COMMISSION OF THE EUROPEAN COMMUNITIES

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2006/0056 (CNS)

Proposal for a

COUNCIL REGULATION

concerning use of alien and locally absent species in aquaculture

{SEC(2006) 421}

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

Aquaculture is a fast-growing sector, where innovation and new outlets are being explored. In order to adapt production to market conditions, it is important that the aquaculture industry should diversify the species reared.

In the past, aquaculture has benefited economically from the introduction of alien species (e.g. rainbow trout, Pacific oyster) and from the farming of species which do not occur in an area owing to biogeographical barriers. It is therefore likely that the aquaculture industry will continue to use new species in order to satisfy the needs of the market. It would thus be prudent to decouple this economic growth from the potential threats to ecosystems posed by alien species by anticipating and preventing negative biological interaction with indigenous populations, including genetic change, and by restricting the spread of non-target species and other detrimental impacts. This is the main objective of this proposal.

It should be noted that there is a significant trade in alien organisms, mainly fish, as ornamental species, but the keeping of these organisms in pet shops, garden centres and commercial and private aquaria is not covered by the Common Fisheries Policy and, consequently, falls outside the scope of this proposal.

Invasive alien species are identified as one of the key causes of loss in biodiversity for the EU and the world at large. Alien species can also have significant economic and social impacts. All this may undermine the attainment of the EU's sustainable development objectives. In its Biodiversity action plan for fisheries (COM(2001) 162, Vol. IV), under Action IX on 'Limiting introduction of new species and securing animal health', the Commission undertook to thoroughly evaluate the potential impact of non-indigenous species in aquaculture and to promote the application of the International Council for the Exploration of the Sea (ICES) Code of Practice on introductions and transfer of marine organisms and the European Inland Fisheries Advisory Commission (EIFAC) Code of Practice and Manual of Procedures for consideration of introductions and transfers of marine and freshwater organisms.

Furthermore, in its strategy for the sustainable development of European aquaculture (COM(2002) 511), the Commission committed itself to proposing management rules on the introduction of alien species in aquaculture. This proposal for a Regulation seeks to introduce an EU framework to ensure adequate protection of the aquatic environment from the risks associated with the use of alien species in aquaculture, building on the existing voluntary ICES and EIFAC rules. For the purpose of the Regulation, aquaculture is taken to include activities such as bottom cultivation of mussels and both stocking and put-and-take fisheries, which use aquaculture techniques as their basis.

- **General context**

The book 'Invasive aquatic species in Europe' (E. Leppäkoski et al, 2002) lists 69 alien species introduced into Europe for aquaculture or restocking since the late 19th century. Of these, 28 are bivalve shellfish, 27 are fish, ten are algae, three are gastropod molluscs, and one is a flowering plant. Two of these - rainbow trout and Pacific oyster - are among the top

European aquaculture species today, which indicates that the introduction of alien species in a controlled manner can be beneficial for the industry. The Pacific oyster is now so widespread that it accounts for an estimated 80% of world oyster production. Nowadays the Pacific oyster is spreading and in some areas is tending to overgrow mussel (*Mytilus edulis*) beds.

Movement of non-native species can also often result in the spreading of parasites and pathogens. For example, the sporozoan, *Bonamia ostreae*, which scientists believe was introduced to the Community via the movement of European oysters from the North American Pacific Coast, has resulted in the decimation of native oyster stocks in the Community. However, the spreading of pathogens already falls within the scope of the Community legislation on animal health and is therefore not covered by this proposal. Likewise, parasites which fall within the scope of the animal health rules are not covered by the alien species rules.

Movement of bivalves can also result in damage to ecosystems owing to the spread of accompanying non-target alien species. Some examples of pests moved with oysters include the slipper limpet, *Crepidula fornicata*, and the sea squirt, *Styela clava*. The Community is fortunate that these introductions to marine and freshwaters have not caused more serious damage, given the number of species and locations of origin. There can be no room for complacency, however, and for this reason the introduction of the current rules is timely.

- **Existing provisions in the area of the proposal**

A relevant provision in this area in Community law is Directive 92/43/EC, the Habitats Directive, which requires Member States to "ensure that the deliberate introduction into the wild of any species which is not native to their territory is regulated so as not to prejudice natural habitats within their natural range or the wild native fauna and flora and, if they consider it necessary, prohibit such introduction". However, it is unclear how both the accidental, non-deliberate introductions and the introductions into non-wild environments are covered by this legislation.

While there is a possibility of some duplication or overlap between the administrative measures already taken in compliance with the Habitats Directive and the new proposal for a Regulation, this is not necessarily a problem, as it is hoped that the experience gained with the former process will enhance the setting up and functioning of the new permit system required by this proposal for a Regulation.

Other Community legislation, such as the Directives on assessment of the effects of certain projects on the environment (Environmental Impact Assessment), animal health for aquaculture and the framework for Community action in the field of water policy, do cover the harmful effects of alien species but are not specific to aquaculture and leave room for risks of spreading of alien species and consequent environmental damage.

- **Consistency with other policies and objectives of the Union**

For the above reasons, it is concluded that the existing provisions are not entirely adequate to govern the use of alien species in aquaculture at the present time. In any case, it is proposed that the granting of permits under this regulation should not remove the need for compliance with any of the existing rules. If a comprehensive Community framework for alien species were to be introduced in the future, this Regulation would be adapted, as necessary, to that framework or would be subsumed into it.

The measures contained in this proposal are a major step in the process of integration of environmental concerns into the Common Fisheries Policy, in line with Article 6 of the Treaty. In this context, this proposal was already anticipated in specific policy texts adopted in the context of the CFP reform[1].

The proposal for a regulation implements actions envisaged in the EC Biodiversity Strategy and in the Biodiversity Action Plan for Fisheries[2], and is expected to contribute to the objective of halting biodiversity loss set by the 6th Environmental Action Programme and by the EC Strategy for Sustainable Development. It will also contribute to the global target of significantly reducing the rate of biodiversity loss as established under the Plan of Implementation of the World Summit for Sustainable Development.

Furthermore, these measures are consistent with the Guiding Principles for the prevention, introduction and mitigation of impacts of alien species that threaten ecosystems, habitats or species, adopted in Decision VI/23 of the Convention on Biological Diversity, to which the European Community is a Contracting Party.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

Formal consultation took place with an expert group of 46 persons representing Member States (15 government experts from EU15 and seven from EU10); EEA-EFTA (three government experts), industry (six nominated by the Aquaculture Working Group of the Advisory Committee for Fisheries and Aquaculture), NGOs (two persons from the UK and one from the Netherlands) and ICES (five persons with experience of the Working Group on Introductions and Transfers), EIFAC (one expert), NASCO (one from head office and one from the industry liaison group) together with four additional private sector experts. A one-day meeting with this group was held in Brussels in December 2003 to debate a previously circulated discussion paper and hear a series of presentations by private-sector experts. Written comments on the draft legislation were received during 2004 and 2005. The proposal was presented and discussed on three occasions in 2004/5 in the Aquaculture Working Group of the Advisory Committee for Fisheries and Aquaculture.

Summary of responses and how they have been taken into account

The initial plan was to incorporate measures for containment of farmed salmon in the proposal. As the existing NASCO guidelines in this area are being evaluated in the light of experience and scientific progress, the responses called for this aspect to be treated separately and not as part of alien species legislation. It was therefore considered appropriate to take this out of the current proposal. The consultees, except for the NGOs, advised against an over-

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1 Communication from the Commission setting out a Community Action Plan to integrate environmental protection requirements into the Common Fisheries Policy, COM(2002) 186; Communication from the Commission to the Council and to the Parliament "A strategy for the sustainable development of European Aquaculture", COM(2002) 511.

2 Communication from the Commission to the Council and the European Parliament - Biodiversity Action Plan for Fisheries, COM(2001) 162 final.

centralised and heavy-handed approach, and the proposal was modified to acknowledge the competence of Member States in this field. On the other hand, there was a call for harmonised guidelines for the application, risk assessment and quarantine stages, and these have been provided in order to allow even application of the legislation across the Member States. The proposal is based to a large extent on these opinions.

- **Collection and use of expertise**

Scientific fields/areas of expertise concerned

The fields of marine and freshwater biology and ecology and aquaculture technology were included.

Methodology used

Formal meeting of stakeholders following circulation of a discussion document. Consultation of the Advisory Committee for Fisheries and Aquaculture and two follow-up rounds of e-mail consultations on draft texts.

Main organisations/experts consulted

i) International organisations such as ICES, EIFAC and NASCO;

ii) specialised research bodies such as Marine Organism Investigations and Hull International Fisheries Institute;

iii) individual experts from Member States administrations, aquaculture industry and NGOs.

Summary of advice received and used

The main conclusion is that there is a broad consensus on the existence of potentially serious risks with irreversible consequences. More concrete technical aspects included the following:

Containment should be dealt with separately. Care should be taken with the definitions, especially to distinguish between species which are native and those which are not native. Stocking based on aquaculture and classic aquaculture should be covered by this legislation. A risk assessment approach incorporating mitigation and protective measures should be included in the procedure, specifying who is to carry out and who is to evaluate the risk assessment. The regulation should not be over-prescriptive, so that detailed management is left to the Member States. There is a need to develop European expertise on quarantine stations. GMOs should be included, and triploids should not be regarded as harmless. The proposal is largely based on these opinions, but GMOs were excluded from the scope as they are already covered by existing and developing Community legislation in the field.

Means used to make the expert advice publicly available

The main conclusions of the stakeholder meeting were presented to the Advisory Committee on Fisheries and Aquaculture, Working Group II, Aquaculture; the minutes of their discussions are available on the Fisheries website. During the e-mail exchange, most messages were copied to all other consultees without a warning about restricted distribution.

- **Impact assessment**

From among the various options examined in the impact assessment it would appear that the present proposal is preferable to the option of not applying the legislation to movements within the Community but distinguishing between introductions, which apply to alien species, and translocations, which apply to species which are locally absent from their range of distribution for biogeographical reasons. Industry commented that the cost of funding the application, risk assessment and quarantine would preclude future applications for the introduction of alien species. Taking this into account, the proposal does not make it mandatory for the applicant to bear the cost of the risk assessment in all cases (see Article 9(1)). As stated above, a large proportion of current aquaculture practices is based on alien species (rainbow trout, Pacific oyster, carp) and operators can associate to share the costs of obtaining the information required both for drawing up the application and, where applicable, for the risk analysis. The proposal also provides for the issuing of permits for successive movements within a period of up to five years, which will also simplify both costs and procedures.

In order to follow current EU practice on risk analysis, it was decided to separate the risk assessment function (advisory committee) from the risk management function (competent authority). For this reason the original option of combining both functions within the competent authority was not put forward. The impact assessment addressed the question of whether the proposal was premature, given that the IMO International Convention on ballast water - which was agreed in February 2004 - will also cover the problem of alien species. In view of the uncertainty of the date of entry into force of this convention, the nature of the risks associated with alien species, and taking account of the precautionary principle, it was concluded that it was not premature to proceed.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

The aim of the proposed legislation as it is currently formulated is to strike the correct balance with regard to subsidiarity and proportionality. Decision making is left to Member States, which will be able to assess under prescribed conditions the risks associated with proposals for introductions. Applicants are obliged to submit an application giving Member State authorities sufficient information to make a judgment. The content of the application, which is obligatory in all cases, is sufficiently comprehensive to allow an evaluation of whether the movement would be routine or non-routine. It also provides sufficient criteria for a decision to be made at Member State level on whether an environmental risk assessment (ERA) is required and who will be involved in making such an assessment. Evaluation of the completed ERA will in turn inform the decision - as to whether a permit should or should not be granted. In cases where a movement is liable to affect another Member State, a "Community procedure" allows the Commission to consult other Member States and the relevant committees. In this case the Commission can decide to confirm, cancel or amend the decision within a period of six months. The proposal draws heavily on the existing voluntary ICES/EIFAC Codes and on the Canadian National Code on Introductions and transfers of aquatic organisms which develop the ICES code significantly. It does not rule out the voluntary application of the ICES/EIFAC codes at Member State level.

- **Legal basis**

Article 37 of the Treaty is taken as the legal basis, given the specificity of aquaculture activities and the objective of conservation of living aquatic resources within the Common Fisheries Policy (Articles 1(1) and 1(2)(a) and (f) of Council Regulation (EC) No 2371/2002[3]).

- **Subsidiarity principle**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

As stated above, this proposal falls within the ambit of the Common Fisheries Policy, which is the exclusive competence of the Community. Therefore, the subsidiarity principle does not apply.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

  - One of the strong messages taken from the December 2003 Consultation meeting was the need for proportionality and the need to ensure that the new legislation will be embraced by industry and not regarded as just another unworkable legislative burden. Rather than looking for the simplest solution to ban all uses of alien species, the proposal seeks a balance between environmental protection and the needs of the aquaculture industry.

  - The proposal reflects a fair distribution of the financial and administrative burden between all actors.

- **Choice of instruments**

The legislation is proposed in the form of a Regulation. Although a Directive would also be possible in principle, it was felt that in view of the dynamic nature of the aquaculture sector there is a common interest in prescribing detailed rules in the form of a Regulation rather than establishing the obligation of an end-result.

4. BUDGETARY IMPACT

The Regulation may have some implications in terms of staff time to make applications for prospective movements of alien species and in terms of the resources needed for consulting STECF and the Advisory Committee for Fisheries and Aquaculture, but this is routine work for these committees.

[3] OJ L 358, 31.12.2002, p. 59

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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 Commission[4],

Having regard to the opinion of the European Parliament[5],

Having regard to the opinion of the European Economic and Social Committee[6]

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.

(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

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4 OJ C […], […], p. […].
5 OJ C […], […], p. […].
6 OJ C […], […], p. […].

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 flora[7], Council Directive 85/337/EEC of 27 June 1985 on environmental impact assessment[8], 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 animals[9] 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 policy[10].

(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.

(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

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7 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)

8 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.

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

10 OJ L 327, 22.12.2000, p. 1.

Fisheries Policy[11] should provide the scientific advice in this consultation and the Advisory Committee for Fisheries and Aquaculture set up by Commission Decision 1999/478/EEC[12] 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 ecoregions 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 policy[13], and

   c) cases where, on the basis of scientific advice, there are grounds for foreseeing environmental threats due to the translocation.

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.

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[11] OJ L 358, 31.12.2002, p. 59.
[12] OJ L 187, 20.7.1999, p. 70.
[13] OJ No L 327, 22.12.2000, p. 1.

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.

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;

(6) 'alien species' means:

(a) a species, subspecies or a lower taxon 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;

(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) ‘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
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').

Chapter III
Permits

Article 6
Permit

1. Anyone intending to undertake the introduction or translocation of an aquatic organism 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.

2. The applicant shall submit with the application the information listed in Annex I. 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 movement 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.

Article 9
Non-routine movement

1. In the case of non-routine movements, an environmental risk assessment shall be carried out as outlined in Annex II. 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.

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 application.

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/EEC[14], 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.

Chapter IV
Conditions for introduction after issue of a permit

Article 13
Compliance with other Community provisions

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/EC[15]

(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 Community[16].

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.

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14 OJ L 187, 20.7.1999, p. 70, as amended by Decision 2004/864/EC (OJ L 370, 17.12.2004, p. 91)
15 see footnote 9
16 OJ L 169, 10.7.2000, p. 1

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.

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
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.

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/EC[17]

(b) the conditions set out in Directive 2000/29/EC[18].

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.

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17 see footnote 9
18 see footnote 15

Article 22
Monitoring following translocation

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

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 information[19].

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 2371/2002[20].

[19] OJ L 41, 14.02.2003, p. 26
[20] see footnote 11

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

ANNEX I

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.

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) Lifehistory 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.

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?

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 II

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”.

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)[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.

PART 2 –NON-TARGET SPECIES ASSESSMENT PROCESS

Step 1: Likelihood of establishment and spreading of non-taget 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 is 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 consumption[21].

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.).

[21] 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.