



**COUNCIL OF
THE EUROPEAN UNION**

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WORKING DOCUMENT

from: Presidency
to: Working Party on Internal Fisheries Policy
Subject: Proposal for a COUNCIL REGULATION concerning use of alien and locally absent species in aquaculture

PRESIDENCY WORKING DOCUMENT

Delegations will find enclosed a revised Presidency working document (REV 4) established in close cooperation with the Commission. It sets out in the footnotes positions of delegations and integrates modifications to the various provisions.

In response to most recent written and oral comments by the Member States¹, the Commission has provided editorial proposals which are indicated in ***bold, underlined and italics***. Delegations are kindly requested to review this document and, in particular to indicate whether they can accept these editorial changes and whether they can lift any of the remaining footnotes.

The Commission will soon submit additional revisions concerning "closed systems" and "comitology procedure".

The document will be examined by **the Working Party on Internal Fisheries Policy on 7 December 2007** with the view to preparing it for submission to Coreper I.

¹ As indicated during the deliberations of the Working Party on 26 April, 6 July, 13 July, 7 September, 19 October, 26 October, 9, 16 and 24 November 2006 and notified to the Council Secretariat in writing (doc. 9057/06 + ADD 1 - ADD 22 and doc. 14915/06 + ADD 1 - ADD 9).

Proposal for a

COUNCIL REGULATION^{2 3}

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 Commission⁴,

Having regard to the opinion of the European Parliament⁵,

Having regard to the opinion of the European Economic and Social Committee⁶.

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 optimise 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.

² ***NL:*** *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. COM: Insists on a Regulation as this is part of the Common Fisheries Policy and moreover Article 6 is addressed to individuals. DE: Supports COM.*

³ ***DK, FR, UK:*** *Parliamentary scrutiny reservations. DK, ES, MT: General scrutiny reservation. FR: Linguistic reservation on the whole text.*

⁴ *OJ C [...], [...], p. [...]*

⁵ *OJ C [...], [...], p. [...]*

⁶ *OJ C [...], [...], p. [...]*

- (4) Invasive alien species have been identified as one of the key causes of loss of native species and harm to bio-diversity. Under 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~~ **present** risks for ecosystems 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 aquatic habitats 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 flora⁷, Council Directive 85/337/EEC of 27 June 1985 on environmental impact assessment⁸, 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 animals⁹ 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 policy¹⁰.

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. 40. 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.

(8) The potential risks, which may in some cases be far reaching, are initially more evident locally. The characteristics of local aquatic environments throughout the Community ~~may be~~ **are** very diverse and Member States have the appropriate knowledge 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.

(8a) 8a. It should be taken into account that movements of alien or locally absent species to be held in closed aquaculture facilities which are secure and which present a very low risk of escape should not normally be subject to any prior environmental risk assessment.

(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 Policy¹¹ should provide the scientific advice in this consultation and the Advisory Committee for Fisheries and Aquaculture set up by Commission Decision 1999/478/EEC¹² should give the advice of stakeholders in the field of aquaculture and environmental protection.

(9a) 9a. Some alien species have commonly been used in aquaculture for a long time in certain parts of the Community. The activities connected therewith should therefore benefit from a differential treatment facilitating their development without any additional administrative burden on condition that the source has a track record of providing stock can provide stock that is free of non target species.¹³ Member States who wish to restrict the use of such long used species in their territory should be permitted to do so.

¹¹ OJ L 358, 31.12.2002, p. 59.

¹² OJ L 187, 20.7.1999, p. 70.

¹³ **IT, PL, UK: Should allow Member States to regulate private aquaria. COM: Always some risk of escape from closed systems, including that involving human factors. Ornamental fish covered, if they have contact with open waters.**

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 and any associated non-target species on aquatic habitats and in this manner contribute to the sustainable development of the sector.

Article 2¹⁴ *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 Community¹⁵.
2. This Regulation shall not apply to translocations of aquatic organisms within Member States, except for cases where, on the basis of scientific advice, there are grounds for foreseeing environmental threats due to the translocation. ~~The advisory committee to be established~~ **In the case that an advisory committee has been appointed** under Article 5 **it** will be responsible for assessing the risks, ~~if any~~.
3. This Regulation shall cover all aquaculture ~~facilities~~ **activities** located within the jurisdiction of Member States irrespective of their size or characteristics. It shall cover all alien and locally absent aquatic organisms farmed. It shall cover aquaculture using any form of aquatic medium¹⁶. **The risk assessment in Article 9 shall not apply retrospectively to species listed in Annex IV.**

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¹⁴ ***DK, FI: Movements or introductions of alien species in the closed aquaculture system with recycling water should be defined as routine movements. COM: See new definition of 'routine movement', Article 3 (16). COM: 'With recycling of water' now in 3.16.***

¹⁵ ***UK: Add: "It shall apply to transfers or introductions of alien or locally absent species within Member States." Paragraphs 2 and 3 would then be redundant. COM: the term transfer is taken to mean translocation.***

¹⁶ ***CY, DK, DE, NL: It should be appropriately reflected here that land-based, indoor, closed recirculation systems are very bio-secure. The risk of escape of aquaculture organisms is negligible. COM: See new whereas 8 a) and amended Article 3.16.***

¹⁷ ***DE, FR, HU, IT, NL, SI: Closed systems to be exempted. DK, NL: Given the exemption for ornamental aquatic animals below, should add a similar exemption for recirculation systems. Add "This Directive shall not apply to aquaculture in closed aquaculture facilities". COM: See amended Article 3.16 and last sentence of paragraph 1 of Annex I.***

4. This Regulation shall not apply to the keeping of ornamental aquatic animals or plants in pet-shops, garden centres, contained garden ponds or¹⁸ aquaria which comply with Article 6 of Decision 2006/656/EC¹⁹ or in facilities which are equipped with effluent treatment systems which fulfil the aims set out in Article 1.
5. This Regulation, except for Articles 3 and 4²⁰, shall not apply to the species listed in Annex IV, provided that non-target species are not introduced and that Member States do not wish to restrict the use of the species concerned in their territory.²¹

Article 3
Definitions

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

- (1) 'aquaculture' means the activity defined in Article 3, paragraph (d) of Regulation (EC) No 1198/2006²²;
- (2) 'open aquaculture facility'²³ means a facility where aquaculture is conducted in an aquatic medium not separated from the wild aquatic medium by barriers preventing the escape of reared specimens or biological material that might survive and subsequently reproduce;

¹⁸ ***PT, UK:*** Need legal assurance that Member States can regulate. ***COM:*** MS can always legislate (subject to notification procedure) in areas not covered by harmonised Community legislation, Decision 2006/656/EC on health of ornamental fish imports not withstanding. ***UK:*** Can lift footnote if the following text added: "However, nothing in this paragraph shall prevent Member States from regulating the keeping of alien or locally absent species in these facilities through national regulations." ***PL, PT:*** Support UK text. ***COM:*** Accept, but as new recital 10.

¹⁹ OJ L 271, 30.9.2006, p. 71.

²⁰ ***DK:*** Delete "... except for Articles 3 and 4...".

²¹ ***NL:*** Add "This Regulation shall not apply for aquaculture practised under closed conditions". ***DK:*** Like NL, not convinced these species should be subject to Article 4. Need scope for additional adjustments in Annex IV. ***SE:*** Add "and carry no disease" ***COM:*** need to reconcile SE comment with footnote 73.

²² OJ, L 223, 15.08.2006, p. 1.

²³ ***COM:*** This footnote should be located beside 'closed aquaculture facilities'. ***UK:*** Comparable to a 'lifetime quarantine unit'; should be excluded from full risk assessment, but could be subject to a review of site security. ***COM:*** Much stricter conditions apply for quarantine facilities as per Annex III. Closed systems excluded from full risk assessment under Annex II, as involve routine movements.

- (3) ‘closed aquaculture facility’²⁴ means a facility where aquaculture is conducted in an aquatic medium separated from the wild aquatic medium by 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’ for the purpose of this Regulation means artificially induced tetraploid organisms (4N)²⁵. These are aquatic organisms in which the number of chromosomes in the cells has been doubled through cell manipulation techniques;
- (6) ‘alien species’ means²⁶:
- (a) a species and subspecies of an aquatic organism occurring outside its known **natural** range and the area of its **natural** dispersal potential²⁷;
 - (b) polyploid organisms, and fertile artificially hybridised species irrespective of their natural range or dispersal potential;
- (7) ‘locally absent species’²⁸ 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 translocated²⁹;

²⁴ **AT:** *Scrutiny reserve on treatment of closed systems.*

²⁵ **UK:** *Impractical to regulate 'tetraploid organisms', infertile organisms not to be included. Even if not reproducing, competitive threat to indigenous species.*

²⁶ **DE:** *This should be re-worded to refer solely to species which have not hitherto been encountered on the Community territory. In current form, this covers the majority of all European fresh water species. **COM:** most European freshwater species are in their natural range*

²⁷ **CZ:** *This needs to be further defined. **COM:** meaning should now be clear. Does this mean that non-indigenous species dispersed over the area are not seen as alien **COM:** No. i.e. the Regulation could be used only in case of new introduction?*

²⁸ **DE:** *This definition should be entirely deleted from the text of Regulation.*

²⁹ **DE:** *This definition should be strictly limited to non-target fish species. **IE:** Further guidance needed on the processes and procedures determining the risk of transfer of "non-target species". **COM:** Offers to produce guidance note between time of adoption and entry into force. These procedures need to be harmonised across the Community to avoid an adverse impact on trade in aquatic organisms. Will COM draw a list of "non-target" species? **COM:** Specific questions on this introduced in Annex I, C, 2, cannot predict non-target species so cannot list them in advance, guidelines could be updated to provide historic list.*

- (9) ‘movement’ means introduction and/or translocation;
- (10) ‘introduction’ means the process by which an alien species is intentionally moved outside its natural range for 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 bio-geographical reasons;

- (12) ‘pilot release’ means the introduction of alien species or translocation of locally absent species on a limited scale to assess ecological interaction with native species and habitats in order to test the risk assessment assumptions³²;
- (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 and 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 of aquatic organisms from a source which has a low risk of transferring non-target species and which, on account of the characteristics of the aquatic organisms and/or the method of aquaculture to be used, **such as closed systems, as defined in (3), with recycling of water** does not give rise to adverse ecological effects;
- (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 is introduced or the locally absent species is translocated.

³⁰ ***FI: Establish criteria on the basis of which the competent authority could decide and list these species. DE: Can lift this footnote if criteria for developing the list are developed.***

³¹ ***DK: Add definition: "(11a) "release means the movement of an aquatic organism into an aquaculture facility."***

³² ***DE: Clarify this provision; especially as to where and when (SE) such interaction would take place.***

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 may be expected to 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 5³³

Decision making and advisory bodies³⁴

Member States shall designate the competent authority or authorities responsible for ensuring compliance with the requirements of this Regulation ('the competent authority'). Each competent authority shall **may** appoint to assist it an advisory committee, which shall include appropriate scientific expertise ('the advisory committee')³⁵. **If a Member State does not appoint an advisory committee then "the competent authority" or "competent authorities" should assume the tasks assigned to the advisory committee in this Regulation.**

³³ **CY, DE, DK, EE, ES, FR, NL:** *The administration of permit procedure (Chapter III) seems burdensome and costly for the sector. COM: not when revised articles 3, 5 and 6 are considered.*

DE, ES, IT: *System to be established, has to be compatible with existing internal administrative and constitutional arrangements. COM: Uses wording of European Parliament's proposed amendment 8. ES: reservation on Art. 5.*

³⁴ **UK:** *these bodies should be defined in Article 3 (Definitions).*

³⁵ **EE:** *For balanced analysis, to include economic and social expertise. SK: Financing for "the competent authority"?*

Chapter III Permits³⁶

Article 6³⁷ Application for a Permit

1. Anyone intending to undertake the introduction of an alien species or the translocation of a locally absent species not covered by Article 2(5) 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 seven years.³⁸
2. The applicant shall submit with the application a dossier following the guidelines listed in Annex I³⁹. The advisory committee shall give an opinion on whether the application contains all the information required to assess whether the proposed movement is routine or non-routine and is therefore admissible and shall inform the competent authority of its opinion.
3. By the end of a ~~seven-year~~ ***the permit*** period an application for another ~~7-year~~ permit may be submitted by referring to the former permit. If there have been no documented adverse effects on the environment, the proposed movement should be considered a routine movement.

³⁶ ***FI:*** Application process should be two-phased: Upon application, the competent authority/advisory committee to decide whether the question of routine or non-routine movement. In the case of a routine movement the application should be lighter. ***COM:*** New architecture allows two-phased approach. ***NL:*** Opposes the Cions proposed permit procedure. Has legislation already in place (Art. 22 of the Bird and Habitat Directive). ***COM:*** Scope of Art. 22 is deliberate introductions into the wild.

³⁷ ***UK:*** Caution about allowing exemptions. Not sufficient scientific evidence of interactions between tetra- and diploids. ***PL:*** Need penalties for not meeting obligations. The advisory committee should define the cases when reviews are not necessary.

³⁸ ***FR:*** If the committee is optional, redraft Articles 6 and 7 to state explicitly that all closed system movements are routine. ***COM:*** This is understood from 3.16 as redrafted. ***DK, NL:*** Agree with FR. ***PL:*** Permits should be adjusted in the light of the species concerned. ***FI, EE:*** Duration to be based on a case by case analysis. ***COM:*** See redrafting under Article 6, now caters for variable duration.

³⁹ ***CY, DK:*** 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 possibility to grant exemptions on a case-by-case basis. Preparation of standard, pre-filled forms for the most common species would facilitate the procedure.

Article 7
Type of 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 release must be preceded by quarantine or pilot release⁴⁰ and shall inform the competent authority of its opinion.

Article 8
*Routine movement*⁴¹

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*⁴²

1. In the case of non-routine movements, an environmental risk assessment shall be carried out as outlined in Annex II⁴³. 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.

⁴⁰ ***CY, UK:*** *With preceding quarantine or pilot release, is this still a routine movement?*
COM: *Yes, but by adding 'in exceptional cases' to Art. 14 have emphasised that this would not be normal procedure. MS have the choice to require them.*

⁴¹ ***CY, NL:*** *Unrealistic to require authorisation of routine movement. The cumbersome CITES regime imposing high structural costs on MS, should not be recreated. Translocation between ecoregions is very complex.*

⁴² ***CZ, LT:*** *To define when competent authority (MS) or when applicant is responsible for an environmental risk assessment and its costs. COM: this is left to competent authority. UK: The applicant should bear the costs. Short term cost would not deter the industry from expanding. IE: 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? COM: The number of environmental risk assessments will be small under the revised proposal. State aid is not ruled out in conjunction with the European Fisheries Fund. Public experts from Community have participated in the Introductions Working Group, ICES-WGITMO, since early 1970s giving a pool of expertise to be tapped. Community funded project 'Delivering Alien Invasive Inventories for Europe' (DAISIE) provides valuable information for MS on expertise and other aspects of alien species, see 'www.europe-aliens.org'.*

⁴³ ***DK, UK:*** *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. DK: In general, procedure for permits remains too burdensome. COM: No risk assessment for Annex IV species.*

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 the 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 in the sense of Annex II, part 1, 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 examination 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~~ **to be duly motivated** on scientific grounds **and, where scientific information is as yet insufficient, on the grounds of the precautionary principle.**⁴⁵

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 six months from the date of the submission of the application.~~ **The applicant shall be informed in writing within a reasonable time of the decision to issue or refuse a permit, and in any case shall not be informed later than six months from the date on which he submitted the application, excluding time when applicant provides additional information if advisory body committee so requests.**

⁴⁴ ***DK:*** Following the EP opinion add: "1a. Risk assessment should not be required retrospectively. ***COM:*** see new Art. 2.5 Movements of alien or locally absent species to be held in closed aquaculture facilities should not normally be subject to any prior environmental risk assessment. ***COM:*** agree, see comment for FN 23.

⁴⁵ ***DE:*** Warns that too strict use of this principle could have adverse effects. ***CZ:*** Specify "scientific grounds". Same basis for all. ***COM:*** Grounds are outlined in Annex II.

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 11⁴⁶

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~~ ***neighbouring*** 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/EEC⁴⁷, confirm, reject or amend the proposed decision to grant a permit.

⁴⁶ ***DE: Mechanism allowing the neighbouring MS to be informed, if necessary? Highlights that for DE, with many rivers but only 2 river systems not crossing into other countries, this Article implies a considerable administrative burden. CY: Not practical to inform all countries i.a. in marine cage culture where no physical barriers. Requests derogation. COM: Only required to inform neighbouring MS, COM would inform other MS as necessary.***

⁴⁷ OJ L 187, 20.7.1999, p. 70, as amended by Decision 2004/864/EC (OJ L 370, 17.12.2004, p. 91).

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 12⁴⁸
Withdrawal of permit

At any point in time the Competent Authority can withdraw the permit, temporarily or permanently, if unforeseen events with negative effects on the environment or on native populations occur⁴⁹. Any withdrawal of a permit must be justified on scientific grounds and, where scientific information is as yet insufficient, on the grounds of the precautionary principle.

Chapter IV

Conditions for introduction after issue of a permit⁵⁰

Article 13
Compliance with other Community provisions

A permit may only be issued for an introduction under this Regulation, where it is apparent that requirements under other legislation can be met, and in particular:

- (a) the animal health conditions set out in Council Directive 2006/88/EC⁵¹
- (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 Community⁵².

⁴⁸ ***PL:*** *Seeks certainty that no possibility of compensation in case of withdrawal of permit.*

⁴⁹ ***CZ:*** *Sanction procedure?* ***COM:*** *Will check with CION/LS.*

⁵⁰ ***DE, NL, UK:*** *If a new operator wishes to make an introduction of particular species in a Member State, the full rigour of analysis should be reduced given that there is already a history of introductions of those particular species within the given Member State.*

⁵¹ *OJ L 328, 24.11.2006, p14*

⁵² *OJ L 169, 10.7.2000, p. 1.*

Article 14

Release into aquaculture facilities in case of routine introductions

In the case of routine introductions the release of aquatic organisms into open or closed aquaculture facilities shall normally be allowed without quarantine or pilot release⁵³, unless, in exceptional cases, the competent authority decides otherwise on the basis of specific advice given by the advisory committee. **Movements from a closed aquaculture facility to an open aquaculture facility should not be regarded as routine.**

Article 15

Release into open aquaculture facilities in case of non-routine introductions

1. In the case of non-routine introductions, the release of aquatic organisms into open⁵⁴ aquaculture facilities shall be subject, if necessary, 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.
- 4.⁵⁵ **If appropriate**, only progeny of the introduced aquatic organisms may be used in⁵⁶ aquaculture facilities of the receiving Member State, provided that no non-target species are found during quarantine. If the latter condition is met the parent stock may be released in cases where the organisms do not reproduce in captivity or are fully reproductively sterile.

⁵³ **UK:** *Movements can hardly be 'routine' if quarantine required; remove references to quarantine in this context.* **COM:** *same question as FN 40, 'in exceptional cases' inserted in Art 14.* **DK:** *Clarify text on quarantine aspects.* **COM:** *see Annex III for details of quarantine*

⁵⁴ **CY:** *All closed aquaculture facilities should be excluded under this Regulation.*

⁵⁵ **DK:** *This paragraph should only apply to new species; as it stands could potentially restrain international trade.* **COM:** *Art.14.4 now qualified by 'if appropriate'.*

⁵⁶ **CY:** *Add "grow-out".* **COM:** *Trade term which would be difficult to translate appropriately and not required as Article 15 renamed "Release into open aquaculture facilities".*

Article 16⁵⁷
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.⁵⁸

Article 17
Contingency plans⁵⁹

For all non-routine introductions and pilot releases⁶⁰, the applicant **may** draw up a contingency plan for the approval of the competent authority, 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 can be withdrawn, temporarily or permanently as per Article 12.

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⁵⁷ ***UK:*** *This Article and its associated definition should be removed. If there is such a degree of risk that 'pilot release' appears desirable, then the appropriate resort is to quarantine or the keeping of the species concerned in indoor closed tank-based facilities. Since open containment systems are notoriously less than escape-proof, 'pilot release' into such facilities poses an unacceptable risk of causing irreversible damage to the environment.*
COM: *Sees quarantine as fundamentally different from pilot release, assumptions are tested in open in the latter under reduced density*

⁵⁸ ***AT:*** *How to assess biological interactions during pilot release in open aquaculture facilities? Timeframe?* ***COM:*** *= monitoring period of Art. 18*

⁵⁹ ***CY:*** *Should be amended so as to cover cases where the implementation of such contingency plan can be carried out.*

⁶⁰ ***UK:*** *There is no guarantee sought that applicants will have resources or expertise to put these plans into place should this prove necessary. Member State might be considered responsible for execution of the plan by virtue of Article 4.* ***COM:*** *Contingency plan should cover resources.*

⁶¹ ***DE, FR:*** *Pilot releases in Art. 16 and contingency plans in Art. 17 assume scientific and budgetary expertise that is unavailable to most applicants.* ***COM:*** *Not costly high tech. issues more a matter of having eyes wide open and good planning.* ***UK:*** *Opposes "a pilot release".*

Article 18⁶²
Monitoring

1. Alien species shall be monitored after their release⁶³ for a period of two years or a full generation cycle⁶⁴, 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.

⁶² ***IE:*** *Has COM considered a possibility to apply state aid under this provision? Detailed guidance necessary to ensure a harmonised approach to monitoring. **COM:** De minimis, subsidiarity issue. **DK, NL:** Level of monitoring requirements should reflect the ecological risks concerning the culture system used. **UK:** Is monitoring required for 'routine releases'? **SE:** Monitoring period to be specified. **COM:** See footnote 60. Time in aquaculture and the generation time of aquaculture organisms are highly variable. **PL:** Will COM provide financial assistance for monitoring?*

⁶³ ***DK:*** *Add "release into open aquaculture facilities..."*

⁶⁴ ***CZ:*** *Too short to evaluate impact on ecosystem or negative interaction with environment. **COM:** Considers 2 years as adequate. **COM:** MS can require stricter/longer monitoring if they so wish.*

Chapter V

Conditions for translocations after issue of a permit

Article 19

Compliance with other Community provisions

A permit may only be issued for a translocation under this Regulation where it is apparent that requirements under other legislation can be met and in particular:

- (a) the animal health conditions set out in Directive 2006/88/EC⁶⁵
- (b) the conditions set out in Directive 2000/29/EC⁶⁶.

Article 20

Non-routine translocation into open aquaculture facilities

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 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.

⁶⁵ OJ L 328, 24.11.2006, p14

⁶⁶ OJ L 187, 20.7.1999, p. 70.

Chapter VI Register

Article 23⁶⁷ *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 *freely* available to the *Member States and* 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 and repealing Council Directive 90/313/EEC⁶⁸.

Chapter VII Final provisions

Article 24 *Adaptation to technical progress*

Amendments to Annexes I, II, III and IV necessary in order to adapt them to technical and scientific progress shall be adopted in accordance with the procedure referred to in Article 30(2) of Regulation (EC) No 2371/2002.

Article 25 *Entry into force*

This Regulation shall enter into force one year following 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

⁶⁷ ***PL:*** *Need more transparency and information exchange; prefer a single EU registry.*

⁶⁸ *OJ L 41, 14.02.2003, p. 26.*

ANNEX I^{69 70}

Application

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

Wherever possible, information is to be supported with references from the scientific literature, and notations to personal communications with scientific authorities and fisheries experts. ~~Applications lacking detail may be returned to the applicant for additional material, resulting in a delay in assessing the proposal.~~ Applicants are advised to distinguish between movements to 'open' or 'closed' aquaculture facilities.

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

A) Executive summary

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

B) Introduction

- 1) Name (common and scientific) of the organism proposed for introduction or translocation, indicating the genus, species, subspecies or lower taxonomic classification where applicable.

⁶⁹ ***CY, DK, IE, PT, UK:*** 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. ***NL:*** Various establishments for aquaculture - these still need to be further looked at. ***COM:*** For closed systems relevant points in Annex I are: B.1, B.8, D.1, E.4, G.1.b, G.1.e, G.2 & H.

⁷⁰ ***CZ, DE, DK, EL, IT, NL, SI:*** To be simplified, adequate and appropriate information, not an academic exercise. Where possible, pre-filled forms for most common species. ***FI:*** Application should focus on the technical aspect of movements. Advisory Committee or competent authority to draw up scientific impact analysis. ***PT:*** With a view to accelerate the procedure and ensure qualitative information, these requirements to be reconsidered. The applicant will not have all the information at the time of submitting application. Proposes "Executive Summary" for application (cf. ***PT:*** Proposal in doc. 9057/06 ADD 13). ***IT:*** Procedures established in Annex I and II seem to imply considerable costs. ***FR:*** Little or no information is available on exotic species and new species to fish farming, even to the scientific community, and it difficult to predict how species will adapt to a new environment. ***COM:*** The items in this list are a menu to choose from. Expertise does exist at public and private levels in the Community.

- 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?
 - 6) What is the geographic area of the proposed introduction? Describe the habitats, ecosystem and protection status of the receiving environment. Include a map.
 - 7) Describe the numbers of organisms it is proposed 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) Does the stock from which the introduction/translocation will be made have a link with any known non-target species?
 - 3) What is the distribution of such non-target species within the area of origin of the stock to be introduced/translocated?
 - 4) Record where the species was introduced previously and describe the ecological effects on the environment of the receiving area (predator, prey, competitor, and/or structural/functional elements of the habitat).
 - 5) What factors limit the species in its native range.
 - 6) Describe the physiological tolerances (water quality, temperature, oxygen, and salinity) at each life history stage (early life-history stages, adult and reproductive stages).
 - 7) Describe the habitat preferences and tolerances for each life-history stage.
 - 8) Describe the reproductive biology.
 - 9) Describe the migratory behaviour.
 - 10) Describe the food preferences for each life-history stage.
 - 11) Describe the growth rate and lifespan (also in the area of the proposed introduction, if known).

12) [Describe the known pathogens and parasites of the species or stock⁷¹.]

13) Describe the behavioural traits (social, territorial, aggressive).

D) Interaction with native species

- 1) What is the potential for survival and establishment of the introduced organism if it escapes? (This question applies to movements into open and closed aquaculture facilities.)
- 2) What habitat(s) will the introduced species be likely to occupy in the proposed area of introduction and will this overlap with any vulnerable, threatened or endangered species? (Indicate if the proposed area of introduction also includes contiguous waters.)
- 3) With which native species will there be a niche overlap? Are there any unused ecological resources of which the species would take advantage?
- 4) What will the introduced organism eat in the receiving environment?
- 5) Will this predation cause any adverse impacts on the receiving ecosystem?
- 6) Will the introduced organisms survive and successfully reproduce in the proposed area of introduction or will annual stocking be required? (This question applies to species not intended for closed aquaculture facilities.)
- 7) Will the introduced organisms 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.

⁷¹ ***DK:*** 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. ***COM:*** See footnote 21

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

F) Monitoring

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

G) Management plan

- 1) Describe the management plan for the proposed introduction. This should include but not be restricted to the following information:
 - (a) measures taken to ensure that no other species (non-target species) accompany the shipment;
 - (b) who will be permitted to use the proposed organisms and under what terms and conditions;
 - (c) will there be a pre-commercial phase for the proposed introduction?
 - (d) description of the contingency plan for the removal of species;
 - (e) description of the quality assurance plan for the proposal, and,
 - (f) other legislative requirements that need to be met.
- 2) Describe the chemical, biophysical and management measures being taken to prevent accidental escape of the organism and non-target species, to and their establishment in, non-target recipient ecosystems. Give details of the water source, effluent destination, any effluent treatment, proximity to storm sewers, predator control, site security and measures to prevent escapes, if necessary.
- 3) Describe contingency plans 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 as foreseen under Article 9⁷²

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”.

⁷² ***DK: "While recognising the precautionary principle, DK is highly concerned as to the potential extent of the work implied by environmental risk assessments as prescribed by Article 9 and Annex II." COM: MS can require applicant to do all the work.***

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⁾
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). The 'harmfulness' of a establishment and spreading should be taken into account, together with risk/benefit ration, in arriving at the final 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 the following risk levels:

A high-risk movement:

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

A medium-risk movement:

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

A low-risk movement:

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

The proposal can only be approved as presented (no mitigating measures required) if the overall estimated risk potential is Low and if the overall certainty for which the overall risk has been estimated is Very Certain or Reasonably Certain.

If, as a result of a first analysis, a High or Medium category is attributed to the overall risk, then containment or mitigation proposals are to be incorporated in the application, which will be subject to subsequent risk analysis until the final rating for the overall risk becomes Low with a Very Certain or Reasonably Certain assessment. Descriptions of these additional steps, together with detailed specifications of the containment or mitigation measures, will become an integral part of the Risk Assessment.

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 of 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 consumption⁷³.

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

⁷³ OJ L 273, 10.10.2002, p. 1.

- samples submitted to experts to test for non-target species;
- any abnormal conditions affecting quarantine operation (power cuts, building damage, serious weather conditions, etc.).

Disinfection

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

Annex IV

List of species foreseen by Article 2.5⁷⁴

Rainbow trout, *Oncorhynchus mykiss*

Brook trout, *Salvelinus fontinalis*

Common Carp, *Cyprinus carpio*

Grass Carp, *Ctenopharyntgodon idella*

Silver Carp, *Hypophthalmichthys molitrix*

Big head carp, *Aristichtys nobilis*

Pacific cupped oyster, *Crassostrea gigas*

Japanese or Manila clam, *Ruditapes philippinarum*

Large-mouth bass, *Micropterus salmoides*

Arctic char, *Salvelinus alpinus*

⁷⁴ ***CY, DE:*** Member States should be able to decide on this list for their own territory. ***CY:*** Listing species in doc. 14915/06 ADD 2. ***DE:*** Salmon should be excluded. Add at least fish species indicated in doc. 14915/06 ADD9. "Member States may restrict the use of a species in their territory." ***CZ:*** Add species as indicated in written comments (doc. 14915/06 ADD5 PECHE 338). ***PL:*** Add sturgeon. Reserve on Annex IV. ***AT:*** Add species indicated in written comments (doc. 14915/06 ADD6 PECHE 338). Supports addition of species requested by CZ and PL. Koi Carps are not to be put on the list of Annex IV, if they are kept together with Common Carps and are thus not considered to be ornamental aquatic animals according to Article 2.5. Scrutiny reserve on whole Annex IV. ***ES:*** Add two species: *peneus japonicus* and *argusumus redus*. ***NL:*** Need more consistency on criteria for Annex IV. ***IT, UK:*** Add: Goldfish - *Carassius auratus*. ***COM:*** Member States may restrict the use of a species in their territory. Proposes comitology procedure. ***DE, EL:*** Reserve on that procedure.