Food and Agriculture Organization of the United Nations

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ANIMAL HEALTH **RISK ANALYSIS** ASSESSMENT No. 7

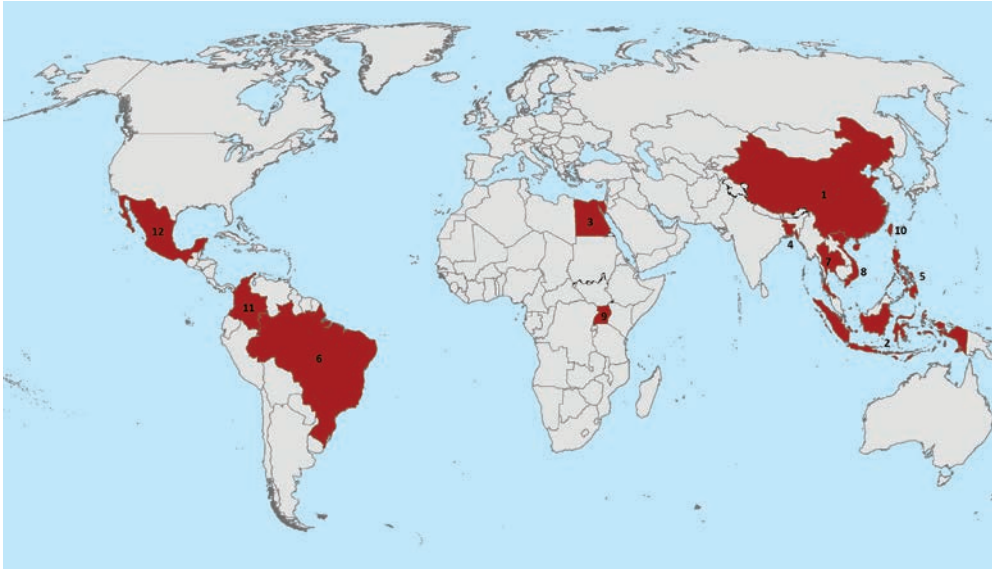
TILAPIA LAKE VIRUS

Expert knowledge elicitation risk assessment

SUMMARY

- The experts who participated in the expert knowledge elicitation (EKE) risk assessment concluded that Tilapia lake virus (TiLV) represents a significant risk to most parts of the world, especially those countries where tilapia aquaculture or fisheries is important from both food security and commercial perspectives.
- The experts considered that the main risk pathway is the translocation of live fish (for aquaculture, direct human consumption or ornamental/aquarium fish-keeping).
- The experts believe that the role of trade in uncooked, chilled/frozen whole fish and fish products (such as fillets) as a pathway for disease spread is small when compared to live fish as a pathway.
- The risk of TiLV to Pacific Island Countries and Territories and North America was generally considered lower than the risk of TiLV to Asia, Africa and South America, in terms of lower likelihood of entry, establishment and spread, and associated consequences.
- The experts considered that of the 16 potential measures presented (divided into (1) movement restrictions, (2) surveillance, (3) basic biosecurity at farm level, and (4) emergency preparedness and response), movement restriction was the most effective in managing the international spread of TiLV. Measures may include: the prohibition of live tilapia imports; sourcing live tilapia only from populations tested and certified to be TiLV-free; and quarantine and post-arrival testing of imported live tilapia.
- The experts also identified the following measures to be the most effective for managing the risk of TiLV spread in countries where the virus is already established: (i) prohibition of live tilapia movement out of infected/buffer zones or from zones of uncertain health status; (ii) basic biosecurity practices at farm level; and (iii) national emergency disease response system targeting TiLV.
- This EKE risk assessment did not take into consideration country-specific circumstances. Therefore, the expert panel recommends that all countries that have significant tilapia populations, whether farmed or wild, undertake their own risk assessments to determine the need for risk management measures and TiLV surveillance to verify disease freedom or extent of spread.

Twelve top tilapia aquaculture-producing countries



N.	Country	Quantity *(tonnes)*	Value *(thousand tonnes)*
1	China	1 866 381	5 074 690
2	Indonesia	1 187 812	1 771 465
3	Egypt	940 309	937 927
4	Bangladesh	342 567	654 853
5	Philippines	259 045	386 135
6	Brazil	239 091	383 497
7	Thailand	208 144	332 210
8	Viet Nam	183 817	252 911
9	Uganda	74 654	147 624
10	Taiwan Province of China	63 028	76 788
11	Colombia	61 800	140 086
12	Mexico	58 191	63 180

Note: The designations employed and the presentation of material in the map(s) do not imply the expression of any opinion whatsoever on the part of FAO concerning the legal or constitutional status of any country, territory or sea area, or concerning the delimitation of frontiers.
Source: FAO. 2018. Fishery and Aquaculture Statistics. Global aquaculture production 1950-2016 (FishstatJ). In: FAO Fisheries and Aquaculture Department [online]. Rome. Updated 2018. www.fao.org/fishery/statistics/software/fishstatj/en; FAO. 2018.

BACKGROUND

Tilapia lake virus (TiLV), described as a novel orthomyxo-like virus, was suspected to be the cause of a significant reduction in tilapia wild catch in the Sea of Galilee in 2009 and has since been reported in several countries in the scientific literature covering Africa, the Middle East, South and Central America and Asia (OIE, 2017b). Given the importance of farmed and wild-caught tilapia, especially as a widespread source of low-cost protein, TiLV represents a potential threat to food security, especially in low-income countries.

It is likely that TiLV has spread undetected beyond the geographical range described in the scientific literature or the range formally reported to the World Animal Health Organization (OIE) because live tilapia is a widely traded commodity and live tilapia clinically or sub-clinically infected with TiLV would most likely have been internationally traded over the years. For this reason, it is important for countries that trade in (especially live) tilapia to consider the country's TiLV health status, assess TiLV risks and implement risk management measures as necessary. This risk assessment provides guidance on general risks associated with TiLV, on how a country-specific risk assessment could be quickly conducted, and guidance on some immediate and longer-term control measures that can be considered for managing the risk of TilV entry, establishment and spread into TiLV-free zones/countries, or for controlling the spread where the virus is already established.

At the time that this expert knowledge elicitation (EKE) risk assessment was completed, there was no evidence of human disease or infection related to TiLV from fish consumption or from exposure to infected animals or water in outbreak areas.

PURPOSE

The purpose of this rapid risk assessment was twofold: (1) to determine the extent of biosecurity risks associated with the spread of TiLV into TiLV-free zones/countries and spread within countries where the disease is already established; and (2) to identify biosecurity measurers to manage these risks.

This assessment is intended to assist countries in setting risk management policies that address concerns about the potential spread of TiLV and serves as a guide only. The scope of this assessment is restricted to an estimation of the risks associated with the intra-national or international movement of live fish, either naturally or through human activities, or the trade in raw, chilled or frozen whole fish or fish products.

METHODS

This rapid risk assessment followed a standardized EKE methodology developed by the Global Early Warning System (GLEWS) to improve the capacity to identify, assess and respond to animal health events that could affect livestock, wildlife, food security or food safety (FAO-GLEWS Rapid Risk Assessment Guidelines, in process), and draws on previous FAO rapid risk analyses on Rift Valley fever (RVF) (FAO, 2017a) and Highly Pathogenic Avian Influenza (HPAI) (FAO, 2017b). This qualitative risk assessment is in response to a pressing demand for guidance on TiLV risks and risk management options, as expressed to FAO by its member countries and other aquaculture stakeholders. The scope of the assessment is therefore restricted to meet the most urgent stakeholder concerns about the risks posed by TiLV, namely the risks associated with the intra-national or international movement of live fish, either naturally or through human activities, or the trade in raw chilled or frozen whole fish or fish products.

Risk questions

The assessment took the form of a questionnaire comprising the following questions:

1. What, in the absence of any controls, is the likelihood of TiLV spreading in a country where it is already present?
2. What, in the absence of any controls, is the likelihood of TiLV spreading from an infected country to China?
3. What, in the absence of any controls, is the likelihood of TiLV spreading within Asia?
4. What, in the absence of any controls, is the likelihood of TiLV spreading from countries of an infected region (e.g. Southeast Asia) to Africa, East Asia, South Asia, North America, South America or Pacific Island Countries and Territories (PICTs)?
5. What would be the consequences of TiLV spreading in a country where it is already present?
6. What would be the consequences of TiLV spreading from an infected country to China?
7. What would be the consequences of TiLV spreading within Asia?
8. What would be the consequences of TiLV spreading from countries of an infected region (e.g. Southeast Asia) to Africa, East Asia, South Asia, North America, South America or PICTs?
9. Based on the available information, including information that you believe could be drawn from knowledge of infectious salmon anaemia virus (ISAV), what proportion of the overall likelihood of TiLV spread (internationally or within a country) is represented by the trade in uncooked chilled/frozen whole fish and fish products (such as fish fillets) as a pathway for disease spread (as compared to translocation of live fish)?
10. Rank from the most to the least feasible the measures for reducing the risk of TiLV spread within an infected country.
11. Rank from the most to the least effective the measures for reducing the risk of TiLV spread within an infected country.
12. Rank from the most to the least feasible the measures for reducing the risk of the international spread of TiLV (national biosecurity controls).
13. Rank from the most to the least effective the measures for reducing the risk of the international spread of TiLV.

Risk questions 1-8 were formulated to gain an understanding of the region-specific likelihood (probability) of TiLV entry, establishment and spread over the next five years, and the consequences (likely impacts) of such spread – these two elements making up the overall region-specific biosecurity risk associated with TiLV. Experts were asked to select from a range qualitative likelihood or impact levels (e.g. low, moderate). As a supplementary question (risk question 9), experts were asked to estimate the relative roles of trade in uncooked chilled/frozen whole fish and fish products (such as fish fillets) and the translocation of live fish in disease spread.

Risk questions 10-13 focused on evaluating the effectiveness and feasibility of measures for managing the risk of TiLV spreading internationally or spreading in countries where the virus is already established.

The complete questionnaire is provided in Annex 1.

Risk profile

To assist in completing the questionnaire, each expert was provided with a TiLV risk profile that summarized the available scientific literature considered pertinent to an estimation of biosecurity risk associated with TiLV (Annex 2). The information presented in the risk profile was taken predominantly from four reviews conducted under the auspices of FAO, the Network of Aquaculture Centres in Asia and the Pacific (NACA) and the OIE: Jansen and Mohan (2017); FAO (2017c); NACA (2017a); and OIE (2017b).

The limited information available about TiLV on which to base a risk assessment was acknowledged, particularly with respect to its epidemiology and virus characteristics. Given these information gaps, experts were asked to consider (to the extent they considered it relevant) the characteristics of other orthomyxoviruses such as ISAV, since TiLV is characterized as a novel orthomyxo-like virus. ISAV, for example, is known to have a high level of host specificity, high potential for pathogen translocation via frozen/chilled fish, ability for the virus to survive in water and fomites, potential for specific pathogen-free, specific pathogen-resistant and vaccine development, and potential for eradication or spread control.

Risk assessment

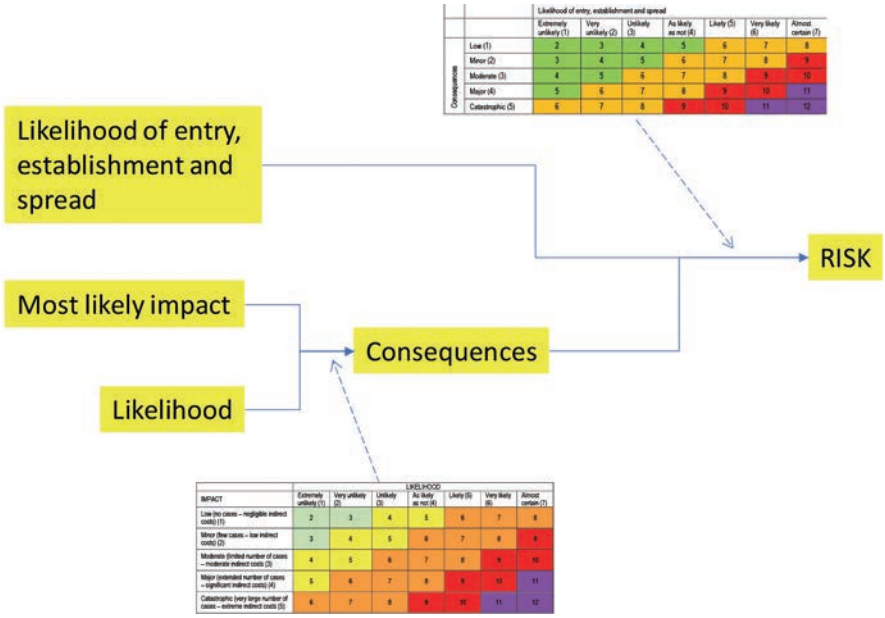
The risk assessment approach was consistent with the OIE Aquatic Animal Health Code (OIE, 2017a). The overall disease risk was arrived at by integrating the estimated likelihood (probability) of TiLV entry, establishment and spread with the likely impacts (consequences) of such spread, with risk matrices used to combine likelihoods and impacts as described (see Figure 1).

The experts were asked to answer risk questions 1-8 (related to the likelihood of disease entry, establishment and spread or consequences) by selecting a response from a set of qualitative likelihood or impact descriptors. A numerical score was assigned to each likelihood or impact level, which allowed responses to be mathematically manipulated to effectively generate an "average" response to each risk question. A step-wise description of the methodology is provided in Annex 3.

Risk assessment experts

The qualitative nature of the assessment parameters meant that responses were based on expert judgement and therefore subjective. To minimize (or at least quantify) the subjectivity related to the parameters under consideration, the input of a relatively large number (14) of aquatic animal health experts was sought.

FIGURE 1. *Risk assessment construct for determining risk using risk matrices*



A call for expression of interest to participate in this EKE risk assessment for TiLV was made via email message to a group of aquatic animal health (AAH) experts from the network of AAH experts of the Aquaculture Branch of FAO's Department of Fisheries and Aquaculture. The expert panel was selected based on their knowledge of TiLV or ISAV, experience in risk assessment or experience in Competent Authority-level management of aquatic animal disease risks. The experts were instructed to answer the questionnaire independently, that is, not to confer with each other. Details of the expert panel are provided in Annex 4.

Risk management

The experts were presented with a series of potential risk management measures for managing the risk of disease spread to TiLV-free countries (international spread) or further spread within countries where TiLV is already present, and asked to rank each measure in terms of effectiveness and feasibility.

The level of risk reduction associated with any one measure or combination of measures was not assessed; that is, there is no direct link between the risk management options and the outcomes of the risk assessment. Since the feasibility of each measure is expected to vary from country to country and the appropriate level of protection may vary from country to country, this part of the assessment is considered best conducted at a country level. It is recommended therefore that interested countries undertake their own detailed risk assessments and develop their preferred risk reduction measures, taking into consideration the experts' views herein on effectiveness and feasibility of the measures in general. Country-specific risk assessments, especially as they relate to potential import controls, should follow a two-step process to first assess unrestricted risks (without risk management measures) and then restricted risks (with measures), to ensure the chosen suite of risk management measures meets the country's appropriate level of protection, as per the OIE international standard (OIE, 2017a).

RESULTS

Risk assessment

The risk assessment findings are summarized in Table 1 and Figures 2a, 2b and 2c. More detailed data that include standard deviation and confidence intervals are provided in Annex 5.

The risk of TiLV spreading (in the absence of any controls) within a country where it is already present was found to be *very high*, whereas the risk of TiLV spreading from infected countries to China or other countries in the Asian region (including East and South Asia), the African region or the South American region was found to be *high* (Figure 2a).

Compared to the other countries or regions considered, the risk of TiLV spreading from infected countries to North America or PICTs was found to be *moderate* (Figure 2a), due to a combination of both lower expected consequences (Figure 2b) and lower likelihood of entry, establishment and spread (Figure 2c).

The experts considered the proportion of the likelihood of TiLV entry, establishment and spread, and thereby the proportion of the risk, represented by trade in uncooked chilled/frozen whole fish and fish products (such as fish fillets) as compared to translocation of live fish, to be 8.5 percent (SD=6.8%).

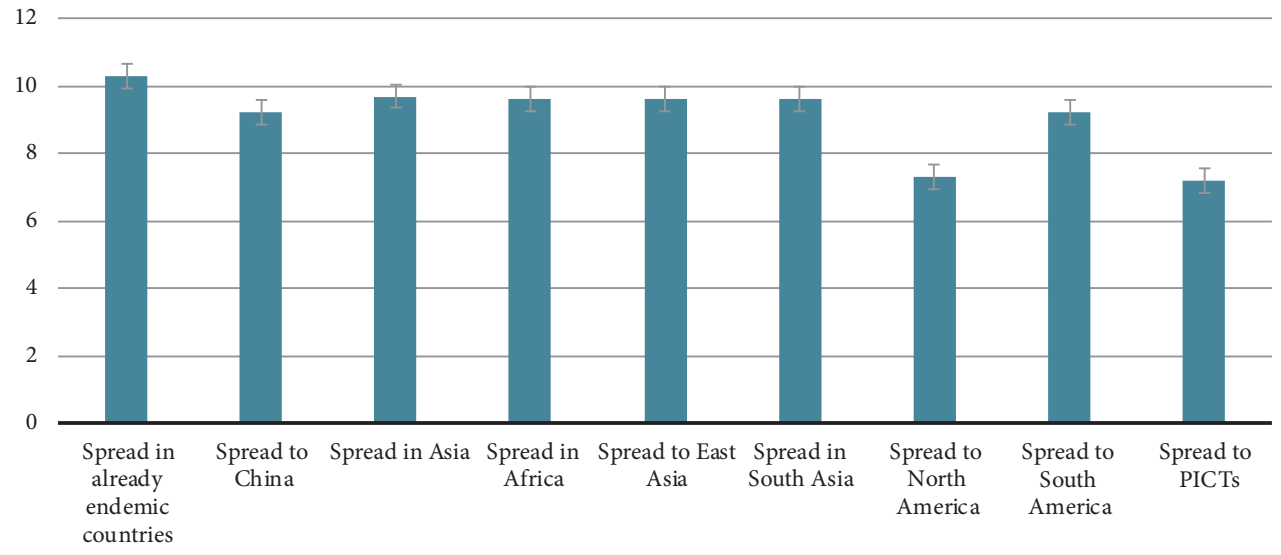
The experts expressed varying degrees on uncertainty in their estimations of the likelihood of TiLV entry, establishment and

TABLE 1 *TiLV risk assessment summary data*

	Spread in already endemic countries	Spread to China	Spread in Asia	Spread in Africa	Spread to East Asia	Spread in South Asia	Spread to North America	Spread to South America	Spread to PICTs
Likelihood of entry, establishment and spread (LEES): mean score (1-7)	6.2 (SD* 0.9)	5.1 (SD 1.1)	5.8 (SD 1.1)	5.6 (SD 1.3)	5.6 (SD 1.1)	5.6 (SD 1.1)	4.1 (SD 1.1)	5.5 (SD 0.8)	3.9 (SD 1.1)
LEES score uncertainty (1-3)	low-medium	medium	low-medium	medium	low-medium	low-medium	medium	low-medium	medium-high
Impact score (1-5)	3.5 (SD 0.9)	3.7 (SD 0.7)	3.5 (SD 0.9)	3.5 (SD 0.9)	3.5 (SD 0.8)	3.6 (SD 0.9)	2.7 (SD 1.1)	3.2 (SD 1.0)	2.9 (SD 1.2)
Likelihood of impact score (1-7)	6.1 (SD 0.7)	5.8 (SD 1.4)	5.9 (SD 1.1)	5.7 (SD 1.2)	5.8 (SD 0.7)	5.6 (SD 1.3)	4.9 (SD 1.1)	5.5 (SD 0.9)	5.1 (SD 1.3)
Likely consequences score (2-12)	9.6 (SD 1.4)	9.4 (SD 1.7)	9.4 (SD 1.7)	9.3 (SD 1.8)	9.3 (SD 1.1)	9.2 (SD 2.0)	7.6 (SD 1.6)	8.7 (SD 1.3)	7.9 (SD 2.1)
Likely consequences descriptor	major	major	major	major	major	major	moderate	major	moderate
Consequences final score (1-5)	4.1 (SD 0.7)	4.0 (SD 0.8)	3.9 (SD 0.7)	3.9 (SD 0.8)	3.9 (SD 0.6)	3.9 (SD 1.0)	3.2 (SD 0.7)	3.6 (SD 0.5)	3.3 (SD 0.9)
Overall risk score (2-12)	10.3 (SD 1.3)	9.2 (SD 1.5)	9.7 (SD 1.7)	9.6 (SD 1.8)	9.6 (SD 1.6)	9.6 (SD 1.9)	7.3 (SD 1.6)	9.2 (SD 0.8)	7.2 (SD 1.8)
Overall risk description	very high	high	high	high	high	high	moderate	high	moderate

* Standard deviation

FIGURE 2A. *Overall risk scores (score range 1-12) of the entry, establishment and spread of TiLV internationally or within already infected countries*



spread. The "average" level of uncertainty across all the likelihood estimations raged from low-medium to medium, except for the case of PICTs, for which the likelihood of TILV entry, establishment and spread was medium-high (Figure 3, Table 3).

Risk management

The relative effectiveness and feasibly of measures to manage the risks of international spread of TiLV and the risks of spread within counties where TiLV is already present is summarized in Tables 2 and 3.

The five most *effective* of the 16 risk management measures to reduce the risk of TiLV *spreading internationally* were:

1. Prohibition of live tilapia imports based on risk assessment.
2. Importation of live tilapia only from populations tested and certified to be TiLV-free, WITH post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country.
3. Quarantine and post-arrival testing of imported live tilapia shipments.
4. Surveillance of establishments with imported fish and implementation of strict biosecurity and emergency response arrangements in these establishments.
5. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres.

FIGURE 2B. *Overall level of consequences (score 1-5) of TiLV entry, establishment and spread internationally or within already infected countries*

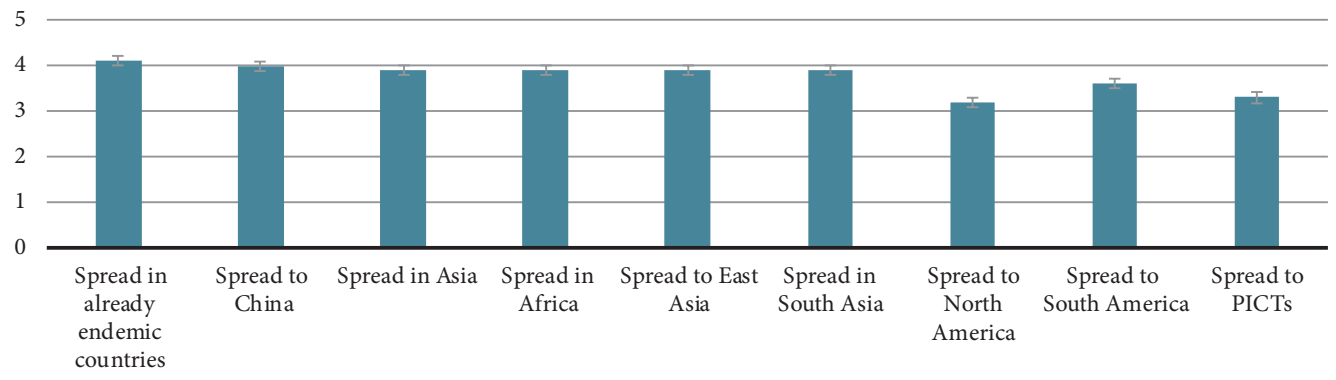


FIGURE 2C. *Likelihood (score 1-7) of TiLV entry, establishment and spread internationally or within already infected countries*

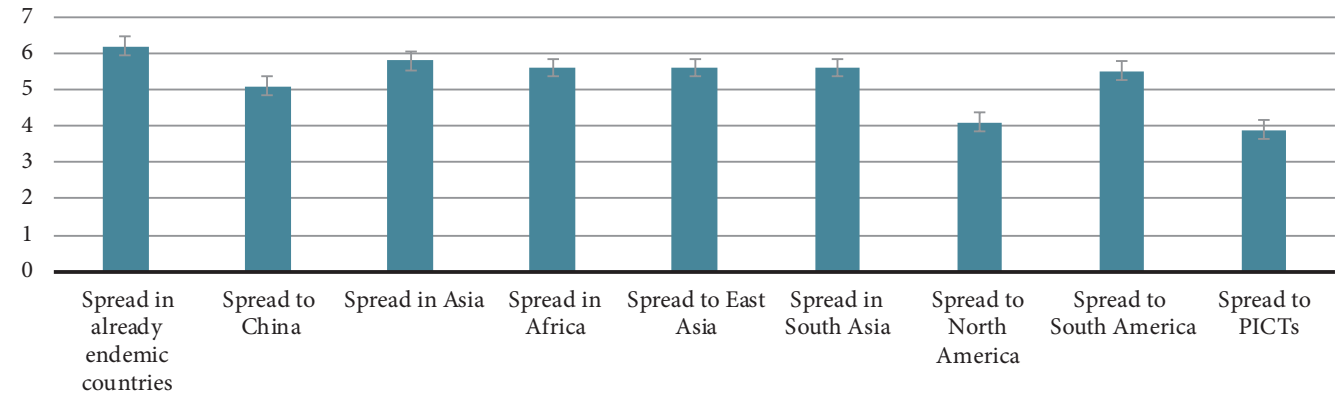
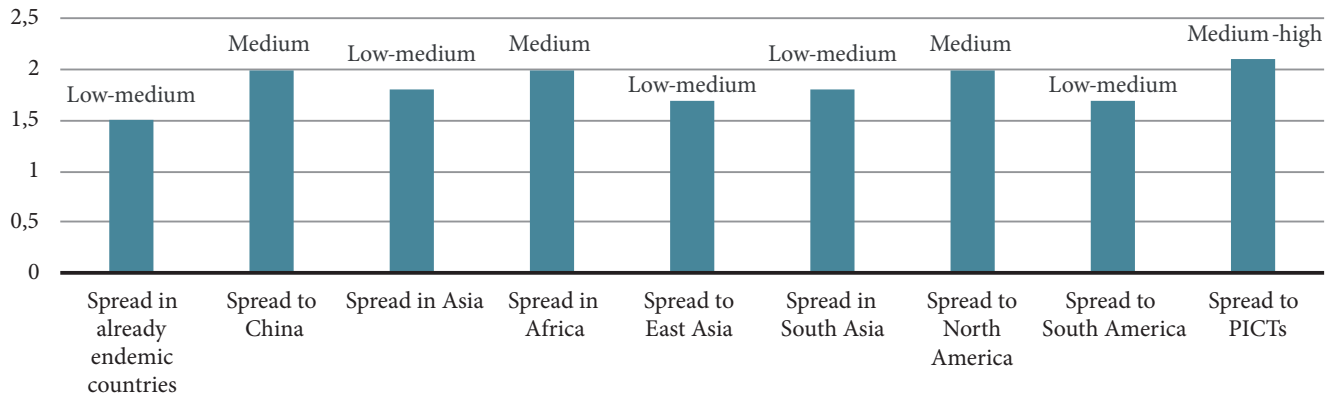


FIGURE 3. *Relative levels of uncertainty in expert estimation of the likelihoods of entry, establishment and spread of TiLV*



These five measures ranked 8th, 12th, 11th, 5th and 6th, respectively, in terms of feasibility.

Of the 16 measures, the five considered generally most *feasible* were:

1. Immediate notification of unexplained tilapia mortalities to Competent Authorities.
2. Basic biosecurity practices at farm level (e.g. good record-keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment).
3. Immediate investigation of unexplained mortalities.
4. Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing

same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records).

5. Surveillance of establishments with imported fish and implementation of strict biosecurity and emergency response arrangements in these establishments.

The five most *effective* of the 14 risk management measures to reduce the risk of TiLV spread *within countries* were:

1. Prohibition of live tilapia movement out of infected/buffer zones or from zones of uncertain health status.
2. Basic biosecurity practices at farm level (e.g. good record-keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment).
3. National emergency disease response system targeting TiLV.
4. Immediate notification of unexplained mortalities to Competent Authorities.
5. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres.

These five measures ranked 9th, 2nd, 6th, 1st and 7th, respectively, in terms of feasibility. Of the 14 risk management measures, the five most *feasible* were:

1. Immediate notification of unexplained mortalities to Competent Authorities.
2. Basic biosecurity practices at farm level (e.g. good record-keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment).
3. Immediate investigation of unexplained mortalities.
4. Immediate notification of unexplained mortalities for early warning to neighbouring farms.
5. Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records).

TABLE 2 *Risk management measures for reducing the risk of the international spread of TiLV, ranked according to effectiveness and feasibility*

		Effectiveness rank	Feasibility rank
A	Prohibition of live tilapia imports based on risk assessment?	1	8
B	Importation of live tilapia only from populations tested and certified to be TiLV-free, WITH post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country	2	12
C	Quarantine and post-arrival testing of imported live tilapia shipments	3	11
D	Surveillance of establishments with imported fish and implementation of strict biosecurity and emergency response arrangements in these establishments	4	5
E	Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres	5	6
F	Immediate notification of unexplained mortalities to Competent Authorities	6	1
G	Basic biosecurity practices at farm level (e.g. good record keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment)	7	2
H	Ongoing programme of national monitoring and surveillance for TiLV	8	9
I	National emergency disease response system targeting TiLV	9	10
J	Immediate investigation of unexplained mortalities	10	3
K	Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records)	11	4
L	Importation of live tilapia only from populations tested and certified to be TiLV-free, WITHOUT post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country	12	13
M	Immediate notification of unexplained mortalities for early warning to neighbouring farms	13	7
N	Prohibition of uncooked tilapia imports (whole or product) based on risk assessment?	14	14
O	Importation of uncooked tilapia (whole or product) only from populations tested and certified to be TiLV-free, WITH random post-arrival testing of imported live tilapia shipments to verify effectiveness of health controls in source/exporting country	15	16
P	Importation of uncooked tilapia (whole or product) only from populations tested and certified to be TiLV-free, WITHOUT random post-arrival testing of imported live tilapia shipments to verify effectiveness of health controls in source/exporting country	16	15

TABLE 3 *Risk management measures for reducing the risk of TiLV spread within an infected country, ranked according to effectiveness and feasibility*

		Effectiveness rank	Feasibility rank
A	Prohibition of live tilapia movement out of infected/buffer zones or from zones of uncertain health status	1	9
B	Basic biosecurity practices at farm level (e.g. good record-keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment)	2	2
C	National emergency disease response system targeting TiLV	3	6
D	Immediate notification of unexplained mortalities to Competent Authorities	4	1
E	Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres	5	7
F	Immediate investigation of unexplained mortalities	6	3
G	Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records)	7	5
H	Immediate notification of unexplained mortalities for early warning to neighbouring farms	8	4
I	Restrict movement of live tilapia out of infected/buffer zone to only fish from populations tested and certified to be TiLV-free	9	12
J	Quarantine and post-arrival testing of tilapia imported from an infected zone or a zone of unknown health status	10	11
K	Ongoing programme of national monitoring and surveillance for TiLV	11	8
L	Surveillance of establishments with fish imported from free TiLV sources or sources of unknown health status AND implementation of strict biosecurity and emergency response arrangements in these establishments	12	10
M	Prohibition of uncooked whole tilapia or tilapia product movement out of infected/buffer zones or from zones of uncertain health status	13	13
N	Restrict movement of uncooked tilapia (whole or product) out of infected/buffer zones to only fish from populations tested and certified to be TiLV-free	14	14

PRELIMINARY ANALYSIS

There was expert consensus that TiLV represents a significant risk to most parts of the world, especially those countries where tilapia aquaculture or fisheries is important from a commercial or food security perspective. Risks to PICTs and North America were generally considered less than those to Asia, Africa and South America, as a function of lower likelihood of entry, establishment and spread and associated consequences.

The role of trade in uncooked chilled/frozen whole fish and fish products (such as fish fillets) as a pathway for disease spread compared to translocation of live fish (for aquaculture, direct human consumption or ornamental/aquarium fish-keeping purposes) was considered by the panel to be relatively small, at an average of 8.5 percent. Research on the viability of TiLV in frozen tissues and investigation of potential pathways whereby fish in receiving waters could be exposed to virus in chilled or frozen fish products intended for human consumption would be useful in refining this risk estimation, as the currently available information is limited. In a recent experiment conducted in Thailand, it was reported that the risk of TiLV transmission via frozen tilapia fillet was minimal (Thammatorn, Rawiwan and Surachetpong, 2019).

Gaps in the scientific community's knowledge of TiLV, as well as the qualitative nature of the assessment parameters and the subjectivity of the questionnaire responses naturally affect the accuracy of the experts' risk estimations. However, within these constraints we have optimized the accuracy of the risk estimations by ensuring the input of a relatively large panel of experts and by ensuring that the panel members have sufficient breadth and depth of expertise. The assessment's limitations and strengths must be kept in mind when interpreting its conclusions.

From the 16 potential measures presented, the expert panel considered the following five the most effective for managing the international spread of TiLV:

1. Prohibition of live tilapia imports based on risk assessment?
2. Importation of live tilapia only from populations tested and certified to be TiLV-free, WITH post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country.
3. Quarantine and post-arrival testing of imported live tilapia shipments.
4. Surveillance of establishments with imported fish and implementation of strict biosecurity and emergency response arrangements in these establishments.
5. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres.

Similarly, the panel identified 14 measures for managing risk of further TiLV spread in countries where the virus is already established. The following five ranked as most effective:

1. Prohibition of live tilapia movement out of infected/buffer zones or from zones of uncertain health status.
2. Basic biosecurity practices at farm level (e.g. good record-keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement,

control of facility access, disinfection of personnel, vehicles and equipment).

3. National emergency disease response system targeting TiLV.
4. Immediate notification of unexplained mortalities to Competent Authorities.
5. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres.

The experts also ranked the measures in terms of general feasibility (Tables 4 and 5). The feasibility of effective implementation depends largely on the capacity and capability of individual countries, including with respect to the legal basis of any controls, laboratory diagnostic services and financial resources to implement measures on the ground. The discrepancy between those measures considered the most effective versus most feasible reflects the experts' general view of country-level capacities and highlights a need for gap analysis and the doubling of national and international efforts in building aquatic animal health biosecurity capacity.

Countries considering implementing risk management measures should therefore consider all options and decide on the suite of measures that best suits local circumstances, noting that no single measure alone is likely to bring a meaningful level of risk reduction. National-level risk management measures targeting international trade must also be based on risk analysis (consistent with OIE standards) and be commensurate with the level of risk reduction needed to meet the country's appropriate level of protection.

The recommended measures for managing TiLV risks generally align with those made previously in FAO's GIEWS Special Alert No. 338, NACA's TiLV Disease Advisory and the OIE's TiLV Disease Card. FAO recommended that live tilapia imports be subject to TiLV testing, international health certification attesting to TiLV freedom, and post-arrival quarantine observation, and that importing countries establish contingency plans to contain and eradicate TiLV in the event of an outbreak (FAO, 2017c). For countries where TiLV has been confirmed, FAO recommended active surveillance to determine the extent of spread and measures to manage the risk of further spread, including building public and farmer awareness of the disease.

NACA advocated for countries with confirmed TiLV to build awareness and capacity programmes through the various levels of the value chain, including farmers, hatchery operators, extension service providers and consumers, and for affected counties to set up a TiLV task force with representatives from key national institutions, introduce a simple, practical surveillance plan to map the spread of TiLV, monitor movement of fish from affected farms, initiate research to understand the role of TiLV in mass mortalities, designate and equip one or two national laboratories for TiLV diagnosis, and facilitate development of regional and international projects for donor support (NACA, 2017a). For at-risk countries that are TiLV-free, NACA recommended preventive measures to mitigate the risk of TiLV introduction, including risk analysis, screening of live tilapia imported for aquaculture purposes, investigation of reported tilapia mortalities and the development of contingency plans for responding to TiLV outbreaks. In 2017, NACA added TiLV to its regional Quarterly Aquatic Animal Disease (QAAD) reporting requirements for Asia-Pacific (NACA, 2017b).

The OIE's disease card recommended restrictions on the movement of live tilapia from farms and fisheries where the virus is known to occur, as well as generic biosecurity measures to minimize fomite spread via equipment, vehicles or staff (i.e. cleaning and disinfection) (OIE, 2017b).

This assessment's findings are also generally consistent with the conclusions of a recent review of TiLV by Jensen *et al.* (2018) which identified the need for national and international biosecurity efforts, effective application of best management practices in aquaculture, capacity building and collaboration between international and national stakeholders as priorities.

The outcomes of this risk assessment present a basis for prioritizing action on TiLV, including risk assessment and national Competent Authority and industry sector-level measures to manage TiLV risks, whether for TiLV-free or already affected countries.

Importantly, this assessment did not take into consideration country-specific circumstances. Therefore, it is recommended that all countries that have significant tilapia populations, whether farmed or wild, undertake their own risk assessments, ensuring that these assessments meet the minimum international standard (OIE, 2017a). Attention needs to be paid especially to country-specific risks in terms of international trade activity in live tilapia and fresh frozen products. To support risk assessment, it is also recommended that these countries undertake TiLV surveillance to verify disease freedom or extent of spread.

Contingent on the outcomes of country-specific risk assessments supported by suitably qualified panels of experts, at-risk countries could move quickly to adopt a suite of measures taken from those recommended by FAO, NACA and the OIE, and by the expert panel conducting this assessment, as appropriate to each country's capabilities and capacities. The risk questionnaire could also be readily adapted to a country-specific questionnaire, and the method overall can be applied using current information (including the information provided in Annex 2, updated as necessary) to facilitate early interventions.

To the best of our knowledge, the method used in this assessment is the first time that an EKE-based rapid risk assessment approach has been used to assess aquatic animal disease risks. Notwithstanding its inherent limitations, the method represents a ready means by which countries can rapidly assess risks and identify priority management measures.

ANNEX 1. TILV RISK ANALYSIS QUESTIONNAIRE

1. What, in the absence of any controls, is the *likelihood* of TiLV spreading within a country where it is already present in the absence of any controls?

LIKELIHOOD ESTIMATION (Extremely unlikely; Very unlikely; Unlikely; As likely as not; Likely; Very likely; or Almost certain)	LEVEL OF UNCERTAINTY (Low, Medium or High)

2. What, in the absence of any controls, is the *likelihood* of TiLV spreading from an infected country to China in the absence of any controls?

LIKELIHOOD ESTIMATION (Extremely unlikely; Very unlikely; Unlikely; As likely as not; Likely; Very likely; or Almost certain)	LEVEL OF UNCERTAINTY (Low, Medium or High)

3. What, in the absence of any controls, is the *likelihood* of TiLV spreading within the Asian region in the absence of any controls?

LIKELIHOOD ESTIMATION (Extremely unlikely; Very unlikely; Unlikely; As likely as not; Likely; Very likely; or Almost certain)	LEVEL OF UNCERTAINTY (Low, Medium or High)

4. What, in the absence of any controls, is the *likelihood* of TiLV spread from countries of an infected region (e.g. Southeast Asia) to the following potentially uninfected regions:

	LIKELIHOOD ESTIMATION (Extremely unlikely; Very unlikely; Unlikely; As likely as not; Likely; Very likely; or Almost certain)	LEVEL OF UNCERTAINTY (Low, Medium or High)
a. Africa		
b. East Asia		
c. South Asia		
d. North America		
e. South America		
f. Pacific Island and Country Territories (PICTs)		
g. Other countries or region/s where tilapia is present (please state countries or region considered, adding new rows to the table as necessary)		

5. What would be the *consequences* of TiLV spreading within a country where it is already present?

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

6. What would be the *consequences* of TiLV spreading from an infected country to China?

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

7. What would be the *consequences* of TiLV spreading within the Asian region?

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

8. What would be the *consequences* of TiLV spread from countries of an infected region (e.g. Southeast Asia) to the following potentially uninfected regions:

a. Africa

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

b. East Asia

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

c. South Asia

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

d. North America

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

e. South America

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

f. Pacific Island Countries and Territories (PICTs)

	LIKELIHOOD						
IMPACT	Extremely unlikely (1)	Very unlikely (2)	Unlikely (3)	As likely as not (4)	Likely (5)	Very likely (6)	Almost certain (7)
Low (1)							
Minor (2)							
Moderate (3)							
Major (4)							
Catastrophic (5)							

Insert an "x" in one box, indicating what you consider to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely).

9. Based on the available information, including information that you believe could be drawn from knowledge of ISAV, what proportion of the overall likelihood of TiLV spread (internationally or within a country) is represented by the trade in uncooked chilled/frozen whole fish and fish products (such as fish fillets) as a pathway for disease spread (as compared to translocation of live fish)?

PROPORTION OF LIKELIHOOD (0-1%, 1-10%, 10-33%; 33-66%, 66-90%, 90-99% or 99-100%)	LEVEL OF UNCERTAINTY (low, medium or high)

10. Rank from the most to the least feasible the following measures to reduce the risk of TiLV spread *within an infected country*

CONTROL MEASURE	RANK
a. Prohibition of live tilapia movement out of infected/buffer zones or from zones of uncertain health status	
b. Prohibition of uncooked whole tilapia or tilapia product movement out of infected/buffer zones or from zones of uncertain health status	
c. Restrict movement of live tilapia out of infected/buffer zone to only fish from populations tested and certified to be TiLV-free	
d. Restrict movement of uncooked tilapia (whole or product) out of infected/buffer zones to only fish from populations tested and certified to be TiLV-free	
e. Quarantine and post-arrival testing of tilapia imported from an infected zone or a zone of unknown health status	
f. Surveillance of establishments with fish imported from free TiLV sources or sources of unknown health status AND implementation of strict biosecurity and emergency response arrangements in these establishments	
g. Ongoing programme of national monitoring and surveillance for TiLV	
h. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres	
i. National emergency disease response system targeting TiLV	
j. Basic biosecurity practices at farm level (e.g. good record-keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment)	
k. Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records)	
l. Immediate investigation of unexplained mortalities	
m. Immediate notification of unexplained mortalities to Competent Authorities	
n. Immediate notification of unexplained mortalities for early warning to neighbouring farms	
o. Other	
p. Other	

11. Rank from the most to the least effective the following measures to reduce the risk of TiLV spread *within an infected country*

CONTROL MEASURE	RANK
a. Prohibition of live tilapia movement out of infected/buffer zones or from zones of uncertain health status	
b. Prohibition of uncooked whole tilapia or tilapia product movement out of infected/buffer zones or from zones of uncertain health status	
c. Restrict movement of live tilapia out of infected/buffer zone to only fish from populations tested and certified to be TiLV-free	
d. Restrict movement of uncooked tilapia (whole or product) out of infected/buffer zones to only fish from populations tested and certified to be TiLV-free	
e. Quarantine and post-arrival testing of tilapia imported from an infected zone or a zone of unknown health status	
f. Surveillance of establishments with fish imported from free TiLV sources or sources of unknown health status AND implementation of strict biosecurity and emergency response arrangements in these establishments	
g. Ongoing programme of national monitoring and surveillance for TiLV	
h. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres	
i. National emergency disease response system targeting TiLV	
j. Basic biosecurity practices at farm level (e.g. good record keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment)	
k. Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records)	
l. Immediate investigation of unexplained mortalities	
m. Immediate notification of unexplained mortalities to Competent Authorities	
n. Immediate notification of unexplained mortalities for early warning to neighbouring farms	
o. Other	
p. Other	

12. Rank from the most to the least feasible the following measures to reduce the risk of the *international* spread of TiLV (national biosecurity controls)

CONTROL MEASURE	RANK
a. Prohibition of live tilapia imports based on risk assessment	
b. Prohibition of uncooked tilapia imports (whole or product) based on risk assessment	
c. Importation of live tilapia only from populations tested and certified to be TiLV-free, WITH post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country	
d. Importation of live tilapia only from populations tested and certified to be TiLV-free, WITHOUT post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country	
e. Importation of uncooked tilapia (whole or product) only from populations tested and certified to be TiLV-free, WITH random post-arrival testing of imported live tilapia shipments to verify effectiveness of health controls in source/exporting country	
f. Importation of uncooked tilapia (whole or product) only from populations tested and certified to be TiLV-free, WITHOUT random post-arrival testing of imported live tilapia shipments to verify effectiveness of health controls in source/exporting country	
g. Quarantine and post-arrival testing of imported live tilapia shipments	
h. Surveillance of establishments with imported fish and implementation of strict biosecurity and emergency response arrangements in these establishments	
i. Ongoing programme of national monitoring and surveillance for TiLV	
j. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres	
k. National emergency disease response system targeting TiLV	
l. Basic biosecurity practices at farm level (e.g. good record keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment)	
m. Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records)	
n. Immediate investigation of unexplained mortalities	
o. Immediate notification of unexplained mortalities to Competent Authorities	
p. Immediate notification of unexplained mortalities for early warning to neighbouring farms	
q. Other	
r. Other	

13. Rank from the most to the least effective the following measures to reduce the risk of the *international* spread of TiLV

CONTROL MEASURE	RANK
a. Prohibition of live tilapia imports	
b. Prohibition of uncooked tilapia imports (whole or product)	
c. Importation of live tilapia only from populations tested and certified to be TiLV-free, WITH post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country	
d. Importation of live tilapia only from populations tested and certified to be TiLV-free, WITHOUT post-arrival testing of imported live tilapia to verify effectiveness of health controls in source/exporting country	
e. Importation of uncooked tilapia (whole or product) only from populations tested and certified to be TiLV-free, WITH random post-arrival testing of imported live tilapia shipments to verify effectiveness of health controls in source/exporting country	
f. Importation of uncooked tilapia (whole or product) only from populations tested and certified to be TiLV-free, WITHOUT random post-arrival testing of imported live tilapia shipments to verify effectiveness of health controls in source/exporting country	
g. Quarantine and post-arrival testing of imported live tilapia shipments	
h. Surveillance of establishments with imported fish and implementation of strict biosecurity and emergency response arrangements in these establishments	
i. Ongoing programme of national monitoring and surveillance for TiLV	
j. Immediate TiLV surveillance of all major tilapia breeding facilities and fry/fingerling dissemination centres	
k. National emergency disease response system targeting TiLV	
l. Basic biosecurity practices at farm level (e.g. good record keeping, quick action at first signs of abnormal fish behaviour, sick/dead fish disposal, control of fish movement, control of facility access, disinfection of farm vehicles and equipment)	
m. Basic husbandry practices (e.g. appropriate stocking density, maintaining good water quality, good nutrition, culturing same age group, avoiding entry of wild fish or potential vectors in earthen pond system, maintaining good farm records)	
n. Immediate investigation of unexplained mortalities	
o. Immediate notification of unexplained mortalities to Competent Authorities	
p. Immediate notification of unexplained mortalities for early warning to neighbouring farms	
q. Other	
r. Other	

ANNEX 2. TILV RISK PROFILE

Introduction

Tilapia Lake Virus (TiLV) disease has been emerging as a significant disease of farmed and wild tilapia since 2009. The pathogen, TiLV, was suspected to be the cause of a significant reduction in tilapia wild catch in the Sea of Galilee in 2009 and has since been reported in the scientific literature in association with farmed tilapia losses in Egypt, Israel, Ecuador, Colombia and Thailand (OIE, 2017b), Chinese Taipei (OIE, 2017c), the Philippines (OIE, 2017d), Malaysia (OIE, 2017e), Peru (OIE, 2018), India (Behera *et al.*, 2018), Indonesia (Koesharyani *et al.*, 2018) and in Lake Victoria (which borders Uganda, Kenya and Tanzania) (Mugimba *et al.*, 2018).

Given the importance of farmed and wild-caught tilapia, especially as a widespread source of low-cost protein, TiLV represents a potential threat to food security in the developing world. TiLV has no known direct human health implications.

This risk profile pulls together the available scientific literature considered pertinent to an estimation of biosecurity risk and is intended to assist in the conduct of an TiLV risk assessment using an expert knowledge elicitation method. Much of the information presented herein is taken directly from four reviews conducted under the auspices of FAO, NACA and the OIE: Jansen and Mohan (2017); FAO (2017c); NACA (2017a); and the OIE (2017b).

Pathogen taxonomy

TiLV is an enveloped, negative-sense, single-stranded RNA virus with 10 segments encoding 10 proteins. TiLV is characterized as an orthomyxo-like virus belonging to the Orthomyxoviridae family, which includes human influenza virus and Infectious Salmon Anaemia Virus (ISAV), with which TiLV has low-level genetic homology. There appear to be a number of genotypes of TiLV that have been associated with a range of fish species and/or tissue tropisms and related pathologies (Tattiyapong *et al.*, 2017a), although the range of TiLV isolates from around the world have over 90 percent genomic homology (Jansen and Mohan, 2017).

Host range

To date, TiLV has only been isolated from species of tilapia, including hybrid tilapia (*Oreochromis niloticus* x *O. aureus hybrids*) in Israel (Eyngor *et al.*, 2014) and Chinese Taipei (OIE, 2017c); Nile tilapia (*O. niloticus*) in Egypt (Fathi *et al.*, 2017), Ecuador (Ferguson *et al.*, 2014), Colombia (Tsofack *et al.*, 2017) and Thailand (Dong *et al.*, 2017a; Surachetpong *et al.*, 2017); and red tilapia (Oreochromis sp.) in Thailand (Dong *et al.*, 2017a; Surachetpong *et al.*, 2017). TiLV was also identified from several wild tilapines including *Sarotherodon galilaeus*, Tilapia zilli, O. aureus, and *Tristamellasimonis intermedia* in the Sea of Galilee, Israel (Eyngor *et al.*, 2014).

Nile tilapia (Oreochromis niloticus) *field outbreak confirming TiLV infection, with clinical signs of corneal opacity and skin erosion.*

The species of tilapia or the strain of tilapia may have a bearing on the extent of clinical disease. Ferguson *et al.* (2014) notes the potential for variation in strain susceptibility based on an observed 60 percent to 70 percent difference in mortality between two strains of *O. niloticus* in Ecuador.

The apparently narrow host specificity of TiLV to tilapines is supported to some extent by the observed absence of mortalities in grey mullet (*Mugil cephalus*) and carp (*Cyprinus carpio*) co-cultivated with tilapia during disease outbreak in Israel (Eyngor *et al.*, 2014). Co-cultivated grey mullet and thin-lipped mullet (*Liza ramada*) were also found to be unaffected during Egyptian outbreaks (Fathi *et al.*, 2017).

Transmission/agent stability

Eyngor *et al.* (2014) demonstrated a disease transmission via cohabitation challenge, resulting in clinical disease in exposed fish similar to clinical signs associated with natural outbreaks. Horizontal disease transmission is likely to be the main mode of disease spread. However, the precise mechanism for transmission is unknown, nor is there information available on virus stability free in the water or in contaminated fomites. Dong *et al.* (2017b) point to some potential evidence for vertical transmission of TiLV, although the authors stress the need for further study.

Factors determining disease manifestation

There is no evidence as yet to suggest that TiLV has a differential impact on smaller/younger fish. Eyngor *et al.* (2014) report TiLV-attributed mortality in a wide weight range of tilapia. Fingerlings have been affected in Ecuador (Ferguson *et al.*, 2014) and Thailand (Dong *et al.*, 2017a; Surachetpong *et al.*, 2017).

Red hybrid tilapia (Oreochromis spp.) *field outbreak sample associated with TiLV infection showing skin redness, erosion, hemorrhage and exophthalmos.*

Small fish up to 50 g were affected in Thailand (Surachetpong *et al.*, 2017). In Egypt, medium (>100 g) and large fish have been affected by an unknown cause of mortality during the summer months, commonly referred to as "Summer mortality", some of which has been tested positive for TiLV (Fathi *et al.*, 2017).

There appears to be some seasonality to the disease, as outbreaks of clinical disease are reported to be associated with water temperatures between 22 and 32°C in Israel (Eyngor *et al.*, 2014), 25 and 27°C in Ecuador (Ferguson *et al.* 2017) and 25°C or above in Egypt (Fahti *et al.*, 2017).

The degree to which stress may play a part in TiLV disease manifestation is highlighted by Dong *et al.* (2017a) and Surachetpong *et al.* (2017), who note the occurrence of disease following transfer to grow-out cages. Fathi *et al.* (2017) identified high stocking rates, as well as large farm size and tilapia mullet polyculture as potential risk factors for clinical disease outbreak.

Clinical signs and pathology

A broad range of non-specific clinical signs typical of systemic infections have been reported, including lethargy, exophthalmia, abdominal distension and scale protrusion, pallor, anaemia and skin congestion. In the Egyptian "Summer mortality" outbreaks, where the role of TiLV in disease aetiology is not well established, haemorrhagic patches and open wounds on the skin are reported in addition to the common signs of systemic infection reported in other countries.

Mortalities reported to be associated with TiLV range from relatively moderate mortalities (5-20%) to high-level mortalities in the 80-90 percent range (OIE, 2017b; Surachetpong *et al.*, 2017, Ferguson *et al.*, 2017).

Histopathologically, published papers described syncytial hepatitis in TiLV outbreaks (Ferguson *et al.* 2014; Del Pozo *et al.* 2017; Dong *et al.* 2017a; Behera *et al.* 2018). Experimental infection reproduced the same pathological change (Behera *et al.* 2018).

Diagnostic testing: molecular methods

Several molecular tests for TiLV have been developed, although there is no independent proficiency testing reported. Eyngor *et al.* (2014) developed the first Reverse transcription polymerase chain reaction (RT-PCR) and subsequently Tsofack *et al.* (2017) developed a nested RT-PCR assay, with reported improved sensitivity. This nested-RT-PCR assay was able to detect TiLV in both fresh and preserved samples of diseased fish. Tsofack *et al.* (2017) also describe a real-time PCR method for quantification. Dong *et al.* (2017a) have developed an alternative semi-nested RT-PCR assay. Most recently, Tattiyapong *et al.* (2017b) report the development of a RT-qPCR (quantitative polymerase chain reaction) assay with a detection limit as low as two viral copies per microliter and that could be used for TiLV detection in various fish tissues, including gills, liver, brain, heart, anterior kidney and spleen.

The tests developed thus far allow for pooling of two to five samples (Tsofack *et al.*, 2017; Dong *et al.*, 2017a; Fathi *et al.*, 2017; Surachetpong *et al.*, 2017). An *in-situ* hybridization test has also been developed and has been used to support studies to establish TiLV as a primary cause of disease (Bacharach *et al.*, 2016; Dong *et al.*, 2017a).

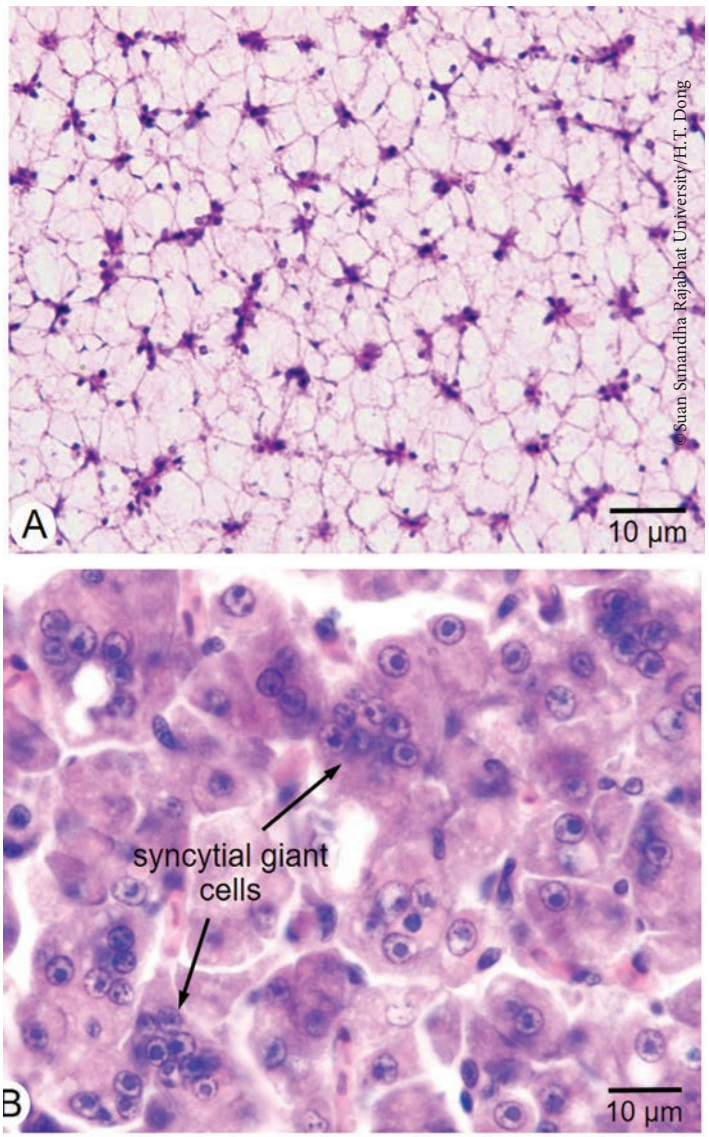
Geographic distribution

Tilapia is a widely traded commodity and given the high likelihood that fish clinically or sub-clinically infected with TiLV would have been internationally traded over the years, there is every chance that the agent has spread beyond the geographical range described in the scientific literature or the range formally reported to the OIE. For this reason, it is important for countries that trade in (especially live) tilapia to assess TiLV risks, undertake surveillance to verify national TiLV health status and implement any risk management measures deemed necessary.

TiLV has been reported in the scientific literature in Israel (Eyngor *et al.*, 2014), Egypt (Fathi *et al.*, 2017), Ecuador (Bacharach *et al.*, 2016; Tsofack *et al.*, 2017), Colombia (Tsofack *et al.*, 2017), India (Behera *et al.* 2018), Peru (OIE, 2018), the Philippines (OIE, 2017d), Malaysia (OIE, 2017e), Thailand (Dong *et al.*, 2017a; Surachetpong *et al.*, 2017), Chinese Taipei (OIE, 2017c), Indonesia (Koesharyani *et al.*, 2018) and in Lake Victoria (which borders Uganda, Kenya and Tanzania) (Mugimba *et al.* 2018).

In Israel, TiLV was found in wild (Sea of Galilee) and farmed tilapia in 2011 and 2013 (Eyngor *et al.*, 2014). Fathi *et al.* (2017) found that 37 percent of randomly selected fish farms in in Egypt were affected by "Summer mortality", although the role of TiLV in these mortalities is uncertain.

Preserved tilapia fingerling tissues sampled in 2011/12 from a farm in Ecuador were found positive for TiLV when subject to more recent testing (Ferguson *et al.*, 2014; Bacharach *et al.*, 2016), as were fish samples from Colombia (Tsofack *et al.*, 2017).



Photomicrographs of the liver sections of normal (A) and TiLV-infected tilapia (B) stained with hemotoxylin and eosin (H&E). Normal hepatocytes showed polyhedral shape and each cell contains single nucleus (A) while the infected liver tissue showed syncytial giant cells with multiple nuclei, typical histopathology of TiLV infection (B)

Surachetpong *et al.* (2017) reported 22 out of 32 Thai farms sampled in 2015 and 2016 to be TiLV-positive. Dong *et al.* (2017b and 2017c) also reported the presence of TiLV in new and preserved samples from three tilapia hatcheries in Thailand, collected between 2012 and 2017.

Given the likely extensive transboundary movement of live tilapia around the world prior to the discovery of TiLV and minimal generic or targeted risk management measures imposed on imported fish by most countries, there is every chance that TiLV would have made its way to several countries around the world. However, whether the agent would have established itself in local fish populations in these importing countries is uncertain – hence the urgent need for TiLV risk assessment, as well as TiLV surveillance in these countries.

The pathogen is under consideration for listing by the OIE, but to date does not meet the OIE's listing criteria as described in its Aquatic Animal Health Code (OIE, 2017a).

Tilapia aquaculture industry and impact of TiLV

Tilapias are the second-most important farmed finfish worldwide (next to the Cyprinids), with Nile Tilapia ranking sixth among the most important cultured species. Their importance is also due to their affordability, being a good source high-quality protein and micronutrients, tolerance to high-density aquaculture and resistance to disease. The top ten tilapia producers for 2015 were: China (1.8 million tonnes), Indonesia (1.1 million tonnes), Egypt (875 000 tonnes), Bangladesh (324 000 tonnes), Viet Nam (283 000 tonnes), the Philippines (261 000 tonnes), Brazil (219 000 tonnes), Thailand (177 000 tonnes), Colombia (61 000 tonnes) and Uganda (57 000 tonnes). In 2015, world tilapia production (aquaculture and capture) amounted to 6.4 million tonnes, with an estimated value of USD 9.8 billion, and worldwide trade was valued at USD 1.8 billion (FAO, 2017d).

As with most aquatic animal diseases, the main mode of TiLV spread is likely to be a direct one through the (local and transboundary) movement of live fish, primarily for purposes of aquaculture or restocking of wild populations. The role played by the trade in uncooked tilapia products is not known, in terms of the virus' survival in frozen/chilled tissue or in terms of pathways by which these products could result in infection of farmed or wild fish stocks.

Live tilapia is a widely traded commodity and there is potential that TiLV may have spread significantly over the years since its first reported occurrence in 2009. The need for tilapia-producing countries to assess risks, undertake surveillance to determine national TiLV health status, and introduce risk management measures where deemed necessary is therefore paramount.

In Israel, the tilapia wild catch (mainly Sarotherodon galilaeus) in the Sea of Galilee dropped significantly from an average level of 257 tonnes per year to 8 tonnes per year in 2008. The drop was linked to TiLV disease. Since 2009, the tilapia catch in the Sea of Galilee has been growing continuously and reached 320 tonnes in 2015. Although tilapia breeders report variable survival rates especially during the hot season, the total production of cultured tilapia in the last decade has been stable, ranging from 7 000 to 8 000 tonnes per year. In Thailand, during 2015 and 2016, TiLV outbreaks resulted in mortalities of 20 to 90 percent, with records indicating many deaths of farmed Nile tilapia and hybrid red tilapia. In Egypt, the unexplained "Summer mortality" of tilapia in recent years had a potential economic impact of around USD 100 million in 2015 (FAO, 2017c).

The role that trade in uncooked whole tilapia and tilapia products (such as fish fillets) might play in disease spread is unknown.

ANNEX 3. RISK ASSESSMENT METHOD

Risk estimation

Experts were asked questions about the likelihood (probability) of TiLV entry, establishment and spread over the next five years, and the consequences (likely impacts) of such spread.

Likelihoods of entry, establishment and spread were described using the following descriptors:

- Extremely unlikely: May only occur in exceptional circumstances.
- Very unlikely: May occur at some point but not often.
- Unlikely: Could occur at some time but not that likely.
- As likely as not: Might occur at some time.
- Likely: Will probably occur in many circumstances.
- Very likely: Will very likely occur very often.
- Almost certain: Can be expected to always occur.

For each likelihood estimation, experts were asked to attribute a level of uncertainty as follows:

- Low: There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions. Experts have multiple and/or direct experiences of the event.
- Medium: There are some but not complete data available; evidence is provided in a small number of references; authors report conclusions that vary from one another. Experts have limited experience of the event.
- High: There are scarce or no data available; evidence is not provided in references but rather in unpublished reports or based on observations or personal communication; authors report conclusions that vary considerably between them. Experts have no experience of the event.

Uncertainty scores of 1, 2 and 3 were assigned to *low, medium* and *high* uncertainty descriptors, respectively, for the purpose of determining the "average" level of uncertainty for each estimation of a likelihood of entry, establishment and spread.

As a supplementary question, experts were also asked to nominate the relative proportion (0-1%, 1-10%, 10-33%; 33-66%, 66-90%, 90-99% or 99-100%) of the overall likelihood of TiLV spread (internationally or within a country) that is represented by the trade in uncooked chilled/frozen whole fish and fish products (such as fish fillets) as a pathway for disease spread (as compared to translocation of live fish).

To assess the consequences (likely impacts) of TiLV entry, establishment and spread, experts were asked to estimate the *most likely* impacts using a consequence assessment matrix (Table 1), by nominating what they considered to be level of impact (ranging from low to catastrophic) most likely to occur and the magnitude of that likelihood (ranging from extremely unlikely to extremely likely). As per the OIE Aquatic Animal Health Code (Chapter 2.1), experts were asked to consider potential direct and indirect adverse health or environmental consequences, as well as socio-economic impacts when considering each level of impact. Examples of direct and indirect impacts include:

Direct impacts

- Aquatic animal infection, disease, production losses and facility closures
- Public health consequences.

Indirect impacts

- Surveillance and control costs
- Compensation costs
- Potential trade losses
- Adverse, and possibly irreversible, consequences to the environment.

The overall consequence level was calculated by simply summing the two numerical scores for the nominated impact descriptor and corresponding likelihood descriptor. The summed score was then converted back to an overall consequence (likely impact) description as follows: ≤3 = low; 3< to 5 = minor; 5< to 8 = moderate; 8< to 10 = major; 10< to12 = catastrophic.

The final step in the risk assessment was to combine (sum) each likelihood of entry, establishment and spread estimation score with the corresponding consequence estimation score, as per the risk matrix shown in Table 2.

The overall risk level was calculated later by summing the respective likelihood and consequence scores to give a final risk score, which was then grouped into one of four levels: ≤5 = low; 5< to 8 = moderate; 8< to 10 = high; or 10< to 12 = very high.

Finally, the mean (as well as standard deviation and 95% confidence intervals) of numerical scores were calculated for the likelihood, consequence and risk estimations of the 14 experts, and the corresponding "average" response descriptor documented.

The experts were presented with a series of potential risk management measures for managing the risk of disease spread to TiLV-free countries (international spread) or further spread within countries where TiLV is already established, and asked to rank each measure in terms of effectiveness and feasibility. Fourteen measures were presented to experts for managing domestic disease spread and 16 measures for international disease spread. It was made clear to the experts that no single measure need necessarily fully reduce the risk to an acceptable level and that invariably a suite of measures would be required.

For each risk management measure, the mean of the numbered ranking attributed by the 14 experts was calculated and compared to means for each of the other measures so as to list the measures in order of effectiveness and in order of feasibility.

TABLE 1 *Consequence assessment matrix*

	LIKELIHOOD						
IMPACT	**Extremely unlikely (1)**	**Very unlikely (2)**	**Unlikely (3)**	**As likely as not (4)**	**Likely (5)**	**Very likely (6)**	**Almost certain (7)**
Low (no cases – negligible indirect costs) (1)	2	3	4	5	6	7	8
Minor (few cases – low indirect costs) (2)	3	4	5	6	7	8	9
Moderate (limited number of cases – moderate indirect costs) (3)	4	5	6	7	8	9	10
Major (extended number of cases – significant indirect costs) (4)	5	6	7	8	9	10	11
Catastrophic (very large number of cases – extreme indirect costs) (5)	6	7	8	9	10	11	12

TABLE 2 *Matrix for determining final risk*

		Likelihood of entry, establishment and spread						
		Extremely unlikely (1)	**Very unlikely (2)**	**Unlikely (3)**	**As likely as not (4)**	**Likely (5)**	**Very likely (6)**	**Almost certain (7)**
Consequences	Low (1)	2	3	4	5	6	7	8
	Minor (2)	3	4	5	6	7	8	9
	Moderate (3)	4	5	6	7	8	9	10
	Major (4)	5	6	7	8	9	10	11
	Catastrophic (5)	6	7	8	9	10	11	12

ANNEX 4. RISK ANALYSIS EXPERTS

- Dr Vishnumurthy Mohan **Chadag**, WorldFish, Malaysia
- Dr Nadav **Davidovich**, Israeli Veterinary Services and Animal Health, Ministry of Agriculture and Rural Development, Israel
- Dr Ha Thanh **Dong**, formerly of Department of Microbiology, King Mongkut's University of Technology Thonburi, Thailand
- Dr Marcela Lara **Fica**, Sernapesca, Chile
- Dr David **Huchzermeyer**, Rhodes University, South Africa
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- Mr Jose **Paclibare**, Private Consultant, Philippines
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ANNEX 5. TILV RISK ASSESSMENT SUMMARY DATA

RISK QUESTION		MEAN	STDEV*	95% confidence interval	Lower bound	Upper bound
1. What, in the absence of any controls, is the likelihood of TiLV spreading within a country where it is already present?	*Likelihood*	6.2	0.9	0.5	5.7	6.7
	Uncertainty	low-medium				
	Impact	3.5	0.9	0.5	3.0	4.0
	Likelihood	6.1	0.7	0.3	5.8	6.5
	Likely consequences	9.6	1.4	0.7	8.9	10.3
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	4.1	0.7	0.3	3.8	4.5
	Overall RISK	10.3	1.3	0.7	9.6	10.9
	RISK description	very high				
2. What, in the absence of any controls, is the likelihood of TiLV spreading from an infected country to China?	*Likelihood*	5.1	1.1	0.6	4.5	5.7
	Uncertainty	medium				
	Impact	3.7	0.7	0.4	3.3	4.0
	Likelihood	5.8	1.4	0.7	5.0	6.5
	Likely consequences	9.4	1.7	0.9	8.5	10.4
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	4.0	0.8	0.4	3.6	4.4
	Overall RISK	9.2	1.5	0.8	8.4	10.0
	RISK description	high				
3. What, in the absence of any controls, is the likelihood of TiLV spreading within the Asian region?	*Likelihood*	5.8	1.1	0.6	5.2	6.4
	Uncertainty	low-medium				
	Impact	3.5	0.9	0.5	3.0	4.0
	Likelihood	5.9	1.1	0.6	5.4	6.5
	Likely consequences	9.4	1.7	0.9	8.5	10.3
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	3.9	0.7	0.4	3.5	4.3
	Overall RISK	9.7	1.7	0.9	8.8	10.6
	RISK description	high				
4. What, in the absence of any controls, is the likelihood of TiLV spread from countries of an infected region (e.g. Southeast Asia) to:						
a. Africa	*Likelihood*	5.6	1.3	0.7	4.9	6.3
	Uncertainty	medium				
	Impact	3.5	0.9	0.5	3.0	4.0
	Likelihood	5.7	1.2	0.6	5.1	6.3
	Likely consequences	9.3	1.8	0.9	8.3	10.2
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	3.9	0.8	0.4	3.5	4.4
	Overall RISK	9.6	1.8	0.9	8.6	10.5
	RISK description	high				

(cont.)

RISK QUESTION		MEAN	STDEV*	95% confidence interval	Lower bound	Upper bound
b. East Asia	*Likelihood*	5.6	1.1	0.6	5.1	6.2
	Uncertainty	low-medium				
	Impact	3.5	0.8	0.4	3.1	4.0
	Likelihood	5.8	0.7	0.4	5.4	6.2
	Likely consequences	9.3	1.1	0.6	8.8	9.9
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	3.9	0.6	0.3	3.6	4.3
	Overall RISK	9.6	1.6	0.8	8.8	10.4
	RISK description	high				
c. South Asia	*Likelihood*	5.6	1.1	0.6	5.1	6.2
	Uncertainty	low-medium				
	Impact	3.6	0.9	0.5	3.1	4.1
	Likelihood	5.6	1.3	0.7	5.0	6.3
	Likely consequences	9.2	2.0	1.1	8.2	10.3
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	3.9	1.0	0.5	3.4	4.5
	Overall RISK	9.6	1.9	1.0	8.6	10.6
	RISK description	high				
d. North America	*Likelihood*	4.1	1.1	0.6	3.5	4.7
	Uncertainty	medium				
	Impact	2.7	1.1	0.6	2.1	3.2
	Likelihood	4.9	1.1	0.6	4.3	5.5
	Likely consequences	7.6	1.6	0.9	6.8	8.5
	likely consequences descriptor	moderate				
	Consequences FINAL SCORE	3.2	0.7	0.4	2.8	3.6
	Overall RISK	7.3	1.6	0.9	6.4	8.1
	RISK description	moderate				
e. South America	*Likelihood*	5.5	0.8	0.5	5.0	6.0
	Uncertainty	low-medium				
	Impact	3.2	1.0	0.5	2.7	3.7
	Likelihood	5.5	0.9	0.5	5.1	6.0
	Likely consequences	8.7	1.3	0.7	8.0	9.5
	Likely consequences descriptor	major				
	Consequences FINAL SCORE	3.6	0.5	0.3	3.3	3.9
	Overall RISK	9.2	0.8	0.4	8.7	9.6
	RISK description	high				
f. PICTs	*Likelihood*	3.9	1.1	0.6	3.3	4.4
	Uncertainty	medium-high				
	Impact	2.9	1.2	0.6	2.2	3.5
	Likelihood	5.1	1.3	0.7	4.4	5.8
	Likely consequences	7.9	2.1	1.1	6.8	9.0
	Likely consequences descriptor	moderate				
	Consequences FINAL SCORE	3.3	0.9	0.5	2.8	3.8
	Overall RISK	7.2	1.8	1.0	6.2	8.1
	RISK description	moderate				

* Standard deviation

ANNEX 6. REFERENCES

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NOTES


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RISK ANALYSIS IN ANIMAL HEALTH

Risk analysis is a procedure, which we all do intuitively in our everyday life as we also do in our professional work to assess the risk of any hazard or threat. In animal health, risk analysis has been most widely used as a decision tool to help select the most appropriate health interventions to support disease control strategies, guide disease surveillance and support disease control or eradication strategies.

It should be remembered that risk is not equal to zero and never stays static. Risk changes as drivers or factors of disease emergence, spread or persistence change such as intensification of livestock production, climate change, civil unrest and changes in international trading patterns. Risk analysis should therefore not be seen as a "one off" but as good practice for animal health systems as part of their regular activities. Therefore, risk analysis process should be repeated and updated regularly.

Risk analysis comprises the following components:

Hazard identification: the main threats are identified and described.

Risk assessment: risks of an event occurring and developing in particular ways are first identified and described. The likelihood of those risks occurring is then estimated. The potential consequences or impact of the risks if they occur are also evaluated and are used to complete the assessment of the risk.

Risk management: involves identifying and implementing measures to reduce identified risks and their consequences. Risk can never be completely eliminated but can be effectively mitigated. The aim is to adopt procedures that will reduce the level of risk to what is deemed to be an acceptable level.

Risk communication: an integrated process that involves and informs all stakeholders within the risk analysis process and allows for interactive exchange of information and opinions concerning risk. It assists in the development of transparent and credible decision-making processes and can instil confidence in risk management decisions.

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