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Veterinary Services

Strategy and Policy

Center for Epidemiology and Animal Health

Hazard Identification: Salmonid Alphavirus (SAV)

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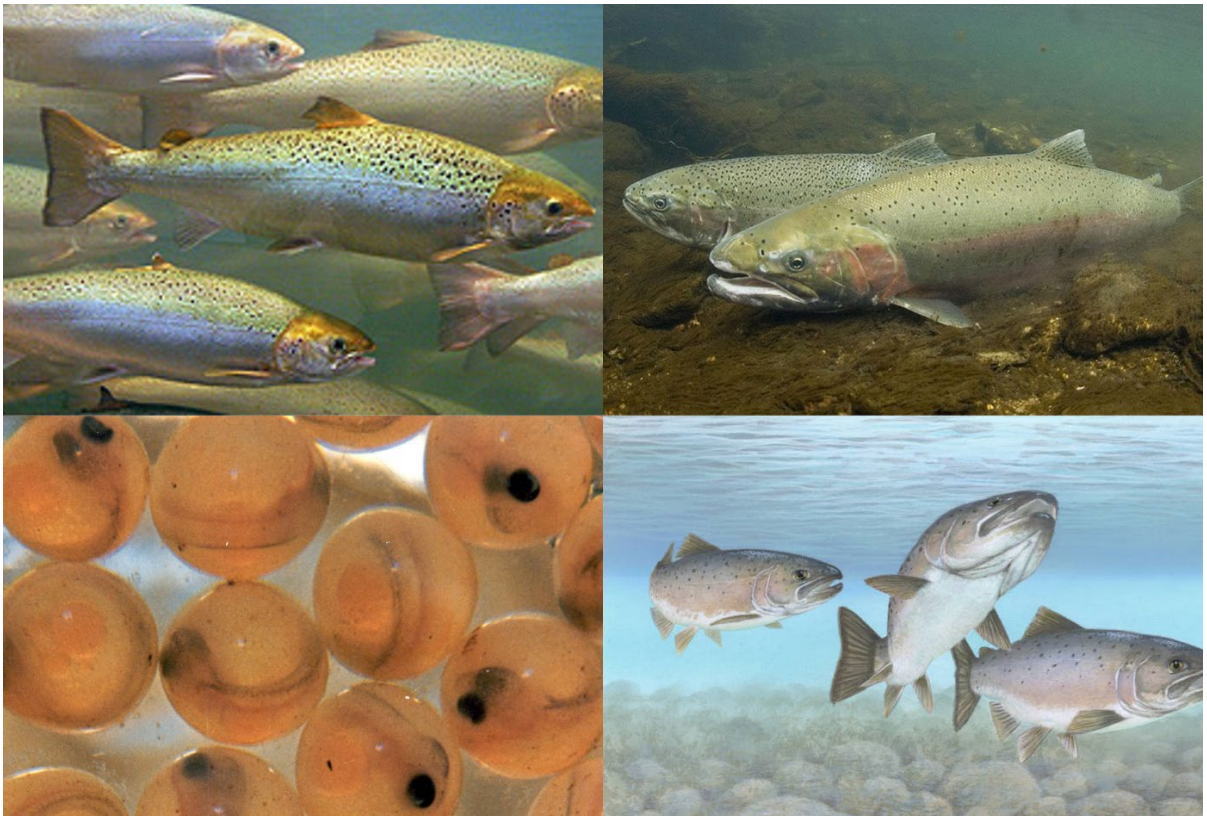

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Introduction

USDA APHIS VS CEAH was asked to generate a Hazard Identification for salmonid alphavirus (SAV). Hazard identification is a process used to identify hazards (biological, chemical, or physical agents) in an animal that may result in adverse consequences in susceptible populations.[1] The hazard identification process is also used to identify pathogenic agents that may be associated with importation of a commodity (live animals, products of animal origin, genetic material, biological products, or pathological material).[1] The hazard must be relevant to the imported species, and it must be determined if the hazard is a) present in exporting countries; b) present or absent in the importing country; c) a notifiable disease or subject to control or eradication in the importing country.[1]

Subjects within the scope of this document include a description of the hazard (SAV), identification of susceptible fish species and the geographic distribution of the hazard, and a summary of the epidemiology of the hazard. To conduct this hazard identification, we referenced World Organisation for Animal Health (WOAH) resources, subject matter expert consultation, and available published data and literature relative to SAV epidemiology. Knowledge and data gaps were present that affected complete evaluation of some tenets of this hazard identification document.

This document follows:

- The WOAH Handbook on Import Risk Analysis for Animals and Animal Products import risk analysis framework, which is accessible via a link in Appendix, Table 1.[2]
- WOAH criteria for determination of host species susceptibility as described in the WOAH Aquatic Animal Health Code and the OIE ad hoc Group on Susceptibility of Fish Species to Infection with OIE Listed Diseases (Appendix, Table 1).[3, 4]
    - Fish species described in published literature that do not meet these criteria or in which infection was inferred using diagnostic methods that are not validated according to WOAH protocols are not included in this assessment. Briefly, species susceptibility to a pathogen requires that:
        - the experimental transmission is consistent with natural pathways of infection,
        - the pathogen is adequately identified, and
        - the presence of the pathogen in the host constitutes an infection.
- Standards in the WOAH Manual of Diagnostic Tests for Aquatic Animals and the WOAH Aquatic Animal Health Code (Appendix, Table 1)[4, 5] regarding improvement of animal health welfare, safe international trade in aquatic animals and their products, and diagnostic approaches to disease diagnosis.
- The understanding that epidemiologically, disease occurs as an interaction occurring in environmental spaces (natural and anthropogenically influenced or derived) where host and pathogen tolerance limits for essential biotic (living) and abiotic (nonliving) environmental factors overlap.[6, 7, 8, 9]

- Definitions of animal agriculture biosecurity as:
  - A series of management steps and practices that identify, prevent, control, and mitigate introduction and spread of pathogens in an animal population, and spread of pathogens to other susceptible populations.[10]
- Measures based on current epidemiological information and understanding of relevant knowledge and data gaps.[11, 12, 13, 14]

Subjects that are not within the scope of this document include an assessment of potential entry and exposure pathways and summaries of likelihood, uncertainty, consequences and overall risk. This document is intended for internal USDA APHIS VS use and distribution to external stakeholders.

Key Findings

- Salmonid alphavirus (SAV) is a World Organisation for Animal Health (WOAH) listed disease.
- SAV is a USDA APHIS listed notifiable disease.
- As of 2025, SAV has not been detected in the United States.
- USDA APHIS and the United States Fish and Wildlife Service (USFWS) do not have regulations or recommendations specific to SAV and the international import or interstate movement of live salmonid fish, eggs, or gametes.
- SAV is present in countries that export susceptible fish and fish products to the United States.
- SAV is highly infectious and can cause large economic losses.
- WOAH identified susceptible fish species include Atlantic salmon, rainbow trout (including steelhead trout), Arctic char, and common dab.
- According to WOAH, Atlantic salmon, rainbow trout, and steelhead trout may serve as reservoir hosts or long-term carriers. Other authors state that evidence is incomplete.
- The reservoir host status of other aquatic animals has not been determined.
- Local transmission is thought to occur via direct transmission and movement of virus in water.
- Long distance transmission is thought to occur via movement of fish and contaminated equipment.
- Risk factors associated with SAV outbreaks include a previous history of SAV infection, high feeding rates, concomitant disease or parasitism, and use of autumn smolts.
- Clinical signs are non-specific.
- During outbreaks, mortality rates range from 3 percent to 50 percent (up to 80 percent).
- Chronic morbidity occurs in surviving fish.
- Diagnosis is dependent upon histopathology and laboratory diagnostic testing.
- There is no treatment. Disease control and prevention is dependent upon vaccination, good farm management, geographical separation of farm sites, and depopulation measures.
- There are gaps in the epidemiology of this disease limiting capability to discern why recurrences happen.

Salmonid Alphavirus

Introduction

Salmonid alphavirus (SAV; family *Togaviridae*, genus *Alphavirus*) is a single stranded, positive-sense, enveloped virus approximately 60–70 nm in diameter. SAV is phylogenetically distinct from mammalian alphaviruses and does not require an arthropod vector for transmission.[5, 15, 16, 17] The genome codes four capsid glycoproteins (E1, E2, E3, and 6K), four nonstructural proteins (nsP1–4), and contains four conserved nucleotide sequence elements (CSEs) and a conserved motif (GDD).[5, 18] Glycoprotein E2 is considered the site of most neutralizing epitopes, while E1 contains conserved, cross-reactive epitopes.[5, 18] SAV is typically divided into six genotypes (SAV1–SAV6) based on phylogenetic analysis of glycoprotein E2 and nsP3.[5, 16, 19] However, recently published whole-genome sequencing of SAV isolated from Ballan wrasse suggests an additional genotype (SAV7).[20, 21] All genotypes are antigenically similar, leading to serological relatedness and antibody cross-reactivity.[5, 22, 23]

Differences in virulence, and environmental/geographical distribution of the genotypes are reported. SAV1 and SAV3 are described as more virulent that the other subtypes.[24, 25, 26] SAV1 and SAV2 are reported to cause disease in freshwater and marine fish, while SAV3–SAV6 are reported to cause disease only in marine species (Table 1, Susceptible Fish Species section).[5] Geographically, SAV1, 2, and 4–6 have been detected in the United Kingdom. In Norway, SAV2 and SAV3 are found in separate enzootic zones.[27, 28, 29, 30]

The WOAH Manual of Diagnostic Tests for Aquatic Animals defines infection with SAV as infection with any SAV genotype.[4, 5] SAV infection causes pancreas disease (PD) in marine-reared Atlantic salmon and steelhead trout, and sleeping disease (SD) in fresh- water reared rainbow trout and Arctic char.[5, 15, 31, 32, 33]

SAV is a foreign animal disease in the United States and is included in the USDA APHIS National List of Reportable Animal Diseases (NLRAD) and National Animal Health Reporting System (NAHRS) lists of reportable diseases (Appendix, Table 1).[34, 35] All animal health professionals, including accredited veterinarians, should coordinate with their State Animal Health Official (SAHO) and Area Veterinarian in Charge (AVIC) upon suspicion or confirmation of NLRAD and NAHRS listed diseases. Confirmed cases of SAV should be reported in accordance with NLRAD Standards. Reporting under NLRAD does not supersede State requirements or notification processes for foreign animal emerging disease incidents or other regulated/high-priority endemic disease reporting requirements (Appendix, Table 1).

SAV is a WOAH listed notifiable disease. Disease notification requirements and requirements for self-declaration of freedom of SAV infection for Member nations are found in the WOAH Aquatic Animal Health Code (Appendix, Table 1).[4, 5] WOAH import/export guidelines specific to SAV are also found in WOAH Aquatic Animal Health Code[4] (Appendix, WOAH Import Recommendations for SAV).

In the United States, there are no Federal regulations specific to SAV and the import of live fish, eggs, or gametes. Pre-import testing for SAV is not specifically required for USFWS import health certification. However, this virus is cultivable in the cell lines that are utilized for other

USFWS import fish health certifications and would likely be detected. The USFWS does require disinfection of salmonid eggs prior to import. Standard disinfection protocols are considered sufficient to prevent surface contamination of eggs.[5, 36] Links to State, Territorial, Tribal, or other local regulation of live fish, eggs, or gametes relative to SAV are found in Appendix, Table 1.

Susceptible Fish Species

Fish species listed in the WOAH Manual of Diagnostic Tests for Aquatic Animals that meet WOAH Aquatic Animal Health Code criteria for listing as susceptible to infection with SAV are found in Table 1.[4, 37]

Table 1. Fish species identified by the World Organisation for Animal Health (WOAH) as susceptible to infection with SAV[4, 37]

Genus species	Common Name	SAV Genotype
Salvelinus alpinus	Arctic char	SAV2
Salmo salar	Atlantic salmon	SAV1, 2, 3, 4, 5, 6
Onchorhynchs mykiss	Rainbow trout, Steelhead trout	SAV1, 2, 3
Limanda limanda	Common Dab	SAV5

Geographic Distribution

SAV is present in Europe and has been detected in countries that export susceptible fish and fish products to the United States. SAV infection in Atlantic salmon (PD) was first described in Scotland and Norway in 1976 and 1989, respectively. Countries reporting presence in Atlantic salmon via the WOAH World Animal Health Information System (WAHIS) database for years that data is available (2014–2019) include Ireland, Norway, and Spain.[17] SAV infection in rainbow trout (SD) was first reported in France in the 1990s, and has subsequently been reported in Croatia, Germany, Italy, Spain, and the United Kingdom (England, Scotland).[33, 38, 39] Search of the WOAH WAHIS database did not identify any reports of SAV in rainbow trout from 2014–2019. The literature reports one SAV detection in farmed Arctic char in Austria in 2018[32]; however, there are no WAHIS database reports relative to Arctic char.[17] As of 2023, SAV has not been detected in United States. In 1987, Kent and Elston published a report of a PD-like event in farmed Atlantic salmon in Washington state.[40] Gross and histopathological changes were suggestive of PD; however, no etiological agent was identified via diagnostic testing.[18, 40] This is the only report of a PD-like condition outside Europe.[18]

Public Health

SAV is not a zoonosis. There are no threats to human health.

Epidemiology

In this section, the epidemiology of SAV in natural host species is summarized. Many of the epidemiological factors, including environmental, pathogen and host factors, associated with SAV are poorly described or understood.

Host Characteristics

Susceptibility to SAV has been most comprehensively documented in Atlantic salmon and rainbow trout (including steelhead trout).[41] SAV infection in these economically important species is associated with mortality losses, chronic morbidity, poor growth, reduced production, carcass downgrading, and economic losses to aquaculture.[5]

Rainbow Trout

All life stages are susceptible to infection; however clinical disease and mortality occur with greatest frequency in fingerlings (10–16 grams).[33] Older fish may exhibit clinical signs of SD or may be subclinically infected.[42] Steelhead trout exhibit clinical signs of PD.[15]

Atlantic Salmon

All Atlantic salmon and steelhead trout life stages are susceptible to infection; however, PD is typically observed in first year smolts after transfer from freshwater to marine pens.[24, 43, 44] According to Kristoffersen et al. (2009), autumn smolts are at greater risk for SAV infection.[45] Occurrence of outbreaks in a given area appears related to the density and proximity of net pens, and local spatiotemporal and hydrological factors.[13, 46, 47] Differences in susceptibility among Atlantic salmon family groups have been observed (such data is not available for steelhead trout).[5, 21, 48]

Arctic Char

Arctic char is a cold-water salmonid species native to the circumpolar north that has been cultured for aquaculture purposes globally, including in Canada.[32] SAV2 infection, described as SD, was first reported in farmed Arctic char in Austria in 2018.[32]

Common Dab

SAV2 infection in wild common dab was first reported in 2010.[49] Subsequent surveys in Scotland and Ireland identified SAV1, 2, and 5 prevalence rates in this species ranging from 3.3 percent to 25 percent.[21, 43, 50, 51] In 2014, common dab derived SAV5 was cultured in a salmonid cell line.[21, 51] Phylogenetic studies suggest that transmission of SAV4 between common dab and farmed Atlantic salmon have occurred.[52] This species does meet WOAH criteria required to confirm species susceptibility.[3]

Other Wild Caught Flatfish Species

SAV has been detected in other wild-caught marine flatfish (Ballan wrasse, European plaice, long rough dab) in Scotland and Ireland (the Scottish sea, and the Irish and Celtic seas, respectively).[21, 49, 51] Published whole-genome sequencing of the SAV isolated from an asymptomatic Ballan wrasse suggests an additional subtype (SAV7). [20] Detections of SAV in these flatfish species is well reported in the literature; however, the role of these species in the epidemiology of SAV has not been determined. As of 2023, the WOAH criteria for species

susceptibility have not been met for any of these fish.[3]

Potential Reservoir Hosts

Recurrence of SAV in sea- and fresh-water aquaculture facilities and SAV introductions into farmed salmon from unknown sources have been documented, suggesting the presence of reservoir hosts.[21] SAV has been detected in wild flatfish; however, the significance of the detections and the capability of these fish species to serve as reservoir or accidental hosts is not known.[45, 51] SAV has been recovered from sea lice collected from Atlantic salmon during PD outbreaks; however, viral replication and transmission capability have not been demonstrated.[15] The potential for crustacean and mollusc species to function as reservoir or accidental hosts has not been determined. The potential for farmed Atlantic Salmon, rainbow trout, and steelhead trout to function as reservoir hosts has not been determined. In farmed Atlantic salmon and rainbow trout at all production stages, SAV infection results in a brief viremia, followed by development of humoral immune responses.[53] Following the viremic period, viral RNA is detectable in individual fish by reverse transcription-polymerase chain reaction (RT- PCR) and virus isolation.[41, 53, 54] Some authors and WOAH state that these findings, and reports of repeated occurrences of SAV at farm sites, are supportive evidence for long-term carrier or reservoir host status.[5, 41, 53, 55] Other authors report that these finding may only represent low levels of residual RNA remaining in host tissues after infection, that the host's immune response is significant enough to prevent recrudescence of the disease, and that evidence to confirm a long-term carrier status is incomplete.[49, 54, 56]

Environmental Characteristics

Many of the extrinsic environmental factors (e.g., dissolved oxygen; presence of other infectious agents and parasites; salinity; suspended organic matter; ultraviolet radiation; water currents; wind) that may be associated with the epidemiology of SAV are not well described.[41, 55, 57] In natural conditions, the temperature range associated with SAV occurrence is 9–15 °C/48.2–59 °F.[38] Extrinsic factors associated with aquaculture (e.g., biosecurity, environmental controls, feeding regimens, fish movement, handling and sorting of fish, health management, management practices, movement and sharing of boats, equipment, and personnel, population density, proximity to fish processing, proximity of net pens and farms, stocking density, vaccination, and other factors) also affect SAV introduction, occurrence, and duration of infection.[41, 52] The capability for SAV to persist in biofilms, organic matter and sediments has not been confirmed.

In the laboratory, optimal growth of SAV in cell culture occurs at 10–14 °C/50–57.2 °F.[38] Differences in optimal growth rates among serotypes within this temperature range have been reported.[38, 58] Infectivity (capability of virus to infect cells) is maintained at temperatures up to 37 °C/98.6 °F.[38, 59] Virus survivability in sterile water, organically loaded salt water, and cell culture ranges from 5.7, 35, and 56 days at 10 °C/50 °F, 20 °C/68 °F, and 4 °C/39.2 °F, respectively.[5, 47, 51, 52, 60] SAV isolated from cell culture and in serum/plasma samples remains viable for years without a significant decline in virus titer when stored at -80 °C/-112 °F.[5] It has been reported that infectivity is lost at or below pH 3.0 and is reduced at pH 11.0.[38]

Pathogen Characteristics

SAV is highly infectious and causes large economic losses in countries where it is highly prevalent. However, information specific to infectious dose, pathogenic mechanisms, virulence factors, how long SAV maintains infectivity is limited.[57] Jarungsriapisit (2016) and Moore (2017) reported that 7 $TCID_{50}$ L^{-1} (50 percent tissue culture infective dose per liter) of SAV3 in seawater is sufficient to induce infection in Atlantic salmon smolts challenged by bath immersion (6 hours immersion in static water).[21, 57, 61] The molecular determinants of virulence have not been identified but appear to be SAV subtype variable. A small number of cell culture studies suggest that genome replication, transcription efficiency, cell receptor binding, and amino acid substitutions in the E2 glycoprotein are associated with virulence and activation of severe inflammatory responses that generate severe pathological damage in infected fish.[62]

Transmission

Transmission of SAV in natural environments is not fully described because many factors associated with transmission (e.g., shedding rate, environmental conditions such as dilution, wind and current strength and direction) have not been determined.[57] Experimentally, viral shedding from infected fish coincides with the viremic period of infection.[41, 63] Virus is shed into the water in feces and mucus.[24, 63, 64] In farmed rainbow trout, it is reported that SAV is transmitted directly from infected resident or introduced rainbow trout or via virus present in the water column, and indirectly by contaminated equipment and personnel.[5, 16, 38, 44] In Norway, transmission among farmed Atlantic salmon is thought to occur via self-sustaining direct transmission events that lead to disease outbreaks and virus present in the water column.[21, 29, 65]

Hydrodynamic, spatiotemporal, and statistical transmission models suggest that ocean currents and water contact time between farms are the variables that best correlate with local PD outbreaks.[18, 44, 47, 66, 67, 68] Long distance outbreaks are thought to occur primarily through the transport or introduction of infected live farmed fish.[44, 66, 67, 68] However, identification of phylogenetically related SAV isolates in marine salmon farms separated by large geographical distances, unexplainable outbreaks, and recurrence of PD in fallowed Atlantic salmon net pens and farms have been reported.[21, 49, 52, 65, 66] It has been suggested that this indicates there are other modes by which the virus enters or moves through the water, or that there other are marine reservoirs through which bidirectional transmission (e.g., escaped farmed Atlantic salmon, other wild fish species, animal vectors) or unilateral transmission (e.g., biofilms, organic matter, sediments) occurs.[21, 49, 50, 51, 52, 65, 66] For example, in 2014, Skjold et al. (2013) reported that SAV can be detected in the lipid film found on the surface of the water around salmon farms and suggested that this oil layer could serve as a protective fomite for SAV transmission between net pens and salmon farms.[44, 55]

Vector transmission of SAV has not been demonstrated. SAV has been detected by RT-PCR in salmon lice during SAV outbreaks.[5, 69] However, transfer of SAV from salmon lice to susceptible fish has not been reported.[5, 21, 43, 69] Other potential methods of SAV introduction include farm management activities (e.g., fish movement and handling, shared equipment and other fomites, lack of biosecurity measures to prevent transmission between sites), fish slaughter practices, and the use of unpasteurized fish, fish meal or fish products in feed.[21] Sufficient evidence for vertical transmission in rainbow trout and Atlantic salmon is lacking. [5, 29, 52, 55, 70]

Clinical Signs and Pathogenicity

Viremia precedes development of clinical signs.[63] During viremia, a substantial quantity of virus is detectable in the serum.[5] Primary target organs include the heart and pancreas; however, virus is also found in brain, kidney, spleen, gills, mucous, and feces.[5, 28] Subclinically infected fish exhibit no clinical signs of disease. When clinical signs do occur, they are not pathognomonic.[32, 39] Initially fish exhibit decreased appetite. As the disease progresses, clinical signs include anorexia, exophthalmos, lethargy, swelling of the abdomen, decreased and slow swimming activity, and “sleepy behavior” (inactivity and laying on their sides on the bottom of enclosures).[15, 16, 32, 38, 39] Increased numbers of fecal casts may be observed. In later stages of the disease growth and rate of gain are reduced.[15] Fish surviving infection appear stunted, slender, and have poor body condition.[15] Differential diagnoses include infectious pancreatic necrosis (IPN), heart and skeletal muscle inflammation disease (HSMI), cardiomyopathy syndrome (CMS), and nutritional myopathies.[5]

Morbidity and Mortality

The duration of SAV outbreaks range from 1–32 weeks.[5, 25, 53] Increased mortality rates typically begin 1–2 weeks after the onset of an outbreak. Mortality rates are affected by virus subtype, and host (fish species, age, overall health), environmental (season, temperature, water quality), and anthropogenic factors (farm management, husbandry, and biosecurity).[5, 24, 27] Cumulative mortality at the farm level typically ranges from 3 percent to 50 percent.[5, 27, 41] However, rates may approach 80 percent or greater if populations are stressed or concurrent disease or parasitism is present.[15] Chronic morbidity may be observed in fish that survive outbreaks.[15, 29]

Treatment

There is no treatment. According to the literature, cumulative mortality may be reduced during outbreaks by minimizing handling and cessation of feeding.[5] Preventative vaccines are commercially available in countries where SAV is present, and have been shown to reduce the risk of infection, viral shedding, cumulative mortality during outbreaks, and downgrading of carcasses at slaughter.[5, 63] Atlantic salmon breeding programs in Ireland and Norway have demonstrated some success in introducing increased SAV resistance.[5, 48]

Diagnostic Testing

Gross pathological findings in Atlantic salmon and rainbow trout are not pathognomonic and include ascites, exophthalmos, petechial hemorrhages in tissues, reddening of the pancreatic area near the pyloric caeca, scale pocket edema, and yellow mucoid content in the gastrointestinal tract. Pale heart muscle or cardiac ruptures may be present.[5, 15] Histopathological changes develop sequentially. Inflammatory cell infiltration and necrosis of exocrine pancreatic tissues are the first lesions to appear. Within two weeks post-infection inflammatory cell infiltration and myocarditis are observed in the heart. At approximately three weeks, inflammatory myositis is present in skeletal muscles.[15, 71] Late in the disease pancreatic peri-acinar and skeletal muscle fibrosis or regeneration may be detected. Occasionally, inflammatory lesions in the peripancreatic fat, and eosinophilic cytoplasmic granules in the kidney are observed.[5, 15, 18]

Diagnostic tests to confirm SAV infection include virus culture and isolation, and PCR assays. WOAH recommended diagnostic tests and protocols for SAV specimen selection, sample collection, transport, and handling are available in the WOAH Manual of Diagnostic Tests for Aquatic Animals, and the WOAH Aquatic Animal Health Code.(Appendix, Table 1).[4, 5] In the United States, confirmatory testing at the National Veterinary Services Laboratories (NVSL) is required following first detections. Samples should be collected and submitted under the direction of State and Federal authorities via guidelines provided by NVSL.[72] Relevant information, including sample submission instructions are in the Appendix, Table 1.

Prevention and Control

Risk factors associated with SAV outbreaks in farmed fish include a previous history of SAV infection, high feeding rates, concomitant disease or parasitism, and use of autumn smolts.[5, 28, 45, 68] In Norway, where SAV is endemic, a combination of vaccination, avoidance of farm practices that increase stress (frequent movement of fish, overhandling, overcrowding), stringent biosecurity, depopulation measures, and geographical separation of net pens and farm sites are used to reduce the occurrence of PD outbreaks.[29, 63] Other preventative husbandry practices include acquisition of fish, eggs, and gametes from SAV-free sources, generational segregation of fish, prompt removal of sick and dead fish, regular cleaning of tanks and net pens, fallowing of farm sites, prevention and control of other parasites and pathogens, and use of site-dedicated equipment and personnel.[5] If use of site-specific equipment is not practical, equipment should be thoroughly cleaned and disinfected before use. Thorough cleaning and disinfection of ponds, raceways, net pens, and equipment followed by fallowing should implemented as control measures following outbreaks.[5] Fish processing is described in published literature as a potential pathway for pathogen introduction.[5, 13] Risk of exposure is proportional to the proximity of processing facilities to hatcheries and fish farms (inland and marine). Ideally processing plants should be located as far as possible from fish farming sites. Processing effluent, solid and sludge wastes should be disinfected and disposed of using methods to prevent pathogen introduction.

Commercially available disinfectants containing alcohol ethoxylate, iodine, potassium peroxymonosulfate (Virkon S™ Lanxess, Cologne France), and quaternary-based compounds (e.g., Virex®, Diversey Global, Fort Mill, North Carolina, USA) with efficacy against other alphaviruses are effective in inactivating SAV.[5, 36, 73] Ultraviolet light, temperatures greater than 60 °C/140 °F, and pH extremes (less than or equal to 4.0, equal to or greater than 12.0) are also reported as effective. [5, 36, 55] The presence of organic matter decreases the effectiveness of disinfectants; therefore, surfaces should be cleaned prior to application of the disinfectant.[36] Standard egg disinfection protocols are considered sufficient to prevent surface contamination of eggs.[5, 36]

Many countries utilize import/export regulations and recommendations in effort to limit or control the risk of SAV introduction. A summary of WOAH import/export guidelines specific to SAV, United States regulations and other regulatory information related to aquaculture in the United States is summarized in the Appendix.

Summary

SAV is an economically important WOAH-listed viral disease affecting marine-reared (Atlantic salmon, steelhead trout) and freshwater-reared (rainbow trout) food fish. The most pronounced consequences of SAV are reduced fish welfare, high morbidity, and mortality, reduced feed conversion ratios, reduced growth and gain in affected fish, and reduced carcass quality. Impacts associated with outbreaks include the costs of outbreak mitigation and control which result in local economic and labor effects. SAV is a WOAH listed disease; therefore, introduction and outbreaks of SAV are likely to have national economic consequences relative to trade.

In regions where SAV is endemic, control of disease occurrence is difficult once introduction has occurred. Reoccurrence of disease has been reported in marine and freshwater fish farms after outbreak mitigation and site fallowing. Currently there are gaps in the epidemiology of this disease that limit capability to discern why recurrences happen. In marine settings, SAV has been detected in some wild fish species, leading to speculation that wild reservoir hosts may be present in the environment. In both marine and freshwater settings, presence of chronically infected farmed fish, or presence of biofilms, organic matter, or other environmental niduses have been considered potential sources of SAV reintroduction. SAV is a WOAH-listed reportable pathogen. Therefore, detection of SAV in cultured fish stocks in the United States would likely result in significant trade impacts. Best practices to prevent introduction of SAV into aquaculture include development of policies that would ensure live fish, eggs and gametes are imported from SAV-free sources and that importation complies with the guidelines described in the WOAH Aquatic Animal Health Code.[4]

Limitations

In this hazard identification the characteristics and epidemiology of SAV in susceptible hosts were summarized using available information collected from WOAH resources, subject matter experts, and available published peer-reviewed materials. Knowledge gaps and limitations identified during the data and literature review process included:

- Some factors associated with the epidemiology of SAV are not fully described or known.
- The reservoir status of susceptible fish species is not fully elucidated.
- The reservoir or transmission host status of other aquatic species (crustacean, mollusc, copepod, other fish species) has not been definitively determined.
- Information specific to virus infectious dose, pathogenic mechanisms, virulence factors, how long SAV maintains infectivity is not fully described.
- Transmission of SAV in the field is not fully described because many factors associated with transmission (e.g., shedding rate, environmental conditions such as dilution, wind and current strength and direction) have not been determined.
- Currently gaps in the epidemiology of this disease limit capability to discern why recurrences of disease at specific farm sites or disease epizootics happen.

Appendix

Tables

Table 1. Links to manuals, websites, and other resources relevant to salmonid alphavirus (SAV).

Topic	Link
National Veterinary Service Laboratory National Animal Health Laboratories	USDA APHIS | Diagnostic Testing at the NVSL USDA APHIS | General NVSL Information USDA APHIS | Laboratory Information and Services USDA APHIS | Laboratories
USDA APHIS National Animal Health Reporting System (NAHRS)	USDA APHIS | National Animal Health Reporting System (NAHRS)
USDA APHIS National List of Reportable Animal Diseases (NLRAD)	USDA APHIS | National List of Reportable Animal Diseases
USDA APHIS Veterinary Services and State authorities	Federal and State Animal Health (usaha.org) USDA APHIS | Contact Veterinary Services
World Organisation for Animal Health (WOAH) 2017 OIE Report of the Meeting of the OIE ad hoc Group on Susceptibility of Fish Species to Infection with OIE Listed Diseases	a-ahg-susceptibility-of-fish-september-2019.pdf (woah.org)
World Organisation for Animal Health (WOAH) 2022 WOAH Aquatic Animal Health Code	Aquatic Code Online Access - WOAH - World Organisation for Animal Health
World Organisation for Animal Health (WOAH) 2022 WOAH Manual of Diagnostic Test for Aquatic Animals	Manual Online Access - WOAH - World Organisation for Animal Health
World Organisation for Animal Health (WOAH) World Animal Health Information System (WAHIS) database	World Animal Health Information System WAHIS - WOAH - World Organisation for Animal Health
World Trade Organization, Sanitary and Phytosanitary Measures	WTO | WTO Agreements Series: Sanitary and Phytosanitary Measures
The United Nations Code of Conduct for Responsible Fisheries based upon UNCLOS and other international laws.	International Agricultural Law and Organizations Aquaculture Overview - National Agricultural Law Center (nationalaglawcenter.org)
FAO Aquaculture Regulatory Frameworks	AQUA-CULTURE REGULATORY FRAMEWORKS (fao.org)
United States Fish and Wildlife Importation Guidelines	Steps for Importing Salmonids into the United States of America | U.S. Fish & Wildlife Service (fws.gov) Information for Importers & Exporters | U.S. Fish & Wildlife Service (fws.gov) CFR-2016-title50-vol1.pdf (govinfo.gov) Help Center Articles - Do I Need a Permit? (servicenowservices.com)
USDA APHIS Import permit information	USDA APHIS | Fish, Fertilized Eggs, and Gametes
USDA APHIS International Regulations (IREGS) website	USDA APHIS | Animal and Animal Product Export Information) Import/Export Requirements for Aquaculture Products (fdacs.gov)

Table 2. Countries for which USDA APHIS has a negotiated export health certificate that can be used to ship live salmonid fish, eggs, and gametes, and their requirements for testing for salmonid alphavirus (as of 2023)

Country	Salmonid Alphavirus Freedom Testing Required
Argentina	No
Armenia	No
Austria	No
Belarus	No
Belgium	No
Bosnia-Herzegovina	No
Brazil	Yes
Bulgaria	No
Canada	Yes
Chile	Yes
China	No
Croatia	No
Cyprus	No
Czech Republic	No
Denmark	No
Estonia	No
Finland	No
France	No
Georgia	Yes
Germany	No
Greece	No

Hungary	No
Ireland, Republic of	No
Isle of Man	No
Israel	Yes
Italy	No
Kazakhstan	No
Kyrgyzstan	No
Latvia	No
Lithuania	No
Luxembourg	No
Malaysia	No
Malta	No
Mexico	No
Morocco	No
Netherlands	No
New Zealand	No
North Macedonia	No
Norway	No
Peru	Yes
Poland	No
Portugal	No
Romania	No
Russian Federation	No

Serbia	No
Singapore	No
Slovakia	No
Slovenia	No
South Africa	Yes
Spain	No
Sweden	No
Switzerland	No
Taiwan	Yes
Turkey	No
Turks and Caicos Islands	No
Ukraine	No
United Arab Emirates	Yes
United Kingdom/ Great Britain	No

Table 3. Countries in which presence of EHN have been reported historically (wild and or farmed fish species) in the WOAH WAHIS database from 2010 through 2022. [17]

Country	Years Reported	Fish Population	Occurence code
Bangladesh	2014–2015	D, W	Disease limited to one or more zones
Ireland	2014–2022	D*	Disease present
Melilla	2017–2018	D, W	Infection/Infestation
Norway	2016–2023	D*	Disease present
Spain	2014–2018	D, W	Infection/infestation limited to one or more zones
	2019–2020	D*	Disease limited to one or more zones
	2021–2023	D*	Disease present
United Kingdom	2014–2015	D*	Disease limited to one or more zones
	2016–2022	D*	Disease present

*No data provided for wild fish populations

Regulatory Information Associated with Salmonid Aquaculture

International Laws Regulating Seas and Fisheries

A comprehensive summary of all international laws regulating seas and fisheries is beyond the scope of this document. Briefly, the United Nations (UN) plays a significant role in the development of international laws. The 1982 United Nations Conference on the Law of the Sea (UNCLOS) sets offshore territorial boundaries that establish zones of exclusive economic and fisheries rights for coastal nations. This is the de facto set of guidelines for the world's oceans.[74] Some nations have not ratified this convention, resulting in different international laws among nations affecting aquaculture. The UN has also developed a Code of Conduct for Responsible Fisheries based upon UNCLOS and other international laws.[74, 75] The Food and Agriculture Organization of the United Nations (FAO) Legal papers Online: Aquaculture Regulatory Frameworks[76] also provides information summarizing significant issues related to the development and implementation of aquaculture regulatory frameworks.

Regulatory Information Associated with United States Salmonid Aquaculture

Marine and inland salmonid aquaculture systems are regulated by Federal, State, and when applicable State, local, and Tribal governments.[77, 78] At the Federal level, "aquaculture" is defined in the National Aquaculture Act of 1980 as "the propagation and rearing of aquatic species in controlled or selected environments."[74, 79] This act calls for development of a National Aquaculture Development Plan identifying aquatic species that have significant potential for culturing on a commercial or other basis by the Secretary of Agriculture, Secretary of Commerce, and the Secretary of the Interior.[74, 80] The act also contains recommendation for aquaculture research and development, technical assistance, design and management of facilities, and coordination of national activities and resolution of legal and regulatory constrains affecting aquaculture.[74, 81, 82] The Joint Subcommittee on Aquaculture was created by enactment of the National Aquaculture Act and amended in 1985 with intention to increase effectiveness and productivity of Federal aquaculture research, transfer, and assistance programs.[74]

Federal agencies with aquaculture regulatory oversight include the Department of Health and Human Services (DHHS) Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the National Oceanic and Atmospheric Administration (NOAA), the United States Coast Guard (USCG), the United States Department of Agriculture (USDA) Animal Plant and Health Inspection Service (APHIS), the United States Army Corps of Engineers, the United States Department of the Interior (USDI) Bureau of Ocean Energy Management (BOEA), the USDI United Fish and Wildlife Service (USFWS).[74, 77, 78]

Marine farms must comply with regulations found in the Clean Water Act[83], the Endangered Species Act[84], the Fish and Wildlife Coordination Act[85], the Magnuson-Stevens Fishery Conservation and Management Act[86], the Marine Mammal Protection Act[87], the National Environmental Policy Act[88], the National Marine Sanctuaries Act[74, 77, 89, 90, 91] Federal agencies and regulations specific to inland aquaculture include many of the agencies described above, with exclusion of agencies specific to marine aquatic systems.

State and within State (county and local) governments regulate aquaculture activities that are permitted or licensed at the community level.[92, 93] Generally, permits address building, community level marketing, processing and trade, fish disease testing and import, fish species certification relative to wildlife management, waste discharge, water use, and zoning.[74, 93, 94] Regulations are not uniform among States and can vary within State based on the geographic location of the aquaculture facility (coastal, inland, wetland, offshore), and associated local environmental impacts.[74, 93, 94] State agencies that provide regulatory oversite include, but may not be limited to, State Departments of Agriculture, Fish and Wildlife, and Natural Resources.[74, 92, 95] Some States may require development of aquaculture-specific Best Management Practices designed to enhance farm biosecurity, production and minimize environmental impacts.[95, 96, 97] For example, Atlantic salmon farming operations Maine participate in the Global Aquaculture Alliance Best Aquaculture Practices program and the Maine Aquaculture Association Code of Practice, Bay Management and Biosecurity programs.[95, 98] As of October 2021, Maine also provides Aquaculture Operational Standards for Land-based Recirculating Aquaculture Systems (RAS).[99].

Regulatory Information Associated with International Trade

The Word Organisation for Animal Health

The World Organisation for Animal Health (WOAH) 2022 OIE Aquatic Animal Health Code describes international standards for protecting aquatic animal and public health.[4] Standards related to the establishment of restrictions designed to prevent introduction of animal health hazards by importing countries are included in these provisions. These standards are based on the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures.[100, 101] The SPS agreement outlines several provisions that Member countries must consider when establishing import restrictions. Members must determine the level of transmission risk, animal health measures, and biosecurity standards required to manage disease risks among live animals and animal products within the country. The level of protection deemed appropriate by a Member should be sufficient to protect human, animal and/or plant health or life within its territory. Member countries must ensure that their sanitary and phytosanitary measures to not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail. Members cannot seek import restrictions that are not equivalent to those established domestically, or apply restrictions in a manner constituting a disguised restriction on international trade.[100, 101]

WOAH Import Information Specific to SAV

WOAH import guidelines relative to SAV are found in the 2022 OIE Aquatic Animal Health Code, which is available via the link in the Appendix, Table 1. Briefly, when:[4]

1. Importing aquatic animals or aquatic animal products from a country, zone, or compartment declared free from infection with SAV. The importing country's Competent Authority should require that the consignment be accompanied by an international aquatic animal health certificate issued by the exporting country's Competent Authority. The international aquatic

animal health certificate should state that, on the basis of the procedures described in 2022 OIE Aquatic Animal Health Code, Chapter 10.4, Articles 10.5.5., 10.5.6., 10.5.7., and 10.5.8., the production site of the aquatic animals or aquatic animal products is a country, zone, or compartment declared free from infection with SAV.

2. Importing aquatic animals for aquaculture from a country, zone, or compartment NOT declared free from infection with SAV. The importing country's Competent Authority should assess the risk in accordance with the 2022 OIE Aquatic Animal Health Code, Chapter 2.1., and consider the following risk mitigation measures:
    a. If the intention is to grow out and harvest the imported aquatic animals, the aquatic animals should be delivered directly to a quarantine facility and held there for the life span of the animals. Before leaving quarantine (either the original quarantine facility or after biosecure transport to another quarantine facility) the animals should be humanely killed and processed into one or more of the aquatic animal products described in the 2022 OIE Aquatic Animal Health Code, or products authorized by the Competent Authority. All transport water, packaging materials, equipment, effluents, and wastes must be treated to inactivate SAV in accordance with 2022 OIE Aquatic Animal Health Code Chapters 4.4., 4.8., and 5.5.
    b. If the intention is to establish a new stock for aquaculture, the exporting country should identify potential source populations and evaluate their aquatic animal health records; test the identified source populations in accordance with 2022 OIE Aquatic Animal Health Code, Chapter 1.4., and select a foundation population (F0) of aquatic animals with a high health status for infection with SAV. The importing country should import the F0 population into a quarantine facility and test for SAV in accordance with 2022 OIE Aquatic Animal Health Code, Chapter 1.4., to determine suitability of the F0 population as broodstock. A first generation (F1) population should be reared in quarantine under conditions that are conducive to the clinical expression of SAV infection. During this period, sampling and testing of the F1 populations for SAV should be performed in accordance with 2022 OIE Aquatic Animal Health Code, Chapter 1.4., and 2022 OIE Manual of Diagnostic Tests for Aquatic Animals, Chapter 2.3.6. If SAV is not detected in the F1 population, it may be defined as free from SAV infection and may be released from quarantine. IF SAV is detected, the F1 population should not be released from quarantine and should be killed and disposed of in a biosecure manner in accordance with 2022 OIE Aquatic Animal Health Code, Chapter 4.8.
3. Importing aquatic animals intended for use in authorized laboratories or zoos from a country, zone, or compartment declared free from infection with SAV. The importing country's Competent Authority should ensure that the consignment is delivered directly to and held in quarantine facilities in the authorized laboratories or zoos. All transport water and ice, equipment, containers and packaging material, facility effluents, wastes and animal carcasses should be treated to ensure inactivation of SAV, or disposed of in a biosecure manner in accordance with 2022 OIE Aquatic Animal Health Code, Chapters 4.4., 4.8., and 5.5.
4. Importing disinfected eggs for aquaculture from a country, zone, or compartment that is NOT declared free from SAV infection. Prior to importation, the importing country's Competent Authority should assess at minimum, the likelihood that the water used during disinfection of

the eggs is or may be contaminated with SAV, and the prevalence of SAV infection in the broodstock (including evaluation of results of testing milt and ovarian fluid). If it is determined that importation is acceptable, the importing country's Competent Authority should mitigate risk of SAV introduction by requesting that the eggs be disinfected prior to importation in accordance with recommendations in 2022 OIE Aquatic Animal Health Code, Chapter 4.5., and that during the interval between disinfection and importation, the eggs do not contact with anything that may impact their health status. The importing country's Competent Authority should require that the consignment of eggs be accompanied by an international aquatic animal health certificate issued by the exporting country's Competent Authority certifying that the risk mitigation procedures were conducted. The importing country's Competent Authority should also consider internal measures such as additional disinfection of the eggs upon arrival in the importing country.

The United States

National Import Information

The United States Fish and Wildlife Service (USFWS) defines fish, including salmonids, as wildlife. This definition describes wildlife as "any wild animal, alive or dead, whether or not bred, hatched or born in captivity, and any part, product, egg, or offspring thereof."[102, 103] Per the Lacey Act of 1900, importation, and transportation of salmonid fish (live or dead), eggs, and gametes into the United States and its territories or possessions is injurious or potentially injurious to the welfare and survival of wildlife or wildlife resources of the United States, the health and welfare of human beings, and the interests of forestry, agriculture and horticulture.[103, 104, 105] These designations place importation and transportation of live salmonid fish, eggs, and gametes under the purview of USFWS which issues permits under wildlife laws and treaties at international, national, and regional levels.[106]

All live (or dead) uneviscerated fish, live fertilized eggs, or gametes of salmonid fish are prohibited entry into the United States for any purpose except by direct shipment. Imports must receive prior written approval from the USFWS Director. Requirements for importation are available in detail in the National Archives and Records Administration, Code of Federal Regulations (CFR), Title 50: Wildlife and Fisheries.[103] Briefly, persons engaged in importation or exportation of wildlife must obtain an import/export license prior to importing or exporting a shipment of wildlife.[103] Shipments must be accompanied by a United States Title 50 Certification Form completed in the country of origin by a USFWS-certified aquatic animal health inspector. This form is valid for six months after date of issue and certifies that the fish stocks from which the shipments originated have been tested for infectious hematopoietic necrosis virus (IHNV), infectious pancreatic necrosis virus (IPNV), Oncorhynchus masou virus (OMV), Viral hemorrhagic septicemia virus (VHSV).[104] Eggs must be disinfected within 24 hours prior to shipment using specific protocols described in CFR, Title 50, and water used for shipping must be derived from pathogen-free water.[103] The USFWS does not require testing of imported live salmonids, eggs, or gametes for SAV.

Imported live salmonid fish, eggs, and gametes arriving at a designated port of entry must be cleared by a USFWS officer prior to department of Homeland Security (DHS) United States Customs and Border Protection (USCBP) clearance and release.[103, 105, 106] Upon release live

fish, eggs, and gametes may be transported and possessed in captivity without a permit.[103] The live fish, eggs, and gametes may not be released into the wild except by a State wildlife conservation agency or persons with prior written permission from such agency.[103] In the absence of such documentation shipments are not released, and the fish, eggs, or gametes remain under detention subject to seizure and delivery to appropriate regional USFWS agents or directors for disposition as described in CFR, Title 50.[103, 105] Links to relevant information associated with USFWS regulations are found in Table 1 of this Appendix.

The United States Department of Agriculture (USDA) Animal Plant Health and Inspection Service (APHIS) requires import permits for live fish, eggs and gametes from species susceptible to Spring viremia of carp virus (SVC) and Tilapia Lake virus (TiLV).[107] USDA APHIS does not have regulations or recommendations specific to SAV and the international import or interstate movement of live salmonid fish, eggs or gametes.

National Export Information

Exporters of fish designated as wildlife are required to obtain export permits from USFWS. Shipments must be declared and cleared by USFWS and USCBP at USFWS designated ports.[103, 105, 106, 108, 109] Many countries of import require documentation of animal health by USDA APHIS. Country specific exportation requirements for Aquaculture/Aquatic Animals may be accessed on the USDA APHIS International Regulations (IREGS) website (Appendix, Table 1).[109, 110] Briefly, the United States has negotiated international export health certificates, completed by an accredited veterinarian and endorsed by a Veterinary Services area office, for shipments of live salmonid fish, eggs, and gametes.[110] Some countries for which USDA APHIS has negotiated an export health certificate applicable for shipment of live salmonid fish, eggs, or gametes require testing for SAV prior to export from the United States (Appendix, Table 2).

State Import and Export Information

USFWS and USDA-APHIS do not have interstate regulations or recommendations specific to SAV and the movement of live salmonid fish, eggs, or gametes. State, Tribal, and local governments may have importation regulations, including requirements for disease freedom testing; however, regulation and requirements among these entities may vary. Information may be accessed via individual State Departments of Agriculture, State Departments of Natural Resources (or similar agencies), or the State Veterinarian.[109, 111, 112, 113]

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