



**COUNCIL OF
THE EUROPEAN UNION**

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COVER NOTE

from: General Secretariat
to Working Party on Internal Fisheries Policy

Subject: Proposal for a COUNCIL REGULATION concerning use of alien and locally absent species in aquaculture

Delegations will find enclosed a working document ("bible") setting out in the footnotes delegations' positions on various provisions, as notified to the Council Secretariat in writing following the deliberations of the Working Party.

Proposal for a

COUNCIL REGULATION^{1 2}

concerning use of alien and locally absent species in aquaculture

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission³,

Having regard to the opinion of the European Parliament⁴,

Having regard to the opinion of the European Economic and Social Committee⁵

Whereas:

- (1) In accordance with Article 6 of the Treaty, environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities, in particular with a view to promoting sustainable development.
- (2) Aquaculture is a fast-growing sector where innovation and new outlets are being explored. In order to adapt the production to the conditions of the market, it is important for the aquaculture industry to diversify the species reared.
- (3) Aquaculture has benefited economically from the introduction of alien species and translocation of locally absent species in the past (for example rainbow trout, Pacific oyster and salmon) and the policy objective for the future is to maximise benefits associated with introductions and translocations while at the same time avoiding alterations to ecosystems, preventing negative biological interaction, including genetic change, with indigenous populations and restricting the spread of non-target species and detrimental impacts on natural habitats.

¹ **DELETED**: *Too detailed. These provisions should be recast as a Directive, with the annexes being treated as indicative of best practice rather than as prescriptive forms to be completed.*

² **DELETED**: *Parliamentary scrutiny reservations.* **DELETED**: *Environmental, economic and social aspects should be taken into account in a balanced manner, in accordance with the CFP.*

³ *OJ C [...], [...], p. [...].*

⁴ *OJ C [...], [...], p. [...].*

⁵ *OJ C [...], [...], p. [...].*

- (4) Invasive alien species have been identified as one of the key causes of loss of bio-diversity. Article 8(h) of the Convention on Biological Diversity (CBD), to which the Community is a Party, each Contracting Party is required, as far as possible and as appropriate, to prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species. In particular, the Conference of the Parties to the CBD has adopted Decision VI/23 on alien species that threaten ecosystems, habitats or species, the annex to which sets out Guiding Principles for the prevention, introduction and mitigation of impacts of such alien species (see: <http://www.biodiv.org/decisions/default.aspx?m=COP-06&id=7197&lg=0>).
- (5) The translocation of species within their natural range to areas where they are locally absent for specific bio-geographical reasons may also induce risks for the ecosystems that have become established in these areas and should also be covered by this Regulation.
- (6) The Community should therefore develop its own framework to ensure adequate protection of the aquatic environment from the risks associated with the use of non-native species in aquaculture. This framework should include procedures for the analysis of the potential risks, the taking of measures based on the prevention and precautionary principles and the adoption of contingency plans where necessary. These procedures should build on experience gained through the existing voluntary frameworks, and notably the International Council for the Exploration of the Sea (ICES) Code of Practice on the Introductions and Transfers of Marine Organisms and the European Inland Fisheries Advisory Commission (EIFAC) Code of Practice and Manual of Procedures for consideration of introduction and transfer of marine and freshwater organisms.
- (7) The measures provided for in this Regulation should be without prejudice to Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora⁶, Council Directive 85/337/EEC of 27 June 1985 on environmental impact assessment⁷, Council Directive 2006/XX/EC of on animal health requirements for aquaculture animals and products thereof, and on prevention and control of certain diseases in aquatic animals⁸ and Directive 2000/60/EC of the European Parliament and the Council of 23 October 2000 establishing a framework for Community action in the field of water policy⁹.
- (8) The potential risks, which may in some cases be on a large geographical scale, are more evident initially in local areas. The characteristics of local aquatic environments throughout the Community may be very diverse and Member States have the appropriate knowledge, monitoring systems and expertise to evaluate and manage the risks to the aquatic environments falling within their sovereignty or jurisdiction. It is therefore appropriate that the implementation of the measures provided for in this Regulation falls primarily under the responsibility of Member States.

⁶ *OJ L 206, 22.7.1992, p. 7. Directive as last amended by Regulation (EC) 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)*

⁷ *OJ L 175, 5.7.1985, p. 4. Directive as last amended by Directive 2003/35/EC (OJ L 156, 25.6.2003, p. 17).*

⁸ *OJ No insert official number of Council Directive (adopted by the Commission 23.8.2005, COM(2005) 362)*

⁹ *OJ L 327, 22.12.2000, p. 1.*

- (9) However, in cases where risks are not negligible and may affect other Member States there should be a Community system for consultation of interested parties and validation of permits prior to their granting by Member States. The Scientific, Technical and Economic Committee for Fisheries (STECF) established under Article 33 of Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy¹⁰ should provide the scientific advice in this consultation and the Advisory Committee for Fisheries and Aquaculture set up by Commission Decision 1999/478/EEC¹¹ should give the advice of stakeholders in the field of aquaculture and environmental protection.

HAS ADOPTED THIS REGULATION:

Chapter I

Subject matter, scope and definitions

Article 1 *Subject matter*

This Regulation establishes a framework governing aquaculture practices in relation to alien and locally absent species to assess and minimise the possible impact of these on the aquatic environment and in this manner contribute to the sustainable development of the sector.

Article 2 *Scope*

1. This Regulation shall apply to the introduction of alien species and to the translocation of locally absent species for their use in aquaculture in the Community.
2. This Regulation shall not apply to translocations of aquatic organisms within a Member States, except for:
 - a) translocations to, from or between the non-European territories of a Member State;
 - b) translocations which take place between waters in different eco regions as defined in Annex II to Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy¹², and ¹³
 - c) cases where, on the basis of scientific advice, there are grounds for foreseeing environmental threats due to the translocation.

¹⁰ OJ L 358, 31.12.2002, p. 59.

¹¹ OJ L 187, 20.7.1999, p. 70.

¹² OJ No L 327, 22.12.2000, p. 1.

¹³ **DELETED:)** *there are species naturally migrating across different eco-regions.*

3. By way of derogation from paragraph 2, Member States may decide that this Regulation applies to translocations within their territory in other cases too.
4. This Regulation shall cover all aquaculture facilities located within the jurisdiction of Member States irrespective of their size or characteristics or of the species of aquatic organism farmed. It shall cover aquaculture using any form of aquatic medium.¹⁴
5. This Regulation shall not apply to the keeping of ornamental aquatic animals or plants in pet-shops, garden centres or aquaria without any direct contact with natural waters in the Community or in facilities which are equipped with effluent treatment systems which fulfil the aims set out in Article 1.¹⁵

Article 3 *Definitions*

For the purpose of this Regulation the following definitions shall apply:

- (1) ‘aquaculture’ means the rearing or culture of aquatic organisms using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment, the organisms remaining the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting;
- (2) ‘open aquaculture facility’ means a facility where aquaculture is conducted in an aquatic medium not separated from the wild aquatic medium by impenetrable barriers preventing the escape of reared specimens or biological material that might survive and subsequently reproduce;
- (3) ‘closed aquaculture facility’ means a facility where aquaculture is conducted in an aquatic medium separated from the wild aquatic medium by impenetrable barriers preventing the escape of reared specimens or biological material that might survive and subsequently reproduce;
- (4) ‘aquatic organisms’ means any aquatic living thing belonging to the Kingdoms Animalia, Plantae and Protista, including any part, gametes, seeds, eggs or propagules of their individuals that might survive and subsequently reproduce;
- (5) ‘polyploid organisms’ means aquatic organisms in which the number of chromosomes in the cells has been changed through cell manipulation techniques;

¹⁴ **DELETED:** *It should be appropriately reflected here that closed systems with recycling water represent neither a biological nor environmental threat to the surrounding ecosystems.*

¹⁵ **DELETED:** *As aquarium fish, tropical fish in strictly closed aquaculture facilities should be equally excluded.*

- (6) 'alien species' means:
- (a) a species, subspecies or a lower tax on of an aquatic organism occurring outside its known natural range and the area of its dispersal potential as a result of deliberate or accidental introduction by humans;
 - (b) polyploid organisms, irrespective of their natural range or dispersal potential;
- (7) 'locally absent species' means a species or subspecies of an aquatic organism which is locally absent from a zone within its natural range of distribution for biogeographical reasons;
- (8) 'non-target species' means any species or subspecies of an aquatic organism that is moved accidentally together with an aquatic organism that is being introduced or translocated;^{16 17}
- (9) 'movement' means introduction and/or translocation;
- (10) 'introduction' means the process by which an alien species is intentionally moved for its use in aquaculture;
- (11) 'translocation' means the process by which an aquatic organism is intentionally moved within its natural range for its use in aquaculture to an area where it previously did not exist because of biogeographical reasons;
- (12) 'pilot release' means the release of aquatic organisms on a limited scale to assess ecological interaction with native species and habitats in order to test the risk assessment assumptions;
- (13) 'applicant' means the natural or legal person or entity proposing to conduct the introduction or translocation of an aquatic organism;
- (14) 'quarantine' means a process by which aquatic organisms any of their associated organisms can be maintained in complete isolation from the surrounding environment;
- (15) 'quarantine facility' means a facility in which aquatic organisms and any of their associated organisms can be maintained in complete isolation from the surrounding environment;

¹⁶ **DELETED**: *Further guidance needed on the processes and procedures determining the risk of transfer of "non-target species". These procedures need to be harmonised across the Community. Will COM draw a list of "non-target" species?*

¹⁷ **DELETED**: *"Traditional non-indigenous" species farmed in Member States over long period of time should be exempted under this Regulation;(i.a. upon establishing a list of such species). **DELETED** proposes to list the following species: *Oncorhynchus mykiss*, *Salvelinus fontinalis*, *Micropterus salmoides*, *Ctenopharyngodon idella*, *Hypophthalmichthys molitrix*, *Aristichthys nobilis*. **DELETED**: *Sturgeon*.*

- (16) ‘routine movement’ means the movement from a known source of aquatic organisms classified as low risk, following longstanding experience in a Member, State which shows no adverse ecological effects and is not liable to affect other Member States;
- (17) ‘non-routine movement’ shall mean any movement of aquatic organisms which does not fulfil the criteria for routine movement;
- (18) ‘receiving Member State’ shall mean the Member State into the territory of which the alien species is introduced or the locally absent species is translocated;
- (19) ‘sending Member State’ means the Member State from the territory of which the alien species are introduced or the locally absent species are translocated.

Chapter II

General obligations of the Member States

Article 4 *Measures for avoiding adverse effects*

Member States shall ensure that all appropriate measures are taken to avoid adverse effects to biodiversity, and especially to species, habitats and ecosystem functions which might arise from the introduction or translocation of aquatic organisms and non-target species in aquaculture and from the spreading of these species into the wild.

Article 5^{18 19} *Decision making and advisory bodies*

Member States shall designate the competent authority responsible for ensuring compliance with the requirements of this Regulation (‘the competent authority’). Each competent authority shall appoint to assist it an advisory committee, which shall include appropriate biological and ecological expertise (‘the advisory committee’).

¹⁸ **DELETED**: *Supports COM proposal for decision making.*

¹⁹ **DELETED**: *The administrative system may be too burdensome for the sector.*

DELETED: *To be compatible with internal administrative arrangements.*

Chapter III Permits

Article 6 Permit

1. Anyone intending to undertake the introduction or translocation of an aquatic organism²⁰ shall apply for a permit from the competent authority of the receiving Member State. Applications may be submitted for multiple movements to take place over a period of not longer than five years.²¹
2. The applicant shall submit with the application the information listed in Annex I²². The advisory committee shall give an opinion on whether the application contains all the required information and is therefore admissible and shall inform the competent authority.

Article 7 Type of the proposed movement

The advisory committee shall give its opinion on whether the proposed movement is a routine movement or a non-routine movement²³ and whether the movement must be preceded by quarantine or pilot release and shall inform the competent authority.

Article 8 Routine movement

In the case of routine movements, the competent authority may grant a permit, indicating, where applicable, the requirement for quarantine or pilot release as set out in Chapters IV and V.²⁴

²⁰ **DELETED**: *Should be clarified. For consistency with Articles 1 and 2 replace "an aquatic organism" by "alien and locally absent species".*

²¹ **DELETED**: *Requests justification for five years.*

²² **DELETED**: *PM comments under Annex I, p. 15.*

DELETED: *Lighter procedure needed (i.a. possibility for issuing "blanket permit" for whole region for a certain species).*

²³ **DELETED**: *Requests information on how to ensure that Member States define these movements in a harmonised way.*

²⁴ **DELETED**: *Should a permit be required in case of routine movements of already widely established species in a given Member State? If yes, is there a simplified procedure to be applied?*

Article 9
Non-routine movement^{25 26}

1. In the case of non-routine movements, an environmental risk assessment shall be carried out as outlined in Annex II²⁷. The competent authority shall decide whether the applicant or an independent body is responsible for conducting the environmental risk assessment and who should bear the cost.
2. On the basis of the environmental risk assessment, the advisory committee shall give its opinion on the risk to the competent authority, using the summary report form set out in Annex II, Part 3. If the advisory committee finds that the risk is low, the competent authority may grant a permit without further formalities.
3. If the advisory committee finds that the risk associated with the proposed movement of aquatic organisms is high or medium, it shall examine the application in consultation with the applicant to see if there are mitigation procedures or technologies available to reduce the level of risk to low. The advisory committee shall forward the results of its appraisal to the competent authority, detailing the level of risk and specifying the reasons for any reduction in risk in the form specified in Annex II, Part 3.
4. The competent authority may only issue permits for non-routine movements in cases where the risk assessment, including any mitigation measures, show a low risk to the environment. Any refusal of a permit must be justified on scientific grounds.²⁸

Article 10
Decision period

1. The applicant shall be informed in writing of the decision to issue or refuse a permit within a reasonable time and in any case not later than one year from the date of the submission of the application²⁹.

²⁵ **DELETED**: *Can a part of the risk assessment focusing on non-target species be carried out in the absence of Part 1 of the risk assessment on ecological and genetic impacts? The position of these operators may be regularised by a five-year permit.*

²⁶ **DELETED**: *The applicant should bear the costs. Short term cost would not deter the industry from expanding.* **DELETED**: *Should be applicable only for "new" species.*
DELETED: *Is there an estimate of the potential cost and logistical requirement involved in providing the specialised scientific information and expertise? Has COM considered application of state aid?*

²⁷ **DELETED**: *. Risk assessment should not be required retrospectively in particular in cases where installations of Pacific oysters and rainbow trout have not given rise to concerns.*

²⁸ **DELETED**: *The application of precautionary principle should be ensured, in particular in case of scientific uncertainty, therefore suggests to amend paragraph 4 as follows: "The decisions shall be based on scientific data. In cases where a potential risk exists but relevant scientific evidence is insufficient (i.e. there is a lack of scientific certainty), a Member State may provisionally adopt measures to avoid a possible adverse effect, until sufficient scientific information has been gained in order to finalize risk assessment".*

²⁹

DELETED: *Whilst recognising the precautionary principle, a delay of one year should be highly exceptional.*

2. Member States which are signatories to ICES may request to have applications and risk assessments regarding marine organisms reviewed by ICES prior to the issuing of an opinion by the advisory committee. In such cases an additional period of six months shall be allowed.

Article 11
Movements affecting other Member States

1. Where the potential or known environmental effects of a proposed movement of an organism are liable to affect other Member States, the competent authority shall notify the Member State or States concerned and the Commission of its intention to grant a permit by sending a draft decision, accompanied by an explanatory memorandum and a summary of the environmental risk assessment as specified in Annex II, Part 3.
2. Within two months of the date of notification, the other Member States concerned may submit written comments to the Commission.
3. Within six months of the date of notification, the Commission shall, after consulting the Scientific, Technical and Economic Committee for Fisheries (STECF), established under Article 33 of Regulation 2371/2002 and the Advisory Committee for Fisheries and Aquaculture, established by Decision 1999/478/EEC³⁰, confirm, cancel or amend the proposed decision to grant a permit.
4. Within 30 days of the date of the Commission's decision, the Member States concerned may refer that decision to the Council. Within a further 30 day period, the Council, acting by qualified majority, may take a different decision.

Article 12
Withdrawal of permit

At any point in time the Competent Authority can withdraw the permit if unforeseen events with negative effects on the environment or on native populations occur.

³⁰ OJL 187, 20.7.1999, p. 70, as amended by Decision 2004/864/EC (OJL 370, 17.12.2004, p. 91).

Chapter IV

Conditions for introduction after issue of a permit ³¹

Article 13 *Compliance with other Community provisions³²*

After a permit is issued under this Regulation, the introduction may only take place if other permits required under Community law have been obtained and if other conditions laid down under the Community rules are fulfilled, and in particular:

- (a) the animal health conditions set out in Council Directive 2006/XX/EC³³
- (b) the conditions set out in Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community³⁴.

Article 14 *Release into aquaculture facilities in case of routine introductions*

In the case of routine introductions the release of aquatic organisms into open aquaculture facilities shall normally be allowed without quarantine, unless the competent authority decides otherwise on the basis of specific advice given by the advisory committee.

Article 15 *Release into aquaculture facilities in case of non-routine introductions*

1. In the case of non-routine introductions, the release of aquatic organisms into open and closed aquaculture facilities shall be subject to the conditions set out in paragraphs 2, 3 and 4.
2. The aquatic organisms shall be placed in a designated quarantine facility within the territory of the Community in accordance with the conditions set out in Annex III for the purpose of constituting a brood-stock.
3. The quarantine facility may be located in a Member State other than the receiving Member State, provided that all Member States concerned agree and that this option has been included in the environmental risk assessment under Article 9.

³¹ **DELETED:** *If a new operator wishes to make an introduction of a particular specie in a Member State, the full rigour of analysis should be reduced given that there is already a history of introductions of that particular species within the given Member State.*

³² **DELETED:** *The permit should only be issued once it has been shown that provisions of other relevant Community rules have been fulfilled.*

³³ See footnote 6.

³⁴ OJ L 169, 10.7.2000, p. 1

4. Only progeny of the introduced aquatic organisms may be used in aquaculture facilities of the receiving Member State, unless the organisms in question are fully reproductively sterile and providing that no non-target species are found during quarantine.

Article 16
Pilot release into open aquaculture facilities

The competent authority may require that the release of the aquatic organisms into open aquaculture systems be preceded by an initial pilot release subject to specific containment and to preventive measures based on the advice and recommendations of the advisory committee.

Article 17
Contingency plans

For all non-routine introductions and pilot releases, the advisory committee shall, in consultation with the applicant, draw up contingency plans, which shall include *inter alia* the removal of the introduced species from the environment, or a reduction in density, for unforeseen events with negative effects on the environment or on native populations. If such an event occurs, the contingency plans shall be implemented immediately and the permit shall be withdrawn as per Article 12.

*Article 18*³⁵
Monitoring

1. Alien species shall be monitored after their release for a period of two years or a full generation cycle, whichever is longer, to assess whether the impacts were accurately predicted or if there are additional or different impacts. The level of spread or containment of the species shall be studied in particular. The competent authority shall decide whether the applicant has the adequate expertise or whether another body is to carry out the monitoring.
2. Subject to the opinion of the advisory committee, the competent authority may require longer monitoring periods to assess any possible long-term ecosystem effects not easily detectable in the period laid down in paragraph 1.
3. The advisory committee shall evaluate the results of the monitoring programme and note in particular any event not correctly anticipated in the environmental risk assessment. The results of that evaluation shall be sent to the competent authority which shall include a summary of the results in the national register established under Article 23.

³⁵ **DELETED**: *Has COM considered a possibility to apply state aid under this provision? Detailed guidance necessary to ensure a harmonised approach to monitoring.*

Chapter V

Conditions for translocations after issue of a permit

Article 19

Compliance with other Community provisions

After a permit has been issued under this Regulation, translocation may only take place if other permits required under Community law have been obtained and if other conditions laid down in Community rules are fulfilled, and in particular:

- (a) the animal health conditions set out in Directive 2006/XX/EC³⁶
- (b) the conditions set out in Directive 2000/29/EC³⁷.

Article 20

Non-routine translocation

In the case of non-routine translocations into open aquaculture facilities, the competent authority may require that release of aquatic organisms be preceded by an initial pilot release with specific containment and preventive measures based on the advice and recommendations of the advisory committee.

Article 21

Quarantine

The receiving Member State may in exceptional cases and subject to approval by the Commission require quarantine in accordance with Article 15 (2), (3) and (4) before release of species from non-routine translocations into open or closed aquaculture facilities. The request for approval from the Commission shall indicate the reasons why quarantine is required. The Commission shall reply to such requests within 30 days.

Article 22

Monitoring following translocation

Following a non-routine translocation, the species shall be monitored in accordance with Article 18.

³⁶ See footnote 6.
³⁷ See footnote 12.

Chapter VI

Register

Article 23 *Register*

Member States shall keep a register of introductions and translocations containing a historical record of all applications made and the associated documentation gathered before the issue of a permit and during the monitoring period.

The register shall be made available to the public in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information³⁸.

Chapter VII

Final provisions

Article 24 *Adaptation to technical progress*

Amendments to Annexes I, II and III necessary in order to adapt them to technical and scientific progress shall be adopted in accordance with the procedure referred to in Article 30(3) of Regulation (EC) No 2371/2002³⁹.

Article 25 *Entry into force*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council
The President

³⁸ OJ L 41, 14.02.2003, p. 26

³⁹ See footnote 11.

ANNEX I^{40 41}

Application

(To be completed by applicant)

Wherever possible, information is to be supported with references from the scientific literature, and notations to personal communications with scientific authorities and fisheries experts. Applications lacking detail may be returned to the applicant for additional material, resulting in a delay in assessing the proposal.

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 utilization of an indigenous species.
- 5) What alternate strategies have been considered in order to meet the objectives of the proposal? What are the implications of a “do nothing” option?
- 6) What is the geographic area of the proposed introduction? Include a map.

⁴⁰ **DELETED:** *Requirements do not make significant distinction between "open" and "closed" systems. Requirements on the "closed" system are disproportionate as to their potential cause of problems to the aquatic environment.*

⁴¹ **DELETED:** *Industry should not be burdened with new administrative requirements. It should be left to the competent authority to decide upon the priority of information required and the possible exceptions on a case-by-case basis. Preparation of standard, pre-filled forms for the most common species would facilitate the procedure.*

7) Describe the numbers of organisms it is proposed introducing (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) 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).

3) What factors limit the species in its native range.

4) Describe the physiological tolerances (water quality, temperature, oxygen, and salinity) at each life history stage (early life-history stages, adult and reproductive stages).

5) Describe the habitat preferences and tolerances for each life-history stage.

6) Describe the reproductive biology.

7) Describe the migratory behaviour.

8) Describe the food preferences for each life-history stage.

9) Describe the growth rate and lifespan (also in the area of the proposed introduction, if known).

10) Describe the known pathogens and parasites of the species or stock.⁴²

11) 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?

⁴² **DELETED:** *Since already within the scope of the Community legislation on animal health, it should be up to the responsible authority to decide which of the veterinary related interventions is required.*

- 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 hybridize 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 quality assurance plan for the proposal, and,
 - (e) 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 to be followed 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 email 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 II⁴³

Procedures and minimum elements to be addressed in an environmental risk assessment

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”.

⁴³ *PM: Cf. footnotes under Article 9.*

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

| Event | Likelihood (H, M, L)⁽¹⁾ | Certainty (VC, RC, RU, VU)⁽²⁾ | Comments in support of assessment⁽⁴⁾ |
|--|---|---|--|
| In the case of closed aquaculture systems, the introduced or translocated species escapes to the surrounding environment. | | | |
| 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 ⁽³⁾ | | | |

(1) H= High, M= Medium, L= Low

(2) VC= Very certain, RC= Reasonably certain, RU= Reasonably uncertain, VU= Very uncertain

(3) 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 colonizing 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).

(4) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of practice.

Step 2: Consequences of establishment and spreading

| Event | Likelihood (H, M, L) | Certainty (VC, RC, RU, VU) | Comments in support of assessment⁽²⁾ |
|---|---------------------------------|---|--|
| 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 above-mentioned events persist even after removal of the introduced species. | | | |
| Final rating ⁽¹⁾ | | | |

(1) 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.

(2) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of practice.

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⁽²⁾ |
|---|-------------------------------------|---|--|
| Establishment and spreading (step 1) | | | |
| Ecological consequences (step 2) | | | |
| Final rating of overall risk potential ⁽¹⁾ | | | |

(1) 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.

(2) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of practice.

The result of this assessment should be expressed in terms of:

High = Introduction 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.

Medium = Introduction is of moderate concern. It is advised that the proposal be rejected unless mitigation procedures can be developed to reduce the risk to Low.

Low = Introduction 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.

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⁽²⁾ |
|--|---------------------------------|---|--|
| 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 ⁽¹⁾ | | | |

(1) 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.

(2) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of practice.

Step 2 Consequences of non-target species establishment and spreading

| Event | Likelihood (H, M, L) | Certainty (VC, RC, RU, VU) | Comments in support of assessment⁽²⁾ |
|---|---------------------------------|---|--|
| 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 above-mentioned events persist even after removal of the non-target species. | | | |
| Final rating ⁽¹⁾ | | | |

(1) 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.

(2) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of practice.

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⁽²⁾ |
|---|-------------------------------------|---|--|
| Establishment and spreading (step 1) | | | |
| Ecological consequences (step 2) | | | |
| Final rating ⁽¹⁾ | | | |

(1) 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.

(2) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of practice.

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 laying down health rules concerning animal by-products not intended for human consumption⁴⁴.

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.).

⁴⁴ OJ L 273, 10.10.2002, p. 1.

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.