



United States Department of Agriculture

Red Sea Bream Iridoviral Disease (RSIVD) Rapid Risk Assessment

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Strategy and Policy

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Key Results

The estimated risk of red sea bream iridoviral disease (RSIVD) introduction into the United States via live animal (fish) imports is *high* due to:

- Non-specific clinical signs of RSIVD that may delay detection and diagnostic testing
- The reported presence of RSIVD in many countries that export to the United States
- Lack of RSIVD surveillance and reporting in many countries
- The relatively broad host range of RSIV in multiple marine species of fish
- Movements of susceptible live fish species in international and domestic trade
- The potential viability of virus in imported seafood and fish products
- The lack of federal and state regulations limiting importation of potentially infected fish
- Previous introduction of RSVID into the U.S. has occurred

The most likely entry pathways are:

- Apparently healthy, infected fish
- Contaminated ballast water

The most likely exposure pathways include:

- Movement of infected live fish among aquaculture facilities, aquariums, or other facilities
- Exposure via aquatic pathways (infected fish in net pens, infected wild fish) associated with release of contaminated ballast water or infected fish or fish products into waterways

This risk assessment is preliminary and is subject to various limitations, such as lack of:

- Quantitative data regarding the epidemiology of RSVID, including data on specific entry and exposure pathways
- Methods to reliably estimate disease consequences in aquaculture systems
- A nationally representative domestic surveillance program

Background

History

Red sea bream iridoviral disease (RSIVD) is caused by red sea bream iridovirus (RSIV) and results in significant mortality in farmed red sea bream (*Pagrus* spp.) and other cultured marine fish [1, 2]. Currently, the World Organisation for Animal Health (OIE) lists approximately 40 fish species as susceptible to RSIVD. The literature describes additional susceptible species [1]. Knifejaw (*Oplegnathus* spp.) and red sea bream are reportedly more susceptible than other species [1].

Pathogenic iridoviruses of fish (*Iridoviridae*, *Megalocyttivirus*) are genetically classified into three major groups: Red sea bream iridovirus (RSIV) group; infectious spleen and kidney necrosis virus (ISKNV) group; and turbot reddish body iridovirus (TRBIV) group [1-4]. Disease caused by RSIV-group viruses primarily occur in marine fish. Disease caused by ISKNV-group isolates occur in marine and freshwater fish. Disease associated with TRBIV-group viruses appear limited to Asian flounder species [2].

In this document, we use the acronym RSIVD to refer to disease caused by infection with RSIV to concur with the OIE *Manual of Diagnostic Tests for Aquatic Animals* [1]. The acronym RSIV will be used when information specific to the pathogenic agent (the virus, not the disease) is presented.

Distribution

The literature reports that RSIV-group viruses are widely distributed in East and Southeast Asia, including in China, Chinese Taipei, Hong Kong, India, Indonesia, Japan, North and South Korea, Malaysia, Micronesia, Papua New Guinea, the Philippines, Singapore, Taiwan, Thailand, and Timor-Leste [1, 2, 5-11]. Between 2010 and 2016, six mortality events attributed to RSIVD occurred in maricultured Florida pompano (*Trachinotus carolinus*) in the Dominican Republic. The identified RSIV (e.g., referred to as pompano iridovirus or PIV) shared greater than 99 percent nucleotide sequence identity to an RSIV genomic sequence in Japan [12].

In 2018, the United States reported to the OIE an RSIVD detection in imported wild common clownfish (*Amphiprion perideraion*, *A. ocellaris*) and wild lionfish (*Pterosis vilittans*) housed in the same system in a public aquarium. Control measures included quarantine of the facility and depopulation of affected tanks.

Current Regulations

In the United States, there is no requirement for health certification regarding RSIVD for movement of any species, including ornamental fish destined to public and private aquariums.

For U.S. exports, countries requiring pre-export testing and/or statements of health claiming shipment or country freedom from RSIVD include Australia, Israel, Kazakhstan, Korea, Kyrgyzstan, Mexico, the Russian Federation, Taiwan, Thailand, Turks and Caicos, and Vietnam[13].

RSIVD is reportable to the OIE and the U. S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) [1, 3].

Hazard Identification

The complete epidemiology of RSIVD is not fully known.

Transmission appears to be horizontal via cohabitation and water [1, 2]. In affected countries, annual net pen outbreaks are reported when naïve juvenile fish are introduced into pens containing older fish that have survived prior infection [1, 2]. Vector transmission (e.g., mechanical, aquatic lifeforms) has not been confirmed; however, mollusks have been implicated as vectors [1, 14]. Vertical transmission is suspected but has not been confirmed [2, 3, 15]. Viral genomic DNA has been detected in asymptomatic cultured fish and wild fish species adjacent to aquaculture areas. It is unknown if the detections in the cultured fish resulted from exposure to infected wild fish or vice versa. [2, 3].

The incubation period is unknown. Juvenile fish less than 1 year of age are most susceptible [1, 2]. Clinical signs are non-specific and may include anemia, partial to full anorexia, abnormal swimming patterns, coelomic distention, dark coloring, fin erosion, lethargy, pale gills, petechial hemorrhage on the skin and gills, skin ulcerations, and increased respiratory effort [1-3]. Enlarged spleen, kidney, and liver; coelomic transudates; and pale viscera may be noted on necropsy [1, 2]. Concurrent infections (bacteria, parasites, fungi) may be present. Morbidity rates are unknown. Mortality rates are variable by fish species, age, and physiological condition; aquaculture management factors; and water temperature (outbreaks tend to occur at 20 – 32°C / 68 – 89°F [1, 3]. Total mortality occurring within 1 week has been reported.

Testing of moribund fish is preferred for detection of RSIV; deceased fish in advanced stages of decomposition are unsuitable [1]. Tissues such as spleen, kidney, heart, and liver are suitable samples for analysis. OIE guidance suggests that tissue and juvenile fish (<3 cm; limit five animals) may be pooled. Samples should be stored at 4°C / 39°F and submitted for testing within 24 hours [1]. Microscopic identification of abnormally enlarged splenic cells in Giemsa-stained impression smears may be used for presumptive diagnosis [2]. Other diagnostic tests include histopathology, immunofluorescent antibody tests using M10 monoclonal antibody, and polymerase chain reaction (PCR) assays [1, 2]. Virus isolation and culture assays are available; however, sensitivity of culture cell lines is variable and viral titers may decrease through serial passage [2]. There are no serological assays [1]. Corroborative diagnostic criteria and case definitions are found in OIE *Manual of Diagnostic Tests for Aquatic Animals: Chapter 2.3.7: Red Sea Bream Iridoviral Disease* [1].

Control methods currently rely on implementation of farm biosecurity and good management practices. Mitigation practices include stocking with pathogen-free fish, improving farm biosecurity and management practices, disease surveillance testing, improving water quality, and avoiding practices that induce stress (e.g., overstocking, overfeeding) [1, 3]. Experimentally, RSIV-infected fish recovered from infection when housed at low water temperatures (< 18°C / < 64°F) for a minimum of 100 days. Surviving fish were reportedly resistant to RSIV challenge [2]. A killed vaccine is commercially available in Japan for use in red sea bream, striped jack (*Pseudocaranx dentex*), Malabar grouper (*Epinephelus malabaricus*), orange spotted grouper (*E. coioides*) and *Seriola* spp. Efficacy in knifejaw is reported to be variable [1]. No vaccine for RSIVD is approved for use in the United States.

There has been limited testing of seafood, trim, or offal for presence of RSIV. In one study, RSIV could not be detected in randomly sampled whole frozen mackerel [5]. The virus is stable in tissues at -80°C / -112°F; however, viability following freeze/thaw cycles is unknown. The virus can be inactivated at 56°C / 132.8°F x 30 minutes [1]. RSIV genomic DNA has been detected in tissues (spleen, kidney, heart, gills, intestine, caudal fin) of fish surviving experimental infection [2].

RSIV is not a zoonotic pathogen; there is no public health risk.

Entry Assessment

In a rapid risk assessment for animal health, an entry assessment describes the pathway(s) that allow introduction of a pathogen into a particular environment and estimates the probability of that occurring. The entry assessment generally consists of the pathway(s) from the point of origin to the port of entry.

The overall likelihood that RSIVD will enter the United States is *high*, with a *low* degree of uncertainty. The likelihood assessment is based on:

- Reported distribution of RSIVD, including countries that export to the United States.
- Earlier RSIVD detections in the United States in 2018 linked to imports of fish [16]; and
- Lack of regulation regarding imports of ornamental and commercial fish.

Sources of uncertainty in this estimate include:

- Lack of data regarding the stability of RSIV in fish products
- Unknown survival characteristics of RSIV in the environment
- Lack of information regarding infectious dose, susceptible species, and epidemiology of RSIV

- Difficulties ensuring compliance with ballast water requirements; and
- Knowledge gaps regarding efficacy of ballast water treatment on viruses

Potential entry pathways may include:

- Imported live fish (ornamental or commercial)
- Imported seafood for human consumption
- Imported raw fish product
- Contaminated ballast water

Entry via Imports of Live Fish

The likelihood that RSIVD could enter the United States via imports of live fish is *high* with a *low* degree of uncertainty. There are currently no Federal import regulations pertaining to RSIVD. Detections of RSIVD in imported wild-caught ornamental fish, including a previously unknown ornamental species (clownfish) in 2018 demonstrate that this is a viable entry pathway.

Entry via Raw, Frozen, or Chilled Seafood for Human Consumption

The likelihood that RSIVD could enter the United States via imports of seafood products for human consumption is *high* with a *high* degree of uncertainty. The United States imports seafood product from countries that have reported RSIVD presence. Imported seafood is required to be prepared in facilities regulated and inspected by the government of the country of origin and must meet USDA and Food and Drug Administration (FDA) processing requirements (e.g., Seafood Hazard Analysis Critical Control Point Plan). Only apparently healthy fish are to be processed; however, RSIV-infected fish may appear healthy [2], and surveillance testing of processing facilities or product for aquatic animal disease pathogens is not required. There is limited data available regarding the stability of RSIV in seafood. The virus is stable in frozen tissues; however, viability following freeze and thaw cycles is unknown. In one study, RSIV could not be detected in randomly sampled whole frozen mackerel [5].

Entry via Imported Raw, Frozen, or Chilled Fish Product or By-Product

The likelihood that RSIVD could enter the United States via imports of fish product or by-product is *high* with a *high* degree of uncertainty. Waste fish, trim, and offal are imported for use as bait and feed products or ingredients. Importation of these products is generally unregulated and does not include testing for foreign aquatic animal disease pathogens. The volume of such imports is generally unknown.

Entry via Contaminated Ballast Water

The likelihood that RSIVD could enter the United States via ballast water is *high* with a *high* degree of uncertainty. Ballast water has historically been considered a principal source of invasive species introduction in coastal and freshwater systems. Presence of RSIV in ballast waters collected in geographic locations close to North America and in harbor waters of the Port of Los Angeles confirms the viability of this pathway [17-20]. Management of ballast water discharge via ballast water exchange and treatment 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 Ballast Water Management Convention D-2 standards for allowable concentrations of living organisms present in ballast water discharge (organisms (org) >10µm to <50µm in size, concentration 10 org/mL water; organisms >50 um, concentration <10 org/mL water), and microorganisms considered “indicators problematic for ballast water” (*Vibrio cholerae* < 1 colony forming unit (cfu)/ 100mL; *E. coli* < 250cfu/ 100mL; intestinal

enterococci <100cfu/ 100mL) [21-23]. The regulations do not contain stipulations regarding viruses. Vessels that do not discharge ballast water at all, discharge only to shore side facilities, or discharge to water treatment systems that will present little threat are not required to install a ballast water treatment system [24]. Vessels operating in only one Captain of the Port (COPT) Zone are exempted from reporting and recordkeeping requirements [24]. COPT Zones are administrative, are not established using ecological or biological bases, and may not be appropriate boundaries for addressing invasive species [23]. Data are lacking on the efficacy of ballast water treatment on viruses, likely because treatment decreases the concentration of viruses present to levels below the limits of detection achievable by currently available assays [23, 25]. In one study, a metagenomics analysis identified 22 viral families, including herpesviruses, in ballast water samples collected from ports on four different continents [25]. Other studies have reported viral concentrations ranging from 1.0×10^9 to 3.3×10^{11} viral particles/liter in ballast water using epifluorescence microscopy and metagenomics [23].

Exposure Assessment

In a rapid risk assessment for animal health, an exposure assessment describes the pathway(s) that allow exposure of a vulnerable animal or human to a pathogen and estimates the probability of that happening. For purposes of this document, exposure assessment generally consists of the pathway(s) from the port of entry to the vulnerable animal or human.

Potential exposure pathways may include:

1. Live fish and transport water
2. Infected fish in marine net pens, infected wild fish, or other aquatic pathways
3. Improperly discarded imported seafood
4. Use of imported waste fish or fish by-product for bait
5. Exposure via contaminated ballast water
6. Accidental, intentional, or malicious release

Exposure via Imported Live Fish and Transport Water

The likelihood that RSIVD will reach susceptible fish in domestic aquaculture via movement of imported infected live fish and the water used to transport them is *high* with a *low* degree of uncertainty. Infected fish may appear healthy [1, 2]. Transmission appears to be horizontal via cohabitation and water [1, 2]; therefore, transport water could serve as a pathway of introduction if it is transferred with the fish into the recipient facility, not treated prior to disposal, or not disposed of via a water treatment pathway. There are data gaps regarding the length of time that RSIV remains viable in water and the infectious dose required to elicit disease.

Exposure to Infected Fish in Net Pens, Wild Fish, or Other Aquatic Pathways

The likelihood that fish reared in net pens will be exposed to RSIVD is unknown due to the extremely high level of uncertainty and lack of qualitative or quantitative data associated with this potential pathway. It is unclear whether RSIVD detections in cultured fish reared in net pens are the result of exposure to infected fish in the net pens, infected wild fish, or other aquatic pathways. The literature presents conflicting evidence including, but not limited to, published reports of detections of viral genomic RSIV DNA in asymptomatic cultured fish and wild fish adjacent to aquaculture areas [2, 3]; reports of annual net pen outbreaks following introduction of naïve juvenile fish into marine net pens containing older fish that have survived RSIV infection [1, 2]; the hypotheses that transmission via aquatic vectors (e.g., water, mechanical, aquatic lifeforms) may occur [1, 14]; and current lack of knowledge regarding whether

genomic RSIV detections in cultured fish are the result of exposure to infected wild fish or other aquatic pathways, or vice versa.

Exposure via Imported Seafood

The likelihood that RSIVD will reach susceptible farmed fish via imported seafood intended for human consumption is *moderate* with a *moderate* degree of uncertainty. Approximately 40 percent of waste seafood from commercial and consumer sources becomes landfill waste. Landfills are required to monitor ground water for contamination; however, it is unknown how monitoring methods might correlate with the presence of aquatic animal pathogens. Scavenging wildlife (e.g., birds, mammals) may serve as fomites or transmission vectors [28, 29]. Disposition of the remaining 60 percent of waste seafood is generally unknown, but may include composting, disposal in natural water systems, or use as bait or food for aquatic animals. Cooked seafood is unlikely to result in RSIVD exposure unless cooking time and temperatures are less than those described for heat inactivation of the virus (56°C /132.8°F for 30 minutes)[1]. The volume of chilled and frozen fish imported into the United States for commercial processing is generally unknown. The virus is stable in tissues at temperatures lower than those used in seafood processing (-80°C /-112°F) but in one study, could not be detected in randomly sampled imported whole frozen mackerel [5]. Seafood products are not routinely sampled for presence of foreign aquatic animal disease pathogens. Solid waste and effluent streams from fish processing plants are subject to Federal and State guidelines and regulation; however, violations have been reported and contamination of ground water and natural water systems may occur [30-32].

Exposure via Imported Raw Fish Product or By-Product

The likelihood that RSIVD will reach susceptible fish via imported fish product or by-product is *high* with a *high* degree of uncertainty. The quantity of imported whole fish, waste fish, trim, offal, or by-product is generally unknown. Raw seafood, waste fish, trim, and offal are reportedly used for bait in commercial and sport fishing, and as food for captive aquatic animals; however, the frequency of use of such products for these purposes are not known. Imported fish meals are unlikely to contain viable RSIV, as the cooking step in production exceeds the heat inactivation parameters (56°C/132.8°F for 30 minutes) described in the literature [1]; however, this pathway has occurred with other pathogens in other animal species [33]. There is limited research regarding tissue viability of RSIV in frozen tissues; however, in one study, RSIV could not be detected in frozen mackerel [5].

Exposure via Discharged Ballast Water

The likelihood that RSIVD will reach susceptible fish after the virus has entered U.S. waters via discharged ballast water is *high* with a *high* degree of uncertainty. Detection of RSIV in ballast waters collected in waters close to North America and in Port of Los Angeles harbor waters of the confirms the viability of this pathway. Discharged ballast water may contain free virus or virus attached to organic matter and plankton, which may be distributed to susceptible fish populations (wild or cultivated in net pens) via water currents [26, 27]. The likelihood will vary with specific conditions (e.g., location of ballast water discharge relative to the location of susceptible fish populations, dispersal of ballast water discharges in water currents that may result in exposure of susceptible fish, environmental conditions, concentration of plankton, and aquatic vectors) [27]. Transmission is reported to occur via water [1, 2]; however, there are data gaps regarding the length of time that RSIV remains viable in water and the infectious dose required to elicit disease.

Exposure via Intentional or Malicious Release

The likelihood that RSIVD will reach susceptible fish via accidental, intentional, or malicious release of infected fish or tainted seafood or fish by-product is *high* with a *high* degree of uncertainty. Subclinically infected fish may be imported and intentionally placed in commercial aquaculture facilities or aquariums; previous introduction of RSIVD into the U.S. via clown fish imported by a public aquarium has demonstrated the viability of this pathway. Susceptible ornamental fish species may be kept as pets by aquarium hobbyists, and intentional and accidental releases of such fish into natural water systems has been documented [35-38]. Release of such fish into aquaculture systems is plausible if gaps in biosecurity permit access of the public to net pens, ponds, raceways, or other rearing structures. Experimental transmission of a megalocytivirus related to RSIV from dwarf gourami (*Colisa lalia*) to Murray cod (*Maccullochella peelii peelii*) has been documented [39]. Examples of accidental release include use of raw seafood, waste fish, trim, and offal for bait in commercial and sport fishing. Malicious release of tainted materials into aquaculture has not been reported but is plausible.

Consequence Assessment

In a rapid risk assessment, a consequence assessment describes the relationship between the exposures to a pathogen and the various consequences of such exposures. These consequences may be evaluated at the local, regional or national level and include:

- Direct consequences, such as production losses or public health impacts
- Indirect consequences, such as prevention and control costs or trade losses (U.S. exports)

The economic consequences associated with the introduction of RSIVD in the United States cannot be accurately estimated given the knowledge gaps regarding the epidemiology of the disease; the number of affected fish species; data limitations regarding the importation of all susceptible live fish and fish products derived from susceptible species; and lack of surveillance and monitoring for RSIVD in imported and domestically reared food fish.

Direct and indirect consequences associated with RSIVD present in edible seafood appears to be unknown. Iridoviral disease epizootics have not been definitively correlated with commercial food fish trade routes [40]. In 2008, the United States imported over 8,000 metric tons of edible sea bream products. In the first half of 2020, top countries from which the United States imported fish included Greece (\$13 million USD); Japan (\$3.1 million USD); New Zealand (\$3 million USD); and Cyprus (\$600,000 USD), with most of the imports arriving in California, New York, Massachusetts, and New Jersey. In the first half of 2020, the United States exported most of its red sea bream product to the Netherlands (\$877,000 USD), Canada (\$741,000 USD), Belgium (\$169,000 USD), and Germany (\$34,000 USD). Top exporting States included Ohio, Rhode Island, New Jersey, and Wisconsin.

If introduced into the farmed fish industry, it is possible that RSIVD will be spread between domestic susceptible fish populations, and under some circumstances, wild fish populations. The magnitude of the consequences would likely be related to the type of aquaculture system in which the disease introduction occurs. For example, in a closed system, detection of a RSIVD may be more easily observed, containment of the outbreak easier to accomplish, and trace out and trace back easier to document. In this scenario, direct and indirect consequences may be minor. If RSIVD is introduced into open rearing systems (i.e., net pens), it may be expected that the direct and indirect consequences could be significant for aquaculture, wild fisheries, and sport fishing. Ecological consequences could potentially result as well.

The direct and indirect consequences that RSVID introduction may have on the U.S. ornamental fish industry cannot be quantified due to lack of surveillance and monitoring for this disease in imported and domestically reared ornamental fish. An outbreak in imported clownfish imported for display in a public aquarium was successfully controlled by depopulation of the affected fish; therefore, it should be expected that there may be minor immediate direct or indirect consequences to an U.S. ornamental fish producer, hobbyist or aquarium. Given the lack of regulatory requirements regarding RSVID surveillance in imported ornamental fish, it would appear that minor to indiscernable direct and indirect consequences would be associated with importation of ornamental fish. The global ornamental fish industry trade involves approximately 5,000 freshwater and 1,450 marine fish species and an estimated 1 billion animals shipped between more than 100 countries annually [40, 41]. Biosecurity measures and regulations to prevent disease spread are limited in this industry. In 2014, the United States was the leading importer of ornamental fish, while Asian countries were the leading exporter (over 57 percent). Importation of ornamental fish requires a U.S. Fish and Wildlife Services permit, which has no health prerequisites relative to RSVID. In 2018, the estimated value of marine ornamental fish exported to the United States was approximately \$6 million USD. In the first half of 2020, top exporting countries to the United States included Hong Kong, Canada, Brazil, and the United Kingdom. Top importing States included California, Florida, Illinois, and North Carolina. In 2018, the United States exported approximately \$4.5 million USD of marine ornamental fish. In the first half of 2020, top exporting States included Hawaii (\$2 million USD); California (\$800,000 USD), and New York (\$7,000 USD). Top countries receiving U.S. exported fish included Hong Kong (\$900,000 USD), Canada (\$900,000 USD), and the United Kingdom (\$300,000 USD) [41, 43].

Risk Estimation

In an import risk analysis process for animal health, risk estimation is defined as the combination of the exposure pathways and the consequences of exposure.

The overall risks posed by RSVID to the domestic aquaculture industry are:

- *High* for live imported fish and transport water. This is due to the high likelihood of entry and subsequent exposure to susceptible fish. If introduced, RSVID would likely spread among domestic fish populations because of the possibility of subclinical infections in fish and the lack of national surveillance. Consequently, the impacts of introduction and spread may be significant, particularly for top exporting states.
- *Moderate* for imported seafood for human consumption. Although the likelihood of entry is estimated to be high, the likelihood of susceptible fish exposure is estimated to be moderate. If farmed fish are exposed, the impacts of introduction and spread may be significant.
- *High* for imported raw fish, fish products and by-products. Raw fish, fish products and by-products are reportedly used as bait in commercial and sport fishing. If use of these products as bait results in spread among wild fish or exposure to farmed fish in net pens, the impacts may be significant.
- *High* for contaminated ballast water. If contaminated ballast water exposes wild fish or farmed fish in net pens the impact may be significant.

These risk estimates are associated with a *high* level of uncertainty because of data gaps related to the following:

- Epidemiology of RSIVD, including infectious dose, susceptible species, subclinical infection, and incubation period
- Surveillance and detection of RSIVD in countries exporting fish to the U.S.
- Stability of RSIV in fish products
- Survival characteristics of RSIV in the environment
- Efficacy of ballast water treatment on viruses
- Use of fish products and by-products in commercial and sport fishing
- Domestic pathways of potential spread via infected fish in net pens, wild fish, or other aquatic pathways

Limitations

In this rapid risk assessment, we identified primary pathways of entry and exposure and estimated the chances of these events occurring, given our knowledge of RSIVD epidemiology, current production practices, and existing biosecurity measures. To more accurately characterize the risk, a variety of additional information is needed. Some of these needs are discussed below:

1. Virus characteristics: As noted by OIE, many of the characteristics of RSIVD that are relevant to risk analysis, such as survival outside the host, survival in water, and movement patterns in water, are unknown.
2. Susceptible fish: The total number of species susceptible to RSIVD is not definitively known.
3. Characteristics of the ornamental fish industry: The volumes, types, movement patterns, interactions with commercial fish and other characteristics of the ornamental fish industry are unknown. These are needed to estimate any consequences of RSIVD in this industry and to determine the potential impacts an RSIVD outbreak in this sector would have on the commercial fish industry.
4. Regulatory authority with respect to RSIVD: USDA is the Competent Authority for aquatic animal health, including the regulation of aquatic animal diseases of concern. USDA has no regulations regarding imports of ornamental or commercial fish with respect to RSIVD, and this authority would not lie with any other Federal agency. Some States may regulate the importation or movement of fish; however, requirements of RSIVD surveillance are generally not known.
5. Lack of knowledge regarding presence in wild populations.
6. Lack of information regarding disease presence in domestic commercial, ornamental, and wild fish populations due to lack of a national disease surveillance program. Lack of such program also contributes to potential introduction and movement of sub-clinically infected fish into commercial and aquarium aquaculture systems.
7. Lack of information regarding quarantine of imported fish, and on farm or aquarium biosecurity.

Rapid Risk Assessment Defined

A rapid risk assessment is designed to provide a quick approximate estimate of the risk for a pathogen of interest (i.e., the combined likelihoods of entry and exposure and potential consequences, given that the risk event occurs). The objectives include: 1) estimating the likelihood and potential impacts of emerging or evolving animal health threats, and 2) identifying data gaps.

These assessments often have the following characteristics:

- Are performed with limited resources compared to risk assessments or analyses
- Guide additional data collection or more in-depth risk assessments and analyses
- May have limited information on the pathogen
- Discuss the most likely pathways of entry; may not list or evaluate all potential pathways
- Are qualitative in nature and consider the impact of total uncertainty on likelihood and risk ratings
- Do not evaluate potential consequences in detail
- Do not discuss potential impact of future mitigations

Likelihood, Consequence, Uncertainty, and Risk Categories

For this rapid risk assessment, we have assigned qualitative likelihoods for expressing how likely something would occur. We also use qualitative terms for discussing the uncertainty and information quality associated with these likelihoods. Table 1 defines the terminology for expressing likelihoods, Table 2 defines the terminology for expressing uncertainty, Table 3 defines the terminology for expressing consequences, and Table 4 defines the terminology for expressing risk.

Table 1. Definition of likelihood categories

Term	Definition
Negligible	This event would almost certainly never occur
Low	This event would be unlikely to occur
Moderate	This event would be nearly as likely to occur as to not occur
High	This event would be likely to occur
Very High	This event is almost certain to occur

Table 2. Definition of uncertainty levels [42]

Term	Definition
Low	Available data is well supported, reliable, complete, and accessible from multiple sources or published references, and are in general agreement.
Moderate	Data is available, but has high interpretability issues, potential biases, reliability issues, and/or underreporting.
High	Some data is available but may be incomplete, unreliable, from a small number of published sources, and/or demonstrates conflicting evidence. Includes the combination of anecdotal evidence, personal communications, and expert opinion with available published data, if all sources are in general agreement.

Table 3. Definition of consequence levels

Term	Definition
Indiscernible	The consequences of exposure are so low as to be undetectable
Minor	Minor increases in morbidity/mortality and some decreases in production. Effects of exposure are controllable or reversible.
Significant	Morbidity/mortality are great enough to impose moderate production losses. Effects of exposure may not be reversible.
Major	Morbidity and mortality are great enough to threaten the economic viability of the sector for a lengthy period. Effects of exposure may not be reversible.

Table 4. Definition of risk levels

Term	Definition
Negligible	The determination of “negligible risk” suggests that the risk is low enough that it need not be considered, and no further mitigations are necessary.
Low	The determination of “low risk” suggests that although not a strict requirement, resources to further evaluate or mitigate this risk should be considered. A low risk is greater than a negligible risk due to a potential likelihood of occurrence, associated consequences, or a combination of both.
Moderate	The determination of “moderate risk” suggests that the risk is of a sufficient magnitude that measures to prevent or mitigate the risk should be considered. A moderate risk is greater than a low risk due to a greater likelihood of occurrence, greater consequences, or a combination of both.
High	The determination of “high risk” suggests that the risk is of sufficient magnitude that measures to prevent or mitigate the risk are necessary and the consequences will have significant impact at the regional or national level. A high risk is greater than a moderate risk due to a greater likelihood of occurrence, greater consequences, or a combination of both.

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