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Organization of the
United Nations



General Fisheries
Commission for
the Mediterranean

GUIDELINES ON

assessing and minimizing the possible impacts from the use of non-indigenous species in aquaculture



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European Union

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Preparation of this document

This document presents the guidelines on assessing and minimizing the possible impacts from the use of non-indigenous species in aquaculture that were prepared by the General Fisheries Commission for the Mediterranean (GFCM) of the Food and Agriculture Organization of the United Nations (FAO). Reducing the possible risks of farming non-indigenous species to local biodiversity, natural habitats, ecosystems and related ecosystem services is a priority of the GFCM as addressed in its strategy for the sustainable development of Mediterranean and Black Sea aquaculture (Target 2 “Enhance interactions between aquaculture and the environment while ensuring animal health and welfare”).

The guidelines were developed as part of the 2018–2020 work programme of the Scientific Advisory Committee on Aquaculture (CAQ), discussed by the Commission at its forty-third session (Greece, November 2019) and adopted at its forty-fourth session (online, November 2021) (FAO, 2022a).

This document builds on the work of the CAQ and integrates a review of relevant documents, peer-reviewed articles and information received from aquaculture experts, researchers and practitioners from Mediterranean and Black Sea countries. The data and information gathered were analysed to formulate and share best practices as well as practical recommendations for implementation. The guidelines are based on national and supranational legislation.

As part of their elaboration, these guidelines were shared amongst a wide array of stakeholders and experts in a participatory process to gather their inputs and priorities. The guidelines were then revised based on the results of these consultations to ensure that they aligned with their views. They were developed with the financial support of the European Union.

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Abbreviations and acronyms

CAQ	Scientific Advisory Committee on Aquaculture (GFCM)
CBD	Convention on Biological Diversity
CCRF	Code of Conduct for Responsible Fisheries (FAO)
FAO	Food and Agriculture Organization of the United Nations
GFCM	General Fisheries Commission for the Mediterranean
ICES	International Council for the Exploration of the Sea
IUCN	International Union for Conservation of Nature
SPF	specific-pathogen-free
WOAH	World Organisation for Animal Health
WTO	World Trade Organization

Executive summary

Mediterranean and Black Sea aquaculture is a fast-growing sector that is becoming crucial for food security, employment opportunities and economic growth. To maintain this level of development and to enhance these important benefits, the sector tends to rely on non-indigenous species to diversify the range of species being farmed, adapt to climate change and open up new markets. However, the use of non-indigenous species can also have adverse impacts on biodiversity, natural habitats, ecosystems and related ecosystem services if not managed safely. Countries bordering the Mediterranean and the Black Sea share common aquatic ecosystems and, as a result, any local-scale environmental impacts could have wider impacts. While various aquaculture development plans and strategies exist within the GFCM area of application, the shared ecosystems within the region and the resulting risk of wider impacts underline the need for a common regional framework on aquaculture practices related to the use of non-indigenous species. Recognizing this need, the General Fisheries Commission (GFCM) of the Food and Agriculture Organization of the United Nations (FAO) included the preparation of guidelines on non-indigenous species in the 2018–2020 work programme for its Scientific Advisory Committee on Aquaculture (CAQ) and adopted them in 2021. They are consistent with global experiences and existing supranational and international instruments regarding the use of non-indigenous species in aquaculture, including the GFCM Strategy for the sustainable development of Mediterranean and Black Sea aquaculture.

The main purpose of these guidelines is to provide guiding principles and minimum common criteria to: i) help assess, prevent and minimize the risk of adverse impacts on biodiversity, natural habitats, ecosystems and related ecosystem services associated with the use of non-indigenous species; and ii) promote the development and sharing of a comprehensive knowledge base to address the challenges posed by the use of non-indigenous species. Following an introduction on the background and scope of the guidelines, this document highlights that national regulatory frameworks dedicated to aquaculture should include provisions addressing the introduction of non-indigenous species: the competent authority in each country should draw up and regularly monitor a list of species used in aquaculture and classify them as either “non-indigenous species” or “species that are already present” and countries should establish a minimum standard capacity prior to any introduction of non-indigenous species. Furthermore, it details the application process for an authorization to introduce non-indigenous species and emphasizes that applications should be examined by the competent national authority. Finally, it identifies the necessary conditions that should be fulfilled to minimize the risks of adverse impacts following the introduction of non-indigenous species, including border measures, quarantine and monitoring, as well as surveillance systems.

1. Introduction

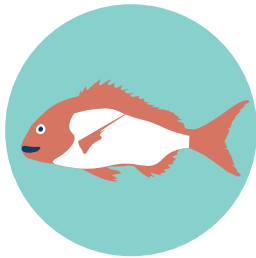
Mediterranean and Black Sea aquaculture is a fast-growing sector that plays a significant role in ensuring food security, generating employment and contributing to national economic growth.

In order to maintain these benefits and to diversify the range of species being farmed, while also adapting to climate change and opening up new markets, the use of non-indigenous species is common across the sector (Figure 1). However, as farming aquatic organisms in coastal and marine areas implies potential interactions between cultured and wild organisms, these non-indigenous species can pose a risk to host ecosystems. While such practices have generated, and could continue to generate, positive economic returns for farmers, it is widely acknowledged that the further spread of non-indigenous species could also represent a major threat to biodiversity, natural habitats, ecosystems and related ecosystem services. The cultivation of non-indigenous species could entail biosecurity risks, have negative impacts on native species and cause changes to the structure and functioning of ecosystems through habitat alteration, predation and disease transmission, including the introduction of new pathogens.

It could also result in reduced biodiversity and in competition between non-indigenous species and native organisms over limited resources, potentially leading to considerable socioeconomic impacts.

While pursuing the sustainable development of aquaculture, countries should be fully aware of the potential ecological and socioeconomic threats posed by the introduction of non-indigenous species and should follow procedures in order to achieve conservation goals and address development challenges. Global experiences and lessons learned from species introductions, as well as international instruments addressing the use of non-indigenous species in aquaculture should be taken into consideration in order to ensure safe introductions of non-indigenous species. Among the existing international instruments, the Convention on Biological Diversity (CBD) represents a milestone in the international effort toward the conservation of biodiversity (United Nations, 1992). Its signatories are bound, as far as possible, and as appropriate, to “ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction” (Article 3) and “prevent the introduction of, control or eradicate those [non-indigenous] species which threaten ecosystems, habitats or species” (Article 8).

FIGURE 1. Examples of non-indigenous species already present in Mediterranean marine aquaculture



Red seabream (*Pagrus major*)

Red seabream occurs naturally in the northwest Pacific Ocean and was introduced into, and has been farmed in, the Mediterranean since 1985, mainly in Croatia, Cyprus, Greece and Italy. It was observed in the wild for the first time in the Adriatic Sea in 2004 and the Ionian Sea in 2018.^a



Whiteleg shrimp (*Penaeus vannamei*)

Whiteleg shrimp is mainly farmed in Egypt, Tunisia and Algeria.



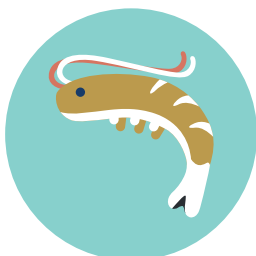
Kuruma shrimp (*Marsupenaeus japonicus*)

Kuruma shrimp is only farmed in Egypt.



Indian white prawn (*Penaeus indicus*)

Indian white prawn is only farmed in Egypt.



Northern brown shrimp (*Penaeus aztecus*)

Northern brown shrimp which originates from the western Atlantic, was first recorded in the Mediterranean Sea in 2009 in Antalya, Türkiye. Three years later, it was recorded in Egypt, where it has been farmed since 2016 by collecting post-larvae and juveniles from the wild. The impacts of northern brown shrimp's introduction on local ecosystems and other penaeids are still unknown.^b

Notes:

^a Cladas, Y., Spala, K., Doudoumis, V., Ketsilis-Rinis, V., Batargias, C. & Koutsikopoulos, C. 2019. Presence confirmation of non-native species *Pagrus major* (Temminck And Schlegel, 1843) in the eastern Mediterranean. *Oceanography & Fisheries*, 9(2): 555756.

^b Sadek, S., El-Soud, W.A. & Galil, B.S. 2018. The brown shrimp *Penaeus aztecus* Ives, 1891 (Crustacea, Decapoda, Penaeidae) in the Nile Delta, Egypt: An exploitable resource for fishery and mariculture? *BioInvasions Records*, 7(1): 51–54.

Countries bordering the Mediterranean and the Black Sea share a common aquatic ecosystem with complex aquaculture–environment interactions and, as a result, any local-scale aquaculture impacts on the environment could have wider-scale implications.

In this context, there is a need to minimize risks to biodiversity, natural habitats, ecosystems and related ecosystem services associated with the introduction of non-indigenous species.

Within the General Fisheries Commission for the Mediterranean (GFCM) of the Food and Agriculture Organization of the United Nations (FAO) area of application, Mediterranean and Black Sea countries boast national aquaculture development plans and strategies while also complying with national, supranational and international regulations on the introduction of non-indigenous species for their use in aquaculture.

Beyond the commitments of countries, effective regional coordination is necessary to prevent any potential trans-boundary issues related to the use of non-indigenous species and to meet national, supranational and international obligations and responsibilities

The discussion on assessing and minimizing possible impacts from the use of non-indigenous species in aquaculture is very relevant – especially in light of the COVID-19 pandemic – as countries and producers are seeking ways to diversify and increase their production and differentiate their products. This trend has resulted in many turning to farming non-indigenous species.

In this context, the status of shrimp farming in the Mediterranean and the Red Sea region, existing farming systems for the development of the sector, and risks regarding management and biosecurity were discussed at the Regional workshop on shrimp farming: opportunities and challenges, held in April 2019 in Monastir, Tunisia.

The meeting was organized by the GFCM, in cooperation with the Ministry of Agriculture, Water Resources and Fisheries of Tunisia, and brought together experts from Algeria, Egypt, Italy, Jordan, Lebanon, Libya, Morocco, Saudi Arabia, Tunisia, Türkiye and the United States of America.

The experts agreed on the need to share and transfer experiences, particularly in relation to the use of specific-pathogen-free (SPF) shrimp larvae, as well as guidelines regarding non-indigenous species in aquaculture. Therefore, the guidelines outlined in this document aim to answer this call and to support these countries in assessing and minimizing the risks associated with farming non-indigenous shrimp species and non-indigenous species in general.

2. Development process

A participatory and consultative process during development of the guidelines ensured that they aligned with the views of key stakeholders, reflecting their priorities, inputs and expertise (Figure 2). This process began in 2014 at the Bari Regional Aquaculture Conference, at which different stakeholders stressed the importance of having tailored tools for the Mediterranean and the Black Sea for the sustainable development of the aquaculture sector.

The guidelines were proposed according to Mediterranean and Black Sea countries' priorities and regional strategy outputs towards the achievement of the United Nations Sustainable Development Goals and following the implementation of several case studies.

In addition, contributions from individual countries, experts and farmers, as well as the collection of best practices and success stories from farming aquatic foods in the region were taken into account.

The GFCM guidelines have already been used by different stakeholders and countries and have been applied and tailored to the national and local levels. This framework of cooperation will be used to continue updating and improving the guidelines with new findings, as well as to improve knowledge sharing within the region and promote the blue transformation of aquaculture.

FIGURE 2. Features of the guidelines' development process



3. Scope

The guidelines follow a regional approach tailored to Mediterranean and Black Sea aquaculture and related stakeholders. They are based on common definitions and concepts constituting a shared template at the regional scale that should subsequently be adapted to national and local conditions.

The overall objective of these guidelines is to support Mediterranean and Black Sea countries dealing with the introduction of non-indigenous aquaculture species in order to prevent harm to biodiversity, natural habitats, ecosystems and related ecosystem services.

This ambition will be achieved through the provision of harmonized guiding principles and minimum common criteria to: i) help assess, prevent and minimize the risks of adverse impacts on biodiversity, natural habitats, ecosystems and related ecosystem services associated with the introduction of non-indigenous species; and ii) promote the development and sharing of a comprehensive knowledge base to address the challenges posed by the introduction of non-indigenous species.

The guidelines specifically aim to:

- support countries in the application of international protocols and measures to **avoid negative impacts from the introduction of non-indigenous species** in aquaculture and ensure their control and responsible use;
- support countries to **develop national aquatic organism health strategies**, possibly within the framework of existing international instruments, and effective programmes for the management of non-indigenous species;
- **define common requirements to avoid negative impacts** from the introduction of non-indigenous species;
- **propose common definitions, concepts, standards and reference documents** to support appropriate measures based on assessment, prevention and precautionary principles;
- **support national and cross-border cooperation** between the various bodies responsible for aquaculture-related transboundary issues; and
- **foster the adoption of appropriate policy instruments** and decision-making processes to avoid negative impacts from the introduction of non-indigenous species.

The guidelines rely on the principles of good governance, accountability, prevention, the precautionary approach and social responsibility. They are based on the best available knowledge and good practices in terms of the introduction of non-indigenous species.

The guidelines are advisory in nature and consistent with existing national, supra-national and international instruments. They should be considered as a tool at the disposal of Mediterranean and Black Sea countries to enhance existing processes.

The varying stages of maturity of aquaculture industries, resulting from regional specificities and different legal contexts in countries bordering the Mediterranean and Black Sea should be taken into account, along with the capacities of developing states to implement the guidelines.

To ensure their effective implementation and secure a level playing field in the region, these guidelines should be adjusted, if necessary, to specific conditions. Preparatory work on implementation needs should be carried out, as appropriate, possibly through the provision of technical assistance.



4. International context

The guidelines take into account relevant international instruments, declarations, initiatives and guidelines, in particular those relating to sustainable aquaculture development and responsible fisheries.



INTERNATIONAL CONTEXT

1992

The CBD, signed in 1992, which has three main goals: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from genetic resources (United Nations, 1992).



1995

The 1995 Code of Conduct for Responsible Fisheries (CCRF) of FAO, particularly its Article 9 warning of the possible adverse effects of the introduction of “non-indigenous species” or “non-native species” (FAO, 1995).

1995

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which entered into force in 1995 and sets out basic rules for food safety and animal and plant health standards (WTO, 1995).

2002

The 2002 Johannesburg Declaration on Sustainable Development adopted at the World Summit on Sustainable Development, which reaffirmed international commitments to the protection of biodiversity (United Nations, 2002).



2005

The International Council for the Exploration of the Sea (ICES) Code of Practice on the Introductions and Transfers of Marine Organisms 2005, which recommends procedures and practices to diminish the risk of detrimental effects from the intentional introduction and transfer of marine (including brackish water) organisms (ICES, 2005).



2006

The guidelines *Alien species in aquaculture: considerations for responsible use*, published in 2006 by the International Union for Conservation of Nature (IUCN), which provide recommendations to decision-makers and managers when using or deciding on the use of non-indigenous species for aquaculture purposes (Hewitt, Campbell and Gollasch, 2006).

2007

Council Regulation (EC) No 708/2007 of 11 June 2007 concerning the use of non-indigenous and locally absent species in aquaculture. This regulation establishes a framework governing aquaculture practices in relation to non-indigenous and locally absent species in order to assess and minimize the possible impacts of these and any associated non-target species on aquatic habitats, as well as the successive regulations amending Council Regulation (EC) No 708/2007 of 11 June 2007 (Council of the European Union, 2007).

2008

The ecosystem approach to aquaculture, formalized in 2007 at an FAO expert workshop as “a strategy for the integration of the activity within the wider ecosystem in such a way that it promotes sustainable development, equity, and resilience of interlinked social and ecological systems” (Soto, Aguilar-Manjarrez and Hishamunda, 2008).



2011

The twenty-ninth session of the FAO Committee on Fisheries (Italy, 2011), which provided recommendations on the role of FAO in improving the integration of fisheries and aquaculture development and management, biodiversity conservation and environmental protection (FAO, 2011).



2014

Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive non-indigenous species, which provides a list of invasive non-indigenous species of concern for the European Union and a set of measures to be taken across the European Union to prevent, minimize and mitigate the adverse impacts of the species included in the list on biodiversity and related ecosystem services and on human health and the economy (European Parliament and Council of the European Union, 2014).

2017

Resolution GFCM/41/2017/1 on a strategy for the sustainable development of Mediterranean and Black Sea aquaculture, which contains specific references to non-indigenous species (FAO, 2017).

2019

The Aquatic Animal Health Code of the World Organisation for Animal Health (WOAH), adopted by the World Assembly of WOAH delegates, which provides standards for the improvement of aquatic animal health worldwide, including standards for the welfare of farmed fish and use of antimicrobial agents in aquatic animal rearing (WOAH, 2019).

2020

The 2020 Shanghai Declaration of the Global Conference on Aquaculture, which provides a roadmap to optimize the role that aquaculture can play in achieving the 2030 Agenda for Sustainable Development (FAO, 2021).

2022

The draft FAO guidelines for sustainable aquaculture elaborated at the eleventh session of the Sub-Committee on Aquaculture in May 2022, which are global in scope and are intended to support the visibility, recognition, and enhancement of the aquaculture sector's important role in contributing to global, regional and national efforts towards the eradication of hunger and poverty and to support socioeconomic development for the benefit of current and future generations (FAO, 2022b).



5. Guidelines

5.1 REGULATORY FRAMEWORK

The national regulatory framework dedicated to aquaculture should include provisions addressing the introduction of non-indigenous species. The provisions should be based on the precautionary principle that all species are potentially harmful and that their introduction is therefore forbidden, unless the estimated risk is low (for example, growing organisms in closed aquaculture facilities).

The national regulatory framework should include a national aquatic organism health strategy aiming to reduce the risks, among others, of spreading pathogens and to address the possible adverse effects on ecological services and biodiversity linked to the introduction of non-indigenous species.

The regulatory framework and strategy should contain specific provisions on:

- a national authority in charge and its competence;
- an advisory committee;
- health certification and procedures including quarantine requirements and those preceding the release of any aquatic organisms;
- the establishment of a national aquatic organism pathogen list;
- the establishment of a list of non-indigenous and well-established species at the national level;

- importation risk analysis requirements and environmental risk assessments;
- the establishment of a national capacity-building programme covering all the diagnostic aspects of aquatic organism diseases (parasitology, bacteriology, virology, histology, immunology and molecular-based techniques);
- the administrative procedures and processes for granting the authorization to introduce non-indigenous species;
- the establishment of a national recording system and register for the introduction of non-indigenous species;
- the establishment of an accessible online information system containing a set of minimum data and information on all requisites needed to apply for authorizations to introduce non-indigenous species;
- the establishment of a monitoring programme for the introduction of non-indigenous species, integrated with a surveillance system of non-indigenous species; and
- the establishment of contingency plans.

5.2 NON-INDIGENOUS SPECIES AND SPECIES THAT ARE ALREADY PRESENT

In each country, the competent authority should draw up a list of species used in aquaculture and classify those that are not indigenous as either “non-indigenous species” or “species that are already present”.

Species that are already present indicate transfauned and acclimated species that have been previously introduced and that:

- do not cause any harm to biodiversity, natural habitats, ecosystems or related ecosystem services;
- are commonly used in aquaculture practices, including capture-based aquaculture;
- are a usual target of capture fisheries; and

- are of importance for local economies and traditions.

For species already present, the species or populations should be listed together with the limits of their geographic distribution. Additionally, a case-by-case assessment of the ecological, economic and social risks posed by these species should be carried out. Based on the results of this risk assessment and on national, supra-national and international regulations, derogations to the provisions of these guidelines might apply to species that are already present.

The list, data and information should be monitored and updated on a regular basis.



5.3 NATIONAL CAPACITY

Prior to any introduction of non-indigenous species, the relevant country should have a minimum standard capacity to handle the entire process while applying national, supranational and international protocols. The minimum standard capacity requirements should include, on the national territory:

- adequate infrastructure at the farm level for quarantine, appropriate to the level and type of containment required;
- established standard operating procedures for health certification and quarantine measures to enable the safe introduction of non-indigenous species;
- laboratories with diagnostic capacities on aquatic organism diseases;
- effective health management measures based on epidemiological knowledge;
- effective capacities to evaluate possible effects on the ecosystem and biodiversity;
- surveillance and monitoring programmes for early diagnosis of pathogens;
- effective enforcement capacity (for example, border customs and inspection, and post-border follow-up);
- effective biosecurity measures in place at the national level and at the farm level; and
- trained staff equipped with a good knowledge base on pathogens present in the exporting and importing countries and on epidemiological issues, as well as with capacities related to control, prevention, risk analysis and management, diagnosis, monitoring and emergency response.



5.4 COMPETENT AUTHORITY AND ADVISORY COMMITTEE

The application for an authorization to introduce non-indigenous species should be examined by the national competent authority, taking into account the advice of an advisory committee.

An advisory committee, or a scientific authority in charge of non-indigenous species, should be established on an ad hoc basis by the competent authority at the national level to assist in the overall process of authorizing the introduction of non-indigenous species. It should comprise representatives from different competent public institutions and research organizations with specific multidisciplinary expertise in aquaculture-related fields (such as, ecology, sociology, biology or veterinary science).

Based on best available knowledge, the advisory committee should:

- review all applications for an authorization to introduce non-indigenous species and advise on their correctness and completeness;
- determine whether the proposed movement of non-indigenous species is a routine or non-routine movement;

- determine whether the release of aquatic organisms should be preceded by a quarantine period or a pilot release study;
- review and assess the pilot release studies for inland contained waters;
- in case of non-routine movements, review the environmental risk assessment undertaken prior to the release and propose mitigation measures, a contingency plan and a monitoring programme based on the environmental risk assessment; and
- provide final advice to the competent authority.

Based on the advice of the advisory committee, the competent authority should decide whether a proposed introduction of non-indigenous species is a routine or non-routine movement, whether it is necessary to quarantine organisms before they are released to aquaculture facilities and whether it is necessary to conduct a pilot release study in small areas to assess potential risks.

The competent authority should also decide whether to undertake a site inspection to assess the ability and capability of an applicant.

5.5 APPLICATION FOR AN AUTHORIZATION TO INTRODUCE NON-INDIGENOUS SPECIES

5.5.1 General provisions to grant an authorization

An authorization to use non-indigenous species in aquaculture should be issued only if it complies with national, supra-national and international instruments regulating animal health conditions.

Appropriate precautionary measures should be undertaken to prevent any potential transboundary issues and adverse impacts, and an authorization should be issued only if there will be minimal risk of negative impacts on biodiversity and on local and adjacent ecosystems.

An authorization should be requested for any use of non-indigenous species in aquaculture and may be linked to the aquaculture consenting process that includes procedures for obtaining or modifying an aquaculture licence and lease.¹

Any applicant intending to introduce a non-indigenous species for aquaculture purposes should apply for an authorization from the competent authority by providing the application documentation detailed in 5.5.2. The successive stages of the application are outlined in Figure 3.

5.5.2 Application documentation

The application should be accompanied by a report including the following information (see Appendix):

- the purpose of the use of non-indigenous species in aquaculture;
- detailed information about farm facilities and location;
- information about the species to be introduced;
- the farming method that will be used;
- the manner by which the health status of the introduced species will be ensured;
- any possible interactions with native species;
- the receiving environment and adjacent water bodies;
- the post-release monitoring programme; and
- management plans and mitigation measures.

¹ Resolution GFCM/41/2017/2 on guidelines for the streamlining of aquaculture authorization and leasing processes.

FIGURE 3. Simplified procedure to apply for an authorization to use non-indigenous species in aquaculture



5.5.3 Environmental risk assessment

In the case of non-routine movement, an environmental risk assessment should be carried out by the applicant or a third-party organization, as decided by the competent authority, in order to determine the associated risks. The assessment should use multiple procedures as well as state-of-the-art scientific methodologies and technologies. It should take into account the risks of genetic mixing and resulting ecological impacts as well as the potential impacts that the introduction of a non-indigenous species might have on native species in the proposed receiving waters.

The results obtained should be classified as either i) low; ii) medium; or iii) high risk. The advisory committee will review the results and provide advice to the competent authority, which may only issue authorization in cases where the assessment, including the mitigation measures, present a low risk to biodiversity, natural habitats, ecosystems and related ecosystem services.

For applications in which the environmental risk assessment results score as medium or high, mitigation measures (procedures or technologies) to minimize adverse environmental and health impacts could be elaborated with the competent authority or the advisory committee to reduce the level of risk to low. The competent authority may issue the authorization if the mitigation measures are viable. Any refusal of an application must be based on scientific grounds and in cases where scientific information is insufficient, it would be justified on the grounds of the precautionary principle.

5.5.4 Once the application is submitted

All applications for an authorization to introduce non-indigenous species should be recorded along with information about the current status of the species, as well as associated documentation for presentation to a national registry managed by the national competent authority.

An applicant should be informed of the time required to assess the application and should then be notified of whether the authorization has been granted, unless the applicant has been requested to provide supplementary information in support of the application.

At the end of the period of authorization, applicants may submit another application for authorization based on their former authorization. If there have been no documented adverse effects on health and the environment, the requested introduction should be considered as routine movement.

The competent authority may withdraw an authorization that has been already issued at any point in time if unexpected adverse impacts on health, the environment or native populations should occur. The withdrawal of the authorization should be justified on scientific grounds and based on the precautionary principle.

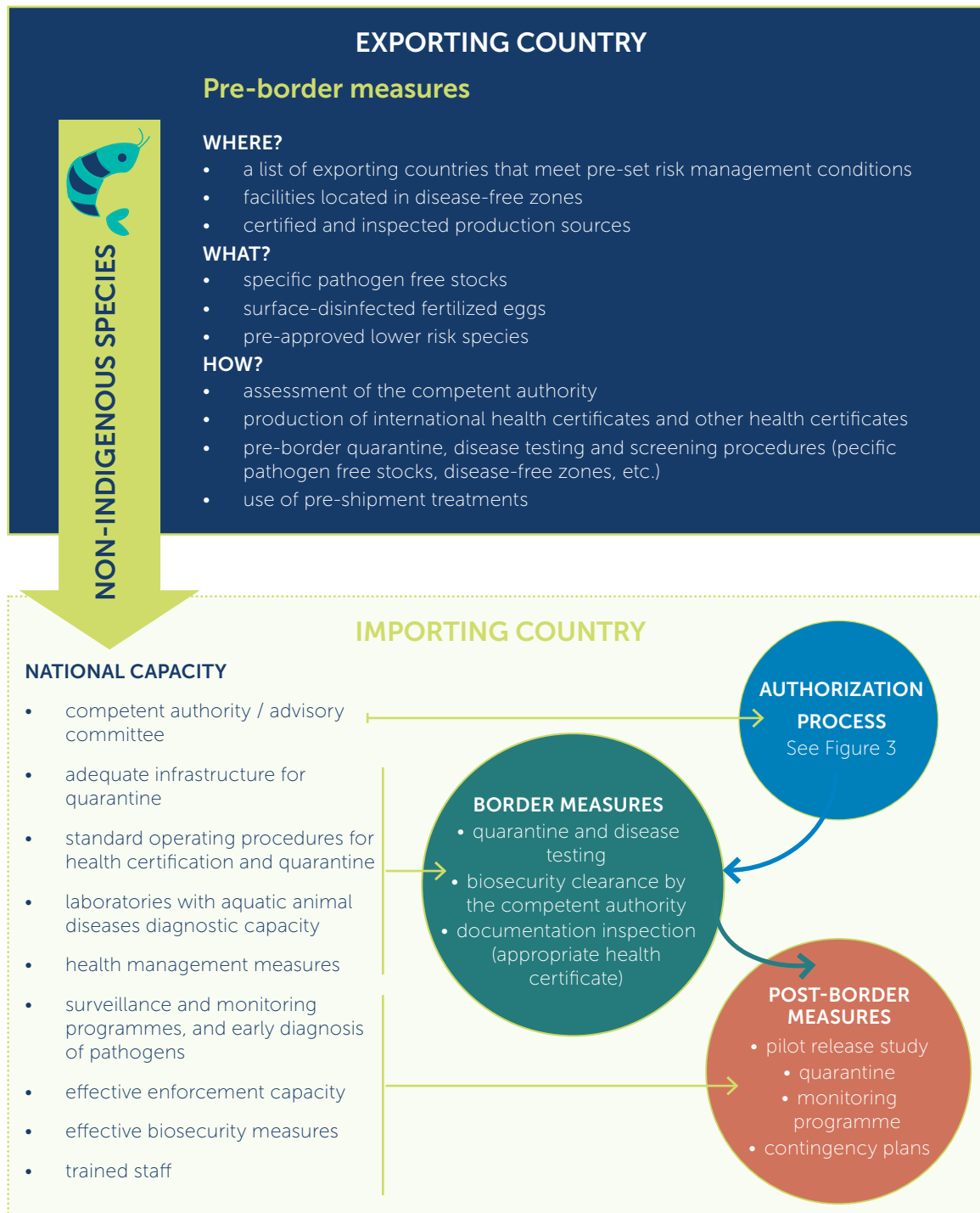
5.6 RISK MANAGEMENT MEASURES

5.6.1 Conditions for safe use

Once an authorization is granted, a series of conditions should be fulfilled to ensure the safe farming of non-indigenous species and to prevent and minimize the risks of adverse impacts on

biodiversity, natural habitats, ecosystems and related ecosystem services (Arthur, Bondad-Reantaso and Subasinghe, 2008; Alday-Sanz *et al.*, 2018). Such conditions are outlined in Figure 4 below.

FIGURE 4. Conditions for safe use of non-indigenous species in aquaculture



5.6.2 Pre-border measures

Pre-border measures should be undertaken in cooperation with the competent authorities of the importing and exporting countries and could include the following:

- Certification of production sources, testing and certification that hatcheries and other aquaculture production facilities are free from specific pathogens.
- The use of SPF stocks that are kept in SPF facilities under rigorous monitoring systems using sensitive and accurate diagnostic methods. However, SPF stocks may harbour other pathogens, and this possibility should be taken into account as it may pose a risk when organisms are under stress.
- The use of stocks from aquaculture production facilities located in disease-free zones in the exporting country.
- Restricting trade to disinfected fertilized eggs instead of adult animals.
- Restricting trade to pre-approved lower-risk species, as determined by risk analyses and defined in a country-specific list. Such conditions might include:
 - disease surveillance, monitoring and reporting programmes;
 - zoning programmes;
 - production facility health certification programmes and a defined specific pathogen list for the stock;
 - evaluation of the competent authority in the exporting country;
 - existence of standard operating procedures or better management practices for production facilities and exporters; and
 - existence of contingency plans.
- Restricting imports to a list of countries that meet pre-set risk management conditions and can thus be pre-approved as lower-risk sources for certain types of aquatic organisms.
- On-site inspection of exporting facilities, including proposed hatchery or other production facilities, to verify that biosecurity measures are in place to support claims of health status.
- Assessment of the competent authority of an exporting country to relieve any concerns about biosecurity threats.
- Production of international health certificates and other health certificates for specific WOA-listed diseases of concern to the importing country, in order to ensure that the introduced organisms are free of these specified diseases.
- Pre-border quarantine and disease testing of the stock or containment of the aquatic organisms to be imported, in order to allow time for any possible disease or infection to become evident.
- The use of pre-shipment treatments that can reduce the risk of pathogen transfer.

5.6.3 Border measures

Border control and quarantine measures are necessary to ensure that intentional introductions have been authorized under relevant legislation and to reduce the risk of unintentional or illegal introduction of non-indigenous species. They might include the following:

- border quarantine and disease testing of the consignment of aquatic animals;
- biosecurity clearance by the competent authority, i.e. an official written notification issued by the competent authority stating that a consignment of aquatic organisms has met pre-border and border requirements as specified in the aquatic animal import health standard and can now be released into the custody of the importer; and
- staff capacity building for the inspection of consignments by the competent authority. This step is a crucial part of the quarantine process.

5.6.4 Post-border measures

Post-border measures might include the following:

- placing a restriction on the initial use of introduced aquatic animals, providing the opportunity to detect any introduced diseases prior to the release of the animals into the natural environment and increasing the chances for control and eradication;
- establishing monitoring programmes; and
- developing contingency plans so that all proposals for introductions include planning for actions to be taken in case animals or pathogens escape from quarantine.



5.6.5 Pilot release study

On the basis of advice provided by the advisory committee, the competent authority may require that the release of the aquatic organisms to farming facilities in inland contained waters should be preceded by an initial pilot release study subject to specific containment and preventive biosecurity measures.

The pilot release study will have to be carried out under the direct supervision of the competent authority and first on a limited scale in order to assess ecological interactions with native species and habitats to test risk assessment assumptions before testing on a larger scale.

5.6.6 Quarantine

Quarantine is an important risk management measure that should be applied to reduce the risk posed by serious aquatic organism diseases. These might result from international or domestic introductions of aquatic organisms or from the introduction of new broodstock or organisms at different stages of the life cycle into hatcheries and other aquaculture production facilities.

The quarantine facilities should be constructed in accordance with the specifications of the competent authority to guarantee an appropriate level of containment (Arthur, Bondad-Reantaso and Subasinghe, 2008).

The severity of quarantine should be proportional to the estimated level of risk, which is a function of the source and destination of introduced aquatic organisms. In particular, first-time introductions of non-indigenous species require stringent quarantine measures. The duration of quarantine should be indicated in the authorization and may vary depending on the time required to complete the relevant health screening procedure. Non-indigenous species should be kept in quarantine long enough to identify all non-target species and confirm the absence of pathogens or diseases.

In the case of non-routine movements, aquatic organisms should be placed in a designated quarantine facility for the purpose of constituting a broodstock. Whenever appropriate, only the progeny of the introduced aquatic organisms may be used in aquaculture facilities and subsequently farmed, on the condition that no potentially harmful non-target species are detected during quarantine. Adult specimens may be released into aquaculture facilities whenever it is scientifically evident that organisms do not reproduce in captivity or are fully reproductively sterile and when the absence of potentially harmful non-target species has been proven.

5.6.7 Contingency plans

Contingency plans should not only refer to pathogens and health but also to measures relating to the ecosystem and biodiversity.

For non-routine movements and pilot release studies, the applicant should prepare a contingency plan describing the measures to be taken to avoid unintentional release, not only of pathogens but of the aquaculture organism itself, in any stage of life, and of any other associated organisms (for example, non-target species, bacteria or parasites). The plan should be developed in case organisms or pathogens escape from quarantine or a serious pathogen is not detected during quarantine and is released into aquaculture facilities or the natural environment.

This contingency plan would facilitate a rapid response that should help to restrict the spread of pathogens and increase the likelihood that they can be contained and eradicated.

Contingency plans should be reviewed and endorsed by the advisory committee and finally approved by the competent authority. They should include health and environmental risk management measures, such as measures to eradicate or substantially reduce the density of the introduced species. If such an event occurs, the contingency plan should be implemented immediately and the authorization should be withdrawn, temporarily or permanently, by the competent authority.



5.6.8 Monitoring programme

Non-routine movement of non-indigenous species to aquaculture facilities should be monitored through a specific monitoring programme in order to:

- determine if an accidental release has occurred;
- determine if disease or parasite infestations exist in the aquaculture facility;
- evaluate any potential impact of the introduced organisms on the environment, ecosystem services and biodiversity;
- assess the range of dispersal and containment of aquatic organisms; and
- identify any events that were not predicted.

The monitoring programme should also be used to confirm that diseases have not spread to new environments and, in cases where pathogens were present but not detected during quarantine, to help minimize their impacts by allowing containment or eradication programmes to be deployed as soon as possible.

The monitoring programme should be based on the environmental risk assessment carried out prior to the release of organisms into aquaculture facilities and endorsed by the advisory committee.

It should be customized for each introduction, according to species, potential dispersal range and geographic location.

The monitoring programme should be carried out by a body appointed by the competent authority in three phases:

- a baseline monitoring study prior to introduction;
- continued monitoring after release into aquaculture facilities; and
- longer-term monitoring following the scale-up of farming activities.

On the basis of the recommendations of the advisory committee, the competent authority should decide upon the duration of the monitoring programme, which should last for at least two years or a full generation cycle, whichever is longer, and be reported to the competent authority.

The competent authority should be alerted immediately if any escapes or significant mortality events occur or if pest infestations, parasites or pathogens are detected. In any of these situations, the competent authority should decide on the necessity and appropriateness of applying eradication programmes or other mitigation measures.

5.6.9 Surveillance system

A surveillance system for non-indigenous species should be established to collect and record data on their occurrence in the environment and any potential trans-boundary threats they might pose.

The surveillance system should allow for the early detection of non-indigenous species and their rapid eradication at an early stage of invasion. However, it must be recognized that, in most circumstances, complete eradication is very difficult and may require extreme measures.



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Glossary

Aquaculture:

The farming of aquatic organisms that implies some sort of intervention in the rearing process to enhance production. Farming also implies individual or corporate ownership of the stock being cultivated (FAO, 2022c).

Aquaculture escape:

The sum of fish escape and escape through spawning (Arechavala-Lopez *et al.*, 2017).

Aquaculture licence:

This authorizes the installation and operation of a facility in the water and describes the activity that can be undertaken. The use of a licence is usually restricted to a specific area, defined species, and specified limit of production (maximum allowed biomass) or stocking density. The series of procedures necessary to obtain a licence shall be called the "licensing process".

Aquaculture lease:

This grants the exclusive right to use an area of water or state-owned submerged lands for marine aquaculture, usually for a defined period of time, in exchange for some sort of payment. The series of procedures necessary to obtain a lease shall be called the "leasing process".

Aquaculture consenting process:

This includes licensing and leasing processes. Aquaculture consenting processes refer to all actions to be undertaken by an investor through aquaculture consenting bodies within a given aquaculture consenting system in order to operate an aquaculture activity.²

Aquatic organisms:

Any species and subspecies living in water belonging to the animalia, plantae and protista kingdoms, including their reproductive products, gametes, fertilized eggs, seeds and propagules, embryos and juvenile stages of their individuals that might survive and subsequently reproduce (Council of the European Union, 2007).

Biodiversity:

The variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part: this includes diversity within species, between species and of ecosystems (FAO, 2022c).

Biosecurity:

A strategic and integrated approach that encompasses the policy and regulatory frameworks for analysing and managing relevant risks of the sectors dealing with: human life and health (including food safety); animal life and health (including fish); plant life and health; and environment (FAO, 2009).

Chain of custody:

Documentation showing all persons or agencies who have had legal responsibility for assuring the conditions of importation (including quarantine) as specified by the competent authority in an aquatic animal import health standard for a consignment of live aquatic animals during the process of its movement from the exporter or facility of origin through biosecurity clearance being granted by the competent authority until release to the importer (Arthur, Bondad-Reantaso and Subasinghe, 2008).

² Where applicable, leases and licences can also be renewed, amended, transferred, suspended or revoked. However, these guidelines specifically address the licensing and leasing processes for a new investor.

Closed aquaculture facility:

A land-based facility where: (i) aquaculture is conducted in an aquatic medium that involves recirculation of water; and (ii) discharges do not connect in any way to open waters before screening and filtering or percolation and treatment to prevent the release of solid waste into the aquatic environment and the escape from the facility of farmed species and non-target species that might survive and subsequently reproduce. In addition, the closed aquaculture facility: (i) prevents losses of reared specimens or non-target species and other biological material, including pathogens, due to factors such as predators (for example, birds) and flooding (for example, the facility must be situated at a safe distance from open waters following a proper assessment made by the competent authorities); (ii) prevents, in a reasonable way, losses of reared specimens or non-target species and other biological material, including pathogens, due to theft and vandalism; and (iii) ensures appropriate disposal of dead organisms (European Parliament and Council of the European Union, 2011).

Containment:

Any action aimed at creating barriers that minimize the risk of a population of a non-indigenous species dispersing and spreading beyond the invaded area (European Parliament and Council of the European Union, 2014).

Early detection:

The confirmation of the presence of a specimen or specimens of a non-indigenous species in the environment before it has become widely spread (European Parliament and Council of the European Union, 2014).

Ecosystem services:

The direct and indirect benefits people obtain from ecosystems including provisioning services, regulating services, cultural services and supporting services (Alcamo *et al.*, 2003).

Eradication:

The complete and permanent removal of a population of a non-indigenous species by lethal or non-lethal means (European Parliament and Council of the European Union, 2014).

Escape through spawning:

The escape of viable, fertilized eggs spawned by cultured organisms inside rearing systems into the wild ecosystem (Somarakis *et al.*, 2013).

Fish escape:

An individual or group of fish juvenile(s) and adult(s) of cultured species that escapes from its rearing system into the ambient environment (FAO, 2022c).

Hazard:

A biological, chemical or physical agent in, or a condition of, an aquatic animal or aquatic animal product with the potential to cause an adverse effect on aquatic animal health or public health (WOAH, 2021).

International aquatic animal health certificate:

A certificate issued by a member of the personnel of the competent authority of the exporting country certifying the state of health of the aquatic animals and a declaration that the aquatic animals originate from a source subjected to official health surveillance according to the procedures described in the WOAH Manual of Diagnostics Tests (Arthur, Bondad-Reantaso and Subasinghe, 2008).

Introduction:

The process by which a non-indigenous species is intentionally moved to an environment outside its natural range for use in aquaculture (Council of the European Union, 2007).

Locally absent species:

A species or subspecies of an aquatic organism that is locally absent from a zone within its natural range of distribution for biogeographical reasons (Council of the European Union, 2007).

Management:

Any lethal or non-lethal action aimed at the eradication, control or containment of a population of a non-indigenous species or escapee, while also minimizing the impact on non-targeted species and their habitats (European Parliament and Council of the European Union, 2014).

Non-indigenous species:

Any live specimen of a species or subspecies of aquatic organisms introduced outside its known natural range and the area of its natural dispersal potential (FAO, 2022c).

Non-routine movement:

Any movement of aquatic organisms that does not fulfil the criteria for routine movement (Council of the European Union, 2007).

Non-target species:

Any species or subspecies of an aquatic organism likely to be detrimental to the aquatic environment that is accidentally transferred together with an aquatic organism being introduced (Council of the European Union, 2007).

Open aquaculture facility:

A facility where aquaculture is conducted in an aquatic medium that is not separated from the surrounding wild aquatic medium by barriers preventing the escape of reared specimens or of biological material that might survive and subsequently reproduce (Council of the European Union, 2007).

Pilot release study:

The introduction of non-indigenous species into aquaculture facilities located in inland contained waters on a limited scale to assess ecological interaction with native species and habitats in order to test the risk assessment assumptions (Council of the European Union, 2007).

Population control:

Any lethal or non-lethal action applied to a population of non-indigenous species that also minimizes the impacts on non-targeted species and their habitats, with the aim of keeping the number of individuals as low as possible (European Parliament and Council of the European Union, 2014).

Quarantine:

A process by which aquatic organisms and any of their associated organisms can be held in complete isolation or reared under conditions that prevent their escape and the escape of any pathogens they may be carrying into the surrounding environment (FAO, 2022c).

Quarantine facility:

A facility in which aquatic organisms and any of their associated organisms can be maintained in complete isolation from the surrounding environment (Council of the European Union, 2007).

Risk analysis:

A detailed examination including risk assessment, risk evaluation and risk management alternatives, performed to understand the nature of potential unwanted negative consequences to human life, health, property or the environment (FAO, 2022c).

Risk assessment:

The scientific evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country (WOAH, 2021; Arthur, Bondad-Reantaso and Subasinghe, 2008).

Routine movement:

A movement of aquatic organisms from a source that has a low risk of transferring non-target species and that, on account of the characteristics of the aquatic organisms and/or the method of aquaculture to be used, does not give rise to adverse ecological effects (European Parliament and Council of the European Union, 2011).

Sustainable development:

Management and conservation of the natural resource base and the orientation of technological and institutional change in such a manner as to ensure the attainment of continued satisfaction of human needs for present and future generations. Such sustainable development conserves land, water, plants and animal genetic resources and is environmentally non-degrading, technologically appropriate, economically viable and socially acceptable (FAO, 2022c).

Target species:

Non-indigenous species intentionally introduced through aquaculture or related activities.

Appendix

Application for an authorization to introduce a non-indigenous species¹

1. Executive summary

Provide a brief summary of the document, including a description of the proposal, potential impacts on native species and their habitats and mitigation steps to minimize these impacts.

2. Introduction

Species	Full classification of species (scientific and common name) to be introduced and its role in aquaculture
Objective	Purpose and rationale for the proposed introduction
Geographic area	Geographic area of the proposed introduction, including description of the habitats, ecosystem and protection status of the receiving environment (map)
Number of specimens	Total number of specimens to be introduced
Source of animals	Description of source(s) of the stock (facility) and genetic stock

3. Life history information of the species to be introduced (for each life history stage)

Species range	Native range (area to which the species is indigenous), native range limiting factors and range changes due to introductions
Biology	Reproduction, migratory behaviour, food preferences for each life history stage, growth rate and lifespan, behavioural traits (social, territorial, aggressive)
Habitat preferences and physiological tolerances	Habitat preferences and physiological tolerances (water quality, temperature, oxygen and salinity)
Previous introductions	Description of previous introductions and ecological effects on the receiving environment (predator, prey, competitor, and/or functional elements of the habitat)
Links with non-target species	Possible links between introduced stock and any known non-target species and their distribution within the area of origin of the stock to be introduced
Aquatic animal health	Manner in which the health status of the introduced species will be ensured

¹ Based on Regulation (EC) No 708/2007 concerning use of alien and locally absent species in aquaculture.

4. Interaction with native species and habitats

Survival and reproduction	Expected survival and successful reproduction in the proposed area of introduction or whether annual stocking is required, survival potential and establishment of escaped introduced organisms
Impact on habitats	Habitat(s) likely to be occupied by the introduced species in the proposed area of release, possible overlaps with any vulnerable, threatened or endangered species, potential impacts on habitats or water quality as a result of the proposed introduction
Impact on native species	Niche overlap with native species, any unused ecological resources of which the introduced species would take advantage, food eaten in the receiving environment by the introduced organism, any adverse impacts on the receiving ecosystem by this predation
Genetic impacts	Hybridization capacity of introduced organisms with native species, likelihood of local extinction of any native species or stocks as a result of the proposed introduction, possible effects of the introduced organisms on the spawning behaviour and spawning grounds of local species

5. Receiving environment and contiguous water bodies

Farm facilities	Detailed information about farm facilities and location
Physical information	Seasonal water body temperatures, salinity, turbidity, dissolved oxygen, pH, nutrients and metals; suitability of these parameters with the tolerances and preferences of the species to be introduced, including conditions needed for reproduction
Species	Species composition of the receiving waters (major aquatic vertebrates, invertebrates and plants)
Habitats	Information on habitats in the area of introduction, including contiguous waters, and critical habitats; suitability of these parameters with the tolerances and preferences of the species to be introduced; level of disturbance of the introduced organisms in the described habitats
Barriers to movement	Natural and/or man-made barriers that should prevent the movement of the introduced organisms to contiguous waters

6. Monitoring programme

Description	Plans for follow-up assessments of the proposed introduced species' success and for the way in which any negative impacts on native species and their habitats will be assessed
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7. Management plan

Description	Measures taken to prevent non-target species from accompanying the shipment or the person/company/authority who will be permitted to use the proposed organisms, terms and conditions of use, pre-commercial phase for the proposed introduction (if any), contingency plan for the eradication of species, quality assurance plan for the proposal, legislative requirements compliant with existing national, supranational and international regulations
Escapee prevention	Chemical, biophysical and management measures to prevent accidental escapes of organisms and non-target species into, and their establishment in, non-target recipient ecosystems; water source, effluent destination, any effluent treatment and waste disposal, proximity to storm sewers, predator control and site security
Contingency plans	Plans to be implemented in the event of an unintentional, accidental or unauthorized release of organisms from the rearing and hatchery facilities or an accidental or unexpected expansion of the range of colonization after release

8. Business data

Description	Name of the owner and/or company, aquaculture licence number and business licence (if applicable) or name of the government agency or department with full contact details
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9. References

Bibliography	All references cited in the preparation of the application
Conducted meetings	Full contact details of scientific authorities and fisheries experts consulted

GUIDELINES ON ASSESSING AND MINIMIZING THE POSSIBLE IMPACTS FROM THE USE OF NON-INDIGENOUS SPECIES IN AQUACULTURE

This publication presents guidelines prepared and adopted by the GFCM to assess and minimize the possible impacts from the use of non-indigenous species in the Mediterranean and the Black Sea. Specifically, it identifies the guiding principles and minimum common criteria needed to minimize the potential adverse impacts of non-indigenous species on biodiversity, natural habitats, ecosystems and related ecosystem services. By recommending practical actions to stakeholders, these guidelines aim to create a common regional framework on aquaculture practices related to the use of non-indigenous species and provide decision-makers with a useful tool for policy development.

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