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 Community taking place after the date this Regulation becomes applicable by virtue of Article 25(1).
- 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.
- 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.
- 5 This Regulation, except for Articles 3 and 4, 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.
- 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.
- 7 Introductions and translocations for use in 'closed aquaculture facilities' may at a future date be exempted from the permit requirement of Chapter III, based on new scientific

information and advice. Advances in the scientific understanding of bio security of modern closed systems are expected inter alia from Community-funded research on alien species. The relative decision will be taken not later than 31 March 2009 following the procedure described under Article 24.

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;
- 3. 'closed aquaculture facility' means a facility where aquaculture is conducted in an aquatic medium, which involves recirculation of water and which is 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 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 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 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;
- 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, for example closed systems as defined in 3, 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.

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 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.

CHAPTER III

PERMITS

Article 6

Application for a permit

- 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.
- 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

- 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.
- 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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- 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

- 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.
- Within two months of the date of notification, the other Member States concerned may submit written comments to the Commission.
- 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.
- Within 30 days of the date of the Commission's decision, the Member States concerned may refer that decision to the Council. Within a further 30 day period, the Council, acting by qualified majority, may take a different decision.

Article 12

Withdrawal of permit

At any point in time, the Competent Authority can withdraw the permit, 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 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 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⁽³⁾.

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 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 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 open aquaculture facilities shall be subject, if necessary, to the conditions set out in paragraphs 2, 3 and 4.
- 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.

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- 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.
- 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 nontarget 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

- 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.
- The advisory committee shall evaluate the results of the monitoring programme and note in particular any event not correctly anticipated in the environmental risk assessment. The results of that evaluation shall be sent to the competent authority which shall include a summary of the results in the national register established under Article 23.

CHAPTER V

CONDITIONS FOR TRANSLOCATIONS AFTER ISSUE OF A PERMIT

Article 19

Compliance with other Community provisions

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.

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CHAPTER VI

REGISTER

Article 23

Register

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

The register shall be made 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⁽⁴⁾.

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

Article 24

Detailed rules and adaptation to technical progress

- Amendments to Annexes I, II, III and IV and their corresponding provisions 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.
- In order for species to be added to Annex IV, the aquatic organism must have been used in aquaculture for a long time (with reference to its life cycle) in certain parts of the Community with no adverse effects, and introductions and translocations must be able to take place without the coincident movement of potentially harmful non target species.
- 3 The Commission shall adopt, in accordance with the procedure referred to in Article 30(2) of Regulation (EC) No 2371/2002, the rules implementing the conditions necessary for adding species to Annex IV, as referred in paragraph 2.
- After the adoption by the Commission of the implementing rules mentioned in paragraph 3, Member States may request the Commission to add species to Annex IV making use of the procedure mentioned in paragraph 1. Member States may provide scientific data to prove coherence with relevant criteria for adding species to Annex IV. The Commission shall decide within five months following receipt of the requests on their suitability excluding time when the Member State provides additional information if the Commission so requests.
- 5 However, Member States' requests to add species to Annex IV received before the date of entry into force of the Regulation, shall be decided before 1 January 2009.

6 Member States concerned may propose in respect of their outermost regions, as referred to in Article 299(2) of the Treaty establishing the European Community, the addition of species to be included in a separate part of Annex IV.

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.

Done at Luxembourg, 11 June 2007.

For the Council

The President

H. SEEHOFFER

- (1) OJ L 271, 30.9.2006, p. 71.
- (2) OJ L 223, 15.8.2006, p. 1.
- (**3**) OJ L 169, 10.7.2000, p. 1.
- (**4**) OJ L 41, 14.2.2003, p. 26.