ASEAN REGIONAL GUIDELINE FOR THE IMPLEMENTATION OF INTERNATIONAL STANDARDS RELATED TO SPS MEASURES

GUIDELINE 4
ANIMAL IMPORT RISK ANALSYS

Supported by:

ASEAN-AUSTRALIA-NEW ZEALAND FREE TRADE AREA
AANZFTA ECONOMIC COOPERATION SUPPORT PROGRAMME (AECSP)

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Under the AECSP, ASEAN Regional Guideline for the Implementation of International Standards related to SPS Measures was prepared by the Ausvet Pty Ltd and approved for public dissemination by the AANZFTA Sub-Committee on SPS, 2019.

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Introduction

The Sanitary and Phytosanitary Measures Agreement

The World Trade Organisation (WTO) recognises each nation's sovereign right to use sanitary and phytosanitary (SPS) measures to protect animal, plant and human health. The Agreement on the Application of SPS Measures (SPS Agreement) is a WTO Agreement that formalises how these SPS measures should be used so that they do not unduly affect trade. The SPS Agreement is necessarily broad and strategic: it outlines the principles to be followed but provides little detail on how to implement these principles. International standards set by the World Organisation for Animal Health (OIE), the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex) Commission provide further guidance, including technical details and recommendations for implementation.

The major features of the SPS Agreement include:

- countries may set their own standards and methods of inspecting products
- regulations must be justifiable and based on science
- regulations should be applied only to the extent necessary to protect human, animal and plant life or health—in other words, measures should restrict trade to the least extent possible
- regulations should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail
- countries are encouraged to use international standards, guidelines and recommendations where they exist, but may implement higher standards provided these are scientifically justified based on appropriate risk analysis that is consistently applied.

Members can use two broad approaches in setting SPS measures, consistent with the SPS Agreement:

- implement the normative standards established by the relevant international standards
- implement SPS measures to suit an individual country's risk tolerance based on a defined appropriate level of protection (ALOP), underpinned by a risk analysis and credible scientific justification.

While Members accept that each country can determine its own ALOP, the SPS Agreement seeks to ensure that SPS measures are the minimum required to provide that protection, are consistently applied, are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.

Sanitary and Phytosanitary Measures Agreement in ASEAN

In recent years, the volume of trade in agri-foods has grown rapidly in Southeast Asia. However, despite formally adopting SPS Agreement principles, many ASEAN Member States (AMS) face difficulties putting into effect these principles and the relevant international standards, guidelines and recommendations. Among AMSs, there is a high degree of variability in the maturity of SPS systems and capacity to implement. Looking forward, as agri-food industries continue to expand in the region increasing the capacity for AMSs to implement the SPS Agreement is of paramount importance.

ASEAN Regional Guideline for the Implementation of International Standards related to SPS Measures

The ASEAN-Australia-New Zealand Free Trade Area (AANZFTA) Economic Cooperation Support Programme (AECSP) aims to assist ASEAN countries to maximise the benefits of AANZFTA with the aim of enhancing trade within the region and between Australia, New Zealand and AMSs. A crucial

component of improving trade is to enhance implementation of the SPS agreement and international standards by AMSs.

Within this context, AANZFTA developed a project to provide assistance to the AMSs to develop their own national SPS standards based on international standards, guidelines and recommendations, where they exist. The immediate aims of the project are:

- To enhance understanding and recommend solutions about the challenges encountered by AMS in developing national SPS standards based on international standards, guidelines (IPPC, OIE, Codex); and
- To develop a regional guideline to assist AMS in their practical implementation of international standards related to SPS measures

The project is divided into two phases. Phase 1 has already been concluded and was a comprehensive study resulting in a report, titled 'Review Report of the Implementation of SPS Agreement and International Standards in ASEAN Member States'

This guideline is the fourth in a series of guidelines produced as part of Phase 2 of the project. These guidelines are complemented by a collection of e-learning modules. These guidelines are deliberately succinct and written in plain language to facilitate accessibility for a wide audience.

Import Risk Analysis Overview

What is risk?

Risk is something we deal with in our daily lives. We are constantly confronting risk. The technical definition of risk is the likelihood of an event occurring and the consequence of that event occurring.

We identify risks all day: when we cross the road, prepare a meal on the stove or buy a chicken from the market. We know we could get run over. We may burn our food or ourselves and the chicken we are buying could be sick. When we approach these risks we immediately and often subconsciously assess them. Will we have time to cross the street? How high should we set the stove? Does the chicken we are buying look healthy? We also manage risk. We wait until the next car has passed. We don't leave the house when the stove is on. We go to the market with a good reputation. We also communicate that risk. We tell our companion that we will cross the street after the next car. We tell our partner that there is food on the stove. We ask the store owner where the chick is from.

Risk is different to danger. Danger shows a higher level of certainty whereas risk can be very small or very large. For example, crossing a busy road represents a danger for a small child. For an adult however, crossing a road is a risk but may not be considered a danger. Danger implies that a risk has reached a certain threshold where action is required. A small child should be assisted when crossing the road.

A hazard is a biological, chemical or physical agent in, or a condition of an animal or animal product (including aquatic animals) with the potential to cause an adverse health effect. Risk is the probability that the hazard will actually cause adverse health effects.

Animal import risk analysis (IRA) is a term used to describe this entire process. It has four components: identification, assessment, management and communication.

Import Risk Analysis

Risks in animal health are no different to the risks we face every day. Importation of animals or animal products involves risk of importing disease. This risk needs to be identified, assessed, managed (when necessary) and communicated. This whole process is called IRA. The OIE describes the process of IRA in four steps (see Figure 1): hazard identification, risk assessment, risk management and risk communication.

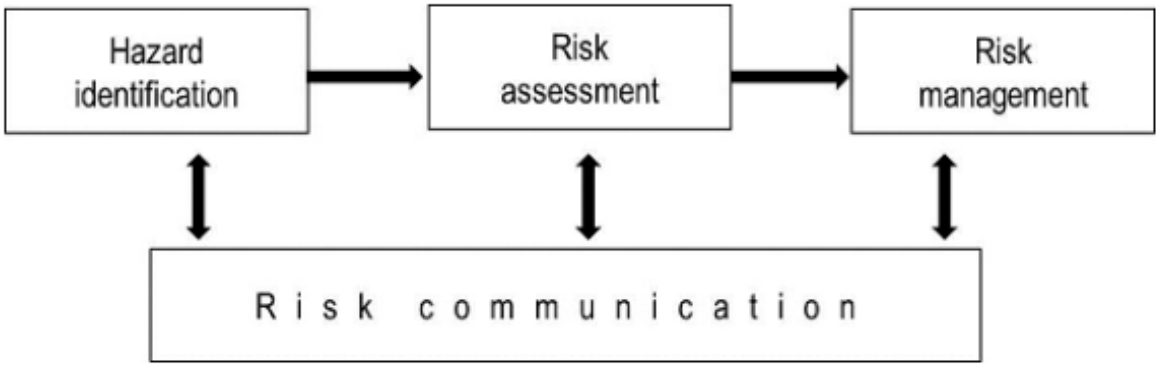

Figure 1 The OIE risk analysis framework

IRA is generally conducted when a country plans to import an animal or animal product or when there is a change in the known epidemiology or distribution of a disease that effects a current trade arrangement.

Hazard identification

Hazard identification is identifying the pathogenic agents that could potentially produce adverse consequences associated with importation of a commodity. It is a multi-step process that involves

developing a very broad list of hazards and then narrowing that list down to the ones that require further risk assessment based on set criteria. Further detail on the hazard identification process is described in Section 2.

Risk assessment

Risk assessment is the component of the analysis that estimates the risk associated with a hazard. Risk can be estimated as a number (quantitative) or described with words (qualitative). Risk assessment itself comprises of four components: entry assessment, exposure assessment, consequence assessment and risk estimation.

Entry assessment

Entry assessment, also known as release assessment, consists of describing the biological pathway(s) necessary for an importation activity to introduce a pathogenic agent into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitively (as a numerical estimate).

Exposure assessment

Exposure assessment consists of describing biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) from a given risk source, and estimating the probability of these exposure(s) occurring, either qualitatively or quantitively. Exposure assessment describes the probability of each hazard infecting an animal or human. Exposure assessment should consider the likelihood of establishment and spread.

Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to the biological agent and the consequences of those exposures. This could include social and economic, as well as consequences related to animal welfare and health.

Risk estimation

Risk estimation consists of integrating the results of entry assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. There is more about this approach in Section 2.

Risk management

Risk management is the process of deciding upon and implementing measures to address the risks identified in the risk assessment, whilst at the same time ensuring that negative impacts on trade are minimised.

Risk communication

Risk communication is the process by which information and opinions regarding hazards and risk are gathered from potentially affected and interested parties during a risk analysis, and by which the results of risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries.

The OIE International Standards and IRA

The OIE has already developed risk mitigation measures for selected hazards (namely, OIE-listed diseases). Whilst it is important to understand all components of IRA, in some cases, countries may only need to identify hazards, refer to the OIE International Standards for their risk mitigation and communicate effectively. The OIE Terrestrial Animal Health Code also has a specific chapter outlining internationally agreed-upon methodologies for import risk analysis.

Resources

E-learning module 4.1.

The World Organisation for Animal Health, *The OIE Terrestrial Animal Health Code, Chapter 2.1* Available: https://www.oie.int/standard-setting/terrestrial-code/access-online/ (accessed 23rd Sept 2019).

How and when to do an Import Risk Analysis

Basic requirements for IRA

There are some core requirements for IRA. These are listed below

- **Clear objectives**: Before making a start, assessors should ask, 'Why are we doing this IRA?'. In many cases, the OIE International Standards will provide sufficient guidance on managing risk and full IRA is not necessary
- **Information**: Any sanitary measures that differ from those recommended by the OIE International Standards, must be evidence-based. To fulfil this requirement, information is needed. Ideally, information includes peer-reviewed scientific literature.
- **Expertise**: An expert team is required for IRA. Ideally, at least one person should have completed some advanced training in IRA.
- **A step-wise approach**: The OIE handbook on IRA outlines eight core steps in IRA. These should be followed systematically.

Human resources for IRA

For countries that complete full IRA, there are many different people involved. Several of these are from within government departments but others include academics, economists, laboratory workers, private veterinarians, consultants or industry representatives. IRA is usually led by a competent authority within a government department (i.e the Ministry or Department of Agriculture). For some commodities, full IRA is not necessary. Government staff may identify hazards for a particular commodity and conclude that all hazards are either OIE-listed diseases for which OIE International Standards already exist or they are already present in the importing country. IRAs also require a skilled multi-disciplinary team for their implementation. Teams for implementation may include veterinarians, statisticians, economists and communication experts.

Using the OIE International Standards risk mitigation instead of full IRA

Full IRA is not always necessary. In some cases, the risk mitigation measures in the OIE International Standards can be applied as an alternative in accordance with the principle of harmonization, described in article 3 of the SPS Agreement.

Article 3 states that *'on as wide a basis as possible, Members shall base their SPS measures on international standards, guidelines and recommendations.'* It also says that *'SPS measures which conform to international standards and recommendations shall be deemed necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement'*. On the contrary, article 3 says that *'Members may introduce or maintain SPS measures which results in a higher level of SPS protection than what would be achieved by measures based on relevant international standards, guidelines or recommendations, if there is scientific justification'*.

Article 5 of the SPS Agreement describes principles related to the assessment of risk and the determination of the ALOP. It states that '*Members shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the* risks *to human, animal or plant life or health…'. 'An assessment that is appropriate to the circumstances'* could be considered hazard identification followed by the use of the OIE International Standards. Alternatively, it could be considered full IRA.

In summary, the OIE International Standards could be used when:

1. The hazard identified is an OIE-listed disease: and
2. The sanitary measures described in the OIE International Standards are sufficient to meet your country's ALOP

On the contrary, full IRA should be considered when:

a. A hazard identified is not an OIE-listed disease: or
b. The sanitary measures described in the OIE International Standards are not sufficient to meet your country's ALOP

Steps in IRA

a. Clearly and precisely define the scope of the IRA
b. State the purpose of the IRA
c. Develop a communication strategy
d. Source information
e. Identify hazards associated with importation of the commodity being considered in the IRA
f. Determine if the OIE International Standards provides sanitary measures for the hazard
g. Risk assessment (when required)
h. Risk management (option identification and evaluation, not implementation, only when required)

If the OIE International Standards provide recommended sanitary measures for the hazards identified in step five and if they are sufficient to reach the importing country's ALOP, then steps g and h may not be necessary.

For further detailed information on each step, consult the OIE IRA Handbook.

When completing an IRA, the assessors should always consider the implications of the SPS Agreement.

The SPS Agreement indicates that:

a. there should be no restrictions on international trade unless there is evidence that this trade comes with an unacceptable level of risk; and
b. any risk management measures that are more stringent than the OIE Standards must be based on evidence.

More detail on hazard identification

Hazard identification can be broken down into the following steps:

a. Broad literature review to develop a list of potential hazards, along with basic epidemiological information for each.
b. Assessment of animal disease status and state of animal health and veterinary services in exporting country (and the importing country).
c. Assessment of whether the identified hazard requires further assessment (based on the second step).

A table like the one shown below can be useful in determining whether a hazard requires further assessment.

Table 1 Example table for hazard identification process

Organism/Disease	Present in importing country	Present in exporting country	Eradication program in importing country	Other (e.g. zoonosis or more virulent strains)	Further assessment required?
Disease A	Y/N	Y/N	Y/N	Y/N	Y/N
Disease B	Y/N	Y/N	Y/N	Y/N	Y/N
Disease C	Y/N	Y/N	Y/N	Y/N	Y/N
Disease D	Y/N	Y/N	Y/N	Y/N	Y/N

Hazards should be considered candidates for further assessment if:

- they are present in the exporting country (or their status in the exporting country is unknown) but not in the importing country
- the importing country considers the hazard to be unwanted and/ has a control program in place for the hazard
- the hazard can travel on the commodity
- there are other factors such as zoonotic potential or the capacity to import more virulent strains of a hazard

More details on risk assessment

Risk assessment can provide a qualitative and/or quantitative measure of risk. Qualitative measures are often preferred, as measurement is less complicated and requires less data. For this reason, guidance on qualitative risk assessment is provided below.

Qualitative risk assessment

Entry assessment

In entry assessment, the assessor describes all pathways by which a hazard may be introduced through the importation activity, and attaches a qualitative probability to the occurrence of each step of the pathway and then across the sum of the pathways. Examples of qualitative probabilities are negligible, extremely low, very low, low, moderate and high.

Exposure assessment

In exposure assessment, the assessor describes all pathways by which animals or humans in the importing country may become exposed to the imported hazard, and attach a qualitative probability to each step of these pathways and then across the sum of the pathways. Examples of qualitative probabilities are negligible, extremely low, very low, low, moderate and high. The exposure assessment should take into consideration the probability of the hazard establishing and spreading within the country. Sometimes the probability of exposure to a hazard can be very high but the probability of establishment and spread is low.

Consequence assessment

In the consequence assessment, the assessor describes the consequences of exposure to the hazard and assign an overall qualitative measure to these. Examples of qualitative probabilities are negligible, extremely low, very low, low, moderate and high.

Risk estimation

For risk estimation, the assessors use matrices to combine the results of entry assessment, exposure assessment and consequence assessment into an overall risk estimate. Figure 2 and Figure 3 are examples

of common matrices used. If any of the three risk assessment steps are assessed to be negligible, the overall risk becomes negligible.

Likelihood of entry	Likelihood of exposure: Negligible	Extremely low	Very Low	Low	Moderate	High
High	Negligible	Extremely low	Very low	Low	Moderate	High
Moderate	Negligible	Extremely low	Very low	Low	Low	Moderate
Low	Negligible	Extremely low	Very low	Very low	Low	Low
Very low	Negligible	Extremely low	Extremely low	Very low	Very low	Very low
Extremely low	Negligible	Negligible	Extremely low	Extremely low	Extremely low	Extremely low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible

Figure 2 Matrix to combine entry and exposure assessments

Likelihood of establishment and/or spread	Overall effect of establishment and spread: Negligible	Very low	Low	Moderate	High	Extreme
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Very low	Low	Moderate	High
Very low	Negligible	Negligible	Negligible	Very low	Low	Moderate
Extremely low	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low

Figure 3 Matrix to combine likelihood of hazard establishment and/or spread with overall consequence

The final package

Where a full IRA is required, an appropriate structure for reporting is as follows:

a. Introduction (indicating the scope and purpose of the review);
b. Methods (describing the methods for each component of risk analysis, including citation of information sources);
c. Hazard identification (including a tabulated list of all possible hazards);
d. Risk reviews (including the risk assessment results for each hazard that required review); and
e. Requirements for importation (outlining the SPS requirements for importation of the commodity that reduce risk to an acceptable level, as informed by the risk management component of the risk analysis).

Resources

E-learning module 4.2.

World Organisation for Animal Health, 2010. Handbook on Import Risk Analysis for Animals and Animal Products, vol I: Introduction and qualitative risk analysis (2nd edn). Paris: World Organisation for Animal Health.

World Organisation for Animal Health, 2004. Handbook on Import Risk Analysis for Animals and Animal products, vol. II: quantitative risk assessment. Paris: World Organisation for Animal Health.

Case studies of Import Risk Analysis

The best way to understand IRA is to conduct it or to examine case studies. Here, two case studies are presented. In each case study, the extent of IRA required is different.

Case study one: Day old chicks

Scenario and preliminary steps

Country A has received a request from a company in their country that would like to import day-old chicks from Country B. Country A has a relatively small poultry industry, and limited veterinary services. They are surrounded by other countries so biosecurity is difficult to implement and they have a number of transboundary animal diseases in their livestock sectors. Usually, they use the OIE International Standards when setting sanitary measures. Country B has a developed commercial poultry sector and a number of smallholders. Country A has not imported animal products from Country B in the past and is unfamiliar with their veterinary services and animal health status. The Chief Veterinary Officer (CVO) of Country A asks a Veterinary Officer (VO) for a recommendation on whether Country A should accept these imports. The VO uses the OIE's IRA Handbook as a reference to take a step-wise approach to this request.

Determine the scope and state the purpose

Firstly, she holds a meeting with relevant stakeholders within her department to determine the scope of the IRA she may need to complete. The group concludes that she needs to assess the biosecurity risks associated with the importation of day-old chicks from Country B to Country A. The purpose of her work will be to identify and assess the likelihood of hazards entering Country A on day-old chicks from Country B and if necessary, suggest risk mitigation measures to minimize this likelihood to reach the ALOP of her country.

Communication strategy

The group identifies the parties most interested in this work will be the poultry industry in her country, the poultry industry in Country B and the governments of both countries and make a list of key contacts in these areas. Given that Country A has not worked with Country B much in the past, the VO sends Country B a questionnaire that aims to gather key details about their veterinary services and the health of animals in their country (including details of their poultry industry and key surveillance parameters). She also calls individuals on the contact list identified by the group and invites them to two workshops where she will update them on her work and ask for input. She releases a draft of her risk analysis online once complete and invite comments from her contact list.

Source information

The VO gathers some key poultry textbooks, looks at a recent IRAs on day-old chicks from another country and contacts an academic at a university that she knows to be a poultry vet. She also conducts a literature review using google scholar.

Hazard identification

By looking through these sources, the VO identifies over 60 hazards that could be imported on day-old chicks. This process takes her many weeks. Of these hazards, most are known to already occur in Country A or there is no desire to control or prevent them. These hazards don't require further assessment.

This leaves three hazards that could potentially be introduced by the importation of day-old chicks requiring further investigation; Avian influenza, infectious bronchitis and Salmonella.

Table 2 Hazards table for day-old chicks

Organism/Disease	Present in Country A?	Under official control or unwanted?	Infection in day old chicks?	Needs further consideration?
Avian influenza (AI)	No	Yes	Yes	Yes
Avian paramyxovirus 1 (APMV-1)	Yes	Notifiable	Yes	No
APMV-2	Yes	Other exotic organism	Yes?	No
Pneumoviruses	Yes	None	Yes?	No
Marek's disease	Yes	Notifiable	No	No
Laryngotracheitis	Yes	None	No	No
Infectious bronchitis	Yes	Unwanted (exotic strains)	Yes	Yes
Group I avian adenoviruses (Inclusion body hepatitis)	Yes	None	Yes	No
Group II avian adenoviruses (Avian adenovirus splenomegaly)	No	None	No	No
Group III avian adenoviruses (Egg drop syndrome)	Yes	No	Yes	No
Avipoxvirus	Yes	None	No	No
Gyrovirus (Chicken infectious anaemia)	Yes	None	Yes	No
Infectious bursal disease	No	Notifiable	No	No
Equine encephalitides	No	Notifiable	No	No
West Nile virus	No	None	No	No
Rotavirus	Yes	None	No	No
Viral arthritis, tenosynovitis	Yes	None	Yes	No
Avian encephalomyelitis	Yes	None	Yes	No
Astrovirus (Avian nephritis virus)	Yes	None	Yes	No
Leucosis/sarcoma complex viruses	Yes	None	Yes	No
Reticuloendotheliosis	Yes	None	Yes	No
Big liver and spleen disease virus	No	Other exotic organism	No	No
Salmonellae	Some	*S.* Pullorum and *S.* Gallinarum notifiable. Other exotic serovars and phage types unwanted	Yes	Yes
Campylobacter spp.	Yes	None	Yes	No
Escherichia coli	Yes	None	Yes	No
Pasteurella multocida	Yes	None	No	No
Pasteurella gallinarum	No	None	No	No
Riemerella anatipestifer	Yes	None	No	No

Organism/Disease	Present in Country A?	Under official control or unwanted?	Infection in day old chicks?	Needs further consideration?
Ornithobacterium rhinotracheale	No	Other exotic organism	Yes	No
Haemophilus paragallinarum	No	Other exotic organism	No	No
Bordetella avium	No	Other exotic organism	No	No
Mycoplasma gallisepticum	Yes	None	Yes	No
Mycoplasma synoviae	Yes	None	Yes	No
Mycoplasma iowae	Yes	Other exotic organism	Yes	No
Pseudomonas spp.	Yes	None	Yes	No
Mycobacterium tuberculosis	Yes	None	No	No
Mycobacterium avium	Yes	None	No	No
Other mycobacteria	Yes (Some)	Other exotic organism (exotic strains)	No	No
Francisella tularensis	No	Other exotic organism	No	No
Megabacteria	Yes	None	No	No
Gram positive contaminants (e.g. staphylococci/streptococci/ enterococci)	Yes	None	No	No
Proteus/Providencia group	Yes	None	Yes	No
Klebsiella spp.	Yes	None	Yes	No
Acinetobacter spp.	Yes	None	Yes	No
Citrobacter spp.	Yes	None	Yes	No
Flavobacterium spp.	Yes	None	Yes	No
Alcaligenes spp.	Yes	None	Yes	No
Serratia spp.	Yes	None	Yes	No
Hafnia alvei	Yes	None	Yes	No
Bacillus spp. (Not *Bacillus anthracis*)	Yes	None	Yes	No
Clostridium perfringens	Yes	None	Yes	No
Chlamydophila psittaci	Yes	None	Yes	No
Borrelia anserina (Avian spirochaetosis)	No	Other exotic organism	No	No
Borrelia burgdorferi (Lyme disease)	No	Other exotic organism	No	No
Brachyspira spp.	Yes	None	No	No
Coxiella burnetii	No	Notifiable organism	No	No
Aegyptianella pullorum	No	None	No	No
Other Rickettsia	Yes/No	Some are in the in register	No	No
Enterocytozoon bieneusi	Yes	None	No	No
Encephalitozoon cuniculi	Yes	None	Yes	No
Other fungi and yeasts	Yes/No	None	No	No
Nematodes, cestodes, protozoa	Yes/No	None	No	No
Ticks, mites, lice	Yes/No	Unwanted (Some genera)	No	No

Further information

After identifying these hazards, the VO gathers more information.

She consults the World Animal Health Information System (WAHIS) and notes that Country B has not reported any outbreaks of AI. Country B has reported cases of Infectious Bronchitis (IB) and Fowl Typhoid. She also receives the questionnaire results which indicate that:

- Country B conducts regular surveillance of their poultry for AI, IB and Fowl Typhoid
- Country B has well-developed veterinary services and laboratories
- Country B has a smallholder poultry sector, as well as a commercial poultry sector
- Country B has never diagnosed AI
- Country B has diagnosed IB and Fowl Tyhpoid a number of times in their smallholder sector.

Determine if the OIE Standards provide sanitary measures for the hazards

The VO refers to the OIE Terrestrial Animal Health Code and learns that all three identified hazards are of OIE-listed diseases. She notes that there are recommendations within Chapter 10.2, 10.4 and 10.7 on sanitary measures appropriate for reducing risk of importing all three diseases on day-old chicks.

Risk assessment

The VO consults with the CVO and a number of staff in her team on her country's ALOP and the group agrees that the OIE International Standards are likely to meet their ALOP. They also agree that their resources are limited so using the OIE International Standards may be the best approach. She therefore recommends that full risk assessment is not necessary.

Risk management

The VO outlines the risk management options described in Chapter 10.2, 10.4 and 10.7.

Conclusion

The VO compiles a report. It includes the table shown above, brief summaries of the three hazards identified and the risk mitigation measures suggested by the OIE Terrestrial Animal Health Code. She circulates this report to the four stakeholder groups identified above and suggests that the day old chicks can only be imported from Country B if the risk mitigation measures outlined are met. Her department plans a visit to Country B where she will conduct an informal audit with a colleague to confirm the information received on the questionnaire. She also commences work on import protocols which will be implemented if the importation is approved.

Case study two: Introduction of giant river prawns

Scenario and preliminary steps

Country A would like to import post-larval giant river prawns (*Macrobrachium rosengergii*) from Country B as part of a plan to develop a commercial aquaculture sector. Country A does not currently have river prawns but has a number of other shrimp species. Country B has a mature aquaculture industry including some commercial producers of giant river prawns. Country A has worked with Country B a lot in the past and knows the capacity of their veterinary services well (including aquatic veterinary services). Country A has very competent veterinary services and the imports department is well resourced. A large team is assembled to conduct an IRA and provide a recommendation on whether the importation should proceed. Country A also has a high biosecurity status overall and enjoys freedom from many common diseases of livestock and aquaculture. Country A therefore has a significant Acceptable Level of Protection and will often conduct full IRA rather than rely solely on the OIE Standards.

Determine the scope and state the purpose

The team meets to clarify their scope and purpose. They agree that they need to assess the biosecurity and risks associated with the importation of post-larval *M.rosengergii* into their country. The purpose of their work will be to identify, assess, manage and communicate the biosecurity risks associated with this importation.

Communication strategy

The team makes a preliminary list of stakeholders, these include the governments of both countries, the shrimp industry in the exporting country and those working on the development of the proposed new industry in Country A. They conclude that all of their stakeholders are contactable by email and have access to the internet. They send an email describing the scope and purpose of their task and invite stakeholders to a series of consultation meetings that occur through the process. They set up a webpage to outline the process and upload their draft IRA. Country A does not send Country B a questionnaire as they know each other's veterinary services well and can call each other for any further information if need be.

Source information

The team conducts a rapid literature review and finds that there is no published literature on diseases of shrimp in either Country A or Country B. The team also contacts a number of aquaculture experts in each country and finds that they also have very limited information on the presence or absence of shrimp diseases in country A or B. The team decides to conduct a systematic literature review of all pathogens of *M.rosengergii* worldwide.

Hazard identification

From the exhaustive literature review, the team identifies over 50 hazards that had been reported in *M.rosengergii*. They tabulate all hazards against key criteria to determine if further assessment is required. An excerpt of their table is shown below

Table 3 Excerpt from list of potential hazards of M.rosengergii

Pathogen	Infects post-larval stage?	Causes clinically significant disease	Further consideration required	References
White Spot syndrome virus (WSSV)	Y	Y	Y	Lo *et al.* 1996; Peng *et al.* 1998; OIE 2004
White tail disease (WTD)	Y	Y	Y	Arcier *et al.* 1999; Tung *et al.* 1999; Qian *et al.* 2003; Romestand and Bonami 2003
Flavobacterium sp.	Y	N	N	Rodriguez *et al.* 2001
Streptococcus sp.	P	N	N	Taufik and Satyani 1986; Phatarpekar *et al.* 2003

After consulting a number of shrimp experts in other countries, the team concludes that hazards will only be retained for further consideration when they are capable of infecting post-larval stages of *M.rosengergii* , may plausibly be present in Country B and have caused significant disease outbreaks. Using this criteria, the team identifies two hazards for further consideration: WSSV and WTD.

Determine if the OIE International Standards provide sanitary measures for the hazards

The team determines that the Aquatic Animal Health Code provides recommendations on both WSSV and WTD. Given Country A's strong ALOP, the team decides to use the OIE Standards to guide them but to still continue with a full IRA.

Risk assessment

The team conducts a visit to Country B to gather information for their full risk assessment. They also hold a workshop where risk pathways are discussed with a range of academics, government employees and aquatic veterinarians. The results of their risk assessment for WSSV is shown below. A similar process was completed for WTD.

Release assessment

The stock from Country B for importation into Country A is unlikely to be infected with WSSV because:

a. The stock has been maintained in relative isolation since it was imported many years ago from another country that is officially free of WSSV
b. There are no reports of wild shrimp in Country B being infected with WSSV
c. There is no evidence to suggest related shrimp species in Country B have ever been infected with WSSV

Release assessment result: *very low*

Exposure assessment

The likelihood of the pathogen escaping from the culture facility in Country A was assessed to be low because:

a. The shrimp will be maintained in covered tanks with no access to waterways or oceans
b. Effluent waters will be disposed of so they do not directly enter natural waterways

Release assessment result: *low*

Consequence assessment

There are a wide range of crustaceans that can become infected with WSSV which means that any introduction into Country A could result in the disease becoming endemic. Whilst aquaculture is not currently a highly developed industry in Country A there are plans for it to grow significantly in the future. An endemic establishment of WSSV would drastically impact any future industry's capacity to export.

Consequence assessment: *high*

Risk estimation

For WSSV, the matrices below were used to make a risk estimation.

Likelihood of entry	Likelihood of exposure: *Negligible*	*Extremely low*	*Very Low*	*Low*	*Moderate*	*High*
High	Negligible	Extremely low	Very low	Low	Moderate	High
Moderate	Negligible	Extremely low	Very low	Low	Low	Moderate
Low	Negligible	Extremely low	Very low	Very low	Low	Low
Very low	Negligible	Extremely low	Extremely low	Very low	Very low	Very low
Extremely low	Negligible	Negligible	Extremely low	Extremely low	Extremely low	Extremely low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible

Likelihood of establishment and/or spread	Overall effect of establishment and spread					
	Negligible	*Very low*	*Low*	*Moderate*	*High*	*Extreme*
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Very low	Low	Moderate	High
Very low	Negligible	Negligible	Negligible	Very low	Low	Moderate
Extremely low	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low

Overall risk estimation: *very low*

Risk Management

The team organises a follow-up workshop to determine appropriate risk management measures. Given Country A's strong ALOP, the team decides to refer to the OIE International Standards but also create their own with the aim of reducing the overall risk to very-low/negligible.

In relation to WSSV, the participants at the workshop agree to recommend the following sanitary measures to reduce the risk estimation:

a. All bloodstock from which the post-larval stock are taken must be tested using the protocols outlined in the OIE International Standards
b. No animals can be removed from the facility without prior permission from the government department responsible
c. The operator of all facilities must keep detailed records of mortalities and report any disease outbreaks immediately to the government department responsible
d. A contingency plan should be developed for events resulting in serious mortalities.

Conclusion

The team compiles a report. It includes the complete table of hazards, brief summaries of the two hazards identified for further work, results of the risk assessment for both hazards and the risk mitigation measures agreed upon in the workshop. The draft report is uploaded onto the website for further comments before being finalised. The final report is presented to the head of the department for an ultimate decision.

Resources

E-learning module 4.3.

Sourcing information for Import Risk Analysis

If a full IRA is required, sourcing information is an important step.

The evidence hierarchy

Some sources of information provide better evidence than others.

In regards to IRA, peer-reviewed literature is considered the best source of evidence, where available. Recently published textbooks and websites from reputable international organisations (such as the OIE and FAO) are considered the next best source of information. Government websites and expert opinion can make a valuable contribution to IRA, but are considered the lowest tier of evidence.

Other sources of evidence may include trade or climate records, or media reports. These sources generally belong in the lowest tier of evidence, though some (e.g. climate records) may justify consideration as higher up the hierarchy.

What sources of information are available to an IRA?

There are many potential sources of information for IRAs.

Peer-reviewed studies published in journals

Peer-reviewed studies provide strong evidence for an IRA. However, relevant studies are not always available, particularly for rare hazards, and literature must be recent to ensure knowledge has not become outdated.

Peer-reviewed studies relevant to an IRA can be found by using a bibliographic database—e.g. Web of Science (which can be expensive to access) or Google Scholar (for which access is free, though note that studies returned using this database are not necessarily peer-reviewed).

Some peer-reviewed studies are open access, which means they are freely available to download. In other cases, peer-reviewed studies may need to be purchased or accessed through a licence. Government departments can buy subscriptions to access peer-reviewed studies.

When considering the journals used to provide input into an IRA, there are several indicators of quality. Considerations include:

- the relevance of the journal to the field;
- the journal impact factor, relative to other journals in that field (in some fields, journals are ranked); and
- the general tone and history of the publication.

Recent studies are best, as they should have been designed with relatively up-to-date knowledge of the field of study in mind, and should consider and discuss previous studies relevant to their work.

Website from reputable international organisations (e.g. OIE and FAO)

The OIE website provides access to:

- information on the official disease status of a country for six key diseases where the disease status is officially recognised by the OIE;
- key documents, e.g. the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code;
- OIE publications (including the OIE Scientific and Technical Review and the OIE Bulletin); and

- the World Animal Health Information Database (WAHIS).

The FAO website also provides information on animal health, and hosts the Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases (EMPRES).

Recently-published textbooks

Textbooks can provide valuable information for an IRA. Most textbooks are subject to a peer-review process. However, it is important that recently-published books are used, to avoid outdated knowledge.

Official government websites

Many countries' official government websites contain information about their animal health disease status and local disease epidemiology. However, be aware that this information may not be up-to-date or complete, and may not have been peer-reviewed. Australia and New Zealand publish their own IRAs on their website.

Expert opinion

Expert opinion can be particularly valuable where there is limited information available from other sources. However, expert opinions can be biased, and there may be disagreement between experts, so it should not be relied on in isolation when other information is available. Methods for obtaining expert opinion can be found in the OIE IRA Handbook.

Exporting country dossiers

Exporting countries can provide dossiers to support a commodity. For example, a freedom dossier that outlines the evidence to suggest that they are free of certain disease(s). These dossiers may be peer-reviewed.

Other related data sources

Other relevant sources may include climate records, trade records or media reports. Climate records can be considered a higher quality source of information; meanwhile, media reports are weaker sources of evidence and should be used with caution. Information from websites that are not operated by reputable organisations or governments should not be used, to avoid the potentially poor-quality information.

Evaluating evidence

Information must be evaluated to decide if it is credible for inclusion in an IRA. Alongside consideration of the evidence hierarchy, here are some other factors to consider.

- Peer review: as per the evidence hierarchy, information is considered more credible if it has undergone the peer-review process.
- Quality publications will generally list the author(s) and the organisation they work for: be careful of those that don't. Consider also the credentials of the author, and whether they could be biased.
- If the information has a reference list, or refers to known experts, it is likely to be more credible than information without any references.

Using the OIE Standards

The OIE Standards provide key information, especially if full IRA is not required. Section 2 describes when the countries might use the OIE Standards instead of full IRA.

Using existing IRAs

In the interests of transparency, Australia and New Zealand publish their IRAs on their website. Existing IRAs provide a good example of basic structure and may include useful epidemiological information on hazards of interested. However, all IRAs are country-specific and shouldn't be blindly replicated. Each country has its own Appropriate Level of Protection (ALOP) and this should guide their approach to IRA. Australia or New Zealand may choose to do a full IRA to address a particular risk question. This does not mean that it is always necessary or appropriate for an ASEAN Member State to do so. Identification of hazards, with the use of OIE International Standards for risk mitigation may be the more appropriate approach.

Resources

E-learning module 4.4

World Organisation for Animal Health, 2019. World Organisation for Animal Health homepage. Available online: https://www.oie.int/ (accessed 23rd Sept 2019).

Food and Agriculture Organisation of the United Nations, 2019. Animal health. Available online: http://www.fao.org/animal-health/en/ (accessed 23rd Sept 2019).

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