Submission to the Fisheries Management & Ecology

European Non-native Species in Aquaculture Risk Analysis Scheme (ENSARS) – a summary of assessment protocols and decision-support tools for use of alien species in aquaculture and stock enhancement

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Abstract

The European Non-native Species in Aquaculture Risk Analysis Scheme (ENSARS) was developed in response to European 'Council Regulation No. 708/2007 of 11 June 2007 concerning use of alien and locally-absent species in aquaculture' to provide protocols for identifying and evaluating the potential risks of using non-native species in aquaculture. ENSARS is modular in structure and adapted from schemes developed for the UK and the European and Mediterranean Plant Protection Organisation. Seven of the eight ENSARS modules contain protocols 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, i.e. transport pathways, rearing facilities, infectious agents, and the potential organism, ecosystem and socio-economic impacts. A concluding module is designed to summarise the risks and consider management options. During the assessments, each question requires the assessor to provide a response and confidence ranking for that response. Each module can also be used individually, and each requires a specific form of expertise. Therefore a multi-disciplinary assessment team is required for its completion.

Key words: decision support, exotic, introductions, invasive, marine, freshwater

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Introduction

The protocols commonly used in non-native species risk analysis schemes are derivatives of hazard assessment protocols developed during the late 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 and Communication, and 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) with industry and the general public to the hazards associated with the release of non-native organisms into the open environment. The risk analysis process involves protocols with which to identify potentially invasive species and then to assess the risks associated with those species. The outcomes of this process are intended to inform decision makers of potential risks, leading either to a prohibition of use or to a risk management programme that strives to reduce or mitigate risks to the environment or natural renewable resources. Amongst the major pathways of introduction for non-native organisms, aquaculture can be more effectively controlled than any of the others (international shipping, pleasure boating, sport fishing) due to its fixed and licensed locations. However, the management approach used to deal with alien species should consider interactions between major pathways of introduction (Savini *et al.* 2010).

Concomitant with the implementation of the strategy for the development of a European sustainable aquaculture leading to an expanding industry (EU 2006), the European Commission passed ‘Council Regulation No. 708/2007 concerning use of alien and locally-absent species in aquaculture’ (henceforth the ‘Regulation’). This Regulation was passed in response to increasing concern regarding non-indigenous species in aquatic ecosystems (Olenin *et al*. 2008), as well as the role that aquaculture might play in their dispersal. The Regulation aims to contribute to aquaculture sustainability, reduce economic distorsion among European countries and support countries having limited regulation on both conservation and aquaculture issues. In the absence of a risk analysis scheme to assess the alien and locally-absent species, Annex II of the Regulation provided a list of criteria to be included in any risk assessment (RA) as foreseen under Article 9 of the Regulation. As part of the implementation of the Regulation, the European Commission funded a Coordination Action ‘IMPASSE’ 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' (IMPASSE 2009). In particular, IMPASSE was intended to provide a scheme consisting of RA protocols and decision-support tools to help assess the safe use of alien species in aquaculture throughout the European Union. The aim of this paper is to provide a summary of the development of the European Non-native Species in Aquaculture Risk Analysis Scheme (ENSARS). A series of trial assessments on fish and invertebrates (the majority of species listed in Annex IV of the Regulation as of most concern regarding introduction into EU States), is provided in an accompanying paper (Copp *et al*. this issue).

Methodology

The overall framework for, and the risk assessment (RA) protocols contained in, ENSARS were developed using the same modular approach and types of questions in the GB Non-native Species Risk Assessment Scheme (Baker *et al*. 2008; Mumford *et al.* 2010), which was itself derived from the European and Mediterranean Plant Protection Organisation (EPPO) pest risk analysis decision-support scheme (EPPO 2009). The International Plant Protection Convention (IPPC) guidelines are recognised by the Sanitary and Phytosanitary Agreement of the World Trade Organization (WTO 1995; FAO 2004). Although designed to assess plant health biosecurity risks associated with trade, the EPPO (2009) scheme is based on general risk assessment principles and, as such, there is much overlap between ecological, plant and animal health issues. Therefore, the modular scheme presented herein draws heavily on the EPPO (2009) decision-support scheme and the underlying IPPC guidelines (FAO 2004).

The various ENSARS modules were constructed using a common format in as much as it consists of a sequence of questions that assessors should answer. 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). This is denoted by a numerical score, ranging from 0 to 3, which was modified from the IPCC (2005) recommended confidence ranking system:

0 – Low confidence (2 out of 10 chance of the score being correct)

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)

As such, the assessors therefore need wide expertise in risk assessment as well as fisheries and aquaculture practices and species ecology.

Each response and confidence ranking should be accompanied by a justification (or rationale) or 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, or indicate whether responses were based on 'expert opinion'. To assist the assessor, explanations have been provided with most of the questions.

It is important for any subsequent 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 the response was based. It is also important to indicate the date on which the information was collected, and any concerns over data/information quality, to permit future refinement of the RAs when new information becomes available. While it is recognised that there are potential positive impacts associated with the use of non-native species in aquaculture, by definition risk analysis focuses on potential negative impacts only. Decision makers will then be required to 'balance' the positive and negative impacts and consider the views of scientists, regulators and industry representatives to support decisions in response to applications under the Regulation and/or to request alternative management options.

Scheme structure

ENSARS consists of seven modules (Figure 1): Entry, Pre-screening (for invasiveness), Organism, Infectious Agent, Facility, Pathway, Socio-economic Impact. These 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 RA area. The outcomes of the modules inform the Risk Summary & Risk Management Module, which is described elsewhere (Cowx *et al*. 2009). Depending upon the assessment required, some of the modules (e.g. Socio-economic Impact, Pre-screening, Infectious Agent) may be required to provide assessments that inform other modules. This is especially the case of the Organism Module, which requires information from the Socio-economic Impact, Pathway, Infectious Agent and Facility Modules to complete the assessment of the target organism. Similarly, some questions in the Facility and Pathway Modules require outcomes generated by the Socio-economic Impact Module.

Entry Module

The assessment process begins with the Entry Module (Fig. 1) in which the assessor is asked to define the reason for undertaking the RA, i.e. assessment of an organism, a pathway, a facility and the surrounding environment. Modules are provided for each of these cases, although for an organism assessment the assessor is also requested to define the reason for the assessment (e.g. in response to an application for the intentional import and/or release of a locally absent organism, a novel contaminant organism has been detected in consignments originating from outside the EU).

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 (Panov *et al.* 2009). This aims to ensure that the questions are answered in a consistent manner relative to the RA area concerned.

Pre-screening Module

In all cases of an organism assessment, the assessor is directed to the Pre-screening Module, which is used to determine whether or not the organism is potentially invasive. The Pre-screening Module comprises a collection of 'toolkits', five of which are taxon-specific and were developed for the UK Department of Environment, Food & Rural Affairs as part of the GB Non-native Risk Analysis Scheme (Baker *et al.* 2008): the freshwater Fish Invasiveness Scoring Kit (FISK; Copp *et al*. 2009), the Freshwater Invertebrate Invasiveness Scoring Kit (FI-ISK; Tricarico *et al*. 2010), the Marine Fish Invasiveness Scoring Kit (MFISK), the Marine Invertebrate Invasiveness Scoring Kit (MI-ISK), and the Amphibia Invasiveness Scoring Kit (AmphISK). These five toolkits are electronic (Excel® based) and are available for free download (http://www.cefas.defra.gov.uk/4200.aspx), including a Spanish-language version of FISK (i.e. S-FISK). The sixth toolkit was developed specifically for ENSARS and is taxonomically generic. It can be used with any aquatic taxon for which the five taxon-specific toolkits are not suitable, but unlike the taxon-specific toolkits, it is currently available in paper version only (Copp *et al*. 2008b).

Adapted from the weed risk assessment (WRA) of Pheloung *et al*. (1999), the five taxon-specific pre-screening modules consist of 49 questions of which most require one of three possible responses (Yes/No/Don't Know). The assessor is required to indicate their level of confidence for each response (very uncertain, moderately uncertain, moderately certain, very certain). Also adapted from the WRA, the generic toolkit differs from the taxon-specific toolkits in both the number of questions (45) and in the manner the questions are formulated. Similar to the modules of ENSARS (Copp *et al*. 2008b) and UK schemes (Copp *et al*. 2005a; Baker *et al*. 2008), the questions in the generic pre-screening toolkit were formulated in a manner inspired by the EPPO (2009) scheme, requesting an indication of likelihood (e.g. very unlikely, unlikely, moderate likelihood, likely, very likely), magnitude (e.g. very limited, limited, moderate, great, very great) or similarity (e.g. not similar, slightly similar, moderately similar, similar, very similar), scored as 0, 1, 2, 3 and 4, respectively. For each response, the assessor is expected to indicate his/her level of confidence in that response (low, medium, high, very high).

Both the generic and taxon-specific toolkits are based on the generally accepted premise that organisms invasive in other parts of the world have an increased chance of being invasive in new areas with similar environmental conditions (e.g. Pheloung *et al*. 1999). This is a precautionary approach since not all introduced populations of a potentially invasive species have equal potential for becoming invasive. The variety of genetic, demographic and ecological factors may also affect the invasiveness potential. By way of example, genetic differences in these factors have resulted in situations where both invasive and non-invasive populations of an introduced species may occur in the same area (Sakai *et al.* 2001). Two of the toolkits (FISK, FI-ISK) have undergone calibration and validation (Copp *et al*. 2009; Tricarico *et al*. 2010), and a detailed description of FISK is provided in Copp *et al*. (2005a). FISK and FI-ISK have been reviewed externally (Verbrugge *et al.* 2012), and FISK was the highest scoring tool assessed in a meta analysis by Snyder *et al.* (2012). Concurrently, FISK v1 underwent a revision procedure to broaden its climatic applicability and to improve dramatically the guidance user interface. The resulting tool, FISK v2 (Lawson *et al*. 2013), and is now available for free download at the URL indicated here above.

The generic and taxon-specific toolkits consist of questions that assess the biogeography and history of the species, the presence of undesirable traits, and species biology and ecology. As in previous schemes (see Copp *et al*. 2005a; Baker *et al*. 2008), these pre-screening toolkits comprise the initial hazard identification phase of the risk analysis process (Copp *et al*. 2005a, 2005b). As an integral component of ENSARS, the pre-screening toolkits provide the assessor with a means of identifying which species are likely to be invasive and therefore in need of comprehensive assessment. Species assessed with these toolkits are categorised as low, medium and high risk, leaving decision-makers to determine which categories (‘medium and high’, or ‘high only’) require full assessment.

Organism Risk Assessment Module

When the Pre-screening Module indicates that a target species is likely to be invasive, the Organism Module provides a means of assessing the potential impacts should that species escape the intended recipient facility. The Organism Module comprises two parts (A and B) and considers the biotic and abiotic conditions within the RA area in relation to the traits of that species to identify whether any unacceptable impacts may accrue after introduction.

Part A of the module summarises the outcome of the pre-screening module to identify whether a full risk assessment is appropriate. This includes a description of the RA area (e.g. river basin or coastal lagoon) followed by a series of questions that considers other issues, such as type of organism (fish, invertebrate or amphibian, and/or an infectious agent), whether additional, non-target alien species are likely to be introduced (e.g. pathogens, parasites, other hull foulants), whether or not the climate of the RA area matches that of the donor region, and whether or not the habitat of the RA area is suitable for the species’ persistence and lifecycle completion. These topics are covered in eight questions that are answered sequentially and, depending on the answer, each provides an exit route to a different module or the option of continuing. In cases where Part A (in conjunction with a pre-screening toolkit) indicates a low risk of potential invasiveness, the RA ceases and the assessor proceeds directly to the Risk Summary and Risk Management Module. However, when pre-screening indicates an organism to be of medium or high risk, Part B, the detailed assessment, must be completed.

Part B (the full risk assessment) comprises 45 questions over four broad assessment topics that examine the risks of: i) introduction into unintended locations, ii) establishment, iii) dispersal (spread); and iv) impact (environmental and socio-economic). Completion of the questions on (i) Introduction Risks is assisted by the outcomes of the Pathways and Facility modules (both described below), which consider the risks of the organism escaping into the wild during their transport (during and after importation) and husbandry (i.e. farming, production and utilisation procedures, reproduction products). The (ii) Risks of Establishment questions consider the various factors that govern whether the organism will form a self-sustaining population. The Establishment questions initially concentrate on abiotic and biotic variables, such as climate matching (e.g. for thermal tolerance), habitat suitability and availability, and biotic interactions, i.e. competition with and predation by resident (in particular native) species. Also considered are the organism's life-history traits, its genetic diversity, response to pathogens and establishment history. The questions on (iii) Dispersal Risks consider how rapidly the species is likely to spread by natural means within the RA area following its release and, consequently, how difficult it will be to contain and control. The questions on (iv) Risks of Impacts consider a series of broad impact areas, encompassing socio-economic impacts, the introduction and/or transmission of infectious agents as well as impacts on biodiversity, ecosystem function, ecosystem services and the genetic integrity of native species. Completion of the initial impact questions is facilitated using the outcome of the Socio-economic Impact Module (described below), with subsequent questions on non-target organisms, including diseases completed using the outputs from the Infectious Agent Module (described below).

The remaining questions deal with ecological impacts of the target species, such as disruptions to ecosystem function (e.g. energy pathways within ecosystems), effects on species diversity, ecosystem services (e.g. resources of commercial and/or social value, such as drinking water quality, angling and recreational amenity), the gene pool of native species and the impacts of non-target species and the control methods used on them. The Organism Module finishes with a summary of the risks (introduction, establishment, dispersal, impacts), bibliographic justification and the assessor's overall confidence in the responses. The reference list should also be completed. The user then proceeds to the Risk Summary and Risk Management Module.

Infectious Agent Risk Assessment Module

The Infectious Agent Module should be completed for each infectious agent identified in the Organism Module as being potentially associated with the target species. The Office International des Épizooties **(**OIE) guidelines on import risk analysis (OIE 2007) were followed in developing this module, which is divided into four parts: A) introduction (eight questions), B) establishment (eight questions), C) spread (eight questions) and D) impact (17 questions).

The questions related to the introduction of the infectious agent focus on previous occurrences of the agent outside its original range and the prevalence of infection at the exporting site. Clinically infected animals are not likely to be exported, thus agents that can exist in a subclinical state (or cause mild or non-specific clinical signs) are less likely to be detected, hence the likelihood of subclinical infection is assessed. Since infectious agents are transported with their natural hosts, it is assumed that they survive transport.

Establishment of the agent is assessed through questions on the presence and geographic distribution of both final and intermediate hosts. More specifically the likelihood that an intermediate host would be present at the site of introduction is determined. This is particularly important for parasitic infectious agents, many of which require an intermediate host to complete their lifecycle. Some pathogens are only likely to cause clinical disease and thus shedding into the environment when stressed and a question related to conditions at the site of introduction is included. Many infectious agents have permissive temperature ranges for infection and disease expression. A question thus compares the water temperature profile of the RA area and the original range of the agent.

Questions to assess the spread of infectious agents concern the geographic distribution of the host(s), likelihood of detection and routes of spread. Long-distance spread (between catchments or marine regions) is particularly important and occurs mainly via human-assisted movements of live (intermediate or definitive) hosts. The survival of the agent outside the host is assessed to determine the importance of mechanical routes of spread. Ultimately, the distribution of infectious agents will be determined largely by the geographic distribution of the host species.

The section on impacts mirrors questions on the impacts of the target species. Impacts on aquaculture are determined first through questions on the impact the agent has on aquatic animal production within the existing geographic range, and whether impact is likely to be comparable in the importing country. A decrease in consumer demand and loss of export markets as well as decreased production are considered. Similarly social and environmental impacts are also assessed through comparison of the original geographic range with the RA area. Disease control is addressed in this section since long term impact will be higher for agents that are difficult to control or for which control measures are environmentally damaging.

The assessor can provide justification and comments against each response. It is likely that for some agents the assessors will have limited information on which to determine a score, which can be reflected by the choice of confidence level attributed to a response. Following completion of the questionnaire, an assessment is made for each component and combined in an overall risk estimate, along with an assessment of certainty. The results help determine the need for risk mitigation.

Facility Risk Assessment Module

The potential ecological and economic impacts of non-native organisms are effectively irrelevant if the target species can be reared in secure aquaculture facilities. In reality, however, aquaculture facilities are very rarely completely secure and, consequently, there is invariably a risk that non-native species or their propagules could escape into the wider environment, especially in the case of *in situ* farming such as mariculture (e.g. oysters, mussels, clams, salmonids). The Facility Module is intended to assess the potential risks of a target organism, or any non-target, non-native organisms associated with the target organism, and any propagules thereof (e.g. fertilised eggs, seeds, dispersal stages, resting stages, vegetative fragments), escaping from a given aquaculture facility into a clearly-defined RA area. The module is divided into three parts: A) facility, target species and management details; B) risk of unintentional release of target organisms from the facility; and C) risk of unintentional release of non-target organisms from the facility. Part A is qualitative and is used to collate background information relevant to specific RAs, whereas parts B and C are semi-quantitative and provide input to the Organism Module. A separate risk assessment should be conducted for each aquaculture facility or, where necessary, for each zone (e.g. hatchery, rearing ponds) within a facility, particularly where hazards or risks differ between zones.

Part A of the Facility Module requires information on the type of facility being assessed (intensive/extensive, open/closed), the organism and life stages to be reared, and the quality management system (such as HACCP, ISO norm’s implementation, insurance quality, accreditation), including the efficiency and competence of the procedure for running the facility, the treatment system and equipment, the level of training and competency of personnel, maintenance and contingency plans, and records of activities, goods and services. Parts B and C, respectively, require information pertaining to the likelihood of target and non-target organisms escaping from the facility, and the mechanisms (e.g. gates, screens, meshes, treatment) intended to prevent their escape. There are 31 questions in total, the majority of which are supported with explanatory guidance intended to assist the assessor select a response with a specified level of confidence. The assessor is expected to provide additional justification and/or comments in support of their responses. Following completion of the questionnaire, the overall probability of unintentional release of target or non-target organisms from the facility is evaluated, accounting for the responses to each of the questions in Parts A–C, and the elements that make unintentional release most or least likely should be identified. A series of trial assessments on fish and invertebrates is provided in an accompanying paper (Copp *et al*. this issue).

Pathway Risk Assessment Module

Using relevant assessment criteria identified in the import RA scheme of the Aquatic Animal Health Code (OIE 2007), the Pathway Module examines the potential risks of escape of non-native organisms by various means (pathways) into the wider environment of a clearly defined RA area. 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; and 3) destination/use of the product. The transfer procedures of eggs, larvae, juveniles and adults from the country of origin (import), between rearing 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). Part A of the module (import procedures) comprises eight questions that examine the risk of non-native organisms dispersing into the wild, with consideration of: i) multiple introduction sources, ii) consignment size (i.e. the quantities of organisms transferred), iii) consignment transit time in relation to risk of organism spill, iv) existing spill prevention protocols, and v) risks of escape by non-target organisms.

Part B (farming procedures) consists of three questions that assess risk based on the complexity of the production chain (e.g. organisms that pass from a hatchery to a growing-on facility and, finally, to a depuration facility have a higher risk of an accidental spill than those imported and transferred straight to market). Part C (destination/use) comprises six questions on the final destination(s) and/or use(s) of the organism. Multiple uses (e.g. stocking, ornamental, food, biocontrol) will result in a higher likelihood of an unintentional release than will a single use. Moreover, the type of market destinations will determine the level of associated risk of escape (e.g. the release of a non-native species in open waters for sport fishing corresponds to a voluntary introduction into the wild). This last part of the module also considers the type of existing national enforcement of regulations and public awareness regarding non-native species and their potential ecological impacts as possible factors in the mitigation of risks. The module finishes with a summary section consisting of three questions that require the assessor to provide a synthesis of the overall risk of the organism escaping into the wild during import, farming and destination/use as well as a summary of the overall confidence ranking of the assessment.

Socio-economic Impact Risk Assessment Module

Before considering possible adverse socio-economic impacts in the RA area, the magnitude and significance of adverse impacts caused by the target organism are first assessed within its existing introduced distribution (MacLeod *et al.* this issue). Information describing impacts within its existing range can then be interpreted with respect to the RA area, taking into account environmental and ecological conditions therein. For example, for impacts to materialise, conditions must be suitable for the alien organism's survival and for populations to build up to sufficient densities to cause measureable impacts. Rather than provide detailed costs of adverse impacts, which in isolation may not be that illuminating, assessors are asked to categorise impacts within a five-category scale of massive, major, moderate, minor and minimal. The significance of such costs must also be recorded. Explanatory notes provided highlight key factors to consider when making judgements. Impacts occurring within a facility are regarded as direct impacts, whilst impacts experienced outside of a facility are indirect. Economic methods to quantify and monetize direct and indirect impacts are described in Jones and Kasamba (2008), and in Copp *et al*. (2008a).

In circumstances where an introduced organism is found in an undesirable location, consideration may be given to eradicating it. The eradication process involves four main activities: surveillance, containment, treatment and/or control measures, and verification, all of which can be very costly. The Socio-economic Impact Module provides guidance to assess the potential costs of eradication through assessors answering six questions, four concern the eradication activities listed above, and two concern the magnitude of costs on producers and the significance of such costs. Suitable economic techniques to measure potential impacts are listed.

If not eradicated, then an introduced organism may spread widely with impacts eventually occurring over a broad area. The Socio-economic Impact Module therefore asks assessors to consider impacts over a wide geographic and temporal scale. Market impacts (e.g. reduced supply of an aquatic commodity through predation, competition or disease) are also considered. Consequent impacts such as loss of employment through decline of a fishery are considered within social impacts. Other costs, such as those borne by government or industry as a result of research, introduced species project management and administration, enforcement, extension and education, advice and publicity are also a component of the module. This complexity of issues emphasises the importance of a team-approach to such assessments.

Finally, guidance is provided on how questions within the Socio-economic Impact Module can be summarised to reach an overall conclusion about potential socio-economic impacts. Where quantitative estimates have been made, the overall potential socio-economic impact can be described (for absolute estimates) 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. The need to recognise and identify uncertainties is again highlighted together with the need to highlight all assumptions for transparency. For example, the process employed by the GB Non-native Risk Analysis Panel (https://secure.fera.defra.gov.uk/nonnativespecies/index.cfm?pageid=51) is based on a summary risk score integrated by the assessor and then subjected to peer review, which includes evaluation of the scores and documentation attributed to the individual questions as well as the implicit "weighting" of the assessor's summary scores for each module to identify inconsistencies between individual and summary scores (see Holt *et al.* 2012).

Discussion

During the past two decades, biological invasions have increasingly become a global concern. The potential impacts of non-native species are numerous, and include loss of indigenous species, shifts in ecosystem function and socio-economic issues (Lodge 1993; Moyle & Light 1996; Mack *et al*. 2000; Manchester & Bullock 2000; Gherardi 2007; Gozlan *et al*. 2010; Kettunen *et al.* 2009). Notwithstanding, some non-native species can have great societal benefits and, especially given the increasing importance of aquaculture production (FAO COFI Report http://www.fao.org/docrep/016/i2727e/i2727e00.htm) to meet demands for aquatic products (Cowx *et al*. 2008; Bostock *et al*. 2010), it is likely that the number of species introductions will increase (Gozlan 2008; Olenin *et al*. 2008). As such, protocols for identifying and evaluating the potential risks of using non-native species in aquaculture are required. It is important to note here, however, that risk assessment deals with adverse impacts only, and any beneficial impacts of a non-native species must not be incorporated into the risk assessment – these are taken into consideration by decision makers when they are balancing the outcome of the risk assessment on adverse impacts against social and economic benefits. It should, however, also be recognised that legislation is in place to prevent the introduction of certain species into some countries to avoid any potential adverse impacts. Adherence to this legislation should be the first step before undertaking RA.

Current legislation can make reference to internationally recognised rules and regulations designed for assessing and minimising the risk of alien species introduction and spread. The European Council Regulation concerning the use of alien and locally absent species in aquaculture (Council Regulation No. 708/2007) cites the ICES Code of Practice as the reference method for the control of alien species; correspondingly other European and Member State legislations could benefit in their enforcement by the adoption of the ENSARS methodology. The international and national mechanisms for the prevention of new marine species introductions, and risk assessment procedures have been developed particularly by the Australian and New Zealand biosecurity strategies (Hewitt & Campbell, 2007; Dahlstrom *et al.* 2011).

Seven of the ENSARS modules evaluate 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 (i.e. transport pathways, rearing facilities, infectious agents, and the potential organism, ecosystem and socio-economic impacts), whereas the final module facilitates the summary and management of the risks. Organisms with the highest probability of escaping into the wider environment (and subsequently having significant detrimental ecosystem and socio-economic impacts) are ranked as the highest risk. By contrast, organisms with a low probability of escaping or of surviving outside the confinement area provided by aquaculture (and having subsequent impacts) are ranked as low risk; organisms with a high probability of escaping (but low probability of having subsequent impacts, or *vice versa*) are ranked as medium risk. Case studies using the ENSARS are presented in Copp *et al.* (this issue).

In the marine environment, some species are released directly in the wild and mariculture practices are conducted in sheltered coastline areas (e.g. fjords, bays) open to the sea, and therefore bivalves have the highest probability of spread into adjacent areas (Ruesink *et al.* 2005; Miossec *et al.* 2009). Methods of risk assessment for these special cases can prove ineffective, as in the North Sea, where the reproduction of Pacific oysters *Crassostrea gigas* (Thunberg) was thought to be limited by low temperatures. However, spat settlement was observed during the warm summers of 1975 and 1976, so new imports from Japan and the USA stopped in 1977. However, imports of marketable oysters from France and Belgium continued. In 1987, oyster spat settlement was observed in Grevelingen Meer and in the Oosterschelde Estuary, with strong expansions taking place between 1989 and 1993, and Pacific oysters currently cover most of the hard-substrata in the low intertidal and sub-littoral zones in the Netherlands (Reise 2008). Similarly, the Mediterranean mussel *Mytilus galloprovincialis* has had substantial ecological effects across a broad geographic scale in South Africa. Since its first detection in Saldanha Bay during the late 1970s, Mediterranean mussels have invaded more than 2000 km of South Africa's southern and western coastlines, becoming the dominant rocky intertidal organism at most sites within this range (Robinson *et al.* 2005). In the Mediterranean Sea, Manila clams *Ruditapes philippinarum* were first introduced to a closed plant, but within a short period became to represent the largest fisheries revenue of the Northern Adriatic Sea (Pranovi *et al.* 2006). Intentional movements of bivalve seed or adults have also been responsible for the introduction of up to 60 non-native invertebrates and algae, often as shell foulants or in packaging material (Savini *et al.* 2010).

A key feature of ENSARS is that the RAs are, as far as is possible, informed using peer-reviewed literature or other sources of reliable information, and there is therefore a 'paper trail' that enables the justification for a decision to be reviewed and subsequently be revised, should new information become available. Critically, the response to each question must be accompanied by the assessor's ranking of his/her confidence in their response and the supporting information. The inclusion of confidence rankings in environmental risk predictions and assessments is now well established (e.g. IPCC 2005; Copp *et al*. 2009; Tricarico *et al*. 2010; Britton *et al*. 2011; Lawson *et al.* 2013). They aid not only in evaluating the relative importance of questions in the assessment process, and as such in identifying knowledge gaps, but also serve to buffer the influence of responses based only on expert opinion or scant literature: this ensures that, whenever possible, decisions have a sound scientific basis and those based on expert judgement due to lacking or limited information can be identified through a low confidence ranking.

Another attribute of ENSARS is that the modules can be used either independently or in combination, as necessary. Indeed, the outputs from many of the modules can be used to inform the inputs to others, thereby increasing the confidence both in the responses to individual questions and the overall RA. The greater the amount of information in support of responses, the greater level of certainty in the responses, especially when each module is completed by an expert competent in that subject area. Importantly, full RAs will not be required in all situations, thereby avoiding unnecessary expenditure in terms of time and resources. For species deemed to be low-risk by the Pre-screening Module, assessors can progress straight to the Risk Summary & Management Module. Similarly, it is not always necessary to provide a response for all of the questions. For example, certain questions may not be relevant to particular species or scenarios, in which case the appropriate answer is ‘not applicable’, with adequate justification for this response provided (and this response does not affect the outcome of the assessment). Alternatively, where the list of responses does not include ‘not applicable’ and the information necessary to answer a question may not exist, then the absence of a response will increase the uncertainty of the assessment. The scheme is therefore sufficiently flexible to be applied to a wide range of scenarios.

Risk assessments are invariably data hungry, and a large number of sources may have to be consulted to obtain sufficient information to complete the process. This is also the case for ENSARS, and information from official sources, databases, scientific and other literature, or expert consultation may be required. Although potentially laborious to collate and analyse, the benefit of a broad base of information is that the questions in ENSARS can be answered with high confidence, and the resulting RAs should be stored in an open-source repository to serve as an information base for subsequent assessments. If there is a lack of data, however, as is often the case, then assessors can use their expertise to answer the questions in ENSARS. Although such an approach increases the subjectivity of the assessment and deviates from the scientific principle of using verifiable means to reach conclusions, it is consistent with international guidelines and is widely used in risk assessment and prioritisation tools (see Kohler & Stanley 1984; Pheloung *et al*. 1999; ICES 2004; Křivánek & Pyšek 2006; EPPO 2009; Britton *et al*. 2011). Furthermore, as mentioned previously, the incorporation of confidence measures serves to assist decision makers in identifying when the underlying information in an RA is based on peer-reviewed, published sources (i.e. higher confidence levels) or on expert opinion (lower confidence levels).

In spite of the associated ecosystem and socio-economic risks, it is likely that the use of non-native species in aquaculture will increase (Bostock *et al*. 2010; Gozlan 2010). Given the complexity of natural ecosystems, and that the potential risks and impacts associated with non-native species are multi-dimensional, a multi-disciplinary team of recognised experts is recommended for completion of RAs on any organism proposed for use in aquaculture. The balance between the resources employed to complete RAs and to address uncertainty will vary according to individual circumstances. A guiding principle to judge the resources required to provide sufficient detail in any RA is that the assessment should be 'fit for purpose'. Indeed, the WTO SPS Agreement recognises the need for a flexible approach, noting that risk management measures should be based on a RA "as appropriate to the circumstances" (WTO 1995). ENSARS thus represents a viable and flexible tool in identifying and evaluating the potential risks of using non-native species in aquaculture.

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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) and the Risk Summary and Risk Management Module (bottom box) into which the risk assessment outcomes feed information (see Cowx *et al.* 2009).