United States Department of Agriculture

Brief Summary
Preliminary Risk Assessment for Tilapia Lake Virus (TiLV)

June 2019

Key Results: The estimated risks of TiLV introduction to United States (U.S.) tilapia populations via import of live tilapia and tilapia products are:

- *Negligible* for frozen tilapia fillets. This estimate is due to the lack of a biologically plausible pathway that would lead to exposure and the inability of the virus to survive in fillets.
- *High* for imported tilapia fingerlings (young fish), germplasm (e.g., eggs and milt), or the shipping water carrying them. This is due to:
    - The high degree of mortality when infection is present;
    - The lack of knowledge about how TiLV is spread;
    - The lack of regulations associated with the importation of tilapia fingerlings;
    - The lack of a surveillance program in the U.S.; and
    - The lack of a response plan in the U.S. should an outbreak occur

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

- The lack of scientific knowledge available regarding TiLV characteristics and spread patterns;
- The likely lack of surveillance and reporting of TiLV in many countries;
- The lack of knowledge about international and domestic tilapia trade movements;
- The scarcity of quantitative data for the topics listed above; and
- The lack of disease consequence models for aquaculture in general.

These limitations result in a moderate degree of uncertainty in how well these estimates reflect the true risks; as additional information becomes available, these estimates may be modified.

Background

Tilapia are produced in various countries throughout the world. Based on a 2018 report of the Food and Agriculture Organization (FAO) of the United Nations, the top 12 tilapia producing countries include: China, Indonesia, Egypt, Bangladesh, Philippines, Brazil, Thailand, Vietnam, Uganda, Taiwan, Colombia, and Mexico. TiLV was identified and described in 2014; however, it has been linked to mortality outbreaks that occurred in Israel and Ecuador in 2009 (Jansen, Dong et al. 2018; Bacharach, Mishra et al. 2016) and Thailand since 2012 (Dong, Ataguba et al. 2017). Currently, TiLV has been found in Africa, Asia, and the Americas.

Tilapia Lake Virus can cause high mortality in susceptible fish; reported mortality rates have ranged from 10 to 90 percent, with mortality peaking within a few weeks of the start of the outbreak. The mechanism of spread between locations is unknown, but TiLV has been detected in fertilized eggs and yolk sac larvae, as well as in fries and fingerlings (Jansen, Dong et al. 2018).

Results

Entry Assessment

Frozen Tilapia Fillets:

The likelihood that frozen tilapia fillets imported into the United States (U.S.) will contain TiLV is *negligible*, with a *moderate* degree of uncertainty. The likelihood assessment is based on:

- Imported fillets are subject the same regulatory requirements as those for domestically produced fillets. Processors must have a Hazard Analysis and Critical Control Point (HACCP) plan in place, maintain a sanitary environment, and only healthy fish are to be processed (Food and Drug Administration 2017); and
- Fillets from tilapia that are sub-clinically infected with TiLV do not appear to carry the virus after being frozen at -20°C for 14 days (Thammatorn, Rawiwan et al. 2019).

The degree of uncertainty is moderate because:

- There is no definitive evidence the TiLV is present in muscle tissue;
- The extent that importers are complying with Food and Drug Administration (FDA) requirements is unknown; and
- The surveillance systems in frozen tilapia fillet exporting countries was not evaluated in this assessment.

Tilapia Fingerlings, Germplasm, and Shipping Water:

APHIS currently does not have any regulations associated with the importation of tilapia fingerlings, germplasm, or the water in which they are shipped. The likelihood that tilapia fingerlings, germplasm, or shipping water carrying TiLV may enter the U.S. via import is *high*, with a *moderate* degree of uncertainty. The likelihood assessment is based on:

- The use of air freight to import fingerlings or germplasm results in a high likelihood that disease is not detected prior to import should a recently infected country export during the incubation period – increases the likelihood;
- The possibility that fingerlings or germplasm may be in an infected, but undetected state – increases the likelihood, although the reported high mortality rates for fingerlings may reduce this possibility;
- The apparent lack of a requirement to certify that the fingerlings are healthy and disease free – increases the likelihood (U.S. Department of Agriculture 2018);
- The inability to quarantine fingerlings or germplasm at U.S. ports of entry – increases the likelihood;
- The disease is not listed as notifiable disease to the World Organisation for Animal Health (OIE), so there is likely little or no surveillance and reporting of TiLV in many countries; and
- The U.S. was among 40 countries determined to be at “high risk” of TiLV spread as result of importing tilapia fingerlings from Thailand between 2012 and 2017 (Dong, Ataguba et al. 2017).

The degree of uncertainty is *moderate* because:

- There is limited information on the survivability of TiLV in water.
- Transboundary pathways of introduction from affected countries are not characterized.

Exposure Assessment

Frozen Tilapia Fillets:

The likelihood that frozen tilapia fillets carrying TiLV will cause infection in farm-raised tilapia is *negligible*, with a *moderate* degree of uncertainty. The likelihood assessment is based on:

- The lack of a biologically plausible pathway that infected fillets could come into contact with farm-raised tilapia, based on how food waste is processed in the U.S. About 40 percent of fish and seafood harvested becomes waste at the retail and commercial level. Most of this waste is sent to landfills. Landfills are required to undertake various measures to prevent groundwater contamination, such as membranes to protect groundwater and monitoring to ensure that groundwater is not contaminated with landfill liquids (U.S. Environmental Protection Agency 2018). The likelihood that waste tilapia fillets will release TiLV into the environment is negligible due to these procedures.

The degree of uncertainty is *moderate* because:

- Lack of knowledge about TiLV's transmission and survival in environmental matrices;
- Lack of information on potential disposal of tilapia filets waste that could reach U.S. waterways; and
- Lack of information on the feeding of waste to fish in the U.S. aquaculture industry.

In addition, there may some reduction of infectivity during processing and cooking. However, as there is no good information on the degree of infectivity reduction, this aspect is not considered in this assessment.

Tilapia Fingerlings, Germplasm, and Contaminated Shipping Water:

The likelihood that infected tilapia fingerlings, germplasm, or the water they are shipped in, will cause infection in farm-raised tilapia is *high* with a *high* degree of uncertainty. The likelihood assessment is based on:

- Shipments of tilapia between locations has been associated with the spread of TiLV; and
- The high likelihood that TiLV could be present in shipping water, and experimental studies suggesting spread of the disease can occur as a result of contaminated water.

The degree of uncertainty is *high* because:

- Lack of information about how tilapia fingerlings and germplasm move within the U.S.;
- Requirements for Certificates of Veterinary Inspection do not appear to apply to movements of tilapia, nor are there other good sources about these movement patterns;
- As noted in the Hazard Identification section above, spread pathways for TiLV and how it becomes established are still not known; and
- There is currently no surveillance program for TiLV in the U.S.

Consequences

The consequences of a TiLV outbreak in the U.S. could be costly for the tilapia industry, depending on how long it would take to detect and respond to the outbreak. In 2013, the total value of tilapia produced in the U.S. was about $42,527,000, or about six percent of all aquaculture production, with production produced on 181 farms (U.S. Department of Agriculture, 2013). Given the popularity of tilapia with consumers; the dollar amounts, relative proportions, and the number of producers has probably increased over time. Little is known about the movement and potential spread of the virus in the U.S., but industry growth increases the potential magnitude of the consequences of an outbreak, should one occur. This assessment did not address specific trade impacts.

Definitions of Categories

For the purposes of this 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 that will apply for expressing likelihoods and table 2 defines levels of uncertainty.

Table 1. Definition of likelihood categories for risk assessment

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 levels of uncertainty (Based on Mastrandrea, et al., 2010)

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.

Questions or comments on data analysis, contact: CEAH at 970-494-7000
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