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RE	Restricted to a group specified by the consortium (including the Commission Services)	
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Executive summary

In response to the European '*Council Regulation No. 708/2007 of 11 June 2007 concerning use of alien and locally-absent species in aquaculture*', and responding directly to *Task 12, priority area 8.1. B.1.3*, a scheme has been developed that seeks to provide '*Guidelines for environmentally sound practices for introductions and translocations in aquaculture, guidelines on quarantine procedures, and risk assessment protocols and procedures for assessing the potential impacts of invasive alien species in aquaculture*'. Development of the European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS) has benefited from the unique breadth of expertise available from consortium members, enabling the direct utilisation of state of the art national and international research and practical experience in the assessment and management of non-native organisms.

The ENSARS is modular in structure and is an adapted form of the pest risk analysis decision support scheme of the European and Mediterranean Plant Protection Organisation (EPPO), which was developed using the guidelines of the International Plant Protection Convention (IPPC) International Standards for Phytosanitary Measures on pest risk analysis, which are recognized by the Sanitary and Phytosanitary Agreement of the World Trade Organization (WTO, 1995). The questions (or types of questions) used in the ENSARS have been developed in conjunction with recent improvements to the GB Non-native Species Risk Assessment Scheme (http://www.defra.gov.uk/wildlife-countryside/resprog/findings/non-native-risks/index.htm) with which the ENSARS is closely related. The ENSARS has been developed with full consideration of the Aquatic Animal Health Code (OIE, 2006).

The ENSARS provides a structured framework for evaluating the risks of escape, introduction to and establishment in open waters, of any non-native aquatic organism being used (or associated with those used) in aquaculture. In addition, it provides evaluation of potential risks posed by transport pathways, rearing facilities, non-target infectious agents, and the potential organism, ecosystem and socio-economic impacts. The ENSARS consists of seven modules. The first six modules comprise the 'risk assessment' protocols (Entry, Invasiveness, Organism, Facility, Pathway, Socio-economic Impact) and these lead into a Risk Summary & Risk Management Module. The Invasiveness component consists of a suite of generic and taxon-specific modules used to assess the potential invasiveness of Amphibia and of freshwater and marine fishes and invertebrates. The various modules have been constructed using a common format and provide general guidance in the assessment of potential risks of introduction, establishment, dispersal and impacts by non-native organisms (NNO) for native species and ecosystems. Because a single person is unlikely to have the necessary expertise to complete all modules of this risk assessment scheme, it is assumed that a multi-disciplinary team of recognised experts will be required to complete the assessment of any given organism.

The assessor, a recognised expert, is required to respond to a sequence of questions, with each answer accompanied by appropriate bibliographic justification or other information (e.g. use of expert opinion) to justify the response and by a ranking (by the assessor) of his/her level of confidence/certainty regarding that response, using the confidence rankings recommended by the International Programme on Climate Change (IPCC): Low confidence (2 out of 10 chance), Medium confidence (5 out of 10 chance), High confidence (8 out of 10 chance), Very high confidence (9 out of 10 chance). These modules can also be used in stand-alone mode, and they could easily be adapted for incorporation into the web-based (electronic) risk modules currently being developed by the EPPO.

User manual for the European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)

Compiled by Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/), with contributions from Dr. J. Robert Britton (Bournemouth University), Dr. Galina Jeney (HAKI-Szarvas), Dr Jean-Pierre Joly (IFREMER-La Tremblade), Dr. Francesca Gherardi (UNIFI-Florence), Dr. Stephan Gollasch (GoConsult), Dr. Rodolphe E. Gozlan (Bournemouth University), Dr. Glyn Jones (CSL-York), Dr. Alan MacLeod (CSL-York), Dr. Laurence Miossec (IFREMER-La Tremblade), Dr. Paul J. Midtlyng (VESO-Oslo), Dr. Andy D. Nunn (HIFI, University of Hull), Prof. Anna Occhipinti Ambrogi (UNIPV-Pavia), Dr. Birgit Oidtmann (Cefas-Weymouth), Prof. Sergej Olenin (KUCORPI-Klaipeda), Mr. Ian C. Russell (Cefas-Lowestoft), Dr. Edmund Peeler (Cefas-Weymouth), Dr. Dario Savini (UNIPV-Pavia), Dr. Elena Tricarico (UNIFI-Florence) and Dr. Mark Thrush (Cefas-Weymouth).

Introduction and background

The protocols used in non-native species risk analysis schemes are derivatives of the hazard assessment protocols developed during the latter part of the 20th century to ensure human health and safety in the nuclear industry (Copp *et al.* 2005a). Four common elements to all risk analysis schemes are:

1) Hazard Identification
2) Hazard Assessment
3) Risk Management & Communication
4) Risk Review and Reporting

These elements should be implemented simultaneously rather than in sequence, given that risks can be reduced merely by communicating (and where necessary 'educating') industry and the general public to the hazards associated with the release of non-native organisms into the open environment. With this framework, the protocols for identifying and assessing risks represent the central mechanics of hazard analysis. The potential risks and impacts associated with non-native species are multi-discipline in nature, given the complexity of natural ecosystems. As such, a single person is unlikely to have the necessary expertise to complete all aspects of risk assessments, and it is assumed that a multi-disciplinary team of recognised experts will be required to complete the assessment of any given organism.

The overall framework of, and the risk protocols contained in, the ENSARS have been developed using the modular approach and questions (or types of questions) used in the UK Non-native Species Risk Assessment Scheme (Baker *et al.* 2008). The UK scheme is based on the International Plant Protection Convention (IPPC) guidelines on pest risk analysis (FAO, 2004) and the detailed European and Mediterranean Plant Protection Organisation (EPPO) pest risk analysis decision support scheme (EPPO, 2007). The IPPC guidelines are recognized by the Sanitary and Phytosanitary Agreement of the World Trade Organization (WTO, 1995). Although designed to assess plant health biosecurity risks associated with trade, the EPPO scheme is based on general principals and as such there is much overlap between plant and animal health issues with regard to risk assessment and risk analysis. Therefore, the modular scheme presented herein draws heavily on the EPPO decision support scheme, which was itself designed following IPPC guidelines. The development of the present scheme stems from concerns over the risks posed by the use of non-native organisms in aquaculture and stock enhancement, which includes associated disease impacts that fall within the scope of the Aquatic Animal Health Code (OIE, 2006).

The European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS) consists of seven modules (Entry, Invasiveness, Organism, Infectious Agent, Facility, Pathway, Socio-economic Impact), which feed information into the Risk Summary & Risk Management Module (Figure 1). This latter module will be presented in a separate document. The collection of tool kits described as the Pre-screening (invasiveness) Module Toolbox comprises a generic toolkit and five taxon-specific toolkits for determining potential invasiveness (freshwater fish, marine fish, freshwater invertebrates, marine invertebrates, Amphibia). These may be used either independently (Copp *et al.* 2005b; Copp *et al.* in press) or as part of ENSARS or other schemes (see Copp *et al.* 2005a, Baker *et al.* 2008). Note that a Spanish-language

version of the freshwater fish toolkit (FISK) will be published in December 2008. All of these pre-screening toolkits are available in electronic form as free downloads from: http://www.cefas.co.uk/4200.aspx, except for the Generic Pre-screening Module, which is currently available in paper version only (see Section 2.1).

The Entry Risk Assessment Module leads to all of the other modules (Figure 1). Depending upon the assessment required, some of the modules (e.g. Socio-economic Impact, Pre-screening, Infectious Agent) may be used to complement other modules (e.g. Organism, Facility, Pathway). This is especially the case of the Organism, which requires information from the Socio-economic Impact, Pathway, Infectious Agent and Facility modules in order to complete the assessment of the target organism.

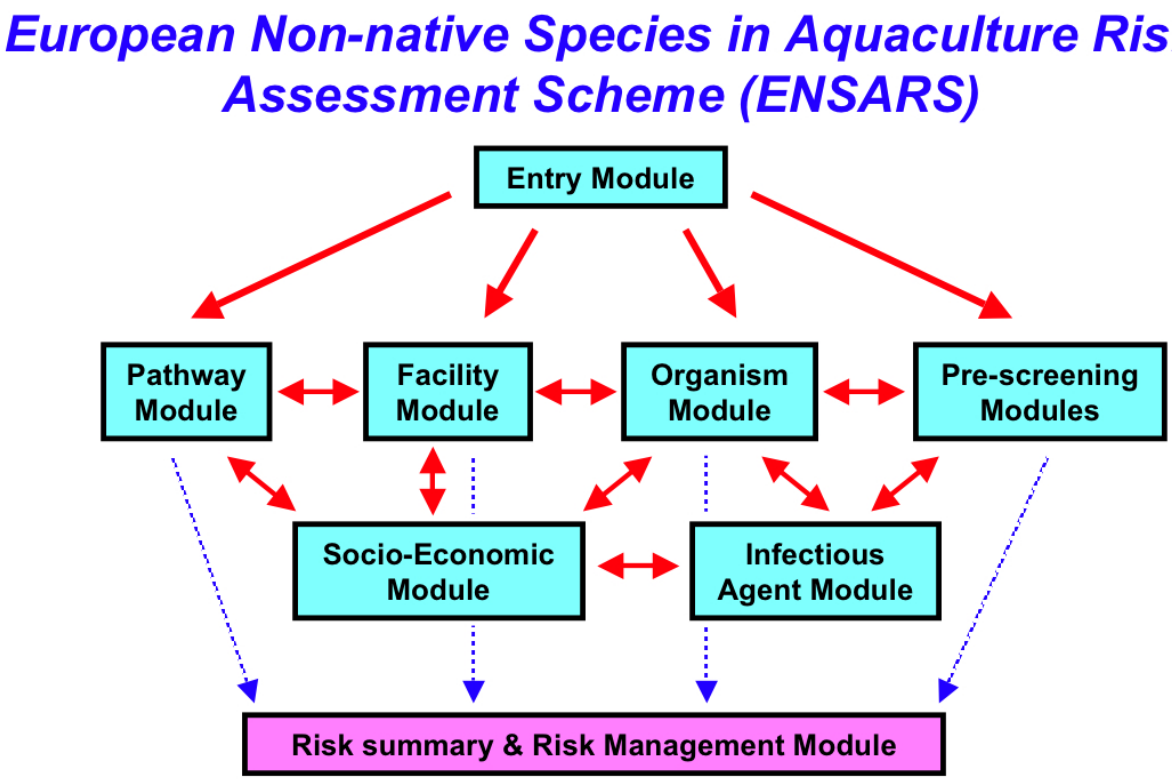


Figure 1. Schematic of the European Non-native Species Risk Analysis Scheme (ENSARS), regarding the Use of Alien and Locally-Absent Species in Aquaculture, consisting of the seven risk assessment modules (upper boxes in light blue) and the Risk Summary & Risk Management Module (lower box in light mauve) into which the risk assessment outcomes feed information (this latter module is not considered here and will be presented in a separate document).

The various modules provide general guidance in the assessment of potential risks of introduction, establishment, dispersal and impacts by non-native organisms with regard to native species and ecosystems in the risk assessment (RA) area. It is essential that the RA area is defined at the start of the assessment process, i.e. defining the geographical area that is deemed/decided to be at risk, with due consideration of potential connectivity between contiguous drainage basins (e.g. via connecting canals) that would effectively determine the true area at risk. This aims to ensure that the questions are answered in a consistent manner relative to the RA area concerned. While it is recognised that there are potential gains (positive impacts) from the use of alien species in aquaculture, by its very nature risk assessment focuses on potential negative impacts. However, the decision of how to "balance" positive and negative impacts is not the role of a risk assessor but of the 'competent authority', which one assumes will include

scientists, government regulators and representatives from industry so as to achieve balanced, realistic, decisions in response to applications under the Regulation.

The various modules of the risk analysis scheme have been constructed using a common format in as much as it consists of a sequence of questions that assessors should answer, with answers being supported by appropriate bibliographic information or by using expert opinion. It is important for any review of an assessment that answers to all questions are explained, to indicate how the answer to each question was reached, and on what information a decision was based. It is also important to indicate the date on which the information was collected to permit future refinement of the risk assessments when new information becomes available. The level of confidence/certainty an assessor has in answers should also be recorded and any concerns over data/information quality noted.

A selection of response options is provided with each question, and each response must be accompanied by a confidence ranking (of the assessor's level of certainty in their response). Each response option is associated with a numerical score, ranging from 0 to 3. This is based on the confidence rankings suggested by the IPCC (2005), although the lowest confidence ranking has not been used due to the lack of statistical reliability associated with it (J. Holt & J. Mumford, personal communication).

Modified IPCC scoring system used:
~~– Very low confidence (1 out of 10 chance)~~
0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)
3 – Very high confidence (9 out of 10 chance)

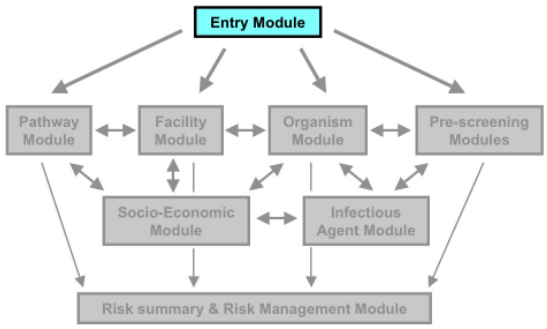
Each response and confidence ranking should be accompanied by a justification (or rationale) or by comments (e.g. an explanation if the question is not applicable to the organism/facility/pathway under assessment). The justifications should include references to bibliographic and other information sources upon which the response was formulated. Explanations may accompany the questions to assist the assessor. Further guidance on how to assess risk levels and uncertainties is given in Section 8.

Information requirements
The process of risk assessment is usually "data hungry" and a large number of data sources may have to be consulted to obtain sufficient information to be able to answer questions. Information from official sources, databases, scientific and other literature, or expert consultation is often required. Data sources should be fully recorded and referenced. In going through the protocol, the risk assessor may find that certain questions cannot be answered. This may be because the question is not relevant, in which case the question can be ignored and the absence of a reply will not affect the outcome of the assessment. Alternatively, it may prove impossible to obtain the information, in which case its absence will increase the uncertainty of the assessment. Conversely great efforts can be taken to investigate and provide very detailed answers to specific questions so as to reduce uncertainty. The balance between resources employed to answer questions and address uncertainty will vary according to circumstances. The WTO SPS Agreement recognises the need for a flexible approach to risk assessment where it notes that risk management measures should be based on a risk assessment, "as appropriate to the circumstances" (WTO, 1995). A guiding principle to judge the resources required to provide sufficient detail in any risk assessment is that the assessment should be 'fit for purpose'..

Section 1

Entry Module – Use of Alien and Locally-Absent Species in Aquaculture

European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)



Prepared by Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/)

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

Q1) What is the reason for undertaking the Risk Assessment ?

Select (tick) one of the response options (enter the corresponding number code (e.g. '1b') and then go to the recommended module):

Organism[1] ☐ Pathway[2] ☐ Ecosystem[3] ☐ Facility[4] ☐

ORGANISM

1a) An application has been made for the intentional import and/or release of a locally absent organism (Use the 'Pre-screening Module')

1b) A non-native organism listed in Annex IV is locally absent and national regulations require an assessment (Use the 'Pre-screening Module').

1c) An existing non-native organism (i.e. not Annex IV listed) requires assessment for likely future spread & impacts in the RA area (Use the 'Pre-screening Module')

1d) A novel contaminant organism has been detected in consignments originating from outside the EU (Use the 'Pre-screening Module').

1e) A novel contaminant organism has been detected in consignments originating within the EU but from outside the RA area (Use the 'Pre-screening Module').

1f) A novel contaminant organism has been detected in existing, regular consignments within the RA area (Use the 'Pre-screening Module').

1g) An existing RA of the organism is being re-evaluated due to new information on the organism's relative risks (Use the 'Organism Risk Assessment Module').

1h) An existing RA of the organism from one EU Member State is being re-evaluated for application in another Member State (Use the 'Organism Risk Assessment Module').

1i) Other reasons [e.g. an outbreak or infestation of a non-native organism has been discovered] (Define reason in Comments Box, then Use the 'Organism Risk Assessment Module').

PATHWAY

2a) A request is made for intentional importation/translocation of a locally-present species (i.e. potential pathway for non-native organisms) (Use the 'Pathway Risk Assessment Module')
2b) Trade is proposed for a new non-native organism or product thereof. (Use the 'Pathway Risk Assessment Module')
2c) A new or existing delivery system requires assessment for risks of escape during transport. (Use the 'Pathway Risk Assessment Module')

ECOSYSTEM

3a) A potential non-native organism threat to a receptor ecosystem has been identified (Use the 'Organism Risk Assessment Module')

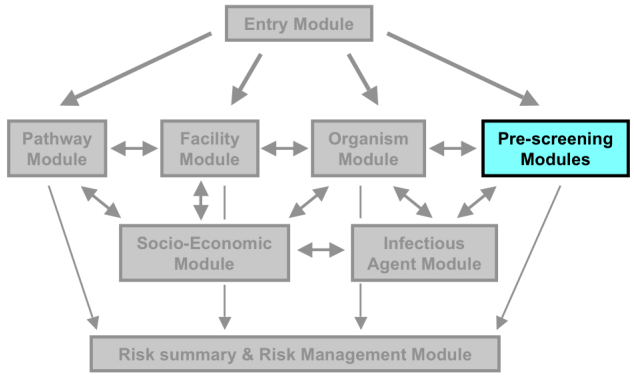
FACILITY

4a) A new facility requires assessment (Use the 'Facility Risk Assessment Module')
4b) An existing facility requires assessment (Use the 'Facility Risk Assessment Module')
4c) A climatic/geologic risk has been identified (Use the 'Facility Risk Assessment Module')

Section 2

Pre-screening (Invasiveness) Toolbox Module – Use of Alien and Locally-Absent Species in Aquaculture

European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)



Prepared by Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/).

The Invasiveness Toolbox consists of a suite of modular toolkits adapted from the Weed Risk Assessment toolkit of Pheloung, Williams & Halloy (1999). The taxon-specific versions (Copp *et al.* 2005a. 2005b) are available via free download (http://www.cefas.co.uk/4200.aspx) for freshwater fishes (FISK), marine fish (MFISK), freshwater invertebrates (FI-ISK), marine invertebrates (MI-ISK) and Amphibia (AmphISK). Of these, calibration of the scores has been undertaken for FISK only (Copp *et al*. unpublished). A generic toolkit have been developed for all other aquatic organisms not covered in the taxon-specific toolkits (see next section).

References cited: see the Introduction of the User Manual

Select (tick) the taxonomic group to which the organism belongs and go to the corresponding toolkit:

☐ Freshwater fishes (go to http://www.cefas.co.uk/4200.aspx and select 'FISK')

☐ Marine fish (go to http://www.cefas.co.uk/4200.aspx and select 'MFISK')

☐ Freshwater invertebrates (go to http://www.cefas.co.uk/4200.aspx and select 'FI-ISK')

☐ Marine invertebrates (go to http://www.cefas.co.uk/4200.aspx and select 'MI-ISK')

☐ Amphibia (go to http://www.cefas.co.uk/4200.aspx and select 'AmphISK')

☐ Infectious agents (go to the section '**Infectious Agent Risk Assessment Module**')

☐ All other (go to the next section '**Generic Pre-screening Module** ')

Once a taxon-specific toolkit has been used, please complete the 'Organism Risk Pre-screening Summary' sheet:

Organism Risk Pre-screening Summary

Organism name:

Organism type (please tick appropriate box):

Target ☐ Non-target, non-infectious ☐ Non-target, infectious agent ☐

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

Risk Summary

Guidance: Using the outputs from the taxon-specific toolkit, provide an overall summary of the risks associated with the four main sections of the pre-screening assessment. In some cases, e.g. taxa for which information is limited, this summary is likely to reflect the assessor's 'gut feeling' after having scrutinized the available information.

Summarise the Domestication & Introduction History of the organism:

Guidance: This summary should reflect the outcome provided in the summary of the taxon-specific toolkit.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:*

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the risks of Establishment & Persistence:

Guidance: This summary should reflect the outcome provided in the summary of the taxon-specific toolkit.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:*

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the risks of Dispersal:

Guidance: This summary should reflect the outcome provided in the summary of the taxon-specific toolkit.

Response options:

0–Very slow ☐ 1–Slow ☐ 2–Intermediate ☐ 3–Rapid ☐ 4–Very Rapid ☐

Certainty/Confidence:*

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the Impact risks & Undesirable traits:

Guidance: This summary should reflect the outcome provided in the summary of the taxon-specific toolkit.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:*

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

** Confidence rankings recommended by the International Programme on Climate Change (IPCC): Low confidence (2 out of 10 chance), Medium confidence (5 out of 10 chance), High confidence (8 out of 10 chance), Very high confidence (9 out of 10 chance)*

Conclusion of the invasiveness risk assessment:

Conclusions on Confidence:

References cited (give cited references in full and in alphabetical order)

Acknowledgments (give acknowledgement to any persons or institutions that provided unpublished information, etc.)

After completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 2.1

Generic Pre-screening Module – Use of Alien and Locally-Absent Species in Aquaculture

Prepared for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/) by Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University), with contributions from Dr. Stephan Gollasch (GoConsult), Dr. Laurence Miossec (IFREMER-La Tremblade), Dr. Edmund Peeler (Cefas-Weymouth), and Mr. Ian Russell (Cefas-Lowestoft).

The Generic Pre-Screening Module contains questions adapted from the Fish Invasive-ness Scoring Kit (FISK) of Copp et al. (2005a. 2005b), which is based on the Pheloung, Williams & Halloy (1999) Weed Risk Assessment, combined with a numerical scoring system as recommended by the UK Non-native Species Risk Analysis Panel (www.nonnativespecies.org), based on the UK scheme (see Baker et al. 2008).

Each question should receive a response, with answers being supported by appropriate information or by using expert opinion. It is important for any review of an assessment that answers to all questions should be explained, indicating how the answer to each question was reached, and on what information a decision was based. It is also important to indicate the date on which the information was collected so that the assessment can be subsequently refined when new data become available. Each response should be accompanied by a confidence ranking (of the assessor's level of certainty in their response). As defined in the Entry Module, the four confidence rankings are as follows:
0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)
3 – Very high confidence (9 out of 10 chance)

A justification (or rationale) should be provided for each response, including references to bibliographic and other information sources upon which the response was formulated. Explanations may accompany the questions in order to assist the assessor.

References cited: see the Introduction Section of the User Manual.

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

DOMESTICATION & INTRODUCTION HISTORY

Q1) What is the extent of the organism's domestication (or cultivation) ?
Guidance: The taxon must have been grown deliberately and subjected to substantial human selection for at least 20 generations, or it must be known to be easily reared in captivity (e.g. fish farms, aquaria or garden ponds). This may be in the organism's native or introduced ranges.

Response options:

0–Very limited		1–Limited		2–Moderate		3–Great		4–Very great	

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2) How often has the organism been introduced outside its natural range?

Guidance: Should be relatively well documented, with evidence of translocation and introduction.

Response options:

0–Very often ☐ 1–Often ☐ 2–Occasionally ☐ 3–Rarely ☐ 4–Very rarely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3) How often has the organism become naturalised (established viable populations) where previously it was 'locally absent' (i.e. native to the region but not the area where introduced) ?

Guidance: To be classed as naturalised, the taxon must have maintained self-sustaining populations for a minimum of 50 years in at least one location outside its native range. If the native range is not well defined (i.e. uncertainty about it exists), or the current distribution of the organism is poorly documented, then make a best estimate (based on available information) and set the Certainly level at Low (0).

Response options:

0–Very rarely ☐ 1–Rarely ☐ 2–Occasionally ☐ 3–Often ☐ 4–Very Often ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4) How often has the organism become naturalised (established viable populations) beyond its native range (i.e. areas outside the organism's native region)?

Guidance: To be classed as naturalised, the taxon must have maintained self-sustaining populations for a minimum of 50 years in at least one location outside its native range.

Response options:

0–Very rarely ☐ 1–Rarely ☐ 2–Occasionally ☐ 3–Often ☐ 4–Very Often ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5) How many invasive races, varieties or congeners is the organism known to have ?

Guidance: One or more species within the genus are known to be serious pests.

Response options:

0-None or very few ☐ 1-Few ☐ 2-Moderate number ☐ 3-Many ☐ 4-Very many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

RISKS OF ESTABLISHMENT & PERSISTENCE

Q6) How similar are the climatic conditions of the RA area and the organism's native range ?

Guidance: Climate matching is based on an approved system such as GARP or Climatch. If not available, then assign the maximum score (4) and the lowest certainty (0).

Response options:

0–Not similar ☐ 1–Slightly similar ☐ 2–Moderately similar ☐ 3–similar ☐ 4–Very similar ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q7) What is the quality of the climate matching data ?

Guidance: The quality is an estimate of how complete are the data used to generate the climate analysis. If not available, then the minimum score (0) should be assigned..

Response options:

0–Very poor ☐ 1–Relatively poor ☐ 2–Relatively good ☐ 3–Good ☐ 4–Very good ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q8) How adaptable is the organism in terms of climatic and other environmental conditions ?

Guidance: Output from climate matching can help answer this, combined with the known versatility of the taxon as regards climate region distribution. Otherwise the response should be based on natural occurrence in 3 or more distinct climate categories, as defined by Koppen or Walter (or based on knowledge of existing presence in areas of similar climate).

Response options:

0-Not adaptable ☐ 1-Slightly adaptable ☐ 2-Moderately adaptable ☐ 3-Adaptable ☐ 4-Very adaptable ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q9) What is the extent of the organism's salinity tolerance ?

Guidance: Presence in low salinity water bodies (e.g. Baltic Sea) does not constitute euryhaline, so minimum salinity level should be about 15 ‰.

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q10) What is the extent of the organism's tolerance to desiccation at some stage of its life cycle?

Guidance: Should be able to withstand being out of water for extended periods (e.g. minimum of one or more hours).

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q11) What is the extent of the organism's tolerance to a range of water velocity conditions (e.g. versatile in habitat use) ?

Guidance: Species that are known to persist in both standing and flowing waters over a wide range of velocities (0 to 0.7 m per sec).

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q12) How likely is the organism to maintain a viable population even when present in low densities ?

Guidance: There should be evidence of a population crash or extirpation due to low numbers (e.g. over exploitation, pollution, etc.).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q13) How likely is the organism to exhibit parental care and/or to reduce age-at-maturity in response to environmental conditions ?

Guidance: Needs at least some documentation of expressing parental care.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q14) How likely is the organism to produce viable gametes or propagules (in the RA area)?

Guidance: If the taxon is a sub-species, then it must be indisputably sterile.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q15) How likely is the organism to be hermaphroditicor to display asexual reproduction?

Guidance: Needs at least some documented evidence of hermaphroditism/asexual reproduction in that Species, Genus or Family.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q16) To what extent is the organism's dependent on the presence of another species (or specific habitat features) to complete its life cycle ?

Guidance: Some species may require specialist incubators (e.g. unionid mussels used by bitterling) or specific habitat features (e.g. fast-flowing water, particular species of plant or types of substrata) in order to reproduce successfully.

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q17) How likely is the organism to produce a large number of propagules or offspring within a short time span (i.e. < 1 year) ?

Guidance: High fecundity is normally observed in medium-to-longer lived species.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q18) How many time units (days, months, years) does the organism require to reach the age-at-first-reproduction? (In the Comments box, indicate the relevant time unit being used)

Guidance: Time from hatching/parturition/germination to full maturity (i.e. active reproduction, not just presence of sexual organs). Please specify the number of time units by category relative to the taxonomic group being assessed.

Response options:

0-None or very few ☐ 1-Few ☐ 2-Moderate number ☐ 3-Many ☐ 4-Very many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q19) How likely are any life stages to survive out of water ?

Guidance: There should be documented evidence of the taxon being able to survive for an extended period (e.g. an hour or more) out of water.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q20) How likely is the organism to tolerate or benefit from environmental disturbance ?

Guidance: The growth and spread of some taxa may be enhanced by disruptions or unusual events (e.g. floods, spates, desiccation), especially human impacts.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q21) To what extent is the organism tolerant of a wide range of water quality conditions relevant to that species ? (In the Comments box, indicate the relevant water quality variable(s) being considered)

Guidance: This is to identify taxa that can persist in cases of low oxygen and elevated levels of naturally-occurring chemicals (e.g. ammonia).

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q22) How many effective natural enemies of the organism are present in the RA area?

Guidance: Potentially effective predators of the taxon may be present in the RA area. Based on available knowledge of food webs in the RA area, provide a best estimate.

Response options:

0-None or very few ☐ 1-Few ☐ 2-Moderate number ☐ 3-Many ☐ 4-Very many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

RISKS OF DISPERSAL

Q23) How likely are any of the organism's life stages to be unintentionally dispersed in the RA area by human activity ?

Guidance: Unintentional dispersal resulting from human activity. For example, is the organism a fouling species, or can it survive in ballast waters? Similarly, is the species' behaviour (e.g. laying eggs on netting) likely to result in accidental introductions via contaminated angling gear, boats, etc?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q24) How rapid is natural dispersal of the organism expected to be following escape or release from captivity in the RA area ?

Guidance: This questions addresses the organism's propensity to disperse by natural means (e.g. sedentary organisms are likely to score low, whereas those from taxonomic groups well known to disperse (or to have migratory behaviours) will score high).

Response options:

0-Very slow ☐ 1-Slow ☐ 2-Intermediate ☐ 3-Rapid ☐ 4-Very rapid ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q25) How likely is natural dispersal of the organism in the RA area to occur as eggs (for animals) or as propagules (for plants: seeds, spores) in the RA area ?

Guidance: There should be documented evidence that eggs/spores/seeds are taken by water currents or displaced by other organisms either intentionally or not.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q26) How likely is natural dispersal of the organism to occur as larvae/juveniles (for animals) or as fragments/seedlings (for plants) in the RA area ?

Guidance: There should be documented evidence that larvae/fragments/seedlings enter, or are taken by, water currents, or can move between water bodies via connections.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q27) How likely are older life stages of the organism to migrate in the RA area for reproduction ?

Guidance: There should be documented evidence of migratory behaviour or active dispersal mechanisms, even at a small scale (tens or hundreds of metres).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q28) How likely are propagules or eggs of the organism to be dispersed in the RA area by other animals (externally) ?

Guidance: For example, propagules or eggs that are dispersed by birds moving between water bodies.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q29) To what extent is dispersal of the organism density dependent ?

Guidance: Where possible, this should be assessed using documented evidence of the taxon spreading out or dispersing when its population density increases. The information may derive from either the organism's native or introduced range (or both).

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

RISKS OF IMPACTS/UNDESIRABLE TRAITS

Q30) In the organism's naturalised range, what is the magnitude of known impacts to wild stocks or commercial species ?

Guidance: Where possible, this should be assessed using documented evidence of real impacts (i.e. decline of native species, disease introduction or transmission), not just circumstantial or opinion-based judgements.

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q31) In the organism's naturalised range, what is the magnitude of known impacts to aquaculture ?

Guidance: Aquaculture incurs a cost from control of the species or productivity losses. If information is not available on the exact species but is for a closely related species, then base the response on the known impacts of the related species.

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q32) In the organism's naturalised range, what is the magnitude of known impacts to ecosystem services ?

Guidance: Various amenities (e.g. angling, water sports) and ecosystem products (e.g. drinking water supply, small-scale fisheries) may be impacted. If information is not available on the exact species but is for a closely related species, then base the response on the known impacts of the related species.

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q33) In the organism's naturalised range, what is the magnitude of known impacts to aquatic ecosystems (structure or function) ?

Guidance: Where possible, this should be assessed using documented evidence that the species has altered the structure or function of natural ecosystems.

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q34) How likely is the organism to smother or out-compete native species ?

Guidance: Some non-native species are known to suppress the growth of native species, or displace them from microhabitat. For example, some non-native plants displace native species by expansive growth, which effectively smothers neighbouring plants.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q35) How likely is the organism to consume or to parasitise an endangered or threatened native species (i.e. previously subjected to little or no predation or parasitism) ?

Guidance: This question is specifically aimed at identifying whether or not the introduced organism would become a predator or parasite of native species that are currently not subjected to water-borne predators and parasites (i.e. this excludes birds and non-aquatic mammals).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q36) How likely is the organism to host, and/or act as a vector for, recognised pests and infectious agents that are endemic in the RA area?

Guidance: The main concerns are existing infectious agents, with the host being an additional vector of the infectious agent in the RA area.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q37) How likely is the organism to host, and/or act as a vector for, recognised pests and infectious agents, that are absent from the RA area?

Guidance: The main concerns are non-native infectious agents, with the host being the original introduction vector of the disease.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q38) How likely is the organism's mode of existence (e.g. excretion of by-products) or behaviours (e.g. feeding) to reduce habitat quality for native species ?

Guidance: Where possible, this should be assessed using evidence that the organism's mode of existence (foraging behaviour) results in an increase in suspended solids, reducing water clarity and thus habitat quality for native species (e.g. as well demonstrated for common carp).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q39) What is the organism's likely capacity to consume native species ?

Guidance: This question is specifically aimed at identifying whether or not the introduced organism would exert an additional (non-natural) predation pressure on one or more native species. Obligate piscivores

are most likely to score highly here, but some facultative species may become voracious predators when introduced to novel environments (e.g. red-eared terrapins are classed as vegetarians in their native North American range but are know to be voracious predators when they escape into ponds and lakes of Europe).

Response options:

0-Very limited ☐ 1-Limited ☐ 2-Moderate ☐ 3-Great ☐ 4-Very great ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q40) What is the organism's potential to disrupt food-web structure/function in suitable aquatic ecosystems of the RA area ?

Guidance: Where possible, this should be assessed using evidence that the introduction of the species (whether or not it establishes a self-sustaining population) disrupts food-web structure and function.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q41) How likely is the organism to hybridize naturally with native species ?

Guidance: Where possible, this should be assessed using documented evidence of interspecific hybrids occurring, without assistance, under natural conditions.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q42) How likely is the organism to be poisonous, or pose other risks to human health ?

Guidance: Applicable if the taxon's presence is known, for any reason, to cause discomfort or pain to animals.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q43) How likely is the organism to be consumed in the RA area ?

Guidance: This should be considered with respect to where the taxon is likely to be present and with respect to the likely level of ambient natural or human predation/foraging, if any. Reasons for lack of consumption of the introduced organism by native species include unpalatability, lack of suitable

predators/herbivores, extreme body defence systems (e.g. strong odours, sharp spines) that protect palatable underlying flesh.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q44) How likely is the organism to achieve a body size that will make it more likely to be released from captivity ?

Guidance: For example, although small-bodied fishes may be abandoned, large-bodied fishes are the major concern, as they can soon outgrow their holding facilities (e.g. aquaria or garden ponds). Similarly, some Amphibia and crustaceans achieve large sizes.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q45) How easily can the organism be controlled or eradicated in the wild with chemical or other agents/means ?

Guidance: Where possible, this should be assessed using documented evidence of susceptibility of the taxon to chemical or other control agents/means.

Response options:

0–Very easily ☐ 1–Easily ☐ 2–Some difficulty ☐ 3–Difficult ☐ 4–Very difficult ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Risk Identification Summary

Guidance: In this section, provide an overall summary of the risks associated with the four main sections of the Generic Invasiveness Pre-screening Module. In some cases, e.g. taxa for which information is limited, this summary is likely to reflect the assessor's 'gut feeling' after having scrutinized the available information.

Summarise the Domestication & Introduction History of the organism:

Guidance: Refer to the outcomes of Questions 1 to 5 of this module.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the risks of Establishment & Persistence:

Guidance: Refer to the outcomes of Questions 6 to 22 of this module.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the risks of Dispersal:

Guidance: Refer to the outcomes of Questions 23 to 29 of this module.

Response options:

0–Very slow ☐ 1–Slow ☐ 2–Intermediate ☐ 3–Rapid ☐ 4–Very Rapid ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the Impact risks & Undesirable traits:

Guidance: Refer to the outcomes of Questions 30 to 45 of this module.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Conclusion of the Generic Invasiveness Risk Assessment Module:

Conclusions on Confidence:

References cited (give cited references in full and in alphabetical order)

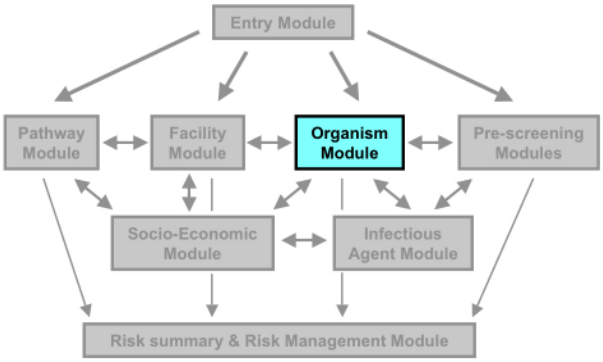
Acknowledgments (give acknowledgement to any persons or institutions that provided unpublished information, etc.)

After completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 3

Organism Risk Assessment Module – Use of Alien and Locally-Absent Species in Aquaculture

European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)



Compiled by Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/), with contributions from Dr. J. Robert Britton (Bournemouth University), Dr. Rodolphe E. Gozlan (Bournemouth University), Mr. Ian C. Russell (Cefas-Lowestoft) and Dr. Edmund Peeler (Cefas-Weymouth).

Introduction

The Organism Risk Assessment Module contains questions adapted from the UK Non-native Species Risk Assessment Scheme (Baker et al. 2008) and is intended to be used to assess the potential impacts of an organism within a clearly-defined risk assessment (RA) area. There should be clear indications that the non-native organism has the potential to have an unacceptable impact on native species and/or ecosystems in the area. Biotic and abiotic conditions in the RA area should be considered to decide whether unacceptable impacts might occur in the RA area. The overall judgement of the potential impact of the organism is based on the replies to a series of questions, expressed using an appropriate phrase from of a set of five alternatives, e.g. minimal, minor, moderate, major, massive. In addition the level of certainty attached to each answer should be given, e.g. certainty is low, medium, high, very high.

The Organism Risk Assessment Module is constructed following the same format as other modules in the present scheme. Each question should receive a response, with answers being supported by appropriate information or by using expert opinion. It is important for any review of an assessment that answers to all questions should be explained, indicating how the decision of how to answer each question was reached, and on what information a decision was based. It is also important to indicate the date on which the information was collected in case subsequent data influences answers to questions. Each response should be accompanied by a confidence ranking (of the assessor's level of certainty in their response). The four confidence rankings are as follows:
0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)
3 – Very high confidence (9 out of 10 chance)

A justification (or rationale) should be provided for each response to questions, including references to bibliographic and other information sources upon which the response was formulated. Explanations may accompany the questions to assist the assessor.

References cited: see the Introduction Section of the User Manual.

Organism Risk Assessment Module

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

PART A (INVASIVENESS SCREENING)

Guidance: The purpose of Part A is to determine whether or not the organism needs to be subjected to a preliminary invasiveness pre-screening assessment, and subsequently submitted to full risk assessment, i.e. is the organism of generally low risk (the risk assessment ceases and the assessor is directed to the Risk Summary & Risk Management Module) or is it of medium-to-high risk (and full risk assessment is required).

Q1.1) Identify the Risk Assessment (RA) area

Guidance: Specify the geographical area that is deemed/decided to be at risk, with due consideration of potential connectivity between contiguous drainage basins (e.g. via connecting canals) that would effectively determine the true area at risk.

Response:

Q1.2) Is the organism likely to be accompanied by one or more non-target organisms (other non-native organisms) that are not present but that could persist in the RA area ?

Guidance: Included in the term 'non-target organisms' are infectious agents, such as parasites and pathogens.

Response options: *YES – (Go to Q1.6)*
NO – (Go to Q1.3)

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.3) Is the climate of the organism's native range (or current introduced range) sufficiently similar to that of the RA area to facilitate the organism's establishment in the RA area?

Guidance: The response should be based on natural occurrence in three or more distinct climate categories, as defined by Koppen or Walter (or based on knowledge of existing presence in areas of similar climate). If available, then use a climate matching model (e.g. GARP, Climatch).

Response options: *YES – (Go to Q1.4)*
NO – (Go to Risk Summary & Management Module)

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.4) Does at least one habitat or host suitable for the survival of the organism occur in the RA area?

Guidance: This question deals only with the 'survival' (i.e. persistence) of the organism in the RA area, without consideration of its ability (or likely ability) to reproduce (and thus complete its life cycle).

Response options: *YES – (Go to Q1.5)*
NO – (Go to Risk Summary & Management Module)

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ■

Justification and/or comments:

Q1.5) Does at least one essential habitat or host (necessary for the organism to persist and to complete its life cycle) occur in the RA area?

Guidance: This question deals with an organism's likelihood of being able to reproduce and eventually establish a self-sustaining population in the RA area.

Response options: *YES – (Go to Q1.6)*
NO – (Go to Risk Summary & Management Module)

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.6) Is the organism an infectious agent ?

Response options: *YES – (Use the Infectious Agents Risk Module for each infectious agent that may be associated with the target organism, then Go to Risk Summary & Risk Management Module)*
NO – (Go to Q1.7)

Justification and/or comments:

Q1.7) Is the organism a fish, invertebrate or Amphibian ?

Response options: *YES – Use the appropriate invasiveness screening toolkit (then Go to Q1.8)*
NO – Use the 'Generic Pre-screening Toolkit – Section 2.1 (then Go to Q1.8)

Justification and/or comments:

Q1.8) Did the invasiveness pre-screening tool indicate the organism is potentially of medium or high risk of being invasive (or harmful) ?

Response options: *YES – Go to Part B (Detailed assessment)*
NO – Go to Risk Summary & Risk Management Module

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART B (DETAILED ASSESSMENT)

Guidance: This Part consists of four sub-sections, which address the risks of Introduction, Establishment, Dispersal and Impacts. The Impact sub-section comprises environmental and socio-economic impacts. Responses to some of the questions are expected to be informed by the outcomes using other assessment modules (e.g. Pathway, Facility, Socio-economic), and this is noted in the question where appropriate.

RISKS OF INTRODUCTION (INTO UNINTENDED LOCATIONS)

Q2.1) Using the outcome of the Pathways Risk Assessment Module: what is the overall risk of escape of the organism into the wild during import procedures ?

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.2) Using the outcome of the Pathways Risk Assessment Module: what is the overall risk of escape of the organism into the wild during farming procedures ?

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.3) Using the outcome of the Pathways Risk Assessment Module: what is the overall risk of escape of the organism due to destination/uses of farmed non-native organisms ?

Guidance: This question refers to the likelihood of escape by the organism 'after' the farming phase has been completed and it is being exploited for its intended use.

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.4) Using the outcome of the Facility Risk Assessment Module: Please indicate the likelihood of TARGET organisms escaping from any of the facilities involved in its production.

Guidance: The response to this question may comprise a single facility (for simple production processes) or the full range of facilities involved in its production (i.e. the response given here may summarized more than one Facility Risk Assessment.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.5) Using the outcome of the Facility Risk Assessment Module: Please indicate the likelihood of NON-target organisms (other than infectious agents) escaping from any of the facilities involved in its production.

Guidance: The response to this question may comprise a single facility (for simple production processes) or the full range of facilities involved in its production (i.e. the response given here may summarized more than one Facility Risk Assessment.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.6) Using the outcome of the Facility Risk Assessment Module: Please indicate the likelihood of NON-target infectious agents escaping from any of the facilities involved in its production.

Guidance: The response to this question may comprise a single facility (for simple production processes) or the full range of facilities involved in its production (i.e. the response given here may summarized more than one Facility Risk Assessment.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments

RISKS OF ESTABLISHMENT

Q3.1) How similar are the climatic conditions that would affect establishment in the RA area and in the area of current distribution ?

Guidance: The response should be based on natural occurrence in three or more distinct climate categories, as defined by Koppen or Walter (or based on knowledge of existing presence in areas of similar climate). If available, then use a climate matching model (e.g. GARP, Climatch).

Response options:

0–Not similar ☐ 1–Slightly similar ☐ 2–Moderately similar ☐ 3–Similar ☐ 4–Very similar ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.2) How similar are other abiotic factors that would affect establishment in the RA area and in the area of present distribution ?

Guidance: Consider all the nonliving components of the environment, for example light, nutrients, salinity, pH, oxygen concentration.

Response options:

0–Not similar ☐ 1–Slightly similar ☐ 2–Moderately similar ☐ 3–Similar ☐ 4–Very similar ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.3) What proportion of the habitats, hosts, or partners (for symbiotic taxa) vital for the survival, development and reproduction of the organism are present in the RA area?

Guidance: Under 'Justification and/or comments', specify the species or habitats. Definitions of responses: None of very low proportion (0–24 %); Low proportion (25–49 %); moderate proportion (50–74 %); high proportion (75–99 %); All (100 %).

Response options:

0–None or very low ☐ 1–Low proportion ☐ 2–Moderate proportion ☐ 3-High proportion ☐ 4–All ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.4) How widespread are the habitats, hosts, or partners (for symbiotic taxa) vital for the survival, development and reproduction of the organism in the RA area ?

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.5) If the organism requires a host or symbiotic partner, then how likely is the organism to become associated with such species in the RA area ?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.6) How likely is competition (with existing species in the RA area) to prevent the organism's establishment in the RA area ?

Response options:

0–Very likely ☐ 1–Likely ☐ 2–Moderate likelihood ☐ 3–Unlikely ☐ 4–Very unlikely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.7) How likely is predation/foraging (by existing organisms in the RA area) to prevent the organism's establishment in the RA area ?

Response options:

0–Very likely ☐ 1–Likely ☐ 2–Moderate likelihood ☐ 3–Unlikely ☐ 4–Very unlikely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.8) How likely is existing environmental management in the RA area to aid establishment?

Guidance: This question aims to determine how likely it is that existing environmental management practices could or would facilitate the organism's establishment (e.g. river regulation structures obstructing the natural connectivity and flow of water courses – this is thought to have been one of the principal reasons for the extinction of burbot *Lota lota* in the U.K. and is the reason that other pelagic-spawning freshwater fishes (e.g. grass carp) are unlikely to find suitable conditions for reproduction in the British Isles)).

Response options:

0–Very likely ☐ 1–Likely ☐ 2–Moderate likelihood ☐ 3–Unlikely ☐ 4–Very unlikely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.9) How likely is it that existing control or husbandry measures (e.g. use of triploids) will fail to prevent establishment of the organism?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.10) How widely distributed is the intended use of the organism in the RA area (in either closed or open systems) ?

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.11) How likely is establishment to be facilitated by the organism's reproductive strategy or life-cycle duration ?

Guidance: Organisms with young age-at-first reproduction, high fecundity and short life expectancy (*r*-selected taxa) become established most readily.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.12) How likely is establishment to be facilitated by the organism's natural capacity to disperse?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.13) How adaptable is the organism ?

Response options:

Not adaptable ☐ Slightly adaptable ☐ Moderately adaptable ☐ Adaptable ☐ Very adaptable ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.14) How likely is low genetic diversity of the founder population to be a constraining factor in the organism's establishment of a self-sustaining, persistent population ?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.15) How often has the organism established self-sustaining populations outside its original range as a result of man's activities?

Response options:

0–Very rarely ☐ 1–Rarely ☐ 2–Occasionally ☐ 3–Often ☐ 4–Very Often ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.16) How likely is the organism to survive environmental stressors in the RA area?

Guidance: Environmental stressors include low oxygen levels, elevated or reduced salinity, dissolved nutrients, natural toxins (e.g. elevated ammonia levels).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.17) How likely is the organism to resist existing infectious agents in the RA area?

Guidance: Existing infectious agents includes both native and non-native parasites and pathogens that are already present in the RA area.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.18) Even if establishment of the organism is unlikely, how likely is it that transient populations (casuals) will persist in the RA area ?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

RISKS OF DISPERSAL

Q4.1) How rapidly is the organism likely to disperse in the RA area by natural means?

Response options:

0–Very slow ☐ 1–Slow ☐ 2–Intermediate ☐ 3–Rapid ☐ 4–Very Rapid ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.2) How rapidly is the organism likely to disperse in the RA area with human assistance?

Response options:

0–Very slow ☐ 1–Slow ☐ 2–Intermediate ☐ 3–Rapid ☐ 4–Very Rapid ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.3) How difficult would it be to contain/control the organism within the RA area?

Response options:

0–Very easily ☐ 1–Easily ☐ 2–Some difficulty ☐ 3–Difficult ☐ 4–Very difficult ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.4) Based on the answers to questions on the potential for establishment and spread, how wide/important is the area threatened by the organism within the RA area?

Guidance: In the Comments box, define the types of ecosystem at risk.

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

RISKS OF IMPACT

Q5.1) Using the outcome of the Socio-economic Impact Assessment Module: Please indicate the likely level of economic costs to eradicate an infestation by the organism from the RA area.
Guidance: Refer to Qs 9–14 in the Socio-economics Impact Assessment Module.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q5.2) Using the outcome of the Socio-economic Impact Assessment Module: Please indicate the likely level of economic losses incurred to local economies should the organism escape captivity and become a pest in the RA area.
Guidance: Refer to Qs1–8 in the Socio-economics Impact Assessment Module to estimate impacts at a local scale if eradication is not attempted.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q5.3) Using the outcome of the Socio-economic Impact Assessment Module: Please indicate the likely level of economic losses incurred to wider /national/EU economies should the organism escape captivity and become a pest in the RA area.
Guidance: Refer to Qs 15–23 in the Socio-economics Impact Assessment Module to estimate impacts at wider scales if eradication is not attempted.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q5.4) How likely are consignments of the organism to contain non-target (non-infectious) organisms?
Guidance: If non-target organisms (other than infectious agents) have been identified as associated with the target organism, then provide a response. If not, then select the not applicable (N/A) option.
Response options:
0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.5) What is the magnitude of threat posed by non-target (non-infectious) organism(s) ?

Guidance: If non-target organisms (other than infectious agents) have been identified as associated with the target organism, then provide a response. If not, then select the not applicable (N/A) option.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.6) Using the outcome of the Infectious Agent Risk Assessment Module: Please indicate how likely is the target organism to be a susceptible species for infectious agents or act as a vector of infectious agents ?

Guidance: If infectious agents have been identified as associated with the target organism, then provide a response using the outcome of the 'Infectious Agent Risk Assessment Module'. If not, then select the not applicable (N/A) option.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.7) Please indicate the likelihood of the non-target infectious agent establishing in the RA area.

Guidance: If infectious agents have been identified, then provide a response using the outcome of the 'Infectious Agent Risk Assessment Module'. If not, then select the not applicable (N/A) option.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.8) If infectious agents have been identified, then indicate the likelihood of the non-target infectious agent dispersing in the RA area.

Guidance: If infectious agents have been identified, then provide a response using the outcome of the 'Infectious Agent Risk Assessment Module'. If not, then select the not applicable (N/A) option.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.9) If infectious agents have been identified, then indicate the likely magnitude of harm posed by the non-target, infectious agents ?

Guidance: If infectious agents have been identified as associated with the target organism, then provide a response using the outcome of the 'Infectious Agent Risk Assessment Module'.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.10) Please indicate the level of harm in the species diversity by the organism in areas where it has already escaped captivity.

Guidance: This assessment may be based on information from invasions outside the RA area as well as within (in the event of re-assessment). In the '*Justification and/or comments*' box, specify which area is being assessed. For the purposes of this question, the following definitions of terms apply:

'harm' = An impact that leads to a decline.

'diversity of species' = Number and abundance of species.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.11) Please indicate the level of harm in ecosystem function by the organism in areas where it has already escaped captivity?

Guidance: This assessment may be based on information from invasions outside the RA area as well as within (in the event of re-assessment). In the '*Justification and/or comments*' box, specify which area is being assessed. For the purposes of this question, the following definitions of terms apply:

'harm' = An impact that leads to a decline.

'ecosystem function' = Pathways of energy with the ecosystems (number and strength).

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.12) Please indicate the likely level of harm in the species diversity if the organism were to escape captivity (or be released into) the RA area.

Guidance: This assessment may be based on information from invasions outside the RA area as well as within (in the event of re-assessment). In the '*Justification and/or comments*' box, specify which

ecosystems in the RA area are being assessed. For the purposes of this question, the following definitions of terms apply:
'harm' = An impact that leads to a decline.
'diversity of species' = Number and abundance of species.
Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.13) Please indicate the likely level of harm to ecosystem function if the organism escaped captivity (or was released into) the RA area?
Guidance: This assessment may be based on information from invasions outside the RA area as well as within (in the event of re-assessment). In the '*Justification and/or comments*' box, specify which ecosystems in the RA area are being assessed. For the purposes of this question, the following definitions of terms apply:
'harm' = An impact that leads to a decline.
'ecosystem function' = Pathways of energy with the ecosystems (number and strength).
Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.14) How likely is it that the organism would adversely impact ecosystem services in the RA area ?
Guidance: Ecosystem services refers to those resources of commercial and/or social value, such as drinking water quality, angling and recreational amenity. In the comments box, specify which ecosystem services in the RA area are being assessed.
Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.15) How likely is the organism to have an adverse impact on the gene pool of native species?
Guidance: For the purposes of this question, 'gene pool' refers to the distribution of functional genetic variation among wild populations.
Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.16) How likely is it that management measures (to control the organism) will have adverse impacts on non-target organisms in the recipient ecosystems ?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5.17) Please indicate how widely the ecosystems at risk in the RA are to be impacted.

Guidance: In the comments box, specify the types of ecosystem that are at risk and therefore considered in this assessment. For the purposes of this question, the term 'ecosystem refers to: Ponds (large, medium, small); Lakes (large, medium, small); reservoirs (large, medium, small); upland rivers (large, medium, small), lowland rivers (large, medium, small); artificial waterways; Estuaries; Coastal waters (fiords, bays, etc.).

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

ORGANISM RISK SUMMARY

Guidance: In this section, provide an overall summary of the risks assessed in Part B (detailed assessment) of the Organism Risk Assessment Module. In some cases, e.g. taxa for which information is limited, this summary is likely to reflect the assessor's 'gut feeling' after having scrutinized the available information.

SUMMARISE INTRODUCTION (ENTRY) RISKS

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

SUMMARISE ESTABLISHMENT RISKS

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐ N/A ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

SUMMARISE DISPERSAL RISKS

Response options:

0–Very slow ☐ 1–Slow ☐ 2–Intermediate ☐ 3–Rapid ☐ 4–Very Rapid ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

SUMMARISE RISKS OF IMPACTS

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Conclusion of the Organism Risk Assessment Module:

Conclusions on Confidence

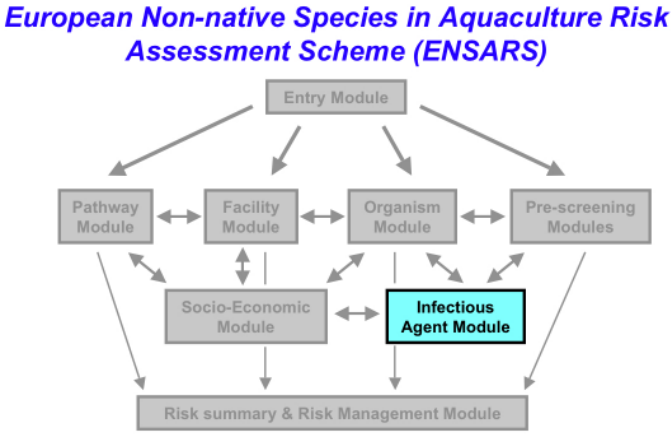
References cited (give cited references in full and in alphabetical order)

Acknowledgments (give acknowledgement to any persons or institutions that provided unpublished information, etc.)

After completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 4

Infectious Agent (non-target organism) Risk Assessment Module – Use of Alien and Locally-Absent Species in Aquaculture



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Introduction

The most important route of spread of exotic pathogens and parasites across international boundaries has been through the movement of live fishes outside their natural range (Gozlan et al., 2006). The impact of a pathogen or parasite in a new host that has no innate immunity can be devastating. Fore example, crayfish plague introduced from the U.S.A. with signal crayfish *Pacifastacus leniusculus* has eliminated the white-clawed crayfish *Austropotambius pallipes* from many parts of Europe (Alderman, 1996). Similarly, a nematode infection of the swimbladder of native European eels *Anguilla anguilla* introduced via the importation of non-native eels from Asia has contributed to the dramatic decline of the native eels population in Europe (Kirk, 2003). It is, therefore, critical that risk assessments for a proposed alien species introduction consider the likelihood of introduction, establishment, spread and impact of exotic pathogens and parasites.

Risk of introduction: The risk of introduction is, firstly, associated with the likelihood that the infectious agent is present at the site of origin. Hence it is important that the site of origin is known. Infectious agents that can exist in a sub-clinical state or cause mild or non-specific clinical signs are less likely to be detected than those that cause severe clinical signs. Vaccination may also mask the presence of the infectious agent. Similarly, if reliable diagnostic tests are not available, then it is more likely that the presence of the infectious agents will not be detected. The status of 'notifiable' infectious agents will generally be better known. Procedures that are in place at the site of origin to screen out infected individuals before export are not considered in this part of the risk assessment, hence this is an unrestricted assessment. They may be assessed in a risk management module.

Since the infectious agents are transported with their natural hosts, it is assumed that the infectious agents survive transport. In a full Import Risk Analysis (IRA) national surveillance and the competence of the veterinary authorities would be assessed. This is considered outside the scope of the present RA module.

Risk of establishment: The infectious agent will only establish at the site of introduction if one or more host species are present. However, the host range for many infectious agents will not be comprehensively known or documented. Hence, even if no known host species are present in the RA area, then zero risk should not be assumed. The quantity and quality of research undertaken to establish the host range

needs to be critically reviewed. Many infectious agents have permissive temperature ranges; introduction at a time when water temperatures are outside this range will not result in establishment (knowledge of seasonal variation in water temperature at the site of introduction is needed). Similarly, parasites from tropical regions, for example, may not establish in temperate climes.

Risk of spread: The likelihood of spread will depends on how rapidly an infectious agent is detected and the effectiveness of control measures (e.g. culling infected stock), if any. For the purposes of this analysis, it is assumed that water-borne spread will occur downstream. The risk of this route of spread will be assessed in the facilities risk assessment. The only effective risk mitigation against the local spread of micro-organisms is disinfection of effluent or discharge to mains drainage (Note: This is only likely in land-based recirculation systems). The spread between river catchments is crucial in determining how widespread the infectious agent becomes. The most important route via human movements of live hosts (or intermediate hosts). It is likely that there will not be human spread of the target organism from the site of introduction (though if this did occur, then the infectious agent is highly likely to spread with the target organism). However, downstream spread of the infectious agent to other farmed and wild populations may occur, which themselves may be moved longer distances. Other routes (e.g. mechanical transmission via anglers) may be important for infectious agents that can survive in a free living state for a reasonable period.

Risk of impacts: An introduced infectious agent may impact the farming sector through decreased production, increased costs and through loss of export markets. Ecological damage may occur if the infectious agent adversely affects wild aquatic animal populations (impacts will be especially severe if endangered fish species are affected). Very few fish infectious agents have a potential to impact human health, however, this must also be considered. Eradication is likely to be extremely difficult, and usually impossible, if the infectious agent establishes in wild aquatic animal population.

Discussion

Hazard identification and the origin of the target organism: A major difference between a RA for the target organism and an infectious agent, non-target organism is the importance of the site of origin. For exotic non-target infectious agents to be identified (hazard identification), the expert must be familiar with the known infectious agents present at the farm, region and country where it is sourced and where it will be introduced (the RA area). The confidence that a hazard identification has produced a comprehensive list of all the potential exotic infectious agents will depend on an assessment of the robustness of the surveillance in the country of origin, the system for reporting and investigating disease outbreaks, the diagnostic facilities, the competence of the veterinary authorities and the legal status of important infectious agents. A more generic RA for the importation of an alien species from any location will have a much higher level of uncertainty associated with the responses to many of the questions related to hazard identification, introduction, and will be considerably less useful. By contrast, the impact of the target organism is not influenced by its origin where as the likelihood.

Scenario tree modelling: The usual procedure for a commodity IRA is construct scenario trees to illustrate the steps in the pathways of introduction (release) and establishment and spread (exposure) for the most important hazards (infectious agents) that may be associated with the proposed importation. Each step is individually assessed (either qualitatively or quantitatively) based on the available evidence. The results from a questionnaire based ‘one size fits all’ RA cannot be as thorough or reliable as a bespoke, scenario tree based risk assessment.

IRA and international trade: Infectious agent IRA are generally initiated in response to proposed new commodity importations, and are, therefore, undertaken for trade and legal reasons. According to the Agreement on the Application of Sanitary and Phytosanitary measures (SPS Agreement) of the World Trade Organisation (WTO) (WTO, 1995), IRAs are required to justify trade restrictions greater than those allowed under international agreements, and should follow guidelines laid down by the World Organisation for Animal Health (OIE). Whilst the RA follows the structure outlined by the OIE (O.I.E., 2006), it is doubtful whether the results from a generic questionnaire would be considered adequate by the WTO as a basis on which to restrict trade. A comprehensive IRA often takes many man-months by a multi-disciplinary team. As an example the Biosecurity Australia IRA on Import Risk Analysis on Non-viable

Salmonids and Non-salmonid Marine Finfish (Kahn et al., 1999) is 409 pages in length. Apart from the approach, the RA in its present form differs from a standard IRA in other ways. Hazard identification precedes a risk assessment, and is not explicitly and comprehensively documented in the present scheme. Risk communication, for example stakeholder involvement, is an important element of IRA and is missing from the scheme. It is general practice to submit the IRA to peer-review, which again is not included in this process.

Uncertainty: The RA will highlight areas of uncertainty. It is important that the risk assessor identifies conflicting data or the absence of information that leads to uncertainty. According to the SPS agreement it is possible for an importing country to restrict trade for a time limited period whilst information is gathered to improve the basis of the RA.

Conclusion

There is an inevitable degree of subjectivity to any scoring scheme. It is, therefore, especially important that the RA allows for the evidence used to be adequately described and fully cited. By the same token identification of gaps in our current knowledge leading to low estimates of confidence are also identified. Risk analysis is a tool to inform decision making, in this case a decision about whether, or under what conditions, to allow introduction of non-native species for aquaculture or stock enhancement purposes. It is quite likely that a proposed introduction of an alien species may present an unacceptable level of risk due to the potential introduction of an infectious agent. The consequences of introducing an infectious agent into the RA area may be disastrous. It is, therefore, important that infectious agent hazards associated with a proposed introduction of an alien species are fully investigated. **The completion of the questionnaire Infectious Agent RA can only be considered as an initial screening tool. It is not likely to provide a sufficiently detailed analysis of the disease risks to support decision-making, nor would is it likely to meet the standards of an IRA required by the WTO.** If any exotic pathogen or parasite hazards are identified, then a full IRA, following OIE guidelines, would be required to produce a robust risk estimation.

Finally it always needs to be remembered that risk assessments are only of use for known hazards. There is always a possibility that organisms emerge as infectious agents in naïve hosts following translocation outside of their natural range.

References

Alderman, D.J., 1996. Geographical spread of bacterial and fungal diseases of crustaceans. Revue Scientific et Techique, Office International des Epizooties (OIE). 15, 603-632.

Gozlan, R.E., Peeler, E.J., Longshaw, M., St-Hilaire, S., Feist, S.W., 2006. Effect of microbial pathogens on the diversity of aquatic populations, notably in Europe. Microbes and Infection 8, 1358-1364.

Kahn, S.A., Beers, P.T., Findlay, V.L., Peebles, I.R., Durham, P.J., Wilson, D.W., Gerrity, S.E., 1999. Import Risk Analysis on Non-viable Salmonids and Non-salmonids Marine Finfish. Australian Quarantine and Inspection Service, Canberra, p. 409.

Kirk, R.S., 2003. The impact of *Anguillicola crassus* on European eels. Fisheries Management and Ecology 10, 385-394.

O.I.E., 2006. Aquatic Animal Health Code. Office International des Epizooties Paris.

WTO, 1995. Agreement on the Application of Sanitary and Phytosanitary Measures. World Trade Organisation, Geneva, p. 21.

Infectious Agent Risk Assessment Module

This module needs to be completed for each pathogen that has been identified as potentially associated with the target organism.

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

PART A – RISKS OF INTRODUCTION into the RA Area

Q1.1) How often has the infectious agent entered and established in new areas outside its original range as a result of man's activities?

Guidance: Use information on the international spread and distribution of the infectious agent.

Response options:

0–Very rarely ☐ 1–Rarely ☐ 2–Occasionally ☐ 3–Frequent ☐ 4–Very frequent ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.2) How widespread is the infectious agent in the exporting country?

Guidance: Percent of farms with susceptible species infected or rivers with the infectious agent present in wild populations

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.3) How likely is the infectious agent to be present at the location where the target organism is sourced?

Guidance: Knowledge of exporting site needed, e.g. approved free status, surveillance programme etc. Level of confidence should be based on type of surveillance. Structured, targeted surveillance generates a high level of confidence.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.4) How likely is the infectious agent to be present in the exported animals?

Guidance: Prevalence may depend on age of the animals exported, screening/testing measures to identify infected hosts.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.5) How likely is the infectious agent to exist in a sub-clinical or latent state in the target organism?

Guidance: Some infectious agents are recognised to cause a persistent carrier status in some recovered animals – it is unlikely that clinically sick animals will be exported thus the main risk is from sub-clinically infected individuals.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.6) Is the infectious agent 'notifiable' in the exporting country ?

Guidance: The term 'notifiable' refers to organisms that are listed as undesirable.

Response options:

0–No ☐ 1–Yes ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.7) How likely is vaccination against the infectious agent to be practised at the exporting site?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.8) How reliable are the diagnostic tests?

Guidance: Are there data on test characteristics (sensitivity/species) ?

Response options:

0-Very reliable ☐ 1–Reliable ☐ 2–Unreliable ☐ 3–Very unreliable/ non-existent ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART B – RISK OF ESTABLISHMENT

Q2.1) Does at least one host species for the infectious agent exist in the RA area?

Guidance: Check OIE manual for list of recognised hosts.

Response options:

Yes (Go to Q2.2) ☐ **No** (Go to Q2.3) ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.2) How many known host species exist in the RA area (in the wild and/ or in farms)?

Guidance: Check OIE manual for list of recognised hosts. Quantity and quality of published data should be used to determine confidence of your response.

Response options:

0-Very few ☐ 1-Few ☐ 2-Moderate number ☐ 3-Many ☐ 4-Very many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.3) Does the infectious agent need an intermediate host to complete its lifecycle?

Response options:

Yes (Go to Q2.4) ☐ **No** (Go to Q2.6) ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.4) How abundant are the intermediate host(s) in the RA area?

Response options:

0-Very low abundance ☐ 1-Low abundance ☐ 2-Moderate abundance ☐ 3-Abundant ☐ 4-Very abundant ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.5) If the infectious agent has an intermediate host, how likely is it to become associated with such organisms at the site of introduction?

Guidance: Cite information on the presence or absence of the intermediate host(s) at the site of introduction.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.6) How likely is it that the water temperatures in the RA area will be conducive to establishment of the infectious agent?

Guidance: This will be particularly important for parasites. Other pathogens also have recognised permissive temperature ranges, which means that introductions at some times of the year will not lead to establishment. Data on water temperature data are needed.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.7) How likely is it that the target organism (or non-target organisms) will excrete the pathogen/shed the parasite at the site of introduction?

Guidance: stress may lead to recrudescence of sub-clinical infections. Highly infectious pathogens are more likely to be excreted.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.8) How likely is it that excretion of the infectious agent will result in its establishment in the RA area (i.e. on average more than one new infection per infected animal) ?

Guidance: Factors to consider include: minimum infectious dose, host density and level of excretion/shedding.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART C – RISKS OF SPREAD WITH RA AREA

Q3.1) How widespread is the host organism (or host organisms) in the RA area?

Guidance: Use the distribution of farmed populations and the proportion of available aquatic habitat containing the host species.

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.2) How abundant is (are) the host organism(s) in areas where it is (they are) present?

Response options:

0-Very low abundance ☐ 1-Low abundance ☐ 2-Moderate abundance ☐ 3-Abundant ☐ 4-Very abundant ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.3) How widespread are the intermediate host organisms (if any) in the RA area?

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.4) How likely is the infectious agent to be rapidly detected?

Guidance: This depends on severity and nature of the clinical signs. For many fish diseases clinical signs do not provide an unambiguous indication of the infectious agent.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.5) How frequent are human movements of host or intermediate host species between river catchments (or marine farming areas) in the RA area?

Guidance: Knowledge of live organism movements is needed. Most human movements will be due to farming and restocking. Anglers may make some movements (very low frequency). Definitions of responses:

None (No movements); Few (up to 5 per year); moderate number (>5–15 per year); Many (>15–30 per year); Very many (>30 per year).

Response options:

0-None ☐ 1-Few ☐ 2-Moderate number ☐ 3-Many ☐ 4-Very many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.6) How long can the infectious agent survive off the host in the aquatic environment?

Guidance: The quantity and quality of published data should influence the level of confidence. Definitions of each response: Extremely short (up to 12 hours); Very short (12–24 hours); Short (24–36 hours); Long (36 hours to 7 days); Very long (> 7days).

Response options:

Extremely short ☐ Very short ☐ Short ☐ Long ☐ Very long ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.7) How long can the infectious agent survive desiccation?

Guidance: The quantity and quality of published data should influence the level of confidence. Definitions of each response: Extremely short (up to 12 hours); Very short (12–24 hours); Short (24–36 hours); Long (36 hours to 7 days); Very long (> 7days).

Response options:

Extremely short ☐ Very short ☐ Short ☐ Long ☐ Very long ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.8) How important is/was mechanical spread of free-living infectious agent between drainage basins in its natural range?

Guidance: evidence from outbreak investigations and surveys needed.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.9) How rapidly (on average) has the infectious agent spread when introduced into new areas?

Guidance: Published surveillance reports should be cited if available. Definitions of each response: Very slow (> 26 weeks); Slow (12–26 weeks); Intermediate (3–12 weeks); Rapid (1–3 weeks); Very rapid (days).

Response options:

0–Very slow ☐ 1–Slow ☐ 2–Intermediate ☐ 3–Rapid ☐ 4–Very Rapid ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summary of establishment and spread

Based on the answers to questions on the potential for establishment and spread define the area endangered by the organism.

Response:

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART D – RISKS OF IMPACT

The risks of impact of the pathogen needs to be assessed by completing Section 7 (Socio-economic Impact Risk Assessment Module) and the questions (4.5–4.7) in this Part (D) of the present module.

Q4.1) How likely is it that the infectious agent is a potential threat to human health?

Guidance: A pathogen may present a threat to human health if the pathogen is known to be zoonotic (i.e. capable of infecting humans) or it produces toxins that when ingested causes illness.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.2) How important is environmental harm caused by the infectious agent (through impact on wild aquatic animal populations) within its existing geographic range?

Guidance: The evidence that the pathogen has caused decline in aquatic animal species must be assessed; generally conclusive proof is illusive. The importance of the decline will depend on the species affected and the potential knock-on ecological effects.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.3) How easily can the infectious agent be controlled?

Guidance: Evidence of control and elimination of the pathogen within its original distribution of from areas to which it had spread and the characteristics of the pathogen should be assessed to determine the response to this question. Generally establishment of the pathogen in wild animal reservoirs means the pathogen is very difficult / near impossible to control. Pathogens that survive for long periods in the environment or can persistently infected hosts (without clinical signs) are also more difficult to control.

Response options:

Response options:

0–Very easily ☐ 1–Easily ☐ 2–Difficult ☐ 3–Very difficult ☐ 4–Near impossible ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.4) How likely is it that management measures (to control the infectious agent) will have adverse impacts on non-target organisms in the recipient ecosystems ?

Guidance: Control measures that require removal of the host species are likely to be very disruptive. Control that focuses on farmed populations are not generally disruptive to the environment.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.5) Using the outcome of the Socio-economic Impact Assessment Module: Please indicate the likely magnitude of economic losses incurred to local economies should the infectious agent escape captivity and become a pest in the RA area.

Guidance: Refer to Qs1–8 in the Socio-economics Impact Assessment Module to estimate impacts at a local scale if eradication is not attempted.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.6) Using the outcome of the Socio-economic Impact Assessment Module: Please indicate the likely magnitude of economic costs to eradicate an infestation by the infectious agent from the RA area.

Guidance: Refer to Qs 9–14 in the Socio-economics Impact Assessment Module.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.7) Using the outcome of the Socio-economic Impact Assessment Module: Please indicate the likely magnitude of economic losses incurred to wider national/EU economies should the infectious agent escape captivity and become a pest in the RA area.

Guidance: Refer to Qs 15–23 in the Socio-economics Impact Assessment Module to estimate impacts at wider scales if eradication is not attempted.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4.8) Indicate how widespread in the RA area are the economic and environmental likely to occur.

Guidance: Some parts of the risk assessment area are likely to be vulnerable to the pathogen due to the existence of susceptible wild or farmed aquatic animal populations. Please specify those parts of the RA area where economic and environmental are most likely to occur. Definitions of responses:

Not widely (≤ 5 %); Limited (6–25 %); Moderately widely (26–50 %); Widely (51–75 %); Very widely (>75 %).

Response options:

0–Not widely ☐ 1–Limited ☐ 2–Moderately widely ☐ 3–Widely ☐ 4–Very widely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

INFECTIOUS AGENT RISK SUMMARY

Guidance: In this section, provide an overall summary of the risks assessed in the Infectious Agent Risk Assessment Module. In some cases, e.g. taxa for which information is limited, this summary is likely to reflect the assessor's 'gut feeling' after having scrutinized the available information. These summaries are intended to inform the 'Risk of Impact' section (Qs 5.6–5.9) of the 'Organism Risk Assessment Module'.

Summarise the likelihood of the target organism acting as a vector of infectious agents.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the likelihood of the non-target infectious agent establishing in the RA area.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the likelihood of the non-target infectious agent dispersing in the RA area.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the magnitude of harm posed by the non-target, infectious agents ?

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Conclusion of the Infectious Agent Risk Assessment Module:

Conclusions on Confidence:

References cited (give cited references in full and in alphabetical order)

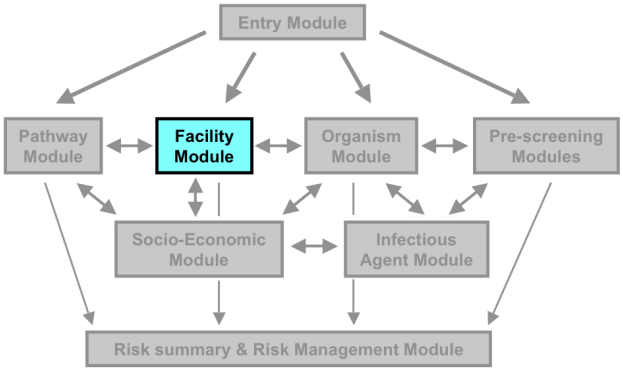
Acknowledgments (give acknowledgement to any persons or institutions that provided unpublished information, etc.)

Upon completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 5

Facility Risk Assessment Module – Use of Alien and Locally-Absent Species in Aquaculture

European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)



Compiled by Dr. Andy D. Nunn (HIFI, University of Hull) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/), with contributions from Dr. Galina Jeney (HAKI-Szarvas), Dr. Jean-Pierre Joly (IFREMER-La Tremblade), Dr. Laurence Miossec (IFREMER-La Tremblade), and Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University)

Introduction

The Facility Risk Assessment Module is intended to be used to assess the potential risks of a particular organisms, which have been highlighted as of potential concern, escaping into a clearly-defined risk assessment (RA) area as a result of the use of non-native species in aquaculture and stock enhancement It also covers the impacts to be considered in consequence assessment of the Aquatic Animal Health Code (OIE, 2006). Some questions may request information that smaller enterprises may not be able to provide, or may encounter difficulties to obtain (e.g. due to resource limitations). In such cases, the assessor may have to provide a best estimate, based on the available information, and the reduced level of certainty should be reflected in the confidence level attributed to the response.

Each question should receive a response, with answers being supported by appropriate information or by using expert opinion. It is important for any review of an assessment that answers to all questions should be explained, indicating how the decision of how to answer each question was reached, and on what information a decision was based. It is also important to indicate the date on which the information was collected in case subsequent data influences answers to questions. Each response should be accompanied by a confidence ranking (of the assessor's level of certainty in their response). The four confidence rankings are as follows:

0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)
3 – Very high confidence (9 out of 10 chance)

A justification (or rationale) should be provided for each response to questions, including references to bibliographic and other information sources upon which the response was formulated. Explanations may accompany the questions to assist the assessor.

References cited: see Introduction Section of the User manual

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

PART A (Facility, target species and management details – this Part is qualitative and so does not feed back to the Organism Risk Assessment Module)

Q1.1) What type of facility is being assessed?

Guidance: Provide any additional comments/justification (e.g. rearing structure: cage, ponds, tanks, raceways, bags, ropes; number/density/volume of target organisms to be reared/kept at the facility).

Intensive – closed: intensive rearing facilities for on-growing based on recirculation systems. Such facilities tend to be enclosed and the effluent is continuously treated; little exchange of water occurs and the system is usually only topped up with a small percentage of the volume of water in the system.

Intensive – open: intensive rearing facilities outside of buildings, taking water from and returning to available sources (surface, ground). These facilities may or may not be supplied with effluent treatment.

Extensive – gated: extensive rearing facilities with barriers to entry (e.g. security structures that limit or block unauthorized access). These facilities are only provided with a physical barrier, and coastal facilities of this type include marine lagoons and open-water floating-cage (fish rearing) facilities.

Extensive – open: extensive rearing facilities with little or no barrier to entry (e.g. possible to access by unauthorized persons). This category includes wild environments – lakes, rivers, marine lagoons, natural fjords and bays, and includes ranching or culture-based fisheries.

Response options:

Intensive – closed ☐ Intensive – open ☐ Extensive – gated ☐ Extensive – open ☐

Justification and/or comments:

Q1.2) What non-native taxon/taxa (target species) will be reared at the facility?

Response options:

Amphibia ☐ Crustaceans ☐ Fishes ☐ Molluscs ☐ Plants ☐ Other ☐

Justification and/or comments:

Q1.3) How many taxa (target species) will be reared simultaneously?

Guidance: This is the total number of taxa reared simultaneously (i.e. native and non-native target species combined).

Response options:

One ☐ Two ☐ Three ☐ Four ☐ >four ☐

Justification and/or comments:

Q1.4) What life stages(s) will be reared at the facility?

Response options:

Eggs ☐ Larvae ☐ Juveniles ☐ Adults ☐

Egg–larva ☐ Egg–juvenile ☐ Egg–adult ☐ Larva–juvenile ☐ Larva–adult ☐ Juvenile–Adult ☐

Justification and/or comments:

Q1.5) How precise is the written procedure for running the facility?

Guidance: The facility should document the technical system, the procedure and instructions used to run the facility. The procedure must give general information on the consequences of alien organisms escaping the facility and must contain sufficient technical details (e.g. sketch of hydraulic system, clear operating procedures or instructions) so that a technician with limited or no experience in the field can easily run the facility.

Response options:

Very precise ☐ Precise ☐ Moderately precise ☐ Low precision ☐ No written procedure ☐

Justification and/or comments:

Q1.6) How accurate and precise are the records of activities at the facility?

Guidance: Daily activities linked to the management of facility and animals must be recorded: movements of organisms in and out, feeding, water flow, filters exchange, etc.

Response options:

Very high ☐ High ☐ Moderate ☐ Low ☐ No info available ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.7) How accurate and precise are the records of goods and services at the facility?

Guidance: All goods and services provided by external suppliers must be recorded, especially those regarding external maintenance of equipment (e.g. filtering systems, treatment of effluents).

Response options:

Very high ☐ High ☐ Moderate ☐ Low ☐ No info available ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.8) Is there a maintenance plan for all equipment?

Guidance: Each item of equipment used by the facility must have a scheduled maintenance, particularly those involved in the treatment of effluents. The maintenance must be planned in advance and the plan recorded. The dates of past maintenance must be recorded and easily available.

Response options:

Yes ☐ No ☐

Justification and/or comments:

Q1.9) If there is a treatment system, then what is the level of training of personnel authorised to use the treatment system?

Guidance: Initial training and continuing education and/or experience of the personnel authorised to use the treatment system must be precisely recorded.

Response options:

No system or Very low level ☐ Low ☐ Medium ☐ High ☐ Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.10) Is there a fail-safe back-up system for treatment of effluent, solid waste and dead animals?

Guidance: In case of breakdown of the main system for treatment of effluent (and/or solid waste and/or dead animals) the facility must have a back-up system (e.g. a double system or tanks isolated from the surrounding environment) that can treat or at least retain safely effluent, solid waste or dead animals until the system is repaired.

Response options:

Yes ☐ No ☐

Justification and/or comments:

Q1.11) What is the efficacy of the contingency plan in case of accidental effluent discharge without treatment?

Guidance: The facility must supply all information about preparation and response to a possible accidental effluent discharge. A written procedure taking into account the following information would be highly appreciate: most appropriate procedure to react to such an accident, actions taken to minimize environmental damage, personnel training regarding these actions, list of key persons and external helpful organisations to contact.

Response options:

Very high ☐ High ☐ Medium ☐ Low ☐ No contingency ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.12) What is the magnitude (i.e. volume) of effluent will be produced by the facility?

Guidance: Definitions of each response:

Very low: 100 m^{-3} per year;

Low: 1000 m^{-3} per year;

Moderate: 10 000 m^{-3} per year;

High: >10 000 m^{-3} per year.

Response options:

None/not applicable ☐ Very low ☐ Low ☐ Moderate ☐ High ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.13) Overall, how effective is the quality management system?

Guidance: This is a summary of the responses to the previous questions in the facility, target species and management sub-section. Please take into account the following pieces of information: how precise are written procedure and instructions, the level of training and competency of personnel, their awareness of the possible consequences of organisms escaping the facility, the apparent quality and maintenance of equipment, accuracy of records. A facility accredited against ISO 9001 (Quality Management) and/or ISO 14001 (Environmental Management) standards can be considered having a very high effectiveness.

Response options:

Very low effectiveness ☐ Low effectiveness ☐ Moderate effectiveness ☐ High effectiveness ☐ Very high effectiveness ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART B (Risk of unintentional release of TARGET organisms from the facility – this Part is semi-quantitative and feeds back to the Organism Risk Assessment Module)

Q2.1) What is the effectiveness of mechanisms (e.g. gates, screens, meshes) aimed at preventing the unintentional release of target organisms?

Response options:

0–Very high ☐ 1–High ☐ 2–Medium ☐ 3–Low ☐ 4–Very low ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.2) How frequently will live target organisms be transported to and from the facility?

Response options:

0–Very often ☐ 1–Often ☐ 2–Occasionally ☐ 3–Rarely ☐ 4–Very rarely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.3) What is the likelihood of live target organisms (or their propagules) escaping the facility in the effluent?

Guidance: The term "propagules" refers to entities of organisms (e.g. fertilised eggs, seeds, dispersal stages, resting stages, vegetative fragments) that may lead to the establishment of populations of those organisms outside of the facility. As regards effluent, the following response guidance is provided:
Very unlikely: no effluent discharged (i.e. closed systems);
Unlikely: effluent treated by irradiation, chlorination or ozonation;
Moderately likely: untreated effluent discharged to sewer:
Likely: untreated effluent discharged to off-line surface waters (e.g. isolated still waters);
Very likely: untreated effluent discharged to on-line surface waters (e.g. rivers/streams and floodplain water bodies) or the marine environment (e.g. cage culture).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.4) What is the likelihood of live target organisms (or their propagules) escaping the facility in the solid waste (i.e. waste products, excess food, dead organisms, etc.)?

Guidance: The term "propagules" refers to entities of organisms (e.g. fertilised eggs, seeds, dispersal stages, resting stages, vegetative fragments) that may lead to the establishment of populations of those organisms outside of the facility. As regards solid waste, the following response guidance is provided:
Very unlikely: solid waste incinerated;
Unlikely: solid waste treated by irradiation, chlorination or ozonation;
Moderately likely: untreated solid waste discharged to sewer or sent for storage, composting, land fill or land application:
Likely: untreated solid waste discharged to off-line surface waters (e.g. isolated still waters);
Very likely: untreated solid waste discharged to on-line surface waters (e.g. rivers/streams and floodplain water bodies) or the marine environment (e.g. cage culture).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.5) How vulnerable is the facility to environmental, climatic and/or geological perturbations (e.g. storms, floods, sea-level rise, earthquakes)?

Response options:

0–Very vulnerable ☐ 1–Low vulnerability ☐ 2–Moderate vulnerability ☐ 3–Vulnerable ☐ 4–Very vulnerable ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.6) Overall, what is the likelihood of unintentional release of target organisms from the facility?

Guidance: This is a summary of the responses to the previous questions Q2.1–2.5 in Part B of the present module. This summary is intended to be used to inform question 2.4 of the 'Organism Risk Assessment Module' regarding the target organism.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART C (Risk of unintentional release of non-target organisms from the facility – this Part is semi-quantitative and feeds back to the Organism Risk Assessment Module)

Q3.1) What is the effectiveness of mechanisms (e.g. gates, screens, meshes) aimed at preventing the unintentional release of non-target organisms.

Response options:

0–Very high ☐ 1–High ☐ 2–Medium ☐ 3–Low ☐ 4–Very low ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.2) How frequently are the mechanisms checked and maintained.

Response options:

0–Very often ☐ 1–Often ☐ 2–Occasionally ☐ 3–Rarely ☐ 4–Very rarely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.3) How frequently will live or dead target organisms be transported to and from the facility.

Response options:

0–Very rarely ☐ 1–Rarely ☐ 2–Occasionally ☐ 3–Often ☐ 4–Very often ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.4) How frequently is the facility inspected for non-target organisms.

Guidance: Non-target organisms includes infectious agents.

Response options:

0–Very often ☐ 1–Often ☐ 2–Occasionally ☐ 3–Rarely ☐ 4–Very rarely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.5) How frequently is the facility cleaned/disinfected/drained/emptied.

Response options:

0–Very often ☐ 1–Often ☐ 2–Occasionally ☐ 3–Rarely ☐ 4–Very rarely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.6) How effective is the quarantine procedure/structure present at the facility.

Response options:

0–Very low effectiveness ☐ 1–Low effectiveness ☐ 2–Moderate effectiveness ☐ 3–High effectiveness ☐ 4– no quarantine procedure/structure ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.7) What is the likelihood of live non-target organisms (or their propagules) escaping the facility in the effluent.

Guidance: The term "propagules" refers to entities of organisms (e.g. fertilised eggs, seeds, dispersal stages, resting stages, vegetative fragments) that may lead to the establishment of populations of those organisms outside of the facility. As regards effluent, the following response guidance is provided:
Very unlikely: no effluent discharged (i.e. closed systems);
Unlikely: effluent treated by irradiation, chlorination or ozonation;
Moderately likely: untreated effluent discharged to sewer:
Likely: untreated effluent discharged to off-line surface waters (e.g. isolated still waters);
Very likely: untreated effluent discharged to on-line surface waters (e.g. rivers/streams and floodplain water bodies) or the marine environment (e.g. cage culture).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.8) What is the likelihood of live non-target organisms (or their propagules) escaping the facility in the solid waste (i.e. waste products, excess food, dead organisms, etc.).

Guidance: The term "propagules" refers to entities of organisms (e.g. fertilised eggs, seeds, dispersal stages, resting stages, vegetative fragments) that may lead to the establishment of populations of those organisms outside of the facility. As regards effluent, the following response guidance is provided:
Very unlikely: solid waste incinerated;
Unlikely: solid waste treated by irradiation, chlorination or ozonation;
Moderately likely: untreated solid waste discharged to sewer or sent for storage, composting, land fill or land application:
Likely: untreated solid waste discharged to off-line surface waters (e.g. isolated still waters);
Very likely: untreated solid waste discharged to on-line surface waters (e.g. rivers/streams and floodplain water bodies) or the marine environment (e.g. cage culture).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.9) How vulnerable is the facility to environmental, climatic and/or geological perturbations (e.g. storms, floods, sea-level rise, earthquakes).

Response options:

0–Very low vulnerability ☐ 1–Low vulnerability ☐ 2–Moderate vulnerability ☐ 3–High vulnerability ☐ 4–Very high vulnerability ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.10) How likely are non-target organisms to reproduce in the facility?

Guidance: Non-target organisms includes infectious agents.

Response options:

0–Very likely ☐ 1–Likely ☐ 2–Moderate likelihood ☐ 3–Unlikely ☐ 4–Very unlikely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.11) Summarise the overall likelihood of non-target (non-infectious) organisms escaping the facility.

Guidance: This is a summary of the responses to the previous questions Q3.1–3.10 in Part C of the present module. This summary is intended to be used to inform question 2.5 of the 'Organism Risk Assessment Module' regarding the target organism.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.12) Summarise the overall likelihood of a non-target infectious agents escaping the facility.

Guidance: This is a summary of the responses to the previous questions Q3.1–3.10 in Part C of the present module. This summary is intended to be used to inform questions 2.6 of the 'Organism Risk Assessment Module' regarding the target organism.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderate likelihood ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the Facility Risk Assessment:

Guidance: Evaluate the probability of unintentional release of target or non-target organisms from the facility and indicate the elements that make unintentional release most likely or those that make it least likely.

Conclusion of the Facility Risk Assessment Module:

Conclusions on Confidence:

References cited (give cited references in full and in alphabetical order)

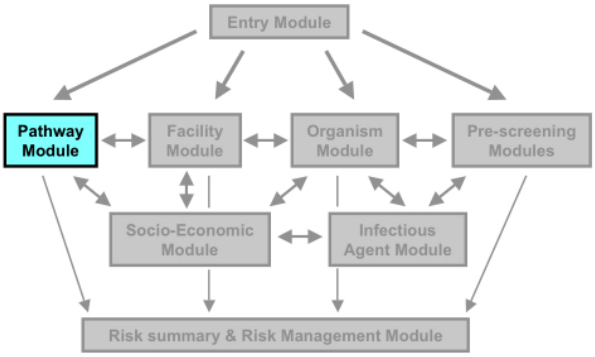
Acknowledgments (to any persons or institutions that provided unpublished information, etc.)

After completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 6

Pathway Risk Assessment Module – Use of Alien and Locally-Absent Species in Aquaculture

European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)



Compiled by Prof. Anna Occhipinti Ambrogi (UNIPV-Pavia) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/), with contributions from Dr. Stephan Gollasch (GoConsult), Prof. Sergej Olenin (KUCORPI-Klaipeda), Dr. Dario Savini (UNIPV-Pavia) and Prof. Gordon H. Copp (Cefas-Lowestoft and Bournemouth University)

Introduction

The Pathway Risk Assessment Module provides guidance for the assessment of potential risks of escape to the wild, of non-native organisms that have been highlighted as of potential concern as a result of their use in aquaculture and stock enhancement. This module also addresses the potential impacts identified as relevant by the import risk assessment model of the Aquatic Animal Health Code (OIE, 2006).

The questions are based on IMPASSE (2008), whereby the introduction pathways of farmed non-native organisms into the wild are related to the three major steps of the production chain:

1) Import procedures
2) Farming procedures
3) Destination/use of the product

The transfer procedures of eggs, larvae, juveniles and adults from the country of origin (Import), between farming facilities (Farming) and towards the market (Destination/use) pose a risk of dispersal into the wild that can be: a) merely accidental (e.g. spill from transportation vessels following accidents); b) due to uncontrolled farming procedures; or c) connected to the actual use of the farmed product, in many cases corresponding to a deliberate introduction into the wild (e.g. stocking into the wild for sport fishing purposes or for commercial fishery enhancement).

The Pathways Module is intended to be used to assess the potential risks of a particular organism escaping into a clearly-defined risk assessment (RA) area. Each question should receive a response, with answers being supported by appropriate information or by using expert opinion. It is important for any review of an assessment that answers to all questions should be explained, indicating how the decision of how to answer each question was reached, and on what information a decision was based. It is also important to indicate the date on which the information was collected in case subsequent data influences answers to questions. Each response should be accompanied by a confidence ranking (of the assessor's level of certainty in their response). The four confidence rankings are as follows:

0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)

3 – Very high confidence (9 out of 10 chance)

A justification (or rationale) should be provided for each response to questions, including references to bibliographic and other information sources upon which the response was formulated. Explanations may accompany the questions to assist the assessor.

References cited: see Introduction section of the User Manual

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Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

PART A (IMPORT PROCEDURES)

Q1.1) From how many geographical sources could the organism be introduced?
Guidance: This refers to where the organism is native, commonly farmed, fished or harvested at a global scale. Guidance on the definitions of each response is as follows:
Very few: One or two sources in the same region (e.g. two countries from the Baltic Sea);
Few: Multiple sources from the same region (e.g. three or more countries from the Baltic Sea);
Moderate number: One or two sources from different regions of one continent (e.g. Mediterranean + Baltic Sea countries);
Several: Multiple sources from different regions of one continent (e.g. Mediterranean + Baltic Sea countries);
Many: Multiple sources from different regions and/or different continents (e.g. Asia and Europe).
Response options:

0–Very few ☐ 1–Few ☐ 2–Moderate number ☐ 3–Several ☐ 4–Many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.2) What is the frequency of introduction of the organism?
Guidance: Definitions of each response: Very low = Once a year; Low = More than once a year, seasonal; Moderate = Monthly; High = Weekly; Very High = daily.
Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.3) What is the magnitude (i.e. tonnes/year; n. ind./year) of the total transfer of the organism along all its pathways of introduction?
Guidance: Definitions of each response:
Very low: Species imported for research, few ind. per year;
Low: Species imported for farming trials, less than 1 ton/year;
Moderate: Species commonly imported (1 to 10 tons/year);
High: Species commonly imported, more than 10 tons/year).

Response options:

0–None/not applicable ☐ 1–Very low ☐ 2–Low ☐ 3–Moderate ☐ 4–High ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.4) How long is the transit time of the organism during import procedures?

Guidance: Definitions of each response: Very long (> 1 month); Long (> 2 weeks); Short (1–2 weeks); Very short (<1 week); Extremely short (1–2 days).

Response options:

0–Very long ☐ 1–Long ☐ 2–Short ☐ 3–Very short ☐ 4–Extremely short ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.5) What is the risk of release (e.g. spill) of the target and associated non-target organism(s) during the transfer procedures?

Guidance: Definitions of each response:
Very low: Accident during ship/air transportation;
Low: Accident during road or rail transportation;
Moderate: Possible leakage of water and organisms from improper packaging during transportation);
High: Transfers that involve water exchange during transport (e.g. eels);
Very high: Transfer procedures that involve submersion of packaging and organisms into open waters before commercialization (e.g. oysters and mussels bags).

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.6) What is the likelihood of the organism reaching the RA area by natural range expansion or secondary introduction ?

Guidance: This refers to cases where the organism is already established in the wild in a neighbouring location (e.g. country, drainage basin), and where there is a possibility of it crossing the frontier/border either naturally or with human assistance. Factors to consider in the assessment include water currents; proximity to national borders; canals; type of reproduction, i.e. a long-lasting planktonic larval stage; and ship traffic. Examples of each response:
Very unlikely: A territorial organism with larvae only reported far from the border of a neighbouring country, with geographic or chemical-physical barriers preventing further spreading;
Unlikely: Organisms with a larval period of short duration;
Moderately likely: Organisms with a larval period of medium duration.
Likely: Organisms with a larval period of long duration.
Very likely: Organisms with long-lasting planktonic larvae near the national border of a country with similar geographic and chemico-physical characteristics to its native or naturalised range, enabling spread over the border, or organisms likely to be transferred by ship fouling and/or ballast water.

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderately likely ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.7) What is the likelihood that the organism will be imported (introduced) during its reproductive season?

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderately likely ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.8) What is the risk level associated with potential escape considering any existing procedures or mitigation actions that could prevent an accidental introduction of the target and its associated non-target organisms into the wild during import?

Guidance: Definitions of each response:
Very low risk: Well-defined mandatory protocols/guidelines and quarantine measures in place; Low risk: Well-defined protocols/guidelines in place;
Moderate risk: Protocols are in place for veterinary or sanitary inspection only;
High risk: Some undefined procedures are in place;
Very high risk: No procedures are in place.

Response options:

0–Very low risk ☐ 1–Low risk ☐ 2–Moderate risk ☐ 3–High risk ☐ 4–Very high risk ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q1.9) What is the overall risk of spreading of the organism into the wild during import procedures?

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART B (FARMING PROCEDURES)

Q2.1) How complex is the farming process of the organism?

Guidance: When an organism is imported and transported straight to market there is a relatively low risk of accidental escape into the wild during transfer; organisms that pass from a hatchery to a growing-on farm and, finally, to a depuration facility have a higher risk of an accidental spill). Definitions of selected responses:
Very simple: Only growing on (fattening) types of farming;

Simple: Different farming types excluding larval production;
Complex: Different farming types including larval production;
Very complex: All procedures including stabilization?.
Response options:

0–No farming ☐ 1–Very simple ☐ 2–Simple ☐ 3–Complex ☐ 4–Very complex ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.2) What is the overall risk of spread of the organism into the wild during farming procedures?
Guidance: Definitions of each response:
Very low: Farming in a 'strict closed system', land based, provided with all available technology to prevent spill of the organism, microorganisms and pathogens, in which accidental spill can occur only in case of uncontrollable natural disasters, e.g. flooding;
Low: Farming in conventional closed systems;
Moderate: Farming in extensive gated systems;
High: Farming in intensive open systems;
Very high: Farming in extensive open systems.
Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2.3) What is the overall risk of spread of the organism into the wild during farming procedures?
Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART C (DESTINATION USE)

Q3.1) How many final destinations/uses (e.g. food market; ornamental, stocking; biocontrol; research; social) does the organism have in the RA area ?
Guidance: For example, mosquito fish are imported and farmed for both ornamental and biocontrol use. Definitions of responses:
Very Few: One possible use; Few: 2 possible uses; Several: 3 possible uses; Many: >3 possible uses.
Response options:

0–None ☐ 1–Very few ☐ 2–Few ☐ 3–Several ☐ 4–Many ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.2) How likely is the major destination/use of the organism to be an effective pathway of introduction into the wild?

Guidance: This refers to stocking as a use that promotes a deliberate introduction into the wild. Definitions of responses:

Very unlikely: Destination is food market of dead products, dried or cooked;

Unlikely: Destination is food market of dead products, frozen or refrigerated – still risk of pathogen introduction;

Moderately likely: Destination is food market of live products;

Likely: Use is live species for ornamental market or research;

Very likely: Use is all purposes of stocking organisms into the wild (e.g. commercial fishery enhancement, restocking, sport fishery enhancement, etc).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderately likely ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.3) What is the level of national enforcement of regulations concerning deliberate release of non-native organisms into the wild?

Guidance: This queries whether there is any existing regulation (both national or regional) in the country of destination that impedes a deliberate introduction into the wild of farmed non-native organisms? Definitions of responses:

High: Regulations are mandatory and followed (very comprehensive enforcement);

Moderate**:** Voluntary regulations, enforcement for certain groups of species;

Low: Regulations exist, but are not in force; enforcement only for certain species;

Very low: Regulations are being developed, enforcement only for a very small number of species;

None: No regulation, no enforcement.

Response options:

0–High ☐ 1–Moderate ☐ 2–Low ☐ 3–Very low ☐ 4–None ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.4) What is the level of public awareness in the country of introduction regarding non-native organisms?

Guidance: Public awareness of non-native species could limit further spread of the organism once introduced for aquaculture purposes. For example, the threat of some well-established invasive species is known to the public via the media (e.g. *Myocastor coipus*, *Silurus glanis*, *Procambarus clarkii*). Greater awareness of the risks involved can help to prevent their further spread.

Response options:

0–High ☐ 1–Moderate ☐ 2–Low ☐ 3–Very low ☐ 4–None ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3.5) How likely is a release of the organism into the wild due to human activities?

Guidance: There is increasing evidence that the appearance of non-native species in the wild is due to unauthorized releases by hobbyists, by the general public during fairs or festivals, and as part of activities associated with cultural/religious beliefs. Definitions of responses:
Very unlikely: Organisms whose only destination is the food market;
Unlikely: Organisms involved in a low number of human activities;
Moderately likely: Organisms involved in a medium number of human activities;
Likely: Organisms involved in a high number of human activities;
Very likely: Organisms that are known to be highly researched and exchanged by aquarists (e.g. *Caulerpa taxifolia*).

Response options:

0–Very unlikely ☐ 1–Unlikely ☐ 2–Moderately likely ☐ 3–Likely ☐ 4–Very likely ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q. 3.6) What is the overall risk of dispersal of the organism due to destination/uses of farmed non-native organisms?

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

SUMMARY OF THE PATHWAY RISK ASSESSMENT

Summarise the overall risk of escape of the organism into the wild during import procedures ?

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the overall risk of escape of the organism into the wild during farming procedures ?

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Summarise the overall risk of escape of the organism due to destination/uses of farmed non-native organisms ?

Guidance: This question refers to the likelihood of escape by the organism 'after' the farming phase has been completed and it is being exploited for its intended use.

Response options:

0–Very low ☐ 1–Low ☐ 2–Moderate ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Conclusion of the Pathway Risk Assessment Module:

Conclusions on Confidence:

References cited (give cited references in full and in alphabetical order)

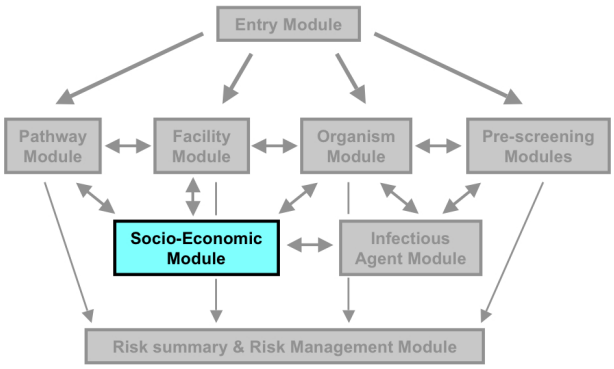
Acknowledgments (give acknowledgement to any persons or institutions that provided unpublished information, etc.)

After completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 7

Socio-economic Impact Risk Assessment Module – Use of Alien and Locally-Absent Species in Aquaculture

European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS)



Prepared by Dr. Alan MacLeod and Dr. Glyn Jones (CSL) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/), with contributions from Prof. Gordon H. Copp (Cefas-Lowestoft & Bournemouth University).

Introduction

The Socio-economic Impact Module provides guidance for the assessment of potential socio-economic impacts of non-native organisms that have been highlighted as of potential concern as a result of the use of non-native species in aquaculture and stock enhancement. It also covers the impacts to be considered in consequence assessment of the Aquatic Animal Health Code (OIE, 2006). While it is recognised that there are potential gains (positive impacts) from the use of non-native species in aquaculture, by its very nature risk assessment focuses on potential negative impacts. However, the decision of how to "balance" positive and negative impacts is not the role of a risk assessor.

The Socio-economic Impact Assessment Module is constructed following the same format as other modules in the risk assessment scheme and is intended to be used to assess the potential impacts of particular organisms within a clearly-defined risk assessment (RA) area. The overall judgement of potential socio-economic impact is based on the replies to a series of questions, expressed using an appropriate phrase from of a set of five alternatives, e.g. minimal, minor, moderate, major, massive. Each question should receive a response, with answers being supported by appropriate information or by using expert opinion. It is important for any review of an assessment that answers to all questions should be explained, indicating how the decision of how to answer each question was reached, and on what information a decision was based. It is also important to indicate the date on which the information was collected in case subsequent data influences answers to questions. Each response should be accompanied by a confidence ranking (of the assessor's level of certainty in their response). The four confidence rankings are as follows:
0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)
3 – Very high confidence (9 out of 10 chance)

A justification (or rationale) should be provided for each response to questions, including references to bibliographic and other information sources upon which the response was formulated. Explanations may accompany the questions to assist the assessor.

References cited: see Introduction section of the User manual.

Socio-economic Impact Module

Author(s) of the Risk Assessment:

Brief summary of the author(s) expertise relevant to this Risk Assessment:

Define the Risk Assessment (RA) Area:

Date of the Risk Assessment:

PART A – MARKET IMPACTS

Q1) What is the magnitude of economic loss from direct market/ commercial impacts caused by the organism within its existing (*introduced*) geographic range?

Guidance: To estimate the socio-economic impact of the organism, information on impacts should be gathered from where the organism already exists. Many introductions, both deliberate and accidental, have had negative effects on indigenous fish communities and other fauna through predation, competition, introduction of infectious agents and changes in ecosystem dynamics (Olenin *et al.* 2008). When direct impacts (impacts experienced within a facility) such as predation and competition affect goods of commercial value, the impacts have a potential market effect. As a result the impact may be described in financial or economic terms. In assessing the magnitude, consideration should be given to impact types, amount and frequency of damage and losses in yield and quality, together with the costs and efficacy of treatment, their efficacy and cost. Where possible impacts should be related to biotic and abiotic conditions. Direct non-market impacts such as impacts on ecosystem services should be considered within the Ecosystems Impact Module. An example of how verbal description of impacts could be interpreted and related to expert judgments and quantitative impacts is shown below.

Minimal	Minor	Moderate	Major	Massive
< €10k/year	€10k–€100k/year	€100k–€1m/year	€1m–€10m/year	> €10m/year

The scale is based on Baker et al. (2008) although users could use alternative scales. It would be helpful to clearly describe or explain scales that are used to aid in developing consistency between assessments.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q2) How significant are such losses?

Guidance: The significance/importance of direct market impacts should be considered in light of the size of the market. Thus impacts of €14,000 per year to an industry worth €1.4 million per year are more important that impacts of €14,000 per year to an industry worth €70 million per year.

Response options:

0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q3) What is the likely magnitude of the potential economic loss from direct market/commercial impacts caused by the organism within the RA Area?

Guidance: In answering questions about potential impacts in the RA area, assume no statutory interventions are made, i.e. take a "regulator does-nothing" approach. Use information from where the organism occurs (questions 1 and 2) and compare it with that in the RA area. Consider the ecological conditions in the RA area – they may be adequate for non-native organisms' survival but may not be suitable for populations to build to levels causing economic impacts. Rates of growth, reproduction, longevity and mortality may all need to be taken into account to determine whether these levels are exceeded (refer to the Organism Risk Module). Bio-economic models and/or partial budgeting/differential costing are techniques that could be used to make quantitative assessments of impacts. However, qualitative assessments based on expert judgment may be just as useful.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q4) How significant are such losses likely to be?

Response options:

0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q5) What is the magnitude of economic loss from indirect market/commercial impacts caused by the organism within its existing ('*introduced*') geographic range?

Guidance: Impacts experienced outside a facility, across wider society as a whole and in related markets are indirect impacts. For example, a reduced level of tourism and subsequent reduced spend by visitors in the local economy due to the impact of a non-native organism on existing populations is an indirect impact. In considering the magnitude, consideration should be given to impact types, amount and frequency of impact. Indirect non-market impacts such as impacts on ecosystem structure and function should be considered within the 'Organism Risk Assessment Module'. Environmental valuation (monetization) of non-market impacts will usually be beyond the scope of the majority of risk assessments due to their high resource requirements, i.e. such studies can be very expensive and very time consuming.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q6) How significant are such losses?

Response options:

0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q7) What is the likely magnitude of potential economic loss from indirect market/commercial impacts caused by the organism within the RA Area?

Guidance: refer back to the *Guidance* under question 5. When answering question 7, refer back to information from where the organism occurs (see questions 5 and 6) and compare it with that in the RA area.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q8) How significant are such losses likely to be?

Response options:

0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

PART B – ERADICATION COSTS

When an introduced organism is found in an undesirable location, consideration may be given to eradicating it. The decision to implement an eradication campaign should result from an evaluation of the circumstances of detection of the introduced organism, the risks identified, estimation of the present and potential distribution of the organism, and an assessment of the feasibility of conducting a successful eradication programme. Eradication attempts are more likely to succeed if the organism is not widely distributed within an area. However, once an introduced organism is established in a wild population, eradication can be extremely difficult, hence the likelihood of success of eradication will depend on how widely the organism is distributed when it is first detected. The need to take action rapidly should be carefully balanced against the need for detailed analysis and planning. It is useful to collect information concerning the origin of the pest, and pathways for its reintroduction (see Pathways Module). The eradication process involves four main activities: surveillance, containment, treatment and/or control measures, and verification.

Q9) Estimate the magnitude of the cost for surveys or surveillance during an eradication attempt.

Guidance: Surveys can be used to delimit infested areas or identify pathways. Surveys should be statistically valid and robust enough to defend statutory actions. In addition to the labour costs involved in surveys, consideration should be given to other potential costs such as technological requirements, diagnostic costs and administration. When resources are available, the feasibility of eradication should also be taken into account. An example of how verbal description of impacts could be interpreted and related to expert judgments and quantitative impacts is shown below.

Minimal	Minor	Moderate	Major	Massive
< €10k/year	€10k–€100k/year	€100k–€1m/year	€1m–€10m/year	> €10m/year

The scale is based on Baker et al. (2008) although users could use alternative scales. It would be helpful to clearly describe or explain scales that are used to aid in developing consistency between assessments.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q10) Estimate the magnitude of the cost for containment during an eradication attempt.

Guidance: Based on survey data, a quarantine area should be determined, the aim of which is to ensure that the introduced organism does not breach containment from this area. Movement out of the area should be regulated to prevent the spread of the introduced organism. Owners of affected facilities should be informed of any regulations. All other stakeholders should also be kept informed. Movement out of the quarantine area should be regulated following clearance or compliance with required measures such as inspection or treatment.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q11) Estimate the magnitude of the cost of treatment for eradication.

Guidance: Methods to eradicate an introduced organism include chemical treatment of infested sites, disinfestation of equipment and facilities, use of traps, lures and other physical controls, and could include restrictions on land/water use. When assessing costs, consider the availability of technology, ease/ difficulty of use, logistical and/or operational limitations, efficacy, non-target effects, time required and the costs to both industry and government. Eradication may involve the use of more than one treatment option. The selection of treatment and/or control options may be limited by legislative restrictions or other factors. In such situations, exceptions for emergency or limited use may be sought. An example of how verbal description of impacts could be interpreted and related to expert judgments and quantitative impacts is shown below.

Minimal	Minor	Moderate	Major	Massive
< €10k/year	€10k–€100k/year	€100k–€1m/year	€1m–€10m/year	> €10m/year

The scale is based on Baker et al. (2008) although users could use alternative scales. It would be helpful to clearly describe or explain scales that are used to aid in developing consistency between assessments.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q12) Estimate the magnitude of the cost to verify eradication.

Guidance: The criteria to be met to achieve eradication should be determined at the start of an eradication programme to determine when it is possible to declare the eradication as successful and thus to withdraw quarantine regulations. Factors to consider include sensitivity of detection technology, ease of detection, life cycle of the introduced organism, environmental effects and efficacy of treatment. How long surveys should continue, to verify the absence of the organism, should also be considered.

Response options:

0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐

Certainty/Confidence:

0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐

Justification and/or comments:

Q13) What is the likely magnitude of eradication costs on producer's profits?
Guidance: Eradication is likely to impose costs on producers. Refer back to questions 9 to 12 and consider the different potential costs likely to be borne by producers. Financial/economic techniques such as 'differential costing' and 'partial budgeting' can be used to estimate eradication costs on producer's profits.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q14) How significant are eradication costs likely to be?
Guidance: Consider the significance of all eradication costs by taking into account responses to questions 9 to 13.
Response options:
0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

PART B – IMPACTS AT A WIDER LOCAL/NATIONAL SCALE

Q15) If eradication is not feasible, for example costs are unacceptable or for other reasons, what is the likely magnitude of costs to "manage" the introduced species on a non-statutory basis, *i.e.* deal with it as a domestic "pest".
Guidance: Consider existing management measures and their efficacy against the introduced organism. It may be useful to refer to the Facility Risk Assessment Module. Additional costs may be incurred as a result of changes in cultural practices and occurrence of the pest in natural habitats. If the organism spreads, direct and indirect impacts (refer to Q3 and Q7) could materialise over wider areas. Various scenarios could be considered. Bio-economic modelling could usefully quantify impacts. Economic consequences over a number of years can be expressed as net present values using an appropriate discount rate.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q16) How significant are such costs likely to be?
Response options:
0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q17) How great a change in commodity prices is the organism likely to cause in the RA area?
Guidance: If an introduced organism impacts on the supply of a commodity, such as reducing its supply through predation, competition or disease, market changes will usually cause the price of the commodity to increase. Economists could use partial equilibrium analysis to predict price changes as supply varies.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q18) How likely is the presence of the organism in the RA area to cause market losses?
Guidance: If the introduced organism is recognised by export markets as a potential threat, its establishment in the RA area could threaten exports. Countries currently importing aquatic commodities from the RA area may impose specific sanitary measures to inhibit the organism's introduction to their country.
Response options:
0–Very Unlikely ☐ 1–Unlikely ☐ 2–Moderately Likely ☐ 3–Likely ☐ 4–Very Likely ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q19) What is the magnitude/value of such export markets?
Guidance: In addition to impacts on existing export markets, impacts to future market access could also be considered.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q20) What is the magnitude of social harm caused by the organism within its existing (introduced) geographic range?
Guidance: Social effects may arise as a result of impacts to commercial or recreational values, human health, biodiversity, aesthetics or beneficial uses. Social effects could be, for example, loss in employment, changing the habits of a proportion of the population (e.g. limiting the supply of a socially/culturally important food), damaging the livelihood of a proportion of the human population, or affecting human use (e.g. water quality, recreational uses, tourism, angling). Effects on human or animal health, the water table and tourism could also be considered, as appropriate.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q21) What is the magnitude of social harm likely to be in the RA Area?

Guidance: Refer to the notes accompanying Q 3 and Q 20.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q22) What is the magnitude of other economic costs resulting from introduction likely to be in the RA Area?
Guidance: Other costs, that can be borne by government or industry, which could be considered, include costs for project management and administration, enforcement, research, extension and education, advice and publicity.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Q23) How significant are such costs likely to be?
Response options:
0–Very low ☐ 1–Low ☐ 2–Medium ☐ 3–High ☐ 4–Very high ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Summarising Socio-economic impacts
Guidance: Where quantitative estimates have been made, the overall potential socio-economic impact can be described by simply summing impacts where appropriate. However, it is likely that many estimates will be qualitative, in which case the most important potential socio-economic impacts should be highlighted together with an estimate of how likely they are to occur in the RA area. Where possible the part of the area most economically at risk should be identified. Major uncertainties should be brought to light and the work required to reduce uncertainties should be described. Where particular scenarios have been used to assess impacts, or economic techniques or bio-economic models have been used to support responses to questions, all assumptions should be documented for transparency.
Response options:
0–Minimal ☐ 1–Minor ☐ 2–Moderate ☐ 3–Major ☐ 4–Massive ☐
Certainty/Confidence:
0-Low ☐ 1–Medium ☐ 2–High ☐ 3–Very high ☐
Justification and/or comments:

Conclusion of the Socio-economic Impact Risk Assessment Module:

Conclusions on Confidence:

References cited (give cited references in full and in alphabetical order)

Acknowledgments (give acknowledgement to any persons or institutions that provided unpublished information, etc.)

After completion of this assessment module, return to the 'Risk Summary & Risk Management Module'.

Section 8

Considerations in summarizing risks and uncertainties – Use of Alien and Locally-Absent Species in Aquaculture

Text adapted by Prof. Gordon H. Copp (Cefas-Lowestoft & Bournemouth University) for the EC Project IMPASSE (www.hull.ac.uk/hifi/IMPASSE/) from the GB Non-native Species Risk Assessment Scheme (http://www.defra.gov.uk/wildlife-countryside/resprog/findings/non-native-risks/index.htm). See also Baker *et al*. (2008).

To accompany the risk assessment modules, the mathematical principles for summarising risks and confidence rankings are discussed here below, as described for the UK scheme (references cited here above). The aim of this section is to identify the means by which the present scheme could be converted into an electronic form. This could link in with recent developments in the risk scheme for Great Britain, which are integral to developments at the EU-level via the EC project PRATIQUE: Enhancements of Pest Risk Analysis Techniques (http:/secure.csl.gov.uk/pratique/index.cfm), which is refining the web-based risk assessment modules developed by the European Plant Protection Organisation (www.eppo.org). As such, the present scheme could be constructed electronically, using the EPPO modules as the building blocks for the IMPASSE modules, and made available throughout the EU as an internet-based assessment system. The common features of the approach used for summarizing risks and uncertainties are discussed here below.

1. Five-point scale. A five-point scale was selected for the assessments to provide an appropriate balance between resolution and simplicity. In different parts of the assessment, the assessor is asked to evaluate the following attributes in response to various questions on a five point scale (0–4): likelihood, number, extent, frequency, speed, controllability, importance, effect or impact (Table 1).

Table 1. Definitions of attributes for each scale point for the types of question appearing in the risk assessment modules.

	Scale point				
Type	0	1	2	3	4
likelihood	very unlikely	unlikely	moderately likely	likely	very likely
number	very few	few	moderate number	many	very many
extent	very rare	rare	occasional	frequent	widespread
frequency	very rarely	rarely	occasionally	often	very often
speed	very slow	slow	intermediate	rapid	very rapid
controllability	very easily	easily	with some difficulty	difficult	very difficult
importance	minimal	minor	moderate	major	massive
effect	minimal	minor	moderate	major	massive

2. Breakdown by major categories. The assessments can be divided into categories. For example, in the Generic Pre-screening (Invasiveness) Module, there are four main categories (see inserted Excel spreadsheet here below): Biogeography & Introduction history, Establishment & Persistence, Dispersal, Impacts. The results are presented for each of these four categories, individually as well as for the assessment as a whole. In particular, it is important to separate dispersal and impact from the other categories. Biogeography & Introduction history provide background information on the organisms, whereas essentially Establishment & Persistence define how likely it is that an organism will establish self-sustaining populations. Dispersal and impact, on the other hand, define the magnitude of the effect should the organism become invasive.

Scoring system:	Biogeography & intro history	Establishment & Persistence	Dispersal	Impacts	Undesirable traits	Impacts + Undesirable traits	Total
SUMMARISING SCORES BY SUMMATION							
SUM of Response Scores							
Number of Questions answered							
Total Number of Questions							
Percentage Questions Answered							
Maximum Score based on number of questions answered							
Low - Medium Threshold							
Medium - High Threshold							
Massive Response to any Organism Impact Questions?							
CALCULATED RISK RATING							
AUTHORS RISK RATING JUDGEMENT							
Number of Scores of 4							
Number of Scores of 0							
SUMMARISING SCORES BY CONDITIONAL PROBABILITY							
RISK RATING by Conditional Probability							
RISK RATING by Conditional probability (Monte-Carlo)							
Monte-Carlo Percent deviation							
SUMMARISING CONFIDENCE BY SUMMATION							
SUM Confidence Scores							
Maximum Score based on number of questions answered							
Low - Medium Threshold							
Medium - High Threshold							
CONFIDENCE RATING							
AUTHORS CONFIDENCE JUDGEMENT							

3. Summarising scores. The assessments can be summarised using two different methods of calculation: score summation and conditional probability. Both approaches have advantages as well as short-comings, and the utility of either cannot properly be assessed until a sufficiently large body of assessments has been accumulated to permit evaluation.

3.1 Summation. Scores for each main category can be summed and a risk rating, high, medium or low assigned according to whether the sum of the scores lay in the top, middle or lower third of the possible range. By summing the scores for all questions, the same procedure can be used to arrive at risk rating for the assessment as a whole. The key advantage of summation is its simplicity and therefore ease of comprehension. Of concern, however, is that if we regard the sequence of scores as representing a range of probabilities, then summation (or averaging) is not the correct method to arrive at an overall value.

3.2 Conditional probability. As an alternative to summation, scores can be treated explicitly as probabilities in order to derive an overall conditional probability that a species would be invasive given the set of scores attributed. As with the summation approach, a high, medium or low risk can be assigned according to whether the final probability lay in the top, middle or lower third of the possible range (i.e. >0.666, 0.3334 – 0.666, <0.3334, respectively).

A number of assumptions must be introduced in order to apply probability theory. Scores have to be initially converted to probabilities using a conversion parameter. This defines the increment in probability terms for each score point increment. The set of starting probabilities are defined as the conditional probabilities that an organism is invasive given that it has a particular score for a particular question. Considering the relatively large number of questions in the assessment, the impact of any one question on the final outcome may be expected to be quite small; indeed a value of 0.017 was used for the conversion parameter in the case studies. The mid point of the scoring scale, i.e. 2, was taken to equate to an even probability, 0.5. Thus a score of 2 gives 0.5, a score of 3 gives 0.5 + 0.017 = 0.517 and a score of 4 gives 0.5 + 2*0.017 = 0.534 and so on. This approach effectively gives the same weight to all questions in the assessment and was used to calculate the overall risk. A correction was made in order to derive separate conditional probabilities for each of the four main categories. The conversion parameter was adjusted for

the number of questions in the category otherwise a smaller range in outcomes would be possible when there were fewer questions and comparisons between the main categories would not be meaningful. Appendix 1 of the UKNNRA User manual (http://www.defra.gov.uk/wildlife-countryside/resprog/findings/non-native-risks/index.htm) provides details of the calculation of the conditional probability.

4. Uncertainty. In recognition of the fact that some questions in the assessment can be answered with more certainty than others, an uncertainty rating was given for each question as well as a score. With the proviso that scores may not be less than 0 or greater than 4, the uncertainty associated with each question in the UK scheme was rated as follows:

0 to indicate no uncertainty
1 to indicate that the score may vary by ± 1, and
2 that it may vary by ± 2

However, subsequent research recommends that the numerical range of scores for confidence should be 0–3, using the confidence rankings are those suggested by the (IPCC (2005). The lowest confidence ranking (i.e. 'Very low confidence') is not used, however, due to the lack of statistical reliability associated with it (J. Holt & J. Mumford, personal communication), so there are four confidence categories:
0 – Low confidence (2 out of 10 chance)
1 – Medium confidence (5 out of 10 chance)
2 – High confidence (8 out of 10 chance)
3 – Very high confidence (9 out of 10 chance)

The overall uncertainty in an assessment is calculated in two ways. Firstly, by summation of the uncertainty scores (for each main category and for the assessment as a whole), and secondly using Monte Carlo simulation. The summation approach was the same as that used for the scoring itself with uncertainty being rated as high, medium or low depending on whether the sum of the uncertainty ratings lay in the upper, middle or lower third of the possible range.

4.1 Monte Carlo simulation. To simulate the variation expected due to uncertainty, the scores used in the conditional probability calculations are allowed to vary within the range specified by their uncertainty rating. Each time a simulation was run, score values were sampled at random from within the appropriate range. Unless the uncertainty rating of all the scores is zero, no two runs of the model are the same and by observing the range of outcomes over a series of simulations, an indication of the variability in the risk rating can be obtained.

5. Author's rating of risk and uncertainty. Authors of the assessments were asked to provide risk and uncertainty ratings based directly on their judgement. These ratings may differ from those calculated from the individual scores for a variety of reasons and if differences do occur it should prompt consideration of why a discrepancy exists.

6. Description of the risk summary worksheets. Three worksheets would be needed to summarise the risk assessment: 'score summary', 'graphical summary' (e.g. bar charts of score and confidence distributions) and 'probability calculator'. These would be similar to those described for the UK scheme, but with modifications to accommodate a four-point confidence scale.

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Risk Summary & Risk Management Module – Use of Alien and Locally-Absent Species in Aquaculture

Risk Assessment Dossier check list

Once the risk analysis process begins, as part of an application regarding the use of a non-native species in aquaculture, a number of assessments will be required and the purpose of the present section is to provide a summary list of all risk assessments that have been undertaken as part of a given application so as to facilitate the summation of risks associated with the proposed use of non-native species and thus inform the decision-making and risk management processes.

Please indicate the initial reason for undertaking the risk assessments:

Organism assessment ☐ Pathway assessment ☐ Facility assessment ☐

Comments (if any):

Name of organism/pathway/facility:

Start date of assessments (day/month/year):
End date of assessments (day/month/year):

Please indicate for each risk assessment module the number of assessments undertaken (and thus comprised in the risk assessment dossier and specify the names of each organism, pathway, facility assessed by that module:

☐ Pre-screening module(s)
- ☐ Freshwater fishes (FISK):
  List of organisms:
- ☐ Marine fishes (MFISK):
  List of organisms:
- ☐ Freshwater invertebrates (FI-ISK):
  List of organisms:
- ☐ Marine invertebrates (MI-ISK):
  List of organisms:
- ☐ Amphibia (AmphISK):
  List of organisms:
- ☐ Other taxa (Generic pre-screening module):
  List of organisms:

☐ Organism Risk Assessment Module:
List of organisms:

☐ Infectious Agent Risk Assessment Module:
List of organisms:

☐ Facility Risk Assessment Module:
List of facilities:

☐ Pathway Risk Assessment Module:
List of pathways:

☐ Socio-economic Impact Assessment Module:
List of organisms: