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**Center for
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Rapid Risk Assessment for Tilapia Lake Virus (TiLV)

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Key Results

The Center for Epidemiology and Animal Health (CEAH) was requested to assess the risk posed to relevant industries by the introduction of tilapia lake virus (TiLV) via tilapia frozen fillets and live fingerlings. Results of the rapid assessment found:

- *Negligible risk* for **frozen** tilapia fillets. This 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 risk* for tilapia fingerlings (young fish) imported or the shipping water carrying them from outside the United States. 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 a surveillance program in the United States; and
 - The lack of a response plan in the United States should an outbreak occur.

There is a moderate degree of uncertainty associated with these risk estimates due to a lack of information on various aspects of TiLV and tilapia production.

Background

Distribution

Tilapia are produced in various countries throughout the world (Fig 1). Tilapia lake virus was identified in Israel in 2014 (Eyngor et al., 2014). However, it appears to have been present in Thailand at least as early as 2012. Since 2012, TiLV has been found in Africa, Asia, and the Americas (Dong et al., 2017a; Jansen et al., 2018; Al-Hussinee et al., 2019). See figure 2 for confirmed TiLV outbreaks as of August 2018.

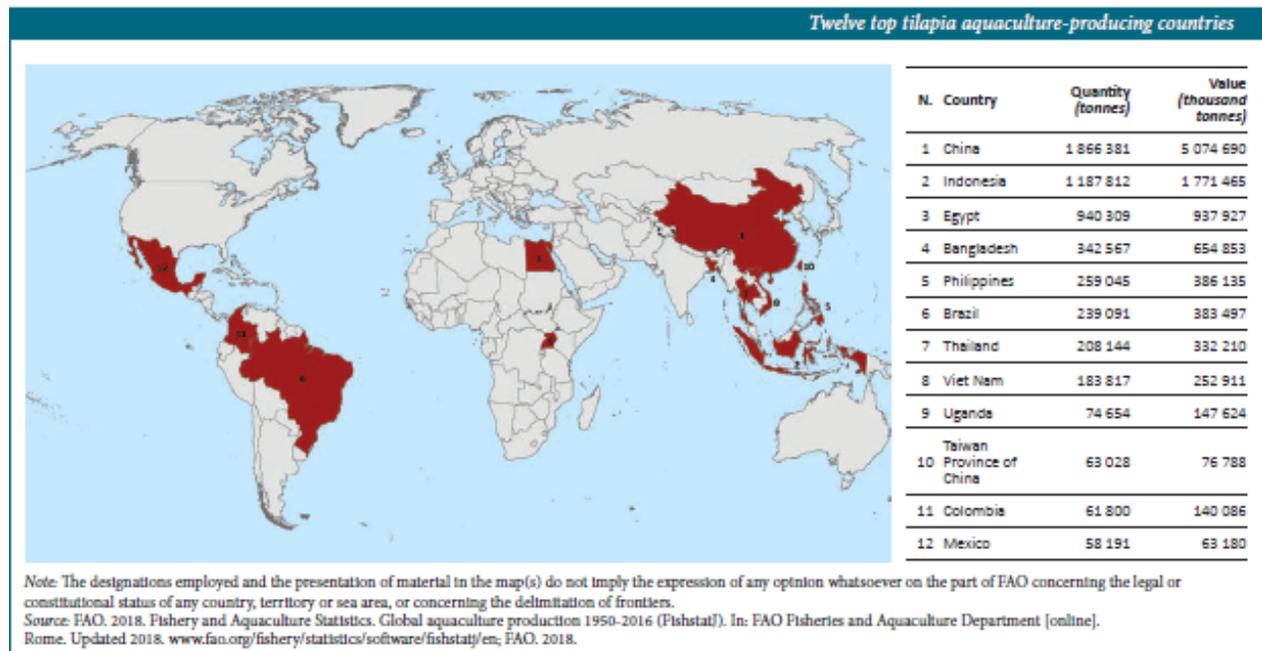


Figure 1. Map showing distribution of top tilapia-producing countries (Food and Agriculture Organization of the United Nations, 2018).

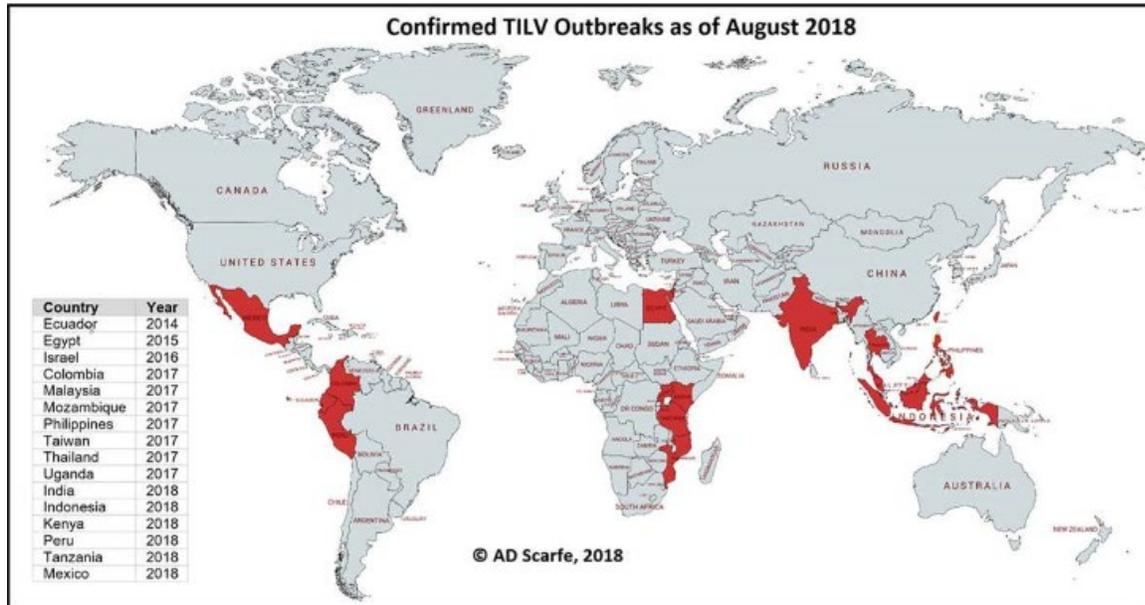


Figure 2. Confirmed TiLV outbreaks as of August 2018 (Tilapia Association of South Africa, 2018).

Hazard Identification

In an import risk analysis process, hazard identification involves identifying the specific pathogen of concern.

TiLV can cause high mortality in susceptible fish; reported mortality rates have ranged from 20 percent to 90 percent, with mortality peaking within 2 weeks of infection. The mechanism of spread between locations is unknown.

Various risk factors have been associated with outbreaks of TiLV. These include:

- Dissolved oxygen
- Water temperature
- Various production practices (Jansen et al., 2018) and
- The physical characteristics of the virus, such as persistence in the environment and vulnerability to virus deactivation measures are unknown (World Organization for Animal Health, [OIE] 2018).

Entry Assessment

In an import risk analysis process for animal health, an entry assessment is defined as a description of the pathway(s) that allow introduction of a pathogen into a particular environment, and an estimate of the probability of that happening. The entry assessment generally consists of the pathway(s) from the point of origin to the port of entry. In this case, we examined:

1. The likelihood that frozen tilapia fillets carrying TiLV will be imported into the United States; and

2. The likelihood that tilapia fingerlings carrying TiLV will be imported into the United States.

Frozen Tilapia Fillets

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

- Imported fillets are subject to the same regulatory requirements as those for domestically produced fillets. Processors must have a Hazard Analysis and Critical Control Point (HACCP) plan in place and maintain a sanitary environment, and only healthy fish are to be processed (Food and Drug Administration [FDA], 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 et al., 2019).

The degree of uncertainty is *moderate* because:

- There is no definitive evidence the TiLV is present in muscle tissue (OIE, 2018);
- The extent that importers are complying with FDA requirements is unknown; and
- The presence and effectiveness of surveillance systems in frozen tilapia fillet exporting countries was not systematically evaluated.

Tilapia Fingerlings

APHIS currently does not have any regulations associated with the importation of tilapia fingerlings. The likelihood that tilapia fingerlings infected with TiLV will be imported into the United States is *high*, with a *moderate* degree of uncertainty. The likelihood assessment is based on:

- The use of air freight to import fingerlings, resulting in the loss of detection time should a recently infected country export during the incubation period, increases the likelihood;
- The possibility that fingerlings 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 of infected but undetected fingerlings entering the United States;
- The inability to quarantine fingerlings at U.S. ports of entry increases the likelihood of infected but undetected fingerlings entering the United States; and
- In one paper on TiLV, the U.S. was identified as being at “high risk” of TiLV spread as result of importing tilapia fingerlings from Thailand between 2012 and 2017 (Dong et al., 2017a).

The degree of uncertainty is *moderate* because:

- There is limited information on the survivability of TiLV in water.
- There is no formal surveillance for TiLV in the United States, so it is unknown if TiLV is present here.

Exposure Assessment

In an import risk analysis process for animal health, an exposure assessment is defined as a description of the pathway(s) that allow exposure of a vulnerable animal or human to a pathogen, and an estimate of the probability of that happening (OIE 2016). The exposure assessment generally consists of the pathway(s) from the port of entry to the vulnerable animal or human. In this case, we will examine:

1. The likelihood that frozen tilapia fillets imported into the United States and carrying TiLV will come into contact with farm-raised tilapia; and
2. The likelihood that tilapia fingerlings will come into contact with farm-raised tilapia.

Exposure Pathways

Spread pathways for TiLV and how it becomes established are still not known. Some potential pathways include:

- Movement via surface water or groundwater
- Movement of infected, but undetected fish
- Movement of contaminated persons, vehicles, or equipment, and
- Movement via birds or wildlife.

There are no confirmed reports of spread via any of these mechanisms. On the other hand, there is no firm evidence that spread via these mechanisms can be excluded.

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 in which infected fillets could come into contact with farm-raised tilapia, based on how food waste is processed in the United States. About 40 percent of fish and seafood harvested becomes waste at the retail and commercial level (Buzby et al., 2014). 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* due to:

- Lack of knowledge about TiLV's physical characteristics as discussed in the Hazard Identification section;
- 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.

Concerns have been raised about tilapia production employees or owners purchasing frozen tilapia fillets for home consumption and causing an outbreak by feeding food waste including frozen tilapia fillets to live tilapia, or by serving as a fomite of infectious virus to live tilapia. The likelihood of this pathway being completed is *negligible*. For this to occur the following pathway would have to be completed:

- The frozen tilapia fillets would have to come from an apparently healthy fish and carry an infectious load sufficient to survive processing and shipment to the consumer;
- The infectious load of virus would have to be carried by the employee, survive transport to the tilapia production facility, and
- Be transferred to live tilapia by feeding frozen tilapia fillets or via fomites in water in sufficient quantities to cause at least one infection in exposed fish.

Although this pathway is estimated to be negligible, there is moderate uncertainty because exposure has occurred when people or equipment move between production facilities without adequate biosecurity measures.

Tilapia Fingerlings and Contaminated Shipping Water

The likelihood that infected tilapia fingerlings, 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 have been associated with the spread of TiLV (Dong et al., 2017a; Dong et al., 2017b; Jansen et al., 2018; OIE 2018; Al-Hussinee et al., 2019); and
- The high likelihood that TiLV could be present in shipping water, as spread of the disease does not require direct physical contact (Eynogor et al., 2014).

The degree of uncertainty is *high* because:

- There is a lack of information about how tilapia fingerlings and germplasm move within the United States;¹
- 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, other spread pathways for TiLV and how it becomes established are still not known; and
- There is no surveillance program for TiLV in the United States.

Consequence Assessment

In an import risk analysis process for animal health, a consequence assessment is defined as describing the relationship between the exposures to a pathogen and the various consequences of such exposures. These consequences include such things as:

¹ While it is known that tilapia, like other fish, move about due to husbandry factors, the extent that these movements are within producer operations (which would tend to keep an outbreak within a single producer) as opposed to between producer operations (which would tend to spread the outbreak to other producers) is unknown.

- Direct consequences, such as production losses or public health impacts; and
- Indirect consequences, such as prevention and control costs or trade losses.

Consequences may be evaluated at the local, regional, or national level.

As the likelihood that contaminated frozen tilapia fillets will cause an exposure is negligible, only the consequences of an exposure resulting from importation of infected tilapia fingerlings will be considered.

As there is no surveillance program for TiLV in the United States, any outbreaks would most likely be detected by increases in mortality in farm-raised tilapia. Once the mortality increase has been detected and reported, it will be necessary to conduct an epidemiological investigation to determine the cause: the mortality increase could be a result of a pathogen or environmental factors. If the cause is a pathogen, tests will have to be conducted to identify the specific one. Meanwhile, the virus may continue to spread and cause outbreaks in other locations. Culture, RT-PCR, and nested RT-PCR have been used for TiLV testing (Tsofack et al., 2017); however, there is no validated TiLV test for use in the United States.

The direct economic consequences of a TiLV outbreak in the United States could be high 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 United States was about \$42,527,000, or about 6 percent of all aquaculture production, and was produced on 181 farms (United States Department of Agriculture, 2013). Given the popularity of tilapia with consumers; the dollar amounts, relative proportions, and the number of producers will probably increase. This will also increase the magnitude of the consequences of an outbreak, should one occur. Specific trade impacts were not addressed in this assessment.

Consequences will also tend to be higher than for “typical” animal diseases due to the lack of:

- A surveillance program, as noted above
- A response plan, and
- An approved TiLV vaccine, though one has been patented (Bacharach, E. and Eldar, A., 2017).

The specific consequences of a TiLV outbreak are not estimated in this assessment due to the lack of information.

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 risk (likelihood combined with consequences) posed by TiLV to the domestic industry is:

- *Negligible* for frozen tilapia fillets. This is due to the negligible likelihood of exposure; and
- *High* for imported tilapia fingerlings (young fish), germplasm (e.g., eggs and milt), and the shipping water carrying them. The risk estimate is based on the difficulties in detecting, responding to, and mitigating potential exposures and the potential for long-term consequences to the tilapia industry. This risk estimate is greater than that reported by the United Nations Food and Agriculture Organization (Food and Agriculture Organization of The United Nations, 2018). This may be due to differing assessments resulting from the considerable uncertainty associated with the source data.

Limitations

To more accurately characterize the risk, a variety of additional information is needed. Specific needs include:

- Scientific knowledge regarding TiLV characteristics and spread patterns
- Knowledge about international and domestic tilapia trade movements
- Disease spread and consequence models for aquaculture in general

These limitations result in some uncertainty in the assessment and final estimation of risk. The overall uncertainty is moderate and implies that the likelihoods and risk estimates could change with additional information.

'Rapid Risk Assessment' Defined

A rapid risk assessment is designed to provide a quick and approximate estimate of the risk (likelihood of entry and exposure, combined with the consequences) for a pathogen of interest. The objectives of a rapid risk assessment include: 1) determining the likelihood and impact of emerging or evolving animal health threats, and 2) identifying data gaps.

These assessments often have the following characteristics:

- Relatively limited information on the pathogen
- Qualitative in nature and do not provide numerical estimates of likelihoods or the variability associated with those likelihoods
- Do not evaluate potential consequences in detail
- Discuss the most likely pathways of entry and do not attempt to list or evaluate all potential pathways
- Serve to guide additional data collection or more in-depth risk assessments if they are needed later
- Do not discuss potential mitigations
- Are performed with comparatively limited resources and short turnaround times compared to a more in-depth/full risk assessment

Likelihood, Uncertainty, Consequence, and Risk Categories

For the purposes of this risk assessment, we have assigned qualitative likelihoods for expressing how likely it is that 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 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 (Mastrandrea et al., 2010)

Term	Definition
Low	Available data are well supported, reliable, complete, and accessible from multiple sources or published references, and are in general agreement.
Moderate	Data are available, but have high interpretability issues, potential biases, reliability issues, and/or underreporting.
High	Some data are available but may be incomplete, unreliable, from a small number of published sources, and/or demonstrate 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 threaten the economic viability of the sector for a lengthy period of time. Effects of exposure may not be reversible.

Table 4. Definition of levels of risk

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.

References

- Al-Hussinee, L., Subramaniam, K., Surachetpong, W., Popov, V., Hartmann, K., 2019. Tilapia Lake Virus (TiLV): a Globally Emerging Threat to Tilapia Aquaculture. University of Florida, Institute of Food and Agricultural Sciences.
- Buzby, J., Wells, H., Hyman, J., 2014. The Estimated Amount, Value, and Calories of Postharvest Food Losses at the Retail and Consumer Levels in the United States. In: Agriculture, U.S.D.o. (Ed.).
- Dong, H., Ataguba, G., Khunrae, P., Rattanarojpong, T., Senapin, S., 2017a. Evidence of TiLV infection in tilapia hatcheries from 2012 to 2017 reveals probable global spread of the disease. *Aquaculture* 479, 579-583.
- Dong, H., Rattanarojpong, T., Senapin, S., 2017b. Urgent update on possible worldwide spread of tilapia lake virus (TiLV).
- Eyngor, M., Zamostiano, R., Tsofack, J.E.K., Berkowitz, A., Bercovier, H., Tinman, S., Lev, M., Hurvitz, A., Galeotti, M., Bacharach, E., 2014. Identification of a novel RNA virus, lethal to Tilapia. *Journal of clinical microbiology, JCM*. 00827-00814.
- Food and Agriculture Organization of The United Nations, 2018. Tilapia Lake Virus: Expert Knowledge Elicitation Risk Assessment.
- Food and Drug Administration, 2017. Guidance for Industry: Seafood HACCP and the FDA Food Safety Modernization Act. In: United States Department of Health and Human Services (Ed.).
- Jansen, M.D., Dong, H.T., Mohan, C.V., 2018. Tilapia lake virus: a threat to the global tilapia industry? *Reviews in Aquaculture*.

- Mastrandrea, M.D., Field, C.B., Stocker, T.F., Edenhofer, O., Ebi, K.L., Frame, D.J., Held, H., Kriegler, E., Mach, K.J., Matschoss, P.R., 2010. Guidance note for lead authors of the IPCC fifth assessment report on consistent treatment of uncertainties.
- Thammatorn, W., Rawiwan, P., Surachetpong, W., 2019. Minimal risk of tilapia lake virus transmission via frozen tilapia fillets. *Journal of Fish Diseases* 42, 3-9.
- Tilapia Association of South Africa, 2018. Confirmed TILV Outbreaks as of August 2018.
- Tsofack, J.E.K., Zamostiano, R., Watted, S., Berkowitz, A., Rosenbluth, E., Mishra, N., Briese, T., Lipkin, W.I., Kabuusu, R.M., Ferguson, H., 2017. Detection of tilapia lake virus in clinical samples by culturing and nested reverse transcription-PCR. *Journal of Clinical Microbiology* 55, 759-767.
- United States Department of Agriculture, 2013. Census of Aquaculture.
- United States Environmental Protection Agency, 2018. Municipal Solid Waste Landfills.
- World Organization for Animal Health, 2018. TILAPIA LAKE VIRUS (TiLV) — AN OVELORTHOMYXO - LIKE VIRUS. In: World Organization for Animal Health (Ed.).
- World Organization for Animal Health (OIE), 2016. Import Risk Analysis for Aquatic Animal Products. (OIE).
-