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COUNCIL REGULATION (EC) No 708/2007

of 11 June 2007

concerning use of alien and locally absent species in aquaculture

(OJ L 168, 28.6.2007, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 506/2008 of 6 June 2008	L 149	36	7.6.2008
►**M2**	Regulation (EU) No 304/2011 of the European Parliament and of the Council of 9 March 2011	L 88	1	4.4.2011
►**M3**	Commission Delegated Regulation (EU) 2022/516 of 26 October 2021	L 104	51	1.4.2022

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COUNCIL REGULATION (EC) No 708/2007

of 11 June 2007

concerning use of alien and locally absent species in aquaculture

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 2

Scope

1. This Regulation shall apply to the introduction of alien species and translocation of locally absent species for their use in aquaculture in the ►M2 Union ◄ taking place after the date this Regulation becomes applicable by virtue of Article 25(1).

2. This Regulation shall not apply to translocations of locally absent species within Member States, except for cases where, on the basis of scientific advice, there are grounds for foreseeing environmental threats due to the translocation. In the case that an advisory committee has been appointed under Article 5 it will be responsible for assessing the risks.

3. This Regulation shall cover all aquaculture 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 medium.

4. This Regulation shall not apply to the keeping of ornamental aquatic animals or plants in pet-shops, garden centres, contained garden ponds or aquaria which comply with Article 6 of Commission Decision 2006/656/EC of 20 September 2006 laying down the animal health conditions and certification requirements for imports of fish for ornamental purpose ([1]) or in facilities which are equipped with effluent treatment systems which fulfil the aims set out in Article 1.

►M2 5. This Regulation, except for Article 3, Article 4(1) and Article 4(2)(a), shall not apply to the species listed in Annex IV. ◄ The risk assessment in Article 9 shall not apply to species listed in Annex IV except in cases where Member States wish to take measures to restrict the use of the species concerned in their territory.

([1]) OJ L 271, 30.9.2006, p. 71.

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6. Movements of alien or locally absent species to be held in closed aquaculture facilities shall not be subject to prior environmental risk assessment except in cases where Member States wish to take appropriate measures.

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7. Chapters III to VI shall not apply to movements of alien or locally absent species to be held in closed aquaculture facilities, provided that the transport is carried out under conditions that prevent the escape of those species and of the non-target species.

Member States shall draw up a list of closed aquaculture facilities in their territory that comply with the definition in Article 3(3) and update that list regularly. By 25 October 2011, the list shall be published on the website set up in accordance with Article 4(2) of Commission Regulation (EC) No 535/2008 ([1]) which lays down detailed rules for the implementation of this Regulation.

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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 Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund ([2]);

2. ‘open aquaculture facility’ 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;

▼M2

3. ‘Closed aquaculture facility’ means a land-based facility:

   (a) where:

      (i) aquaculture is conducted in an aquatic medium which involves recirculation of water; and

      (ii) discharges do not connect in any way to open waters before screening and filtering or percolation and treatment to prevent the release of solid waste into the aquatic environment and the escape from the facility of farmed species and non-target species that might survive and subsequently reproduce;

   (b) and which:

      (i) prevents losses of reared specimens or non-target species and other biological material, including pathogens, due to factors such as predators (e.g. birds) and flooding (e.g. the facility must be situated at a safe distance from open waters following a proper assessment made by the competent authorities);

([1]) OJ L 156, 14.6.2008, p. 6.
([2]) OJ L 223, 15.8.2006, p. 1.

▼M2

(ii) prevents, in a reasonable way, losses of reared specimens or non-target species and other biological material, including pathogens, due to theft and vandalism; and

(iii) ensures appropriate disposal of dead organisms;

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4. ‘aquatic organisms’ means any species living in water belonging to the animalia, plantae and protista kingdoms, including any part, gametes, seeds, eggs or propagules of their individuals that might survive and subsequently reproduce;

5. ‘Polyploid organisms’ means artificially induced tetraploid organisms (4N). These are aquatic organisms in which the number of chromosomes in the cells has been doubled through cell manipulation techniques;

6. ‘alien species’ means:

(a) a species or subspecies of an aquatic organism occurring outside its known natural range and the area of its natural dispersal potential;

(b) polyploid organisms, and fertile artificially hybridised species 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 likely to be detrimental to the aquatic environment that is moved accidentally together with an aquatic organism that is being introduced or translocated not including disease-causing organisms which are covered by Directive 2006/88/EC;

9. ‘movement’ means introduction and/or translocation;

10. ‘introduction’ means the process by which an alien species is intentionally moved to an environment outside its natural range for use in aquaculture;

11. ‘translocation’ means the process by which a locally absent species 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 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 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 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;

▼M2

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, does not give rise to adverse ecological effects;

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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.

CHAPTER II

GENERAL OBLIGATIONS OF THE MEMBER STATES

Article 4

Measures for avoiding adverse effects

►M2 1. ◄ 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.

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2. The competent authorities in the Member States shall monitor and supervise aquaculture activities so as to ensure that:

(a) closed aquaculture facilities comply with the requirements laid down in Article 3(3); and

(b) transport from or to closed aquaculture facilities takes place in conditions that are such as to prevent the escape of alien or non-target species.

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Article 5

Decision making and advisory bodies

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

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CHAPTER III

PERMITS

Article 6

Application for a permit

1. Aquaculture operators 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.

2. The applicant shall submit with the application a dossier following the indicative guidelines listed in Annex I. 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 the permit period an application for another permit may be submitted by referring to the former permit. If there have been no documented adverse effects on the environment, the proposed movement shall be considered a routine movement.

Article 7

Type of proposed movement

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

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 shall 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 the permit without further formalities.

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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 duly motivated on scientific grounds and, where scientific information is as yet insufficient, on the grounds of the precautionary principle.

Article 10

Decision period

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

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 neighbouring Member States

1. Where the potential or known environmental effects of a proposed movement of an organism are liable to affect 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 (EC) No 2371/2002 and the Advisory Committee for Fisheries and Aquaculture, established by Decision 1999/478/EC, confirm, reject 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.

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Article 12

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 occur. 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 and having due regard to national administrative rules.

CHAPTER IV

CONDITIONS FOR INTRODUCTION AFTER ISSUE OF A PERMIT

Article 13

Compliance with other ►M2 Union ◄ 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 Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals;

(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 ([1]).

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Article 14

Release into aquaculture facilities in the case of routine introductions

In the case of routine introductions, the release of aquatic organisms into aquaculture facilities shall be allowed without quarantine or pilot release, 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 shall be considered to be routine or non-routine movements in line with Articles 6 and 7.

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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 open 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 ►M2 Union ◄ in accordance with the conditions set out in Annex III, for the purpose of constituting a brood-stock.

([1]) OJ L 169, 10.7.2000, p. 1.

▼B

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. If appropriate, only progeny of the introduced aquatic organisms may be used in aquaculture facilities of the receiving Member State, provided that no potentially harmful non-target species are found during quarantine. Adult stock may be released in those cases where the organisms do not reproduce in captivity or are fully reproductively sterile, providing the absence of potentially harmful non target species is confirmed.

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 applicant shall 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.

Article 18

Monitoring

1. Alien species shall be monitored after their release into open aquaculture facilities 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.

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CHAPTER V

CONDITIONS FOR TRANSLOCATIONS AFTER ISSUE OF A PERMIT

Article 19

Compliance with other ►M2 Union ◄ 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/EC;

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

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 by 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.

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.

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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 ([1]).

To allow Member States to share the information contained in their registers, a specific information system may be developed in accordance with the procedure referred to in Article 30(2) of Regulation (EC) No 2371/2002.

CHAPTER VII

FINAL PROVISIONS

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Article 24

Amendments of Annexes and detailed rules

1. The Commission may, by means of delegated acts in accordance with Article 24a and subject to the conditions laid down in Articles 24b and 24c:

(a) amend Annexes I, II and III to this Regulation in order to adapt them to technical and scientific progress;

(b) adopt specifications for the conditions necessary for adding species to Annex IV, as provided for in paragraph 3; and

(c) add species to Annex IV where the conditions provided for in paragraph 3 and their further specifications are complied with.

2. When adopting delegated acts as referred to in paragraph 1, the Commission shall act in accordance with this Regulation.

3. In order for its species to be added to Annex IV, an aquatic organism must have been used in aquaculture in certain parts of the Union for a long time (with reference to its life cycle) with no adverse effect, and its introduction and translocation must be possible without the coincident movement of potentially harmful non-target species.

4. Member States may request the Commission to add species to Annex IV. Member States may provide scientific data to prove coherence with relevant criteria for adding species to Annex IV. The Commission shall decide on the suitability of a request within 5 months of its receipt, excluding the time for the Member State to provide additional information if the Commission so requests.

5. Member States concerned may, in respect of their outermost regions as referred to in Article 349 of the Treaty on the Functioning of the European Union, propose the addition of species to be included in a separate part of Annex IV.

([1]) OJ L 41, 14.2.2003, p. 26.

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6. The Commission may adopt detailed rules for the implementation of paragraphs 4 and 5, and in particular the formats, the contents and the particulars of Member States' requests for the addition of species and the information to be provided in support of such requests, in accordance with the procedure referred to in Article 30(2) of Regulation (EC) No 2371/2002.

Article 24a

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 24 shall be conferred on the Commission for a period of 5 years from 24 April 2011. The Commission shall make a report in respect of the delegated power at the latest 6 months before the end of the 5-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 24b.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 24b and 24c.

Article 24b

Revocation of the delegation

1. The delegation of power referred to in Article 24 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 24c

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council, that period shall be extended by 2 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

▼M2

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If either the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

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Article 25

Entry into force

1. This Regulation shall enter into force 20 days following its publication in the *Official Journal of the European Union*.

It shall apply six months after a Commission's Regulation on implementing rules referred to in Article 24(3) enters into force, but not later than 1 January 2009.

2. However, the provisions contained in Chapter I and Chapter II as well as Article 24, shall be applicable as from the date of entry into force of the Regulation.

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

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ANNEX I

APPLICATION

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

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Wherever possible, information is to be supported with references from the scientific literature, and notations to personal communications with scientific authorities and fisheries experts.

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

A. **Executive summary**

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

B. **Introduction**

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

(2) Describe the characteristics, including distinguishing characteristics, of the organism. Include a scientific drawing or photograph.

(3) Describe the history in aquaculture, enhancement or other introductions (if appropriate).

(4) Describe the objectives and rationale for the proposed introduction, including an explanation as to why such an objective cannot be met through the utilisation of an indigenous species.

(5) What alternate strategies have been considered in order to meet the objectives of the proposal?

(6) What is the geographic area of the proposed introduction? Describe the habitats, ecosystem and protection status of the receiving environment. Include a map.

(7) Describe the numbers of organisms it is proposed to introduce (initially, ultimately). Can the project be broken down into different subcomponents? If so, how many organisms are involved in each subcomponent?

(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.

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

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

(8) Describe the reproductive biology.

(9) Describe the migratory behaviour.

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

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

(12) What is the age or age-range of the species concerned?

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

D. **Interaction with native species**

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(1) What is the potential for survival and establishment of the introduced organism if it escapes?

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(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?

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(6) Will the introduced organisms survive and successfully reproduce in the proposed area of introduction or will annual stocking be required?

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(7) Will the introduced organisms hybridise with native species? Is local extinction of any native species or stocks possible as a result of the proposed introduction? Are there any possible effects of the introduced organisms on the spawning behaviour and spawning grounds of local species?

(8) Are there any potential impacts on habitat or water quality as a result of the proposed introduction?

E. **Receiving environment and contiguous waters**

(1) Provide physical information on the receiving environment and contiguous waterbodies such as seasonal water temperatures, salinity, and turbidity, dissolved oxygen, pH, nutrients and metals. Do those parameters match the tolerances/preferences of the species to be introduced, including conditions needed for reproduction?

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(2) List species composition (major aquatic vertebrates, invertebrates and plants) of the receiving waters.

(3) Provide information on habitat in the area of introduction, including contiguous waters, and identify critical habitat. Which of those parameters match the tolerances/preferences of the organisms to be introduced? Can the introduced organisms disturb any of the habitats described?

(4) Describe the natural or man-made barriers that should prevent the movement of the introduced organisms to adjacent waters.

F. **Monitoring**

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

G. **Management plan**

(1) Describe the management plan for the proposed introduction. This should include, but not be restricted to, the following information:

(a) measures taken to ensure that no other species (non-target species) accompany the shipment;

(b) who will be permitted to use the proposed organisms and under what terms and conditions;

(c) will there be a pre-commercial phase for the proposed introduction?

(d) description of the contingency plan for the removal of species;

(e) description of the quality assurance plan for the proposal, and,

(f) other legislative requirements that need to be met.

(2) Describe the chemical, biophysical and management measures being taken to prevent accidental escape of the organism and non-target species, to and their establishment in, non-target recipient ecosystems. Give details of the water source, effluent destination, any effluent treatment, proximity to storm sewers, predator control, site security and measures to prevent escapes, if necessary.

(3) Describe contingency plans in the event of an unintentional, accidental or unauthorised liberation of the organisms from rearing and hatchery facilities or an accidental or unexpected expansion of the range of colonisation after release.

(4) If this proposal is intended to create a fishery, give details of the fishery objective. Who would benefit from such a fishery? Give details of the management plan and, if appropriate, include changes in the management plans for species which will be impacted.

H. **Business data**

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

(2) Provide an indication as to the economic viability of the proposed project.

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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.

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ANNEX II

PROCEDURES AND MINIMUM ELEMENTS TO BE ADDRESSED IN AN ENVIRONMENTAL RISK ASSESSMENT AS FORESEEN UNDER ARTICLE 9

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

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

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

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

PART 1

ECOLOGICAL AND GENETIC RISK ASSESSMENT PROCESS

Step 1

Likelihood of establishment and spreading beyond the intended area of introduction

Event	Likelihood (H, M, L) ([1])	Certainty (VC, RC, RU, VU) ([2])	Comments in support of assessment ([3])
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 ([4])			

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

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

([3]) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

([4]) The final rating for the likelihood of establishment and spreading is assigned the value of the element with the lowest rating (for example, high and low ratings for the above elements would result in a final low rating). Again, both events — probability of the organism successfully colonising and maintaining a population in the intended area of introduction (be it a confined environment such as a facility, or a natural habitat) and the probability of spreading beyond the intended area of introduction (estimated as explained above) — need to occur in order to have establishment beyond the intended area of introduction.

The final rating for the level of Certainty is assigned the value of the element with the lowest level of certainty (e.g. very certain and reasonably certain ratings would result in a final reasonably certain rating). The harmfulness of a establishment and spreading should be taken into account, together with risk/benefit ration, in arriving at the final rating.

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Step 2

Consequences of establishment and spreading

Event	Likelihood (H, M, L)	Certainty (VC, RC, RU, VU)	Comments in support of assessment (1)
Genetic mixing with local populations leads to a loss of genetic diversity.			
Competition (food, space) with or predation on native populations leads to their extirpation.			
Other undesirable events of ecological nature			
Some of the abovementioned events persist even after removal of the introduced species.			
Final rating (2)			

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

(2) 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.

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

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

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

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

A high-risk movement:

(a) has a high risk of damaging biodiversity from spreading and other ecological consequences;

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(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.

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PART 2

NON-TARGET SPECIES ASSESSMENT PROCESS

Step 1

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

Event	Likelihood (H, M, L)	Certainty (VC, RC, RU, VU)	Comments in support of assessment (1)
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 (2)			

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

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

Step 2

Consequences of non-target species establishment and spreading

Event	Likelihood (H, M, L)	Certainty (VC, RC, RU, VU)	Comments in support of assessment (1)
The non-target species compete with or predate on native populations, leading to their extirpation.			
Genetic mixing of the non-target species with local populations leads to a loss of genetic diversity.			
Other undesirable events of ecological or pathological nature			
Some of the abovementioned events persist even after removal of the non-target species.			
Final rating (2)			

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

(2) 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.

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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 ([1])
Establishment and spreading (step 1)			
Ecological consequences (step 2)			
Final rating ([2])			

([1]) The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

([2]) The final rating under risk potential is assigned the value of the element with the lowest risk rating and the final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

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

PART 3

OVERALL ENVIRONMENTAL RISK ASSESSMENT — SUMMARY REPORT

— History, background and rationale for the request:

  — risk assessment summary information

  — summary of the ecological and genetic risk assessment

  — summary of the non-target species risk assessment

— Comments:

— Mitigation measures:

— Concluding statement on total organism potential risk:

— Advice to competent authority:

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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.

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Mortalities and disposal

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

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

Inspection and testing

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

Duration

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

Record keeping

Quarantine facilities must maintain accurate records of the following:

— entry/exit times of personnel,

— number of mortalities and method of storage or disposal,

— treatment of incoming water and of effluent,

— samples submitted to experts to test for non-target species,

— any abnormal conditions affecting quarantine operation (power cuts, building damage, serious weather conditions, etc.).

Disinfection

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

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

▼M1

ANNEX IV

List of species foreseen by Article 2(5) [1]

PART A — General

Acipenser baeri [2], Siberian sturgeon

►M3 *Acipenser gueldenstaedtii* ◄ [2], Russian sturgeon

A. nudiventris [2], Fringebarbel sturgeon

A. ruthenus [2], Sterlet sturgeon

A. stellatus [2], Starry sturgeon

A. sturio [2], Atlantic sturgeon

►M3 *Hypophthalmichthys nobilis* ◄, Big head carp

Carassius auratus, Goldfish

Clarias gariepinus, African catfish

Coregonus peled, Northern Whitefish

Crassostrea gigas, Pacific cupped oyster

Ctenopharyngodon idella, Grass carp

Cyprinus carpio, Common carp

Huso huso [2], Beluga sturgeon

Hypophthalmichthys molitrix, Silver carp

Ictalurus punctatus, Channel catfish

Micropterus salmoides, Large-mouth bass

Oncorhynchus mykiss, Rainbow trout

▼M3

Pagrus major, Red seabream, also known as Japanese seabream;

▼M1

Ruditapes philippinarum, Japanese or Manila clam

Salvelinus alpinus, Arctic char

Salvelinus fontinalis, Brook trout

Salvelinus namaycush, Great lake trout

Sander lucioperca, Pikeperch

Silurus glanis, European catfish

PART B — French overseas departments

Macrobrachium rosenbergii, Giant river prawn

Oreochromis mossambicus, Mozambique tilapia

O. niloticus, Nile tilapia

Sciaenops ocellatus, Red drum

[1] ►M3 Hybrids of species included in this Annex should not be considered as part of this list. ◄

[2] Hybrids of sturgeon species.