## Self-declaration of historical freedom from Salmonid Alphavirus (SAV) for the United States of America

### 1. Introduction

This article is to formally declare historical freedom from Salmonid Alphavirus (SAV), as defined in the World Organisation for Animal Health (<u>WOAH</u>) *Aquatic Animal Health Code* (<u>Aquatic</u> <u>Code</u>), for the United States of America (USA).

This designation meets all requirements of WOAH self-declarations of historical freedom, except concurrent submission by neighboring countries; however, SAV is not known to occur in <u>Canada</u> or in <u>Mexico</u>, the two countries which share watersheds to varying degrees with the USA. SAV is listed as reportable and absent in Mexico and would fall under emerging disease reporting in Canada.

The USA is considered historically free from SAV and conducts surveillance in compliance with the SAV-specific articles of the *Aquatic Code* (10.5.5) and the WOAH <u>Manual of Diagnostic</u> <u>Tests for Aquatic Animals</u> (2.3.8). This self-declaration is also compliant with the following relevant articles in the Aquatic Code:

- Chapter 1.4
  - o Articles 1.4.4–1.4.8
  - o Article 1.4.12
  - o Article 1.4.15

#### 2. History of absence

### 2.1 SAV has never been detected in the USA

SAV has never been detected in the USA or its surrounding waters. The USA has been an active WOAH member country since 1976. Its responsibility toward consistent and accurate reporting of notifiable diseases is evidenced in regular contributions to the World Animal Health Information System (<u>WAHIS</u>).

#### 3. Compliance with basic biosecurity condition requirements of the WOAH Aquatic Code

### 3.1. The United States of America Competent Authority

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (<u>APHIS</u>) is granted the authority to govern the prevention, detection, control, and eradication of animal diseases under the <u>Animal Health Protection Act</u>, in the <u>Code of Federal Regulations</u> (<u>CFR) Title 7 Chapter 109</u>, where animal is defined as any member of the animal kingdom (excluding humans).

USDA APHIS is the Competent Authority for diseases of aquatic livestock in the USA. USDA APHIS Veterinary Services (VS) houses the Chief Veterinary Officer who serves as the <u>USA's delegate</u> to <u>WOAH</u>. The U.S. National Oceanic and Atmospheric Association (<u>NOAA</u>), the U.S. Fish and Wildlife Service (<u>USFWS</u>), the U.S. Food and Drug Administration (<u>FDA</u>), the U.S. Environmental Protection Agency (<u>EPA</u>), and other Federal, State, and Tribal entities with

aquatic animal jurisdiction work jointly to expand outreach, surveillance, response, and legislation to further protect the health of all aquatic animals in the USA.

## 3.2 WOAH-listed diseases are notifiable

USDA APHIS Accredited Veterinarians and APHIS-approved laboratories have an obligation to report the suspicion and detection of any occurrence of listed or emerging diseases to USDA APHIS, the Competent Authority for animal health in the USA. Accredited Veterinarians are required by law (<u>Title 9 CFR Chapter 161.4</u>) to immediately notify Federal authorities of any confirmed or suspected findings of WOAH-listed diseases not known to exist in the USA. APHIS-approved laboratories are required by law to report non-negative results under the authority for laboratory approval. USDA APHIS National List of Reportable Animal Diseases (NLRAD) provides standards for the reporting of suspect or confirmed cases of FADs, program diseases, or diseases not known to exist in the United States. Currently, all States are required to report FADs and evidence of emerging domestic animal diseases to USDA APHIS.

USDA APHIS develops and maintains case definitions for WOAH-listed diseases and other diseases of concern. These case definitions are required under the National List of Reportable Animal Diseases (<u>NLRAD</u>) and follow WOAH guidance.

## 3.3 Training and awareness programs

USDA APHIS administers the National Veterinary Accreditation Program (NVAP) for veterinarians licensed to practice in the USA. This program accredits and authorizes veterinary practitioners to work cooperatively with Federal veterinarians and State Animal Health Officials. Regulations in 9 CFR 161 outline the requirements and standards for Federally Accredited Veterinarians, which include disease reporting. Specifically, Accredited Veterinarians are required to immediately report to the Federal and State Animal Health Official all diagnosed or suspected cases of a communicable animal disease for which USDA APHIS has a control or eradication program, and all diagnosed or suspected cases of any animal disease not known to exist in the USA. Accredited Veterinarians must renew their accreditation every three years. State veterinary licenses also require continuing education earned through courses, meetings, conferences, and online trainings specific for animal health and drug use. Veterinary accreditation is required to conduct certain activities at the State and Federal levels, including the issuance of international export health certification of aquatic animals. There are approximately 70,000 Accredited Veterinarians in the USA and its Territories. The NVAP provides four training modules specifically devoted to aquatic animal health. Additionally, the American Fisheries Society (AFS) provides certification for Aquatic Animal Health Inspectors to serve in aquatic animal health professional roles, not all of whom are veterinarians. AFS certified Aquatic Animal Health Inspectors also conduct health inspections for private and public aquaculture entities.

Awareness and education for producers, veterinarians, and the public, is distributed through various methods including the USDA APHIS website for <u>aquaculture</u>, aquaculture industry webpages, extension and outreach services, industry meetings, professional conferences, and technical documents and resources. Many State aquaculture associations have designed training modules specifically for producers. Examples include <u>Aquaculture/Fish Culture –</u> <u>University of Wisconsin-Stevens Point (uwsp.edu); Fish Health Medicine Program – AAFV</u>

<u>FishVets.org</u>; <u>Aquaculture Training (themaineaquaculturist.org)</u>; <u>Educational Resources | Maine Aquaculture</u>; and <u>Workforce Development – Aquaculture Research Institute (umaine.edu)</u>.

USDA APHIS administers training and professional development to Federal and State Veterinarians, Accredited Veterinarians, diagnosticians, animal health technicians, epidemiologists, port veterinarians, foreign veterinary medical officers, USDA APHIS program specialists, and others whose responsibilities require <u>updated knowledge of animal disease</u> <u>diagnosis and identification</u>. USDA APHIS conducts annual training for Federal employees in a wide variety of topics, including FAD diagnostics, agriculture emergency response, and animal identification.

### 3.4 Laboratory capacity in the USA

The National Veterinary Services Laboratories (NVSL) serves as the national veterinary diagnostic reference and confirmatory laboratory for foreign and emerging diseases of significant concern for animal health. APHIS also oversees APHIS-approved laboratories to conduct frontline testing of aquatic animal pathogens. APHIS-approved laboratories include the National Animal Health Laboratory Network (NAHLN), which is a nationally coordinated network and partnership of Federal, State, and university-associated animal health laboratories. The NAHLN enhances the capability to diagnose specific endemic and foreign high-consequence livestock pathogens in animals and environmental samples. Aquatic animal pathogens currently covered under the NAHLN are spring viremia of carp virus (SVCV), infectious salmon anemia virus (ISAV) and viral hemorrhagic septicemia virus (VHSV). In addition to the NAHLN, APHIS approval is also required of laboratories conducting diagnostic testing to support export health certification. A list of all APHIS-approved laboratories, accompanied by a summary of the diseases for which the laboratories are approved to test, is maintained and available to the public, as is a map of the NAHLN laboratories, depicted alongside the diseases for which they are authorized to test. In addition, the American Fisheries Society Fish Health Section (AFS FHS) provides guidance and inspection for fish health laboratory guality management/guality assurance. Laboratories conducting tests of wild fish, for domestic movement and stock enhancement, generally follow published guidelines.

### 3.5 Diagnostic tests in the USA

Diagnostic tests available to identify SAV include virus isolation (Fryer, 1994), genomic sequencing, and reverse transcription polymerase chain reaction (RT-PCR). Per the WOAH *Aquatic Manual,* "Isolation of field isolates of SAV in cell culture can be challenging." To enhance detection, the *Aquatic Manual* recommends the use of multiple cell lines; e.g., CHSE-214 (Chinook salmon embryo; Lannan et al., 1984), BF-2 (bluegill fry; Wolf, 1966), FHM (fathead minnow; Gravell, 1965), and/or EPC (epithelioma papulosum cyprinid; Fijan et al., 1983), with multiple passages, and/or subsequent testing of apparently negative cultures by immunofluorescence or RT-PCR. Diagnostic sensitivity of virus isolation varies by the stage of infection in the infected fish, with optimum virus recovery during the initial viremic stage. Thus, screening with molecular tests and/or risk-based selection strategies are the preferred surveillance methods (e.g., focused on mortality events or routine moribund/morbidity sampling).

### 3.6. Measures to prevent the introduction of SAV into the USA

USDA APHIS is granted the authority to govern the prevention, detection, control and eradication of animal diseases under the <u>Animal Health Protection Act</u>. The USFWS administers the <u>Lacey Act</u> which specifies that it is unlawful for any person to market, transport or acquire fish or wildlife in violation of any law, treaty, or regulation of the USA.

The Code of Federal Regulations (CFR), Title 50, part 16.13 (1) requires health certification of live or dead un-eviscerated fish from the family Salmonidae, including pathogen testing by viral cell culture, prior to import; and (2) requires surface disinfection of salmonid eggs prior to import. Though SAV testing is not specifically required for USFWS import health certification, SAV is cultivable in the cell lines that are utilized (EPC, CHSE-214). Any suspicion or detection of SAV in the exporting country would trigger reporting of this WOAH-listed pathogen by Member Countries (WAHIS). A 10-year review (2012 through 2022) of USA port authority records identified that all imports of SAV susceptible species were imported into the USA from WOAH Member Countries.

Additionally, Title 50 (CFR) part 16.13 broadly prohibits release of *any* fish species into surface waters without express permission of the receiving State, and APHIS restricts the movement of diseased animals under <u>Title 9 (CFR) 71.2</u> and <u>71.3</u>.

State regulations guide additional aquatic animal health and import requirements locally.

#### 4. Passive Surveillance in the USA

#### 4.1. Broad oversight and extent

The reach and functionality of the USA's passive surveillance infrastructure for aquatic animal health is evidenced by several data sources. As described in Section 3.2, Accredited Veterinarians and APHIS-approved laboratories are required to report suspect or confirmed cases of FADs, or diseases not known to exist in the USA. Suspect cases compatible with a WOAH-listed pathogen trigger Federal investigations, guided by USDA APHIS VS policy. Between 2018 and 2023, USDA APHIS conducted 62 disease investigations in aquatic species, 46 of which were FAD investigations (23 in SAV-susceptible species). Regional laboratories also investigate disease concerns upon producer request. APHIS-approved laboratories conducted over 570 finfish diagnostic investigations in 2022 and 2023 combined.

Reach and functionality is also evidenced through data collected by natural resource agencies. The <u>USFWS operates 70 public hatcheries</u> distributed throughout the country which rear over 100 species of fish, including rainbow trout (*Oncorhynchus mykiss*) and Atlantic salmon (*Salmo salar*), for conservation or stock enhancement. All facilities are inspected, with fish tested biannually, and any unexplained mortality events are promptly investigated. The USFWS conducted over 285 disease investigations in public hatcheries in 2022 and 2023 combined. State natural resource agencies similarly conducted over 1,310 disease investigations in public hatcheries in 2022 and 2023 combined. These tallies, though not species-specific, further demonstrate an active and broad disease detection capacity for aquatic animals in the USA. USFWS testing follows guidance in the <u>Aquatic Animal Health Policy</u> and <u>Handbook</u>, and employs cell lines with some sensitivity to SAV (BF-2, FHM, EPC, or CHSE-214).

The APHIS National Animal Health Reporting Systems (<u>NAHRS</u>) voluntary database compiles State-level designations of pathogens of concern from participating State Animal Health Officials and captures information on both farmed and wild animals. Between 2018 and 2023, 44 States formally designated SAV as absent. Furthermore, APHIS collects reports of endemic pathogen detections through NAHRS and direct reports from laboratories, State and Federal agencies, and private producers. Between 2018 and 2023, several non-SAV disease reports were made in SAV-susceptible species, including at least 16 in rainbow/steelhead trout (*Oncorhynchus mykiss*). SAV has never been reported in NAHRS's history (established in 2004).

**Figure 1.** U.S. Fish and Wildlife Service refugia with managed populations of SAV-susceptible species. Maps generated by USFWS.



Arctic char (Salvelinus alpinus)

Rainbow trout (Oncorhynchus mykiss)

Atlantic salmon (Salmo salar)



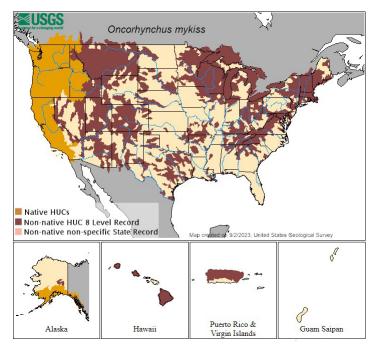
#### 4.2. Conditions are conducive to clinical expression

The WOAH Aquatic Code lists the following species as susceptible to SAV: Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), and common dab (*Limanda limanda*). The species that occur naturally in the USA include Atlantic salmon (*Salmo salar*), Arctic char (*Salvelinus alpinus*), and rainbow trout (*Oncorhynchus mykiss*). These species are also farmed in the USA. USFWS refugia holding SAV-susceptible species are distributed widely throughout the USA (Figure 1). The common dab (*Limanda limanda*) is not known to occur in the USA.

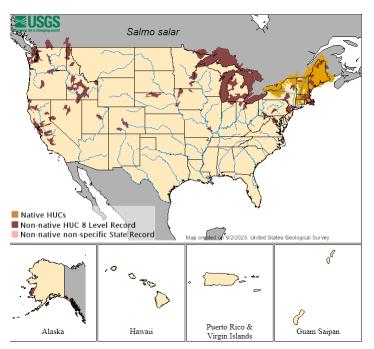
SAV is a cold-water pathogen with infectivity occurring between 48 and 59°F (9 and 15°C) in natural settings (Villoing et al., 2000), and shown to be reduced at 61°F (16°C) in experimental trials (Jarungsriapisit et al., 2020). SAV subtypes 3 through 6 are known to occur in marine settings; subtypes 1 and 2 occur in both marine and freshwater settings. Prevalence is often high, with reported morbidity and mortality rates exceeding 50 percent.

Clinically conducive seasonal environmental conditions are common to much of the range of susceptible species in the USA. Rainbow trout (*Oncorhynchus mykiss*; Figure 2), survive in waters up to 70°F (21°C), but prefer temperatures between 55 and 64°F (12.8 and 17.8°C). Atlantic salmon (*Salmo salar*; Figure 3) prefer temperatures between 39 and 54°F (3.9 and 12.2°C), and Arctic char (*Salvelinus alpinus*; Figure 4) prefer temperatures below 55°F (12.8°C).

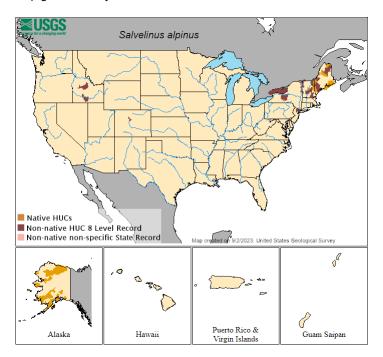
**Figure 2.** Geographic range data for rainbow trout (*Oncorhynchus mykiss*) in the USA. *HUC* stands for hydrologic unit code. Map generated by U.S. Geological Survey (USGS).



**Figure 3.** Geographic range data for Atlantic salmon (*Salmo salar*) in the USA. *HUC* stands for hydrologic unit code. Map generated by USGS.



**Figure 4**. Geographic range data for Arctic char (*Salvelinus alpinus*) in the USA. *HUC* stands for hydrologic unit code. Map generated by USGS.



Environments and species present in the USA would allow for observing SAV-induced morbidity or mortality if the pathogen were to occur. Additionally, Federal agency data supplement this historical absence argument in wild populations (Section 5).

## 4.3. USA populations are not vaccinated for SAV

There are no licensed or approved vaccines being used in the USA for SAV. The current list of USDA approved aquatic animal vaccines is found <u>here</u>.

### 5. Structured Surveillance

## 5.1 USFWS wild fish health survey

USFWS conducts routine surveillance on wild fish populations and maintains a <u>database</u> which catalogues testing data by species, year, and location. Since 1997, and through 2023, USFWS's regional health programs (currently 7 mainland centers) have tested over 9,708 wild-caught fish of SAV-susceptible species (1,954 from 2021 through 2023). <u>Screening protocols</u> consist of pooling tissue from one to five fish and testing by virus isolation, with follow-up molecular testing as needed for virus detection and identification. Though SAV is not specifically mentioned, recommended cell lines have some sensitivity to SAV replication. Regional USFWS programs also periodically <u>conduct additional testing that is not captured in the wild fish database</u>. The described totals above are conservative estimates of national testing effort. SAV has never been detected.

# 5.2 Other Federal testing efforts

USDA and other Federal agencies periodically conduct structured surveillance for research or regulatory purposes. Notable examples target different pathogens but use screening tests with some sensitivity to SAV detection. A long-running <u>example</u> is the Northwest Indian Fisheries Commission (NWIFC), which in conjunction with the State of Washington and USFWS, conducts regional surveillance in hatchery and returning salmonid stocks annually; SAV has never been detected. A broad yet historic example is a USDA APHIS-led (2007 through 2012) surveillance effort focused on VHSV (Gustafson et al., 2014). Twenty-nine States participated in active sampling, which included rainbow trout and Atlantic salmon. The Canadian Food Inspection Agency led a parallel effort in the Great Lakes region of Canada over a similar time frame. SAV was never detected.

# 5.3 State testing efforts

Many States require <u>pre-movement testing</u> for aquatic animals moving inter- and sometimes intra-state. This testing often follows <u>AFS Blue Book</u> standards with virus isolation using cell lines conducive to SAV infection, and typically includes evaluation of 12 to 30 pools of 5 fish. SAV has never been detected. The majority of interstate movement testing is conducted at laboratories that have American Association of Veterinary Laboratory Diagnosticians (<u>AAVLD</u>) certification, International Organization for Standardization (ISO) certification, and/or APHIS approval for aquatic health testing. State natural resource agencies also conduct routine health inspections in their public hatcheries and most follow AFS Blue Book standards.

## 5.4 International movement testing

When required by importing countries, testing for SAV is conducted by APHIS-approved laboratories, who are obligated to report any detections to the Federal and State Animal Health Officials in their region. As of 2023, USDA APHIS has negotiated health certificates for the export of live salmonid fish, eggs, and gametes with around 58 countries; at least 9 of these countries include pre-export testing requirements for SAV.

#### 6. Measures implemented to maintain freedom

The described authorities, passive surveillance, and basic biosecurity conditions have been in place for over a decade and will remain in place for the foreseeable future.

APHIS also recently completed a "Hazard Identification for SAV" and a "Pathways Assessment for Live Salmonid Fish, Eggs, and Gametes Susceptible to Six World Organisation for Animal Health Listed Pathogens," which once released, will provide further guidance on risks and relevant mitigations.

The United States currently has in the rule-making process a proposed Federal rule for the <u>National List of Reportable Animal Diseases</u> (NLRAD), which provides legal obligation to report detections of listed diseases. Also, in the early stages of rulemaking is the Comprehensive Aquaculture Health Program Standards (CAHPS), a system to support and verify aquatic livestock health management for participating producers.

Under the NLRAD, reporting of detections is divided into pathogens that must be immediately reported and those that must be reported monthly. SAV is categorized as a FAD and immediately notifiable, meaning that veterinarians and laboratories must immediately report any suspicion or confirmation of SAV. In turn, APHIS would then submit an immediate notification of confirmed SAV detections to WOAH.

#### 7. References

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