

ANNEX I

APPLICATION

(Indicative guidelines for the dossier to be completed by applicant as foreseen under Article 6)

Wherever possible, information is to be supported with references from the scientific literature, and notations to personal communications with scientific authorities and fisheries experts. Applicants are advised to distinguish between movements to 'open' or 'closed' aquaculture facilities.

For the purpose of this Annex when an application refers to a proposed translocation, rather than an introduction, the terms introduction/introduced are to be replaced by translocation/translocated.

A. Executive summary

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

B. Introduction

- (1) Name (common and scientific) of the organism proposed for introduction or translocation, indicating the genus, species, subspecies or lower taxonomic classification where applicable.
- (2) Describe the characteristics, including distinguishing characteristics, of the organism. Include a scientific drawing or photograph.
- (3) Describe the history in aquaculture, enhancement or other introductions (if appropriate).
- (4) Describe the objectives and rationale for the proposed introduction, including an explanation as to why such an objective cannot be met through the utilisation of an indigenous species.
- (5) What alternate strategies have been considered in order to meet the objectives of the proposal?
- (6) What is the geographic area of the proposed introduction? Describe the habitats, ecosystem and protection status of the receiving environment. Include a map.
- (7) Describe the numbers of organisms it is proposed to introduce (initially, ultimately). Can the project be broken down into different sub-components? If so, how many organisms are involved in each sub-component?
- (8) Describe the source(s) of the stock (facility) and genetic stock (if known).

C. Life history information of the species to be introduced — for each life history stage

- (1) Describe the native range and range changes due to introductions.
- (2) Does the stock from which the introduction/translocation will be made have a link with any known non-target species?
- (3) What is the distribution of such non-target species within the area of origin of the stock to be introduced/translocated?

- (4) Record where the species was introduced previously and describe the ecological effects on the environment of the receiving area (predator, prey, competitor, and/or structural/functional elements of the habitat).
 - (5) What factors limit the species in its native range.
 - (6) Describe the physiological tolerances (water quality, temperature, oxygen, and salinity) at each life history stage (early life-history stages, adult and reproductive stages).
 - (7) Describe the habitat preferences and tolerances for each life-history stage.
 - (8) Describe the reproductive biology.
 - (9) Describe the migratory behaviour.
 - (10) Describe the food preferences for each life-history stage.
 - (11) Describe the growth rate and lifespan (also in the area of the proposed introduction, if known).
 - (12) What is the age or age-range of the species concerned?
 - (13) Describe the behavioural traits (social, territorial, aggressive).
- D. Interaction with native species
- (1) What is the potential for survival and establishment of the introduced organism if it escapes? (This question applies to movements into open and closed aquaculture facilities.)
 - (2) What habitat(s) will the introduced species be likely to occupy in the proposed area of introduction and will this overlap with any vulnerable, threatened or endangered species? (Indicate if the proposed area of introduction also includes contiguous waters.)
 - (3) With which native species will there be a niche overlap? Are there any unused ecological resources of which the species would take advantage?
 - (4) What will the introduced organism eat in the receiving environment?
 - (5) Will this predation cause any adverse impacts on the receiving ecosystem?
 - (6) Will the introduced organisms survive and successfully reproduce in the proposed area of introduction or will annual stocking be required? (This question applies to species not intended for closed aquaculture facilities.)
 - (7) Will the introduced organisms hybridise with native species? Is local extinction of any native species or stocks possible as a result of the proposed introduction? Are there any possible effects of the introduced organisms on the spawning behaviour and spawning grounds of local species?
 - (8) Are there any potential impacts on habitat or water quality as a result of the proposed introduction?
- E. Receiving environment and contiguous waters
- (1) Provide physical information on the receiving environment and contiguous waterbodies such as seasonal water temperatures, salinity, and turbidity, dissolved

oxygen, pH, nutrients and metals. Do those parameters match the tolerances/preferences of the species to be introduced, including conditions needed for reproduction?

- (2) List species composition (major aquatic vertebrates, invertebrates and plants) of the receiving waters.
- (3) Provide information on habitat in the area of introduction, including contiguous waters, and identify critical habitat. Which of those parameters match the tolerances/preferences of the organisms to be introduced? Can the introduced organisms disturb any of the habitats described?
- (4) Describe the natural or man-made barriers that should prevent the movement of the introduced organisms to adjacent waters.

F. Monitoring

Describe the plans for follow-up assessments of the proposed introduced species' success and how any negative impacts on native species and their habitats will be assessed.

G. Management plan

- (1) Describe the management plan for the proposed introduction. This should include, but not be restricted to, the following information:
 - (a) measures taken to ensure that no other species (non-target species) accompany the shipment;
 - (b) who will be permitted to use the proposed organisms and under what terms and conditions;
 - (c) will there be a pre-commercial phase for the proposed introduction?
 - (d) description of the contingency plan for the removal of species;
 - (e) description of the quality assurance plan for the proposal, and,
 - (f) other legislative requirements that need to be met.
- (2) Describe the chemical, biophysical and management measures being taken to prevent accidental escape of the organism and non-target species, to and their establishment in, non-target recipient ecosystems. Give details of the water source, effluent destination, any effluent treatment, proximity to storm sewers, predator control, site security and measures to prevent escapes, if necessary.
- (3) Describe contingency plans in the event of an unintentional, accidental or unauthorised liberation of the organisms from rearing and hatchery facilities or an accidental or unexpected expansion of the range of colonisation after release.
- (4) If this proposal is intended to create a fishery, give details of the fishery objective. Who would benefit from such a fishery? Give details of the management plan and, if appropriate, include changes in the management plans for species which will be impacted.

H. Business data

- (1) Provide the name of the owner and/or company, the aquaculture licence number and the business licence (if applicable) or the name of the government agency or department with a contact name, telephone, fax and e-mail information.

- (2) Provide an indication as to the economic viability of the proposed project.
- I. References
- (1) Provide a detailed bibliography of all references cited in the course of preparing the application.
- (2) Provide a list of names, including addresses, of scientific authorities and fisheries experts consulted.

ANNEX II

Procedures and minimum elements to be addressed in an environmental risk assessment as foreseen under Article 9

To evaluate risks associated with the introduction or translocation of aquatic organisms it is necessary to assess the probability that the organisms will become established and the consequences of that establishment.

The process addresses the major environmental components. It provides a standardised approach for evaluating the risk of genetic and ecological impacts as well as the potential for introducing a non-target species that might impact the native species of the proposed receiving waters.

During the review process, emphasis is not on the ratings but on the detailed biological and other relevant information statements that motivate them. In case of scientific uncertainty, the precautionary principle should be applied.

For the purpose of this Annex, where an application refers to a proposed translocation the terms 'introduction/introduced' are to be replaced by 'translocation/translocated'.

PART 1

ECOLOGICAL AND GENETIC RISK ASSESSMENT PROCESS

Step 1 Likelihood of establishment and spreading beyond the intended area of introduction

Event	Likelihood(H, M, L)^a	Certainty(VC, RC, RU, VU)^b	Comments in support of assessment^c
The introduced or translocated species, escaped or dispersed, successfully colonises and maintains a population in the intended area of introduction beyond the control of the aquaculture facility.			

The introduced species or translocated, escaped or dispersed, spreads beyond the intended area of introduction.			
Final rating ^d			
a H = High, M = Medium, L = Low			
b VC = Very certain, RC = Reasonably certain, RU = Reasonably uncertain, VU = Very uncertain			
c The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.			
d The final rating for the likelihood of establishment and spreading is assigned the value of the element with the lowest rating (for example, high and low ratings for the above elements would result in a final low rating). Again, both events — probability of the organism successfully colonising and maintaining a population in the intended area of introduction (be it a confined environment such as a facility, or a natural habitat) and the probability of spreading beyond the intended area of introduction (estimated as explained above) — need to occur in order to have establishment beyond the intended area of introduction. The final rating for the level of Certainty is assigned the value of the element with the lowest level of certainty (e.g. very certain and reasonably certain ratings would result in a final reasonably certain rating). The harmfulness of a establishment and spreading should be taken into account, together with risk/benefit ration, in arriving at the final rating.			

Step 2 Consequences of establishment and spreading

Event	Likelihood(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
Genetic mixing with local populations leads to a loss of genetic diversity.			
Competition (food, space) with or predation on native populations leads to their extirpation.			
Other undesirable events of ecological nature			
Some of the abovementioned events persist even after removal of the introduced species.			
Final rating ^b			
a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.			
b The final rating for the consequences of establishment and spreading is assigned the value of the element (individual probability) with the highest rating and the final rating for the level of certainty is assigned the value of the element with the lowest level of certainty.			

Status: This is the original version (as it was originally adopted).

Step 3 Risk potential associated to the alien and locally absent species

A single value is given based on the assessments done in Steps 1 and 2:

Component	Risk potential(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment^a
Establishment and spreading (step 1)			
Ecological consequences (step 2)			
Final rating of overall risk potential ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final categorisation of risk potential takes the value of the highest of the two probabilities when there is no probability increment between the two estimates (i.e. if the Risk of establishment and spreading is high and the risk of ecological consequences is medium, the final rating takes the value of the highest of the two probabilities which is high. When there is a probability increment between the two estimates (i.e. a mixture of high and low) the final value is medium.

The result of this assessment will be expressed in terms of the following risk levels:

A high-risk movement:

- (a) has a high risk of damaging biodiversity from spreading and other ecological consequences;
- (b) operates under farming conditions which would increase the risk of such damage;
- (c) involves an aquaculture facility which sells live aquatic animals for further farming or restocking;
- (d) as a consequence, the movement is of major concern (major mitigation measures are required). It is advised that the proposal be rejected unless mitigation procedures can be developed to reduce the risk to low.

A medium-risk movement:

- (a) has a medium risk of damaging biodiversity from spreading and other ecological consequences;
- (b) operates under farming conditions which would not necessarily increase the risk of such damage, taking account of the species and the containment conditions;
- (c) involves an aquaculture facility which sells its products mainly for human consumption;
- (d) as a consequence the movement is of moderate concern. It is advised that the proposal be rejected unless mitigation procedures can be developed to reduce the risk to low.

A low-risk movement:

- (a) has a low risk of damaging biodiversity from spreading and other ecological consequences.

- (b) operates under farming conditions which would not increase the risk of such damage;
- (c) involves an aquaculture facility which sells its products for human consumption only;
- (d) as a consequence the movement is of negligible concern. It is advised that the proposal be approved. Mitigation is not needed.

The proposal can only be approved as presented (no mitigating measures required) if the overall estimated risk potential is low and if the overall certainty for which the overall risk has been estimated is very certain or reasonably certain.

If, as a result of a first analysis, a high or medium category is attributed to the overall risk, then containment or mitigation proposals are to be incorporated in the application, which will be subject to subsequent risk analysis until the final rating for the overall risk becomes low with a very certain or reasonably certain assessment. Descriptions of these additional steps, together with detailed specifications of the containment or mitigation measures, will become an integral part of the risk assessment.

PART 2

NON-TARGET SPECIES ASSESSMENT PROCESS

Step 1 Likelihood of establishment and spreading of non-target species beyond the intended area of introduction

Event	Likelihood(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
A non-target species is introduced as a consequence of the introduction or translocation of the aquatic organisms.			
The introduced non-target species encounters susceptible habitats or host organisms.			
Final rating ^b			

^a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

^b The final rating under likelihood is assigned the value of the element with the lowest risk rating and the final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

Step 2 Consequences of non-target species establishment and spreading

Status: This is the original version (as it was originally adopted).

Event	Likelihood(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment^a
The non-target species compete with or predate on native populations, leading to their extirpation.			
Genetic mixing of the non-target species with local populations leads to a loss of genetic diversity.			
Other undesirable events of ecological or pathological nature			
Some of the abovementioned events persist even after removal of the non-target species.			
Final rating ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating for the consequences is assigned the value of the highest risk rating and final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

Step 3 Risk potential associated with non-target species

A single value is given based on the assessments performed in Steps 1 and 2:

Component	Risk potential(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment^a
Establishment and spreading (step 1)			
Ecological consequences (step 2)			
Final rating ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating under risk potential is assigned the value of the element with the lowest risk rating and the final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

The conditions applicable to the assessment of risk potential associated to the alien species (part 1) are to also apply, *mutatis mutandis*, to this risk potential associated with non-target species (part 2), including the obligation to introduce containment and mitigation measures.

PART 3

OVERALL ENVIRONMENTAL RISK ASSESSMENT — SUMMARY REPORT

- History, background and rationale for the request:
 - risk assessment summary information
 - summary of the ecological and genetic risk assessment
 - summary of the non-target species risk assessment
- Comments:
- Mitigation measures:
- Concluding statement on total organism potential risk:
- Advice to competent authority:

ANNEX III

Quarantine

Quarantine is the means by which live animals or plants and any of their associated organisms are maintained in complete isolation from the surrounding environment so as to prevent impact on wild and farmed species and undesirable changes to natural ecosystems.

It is necessary to keep alien or locally absent species in quarantine long enough to detect all non-target species and to confirm the absence of pathogens or diseases. The unit is to be constructed in accordance with the specifications of the competent authority in the Member State of its location which is to be responsible for approving it. The duration of quarantine must be indicated in the permit. If the facility is not located of the receiving Member State, the advisory committee responsible for the facility and the advisory committee in the receiving Member State must agree on the duration.

Operators are to run quarantine facilities in accordance with the following conditions. In addition the operator must have a quality assurance programme and an operating manual.

For the purpose of this Annex where an application refers to a proposed translocation, the terms introduction/introduced are to be replaced by translocation/translocated.

Effluent and waste disposal

All effluents and wastes generated within the facility must be treated in a manner that effectively destroys all possible target species and associated organisms. To ensure continuous operation and complete containment, quarantine effluent treatment systems must be equipped with fail-safe backup mechanisms.

Treated effluent and waste may contain substances which are harmful to the environment (e.g. antifouling agents) and must be disposed of in a manner which minimises environmental impact.

Details of effluent and solid waste treatment must be prepared, listing the personnel responsible for treatments and timing. The system must be monitored to ensure effective operation and early detection of possible failures.

Physical separation

The organisms which have been transferred must be kept separate from other organisms to ensure containment. This excludes sentinel species which are specifically included to test the effects of the introduced species. The entry of birds, other animals, disease agents and contaminants must be prevented.

Personnel

Access must be restricted to trained, authorised personnel. Footwear, hands and any material used within the facility should be disinfected (see below) before exiting the facility.

Equipment

Upon receipt, all life-stages, tanks, water, shipping containers and equipment in contact with the introduced species, including the transport vehicles, must be handled in such a way as to ensure that there is no escape of the species or associated non-target species from the facility. All shipping and packing material must be disinfected, or burned if burning of the material is authorised.

Mortalities and disposal

Daily records or mortalities must be maintained and must be available for inspection by the competent authority. All mortalities must be kept on site. No mortalities, tissue or shells are to be discarded without approved treatment to ensure complete disinfection. Heat treatment such as autoclaving or chemical sterilisation may be employed.

Mortalities must be reported to the competent authority and Member States must investigate the cause of mortalities in a timely manner. Mortalities must be stored, transported and disposed of, in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽¹⁾.

Inspection and testing

Regular inspections must be carried out for non-target species. If such a species or a previously undetected disease or parasite is identified in an organism, actions necessary to control the situation must be taken. These actions may include destruction of the organisms and disinfection of the facility.

Duration

The required duration of quarantine will vary according to the organism in question, seasonality of non-target species of concern and the rearing conditions.

Record keeping

Quarantine facilities must maintain accurate records of the following:

- entry/exit times of personnel,
- number of mortalities and method of storage or disposal,
- treatment of incoming water and of effluent,
- samples submitted to experts to test for non-target species,
- any abnormal conditions affecting quarantine operation (power cuts, building damage, serious weather conditions, etc.).

Disinfection

Disinfection involves the application of disinfectants in sufficient concentrations and for sufficient time to kill harmful organisms. The disinfectants and concentrations for quarantine disinfection must be based on complete seawater and freshwater disinfection. Similar concentrations must be used for routine facility disinfection. It is recommended that all disinfectants be neutralised before release into the surrounding environment and facilities using seawater must deal with residual oxidants produced during chemical disinfection. In case of an emergency, such as the finding of an imported parasite or disease agent, sufficient disinfectant must be available to enable treatment of the entire facility.

ANNEX IV

List of species foreseen by Article 2(5)

Rainbow trout, *Oncorhynchus mykiss*
Brook trout, *Salvelinus fontinalis*
Common carp, *Cyprinus carpio*
Grass carp, *Ctenopharyngodon idella*
Silver carp, *Hypophthalmichthys molitrix*
Big head carp, *Aristichthys nobilis*
Pacific cupped oyster, *Crassostrea gigas*
Japanese or Manila clam, *Ruditapes philippinarum*
Large-mouth bass, *Micropterus salmoides*
Arctic char, *Salvelinus alpinus*

Status: This is the original version (as it was originally adopted).

- (1) [OJ L 273, 10.10.2002, p. 1](#). Regulation last amended by Commission Regulation (EC) No 2007/2006 ([OJ L 379, 28.12.2006, p. 98](#)).