

10 IMPORT RISK ANALYSIS

10.1 Purpose

Import Risk Analysis (IRA) is the process by which importing authorities determine whether live aquatic animal imports or their products pose a threat to the aquatic resources of their country. This is usually undertaken by the Competent Authority (CA) for the importing country, but risk analyses apply equally to the individual who wants to import live aquatic animals onto their farm or site. Adverse consequences arising from an inadequate or unconscientious IRA add significantly to the cost of any live aquatic animal import.

An import risk analysis involves the steps of hazard identification and characterization, risk assessment, risk management, and risk communication. This is visualized in Figure 10.1.

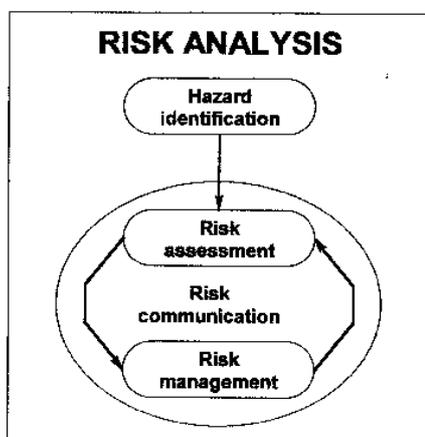
This chapter provides details of methods for Import Risk Analysis and its components in support of Section 11 of the *Technical Guidelines*.

10.2 Import Risk Analysis Process

Hazard identification

This is the first step of any IRA. It identifies the pathogens of concern in the context of the commodity to be imported, and the possible countries of origin of that commodity. The following criteria are an example of such an identification process:

Figure 10.1. The four components of an import risk analysis.



A disease agent is infectious; **and** exotic to the importing country, **or** present in the importing country of parts thereof but subject to official control; **and** would cause significant disease in the importing country.

The risk analysis may be concluded here if the hazard identification fails to identify potential hazards associated with the importation.

An importing country, especially an OIE Member (see Section 10.4, International Trading Obligations), may then decide to permit the importation using the appropriate sanitary standards recommended in the OIE *International Aquatic Animal Health Code* (OIE 2000), thus eliminating the need for a detailed risk analysis as outlined below.

Risk assessment

Quarantine risk is composed of two related factors: (i) the probability of the disease agent entering and becoming established in the importing country, and (ii) the expected impact or significance (consequences) of such establishment. As discussed in the *Technical Guidelines*, evaluating these risks is the risk assessment step in the IRA. The OIE recommends that these risks be addressed in a structured, chronological manner, for example:

- *Release assessment* — assessing the probability that the agent will enter the importing country as a consequence of the importation of the commodity.

- *Exposure assessment* — assessing the probability of susceptible aquatic animals being exposed to a dose sufficient to cause infection, once the disease agent has entered the country in the commodity.
- *Consequence assessment* — assessing the consequences of the disease agent establishing in the importing country.

The OIE categorizes various factors that should be considered in evaluating the probability of an exotic disease agent becoming established as a result of import introduction. These include known epidemiological characteristics of the disease agent; current geographic distribution, prevalence and seasonal dynamics; host range; export source; likelihood of pathogen detection, etc.

Effective IRAs consider all possible avenues (natural and human-mediated) for transmission. These infection “pathways” determine the probability of the pathogen becoming established in the import waters. Pathway analysis involves assessing the probability of occurrence at each critical step in each pathway.

The IRA then evaluates the consequences of disease establishment in an importing country. These may be economic, environmental (ecological) or social. They include impact on fisheries, sustainable aquaculture and biodiversity of native fauna (including threatened or endangered species).

For the final risk estimation, the results from the release assessment, exposure assessment and consequences assessment are integrated to produce overall estimates of risks associated with the hazards identified at the outset. The overall risk posed by a disease agent with low likelihood of establishment and very serious consequences may be similar to the risk posed by an agent with a high likelihood of establishment and less serious consequences.

Risk management

Once the risks associated with the importation of a commodity have been assessed, risk management measures need to be identified which can reduce those risks to a level acceptable to the importing country. It is important to realize that this is a re-iterative process (see Figure 10.1); the risks need to be re-assessed once the measures are taken into account. For example, the disease risks associated with the importation of live trout from country X may have been assessed as too high to be acceptable to the importing country, however, sourcing trout only from particular farms in country X may reduce the risk, since those farms are known to be free of the disease(s) of concern. The reduced risk now needs to be re-assessed, to determine whether it is acceptable to the importing country.

Risk communication

As Figure 10.1 shows, risk communication takes place throughout the entire IRA process. It is important to keep all stakeholders involved in the process, including the potential exporters.

Multidisciplinary approach

Because the factors which need to be considered are broad in scope, many countries use multidisciplinary committees to undertake the IRA. The conclusions from these committees are documented and submitted to the Competent Authority (CA) for use by personnel responsible for import approvals. The committees may suggest mitigative measures (where practical) that importing authorities can use as conditions for import approval (e.g., surface disinfection of eggs, quarantine-isolation of stocks, mandatory reporting and/or submission of samples of in-transit or post-transit mortalities, sterile disposal of all shipping materials). In some cases, the CA may submit the import license back to the committee to ensure that conditions meet scientific criteria, prior to release to the importer.

The multi-disciplinary committee, often called an “Introductions and Transfers Committee (ITC)” or a “Transplant Committee,” can vary substantially in nature and still be effective. Such ITCs may be chaired by a representative from the CA or Chief Veterinary Office (CVO). Membership can be on an *ad hoc* basis, where the import application dictates the types of specialists asked to provide risk assessment and mitigative advice. Alternatively, membership can be general, including specialists across the range of possible applications e.g., different levels of appropriate government representation, aquatic animal health experts (microbiologists, parasitologists, veterinarians), industry association representatives and legal/enforcement advisors. Specialist committees have the advantage of focussed case-by-case examinations, but only work well for countries where the number of different import applications is relatively limited and such specialists are readily available. The broader-based ITC works most effectively for countries or regions with multiple government authorities and a high volume of diverse import applications. It also has the advantage of a broad perspective on perceived and real risks, as well as IRA experience accumulated over time. The two types of committee can work in harmony, with the general format used for “routine” application assessment and specialist groups being assembled for complex or unusual requests. One critical factor for optimum operation of any ITC, however, is sufficient time for accurate analysis.

Applications for live imports that need “rush” IRAs should be discouraged unless there is a well-established certainty that they are low risk. Applications that lack strong back-up data cannot be rushed without high risk.

Questions that need to be addressed follow, quite closely, those of the *ICES Code of Practice* (ICES 1995) and the OIE *International Aquatic Animal Health Code* (OIE 2000). For example:

- Does the source of the import have a health history?
- Is the health history based on reliable surveillance programs or expertise?
- Has the stock undergone any unexplained mortalities in the last two years?
- Are the export waters free of diseases of concern?
- Does the importer have strong control of spread of the introduced stock or its offspring?
- Are the import waters located close to significant aquatic resources (aquaculture investments, non-discretionary fisheries, recreational or tourism-driven aquatic investments, sensitive ecological systems)?
- Are any neighboring resources vulnerable to disease transmission from the imported stock?

10.3 Three Examples of Risk Scenarios

A low-risk example

A grower wants to import shrimp from Person X in Country Y. The exporter has a long history of health surveillance and screening by a diagnostic laboratory with trained and established expertise. The shrimp have suffered no mortalities from diseases of concern to the importer. All mortalities that have occurred have been examined and results are available for import authority review. The importer has a site that is located in the middle of significant shrimp culture investment. IRA determines that this case has low import risk, *but* recommends that the disease history compiled at the export site must be submitted to the CA for evaluation prior to import of the stock. This condition ensures that no surprises accompany the shipment. The exporter is protected by World Trade Organization (WTO) conditions that prevent non-tariff trade barriers being based on unjustifiable restrictions. Documentation reveals no surprises and the grower receives an import license for that specific shipment with no conditions.

A high-risk example

A grower wants to import tilapia from Person X in Country Y. The exporter has stocks from mixed sources with poor documentation on their origins. Person Y has no recent health records and reports sporadic mortalities that have been dealt with by re-stocking. No diagnostic tests have been performed. Country Y has enzootic diseases that are exotic to the

importing country. The fish species affected by these diseases in Country Y are present in the importing waters. The IRA determines that this is a high risk proposal and recommends that the grower find another source. The CA decides not to issue an import license for fish from Person X in Country Y. Refusal documentation cites the lack of health history, mixed stocks, unexamined mortalities and presence of diseases of concern as the reason for refusal.

A moderate-risk example

A grower wants to import scallops from Person X in Country Y. Person X has no health history information, but is willing to get a health check done prior to shipment. The laboratory normally diagnoses fish diseases, but has well-established credibility. There have been no diseases of concern or abnormal mortalities in Country Y. The importer has holding facilities which will contain the imported scallops, although spawn may escape. The scallop species exists in the import waters, but is scarce. The IRA determines that the risk is moderate and recommends pre-shipment screening *plus* quarantine containment of pre-spawning scallops on arrival at the import site. This containment must be maintained until the scallops have spawned and mollusc health specialists have lethally examined all the broodstock. The grower must decide if the cost of quarantine merits use of introduced scallops rather than indigenous stocks.

These examples provide a general indication of only some of the questions/conditions that can influence IRAs and decision-making. Socio-economics also have a strong influence. Job-creation can outweigh concern over indigenous resources if the latter do not provide adequate income or security for a community. The single factor that should *not* influence IRAs is politics. A vote cannot outweigh aquatic animal health risk or food production sustainability.

10.4 International Trading Obligations

Members of the World Trade Organization (WTO) have certain rights and obligations under WTO agreements, including the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the "SPS Agreement"). Under the SPS Agreement, members are encouraged to have health control measures that are consistent with international standards. The SPS Agreement uses the standards, guidelines and recommendations developed by the OIE for animal health and zoonoses as the international benchmark. This means that a Member can adopt the OIE control measures as outlined in the OIE code after the hazard identification step has been conducted, without the need for a more detailed IRA. Members may adopt a higher level of protection, but this must be based on a scientific risk analysis. Such risk analysis needs to address the following elements:

- evaluate the risk of entry, establishment or spread of these diseases, as well as potential biological and economic consequences; and
- evaluate the risk of entry, establishment or spread of these diseases according to the SPS mitigative measures which might be applied

Members are obliged to ensure that the level of protection provided by any mitigative measures is consistent with the SPS "*appropriate level of sanitary or phytosanitary protection*," and that, within this level of protection, the measures proposed are least trade restrictive. The SPS Agreement defines "*appropriate level of sanitary or phytosanitary protection*" as the level of protection deemed appropriate by the member country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. This means, membership to the WTO does not override a country's sovereign right to set its own level of protection.

10.5 Capacity and Institutional Implications

For most countries, conducting an IRA is a new concept and a new process. It is important to understand and embrace the concept of an IRA first, and not be discouraged by the anticipated complexity of the process. As stated above, IRAs can range from an individual

farmer analyzing and assessing the risks associated with a potential, specific importation, to a full range IRA carried out by a multidisciplinary team.

The authority responsible for undertaking an IRA needs to be clearly identified, and the legislative background for resulting import decisions needs to be clarified or, if required, newly established.

Because of the complexities involved, the conduction of a full import risk analysis is now regarded as a distinct scientific discipline; training is essential, and learning from already conducted IRAs is highly recommended.

10.6 References

- ICES. 1995. ICES Code of Practice on the Introductions and Transfers of Marine Organisms 1994. International Council for the Exploration of the Sea, Copenhagen, 12 p.
- OIE. 2000. International Aquatic Animal Health Code. Third edn. Office International des Épizooties, Paris, 153 p.