About the West Coast Shellfish Industry.* Available from: http://pacshell.org/on-the-farm.asp.
102. Harris, J., *Pacific oyster, Crassostrea gigas (Thunberg, 1793).* Aquatic Invasive Species Profile. Aquatic Invasion Ecology, 2008: p. 1-12.