COMMISSION OF THE EUROPEAN COMMUNITIES



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COMMISSION STAFF WORKING DOCUMENT

Annex to the

Proposal for a Council Regulation on the use of alien and locally absent species in aquaculture

IMPACT ASSESSMENT

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1. PROBLEM IDENTIFICATION

The introduction of alien species causes problems in many fields including that of aquaculture. Invasive alien species are identified as one of the key causes of biodiversity loss for the EU and the world at large. Alien species can have significant economic and social impacts which could undermine the achievement of the EU's sustainable development objectives.

The 'Second Report' of the European Community to the Convention on Biological Diversity - Thematic report on alien invasive species, October 2002, is a valuable information resource. The report can be consulted at:

http://biodiversity-chm.eea.eu.int/convention/cbd ec/F1036489359/F1036491559

It lists aquaculture (fish molluscs and crustaceans introduced for production, disease organisms accompanying introduced species) as one of 15 pathways for unintentional and intentional introductions. Among the problems listed are the spread of *Bonamia* in oysters and concerns about two Japanese seaweeds. The spread of *Bonamia* and other parasites and pathogens is already covered by the Community legislation in the field of animal health. One of the two seaweeds mentioned above, *Sargassum muticum*, was introduced to Europe through oyster transplantation and can clog coastal waterways. The second, *Undaria*, was deliberately introduced into France and was recently found in the UK; it has the potential to displace native species and is spreading vigorously. While these examples relate to seawater, there are also potential problems from alien species linked to aquaculture and restocking in fresh water.

Polyploid organisms (with multiple sets of chromosomes) are not included in the customary definition of alien species. However as (a) there is little information on the genetic, ecological and other effects of their movement and release into the natural environment, such as mixing of altered and wild populations of the same species, and (b) they may have a negative impact on the environment since their sterility is not always guaranteed, it was decided to include them in the proposal for a regulation.

Section 3 of the 'Second Report' reviews the 'EU legal and administrative measures relevant to invasive alien species'. The report states that 'the Community does not currently have a horizontal programme or instrument on alien species' but describes, among others, legislation on animal and fish diseases, 'Ecological threat' species (CITES) and introductions damaging to habitats and wild species (Habitats Directive).

In addition to the problem of alien species in aquaculture there is the separate issue of risk to aquaculture from alien species introductions via other sources. The 'Second Report' states that modern aquaculture development in the coastal zone can be at risk of disease transfer from ballast water when the culture facilities are located near shipping routes, and that this risk is very real. This problem is not tackled by the present proposal; it is covered by the International Convention for the Control and Management of Ships' Ballast Water and Sediments adopted by the International Maritime Organisation in 2004. The Convention will enter into force 12 months after ratification by 30 States, representing 35 percent of world merchant shipping tonnage. The Commission services are currently reflecting on the means of ratifying the Convention at Community level. EU legislation to this end would only be

implemented at the time of the Convention's entry into force and it is not possible to predict when that will be.

2. OBJECTIVE OF THE PROPOSAL

The aim of the proposal is to introduce a permit system governing aquaculture practices that involve the introduction of alien species in the European Community and the translocation of species within their natural range to areas where they do not occur. The content of the application for the permit, which is obligatory for all movements to aquaculture facilities in the Community, is sufficiently comprehensive to allow an evaluation of whether the movement would be routine or non-routine. It also provides sufficient criteria for a decision to be made at Member State level on whether an environmental risk assessment (ERA) is required. The screening is carried out by an advisory committee with scientific expertise which is established by the competent authority in the receiving Member State to advise it. The process of setting up the advisory committee will involve the identification of appropriate biological and ecological expertise in Member States concerned; this in itself can be seen as a desirable impact.

The advisory committee will in turn evaluate completed ERAs and advise the competent authority (CA) on whether or not a permit should or should be granted. In line with the EU policy to separate risk assessment from risk management, the final decision is taken by the risk manager (CA). Problems in this area relate to the aquatic environment and there are significant trans-boundary aspects, and risks of a problem becoming widespread in certain cases. If other Member States are liable to be affected by a movement, the Community procedure will apply. The Commission in such cases is required to confirm, cancel or amend the proposed decision to grant a permit within six months from the date of the notification after having consulted the Scientific, Technical and Economic Committee for Fisheries (STECF) established under Article 33 of Regulation 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy and the Advisory Committee for Fisheries and Aquaculture created by Commission Decision 71/128/EEC.

The time frame for taking a decision at Member State level must be not more than one year (a further six months can be added in the case of a referral for review to ICES (International Council for the Exploration of the Sea) and a strict six-month deadline is set for the Community procedure. The proposal draws heavily on the existing voluntary ICES and EIFAC (European Inland Fisheries Advisory Commission) Codes, as it is felt on the basis that the Community should learn from the experience of these bodies.

3. POLICY OPTIONS AND RANGE OF ALTERNATIVES CONSIDERED

3.1. Use of existing nature conservation legislation

The feasibility of making use of the Habitats' Directive was examined in particular. Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora makes it mandatory to assess plans and projects likely to have a significant effect on a Special Area of Conservation (SAC) established under its terms, whether individually or in combination with other plans or projects. This

requirement should be applied to activities that involve the release, translocation or contained use of introduced species in the vicinity of SACs.

While the Birds' and Habitats' Directives are not limited to impacts on protected sites or species, it is left to Member States to decide how to implement the relevant provisions (as regards species coverage, assessment and permit systems, monitoring etc.). The definitions used (for example, the definition of "territory") do not correspond to the ecological approach used under the Convention on Biological Diversity and they do not cater for situations where species native to one area may be invasive elsewhere in the same country, if translocated beyond their natural range.

The vast majority of fish and shellfish are not listed in Annex II of the Habitats' Directive and it is questionable whether it extends to species which are not wild (the situation in aquaculture ranges from semi-wild, such as clam cultivation, to contained installations such as land-based salmonid farming).

In conclusion, it does not appear that the existing Habitats and Birds Directives could be used to achieve the required goals, which means that new legislation is needed. For this new instrument two broad policy options were considered, which are outlined in 3.2 and 3.3 below.

3.2. Comprehensive joint instrument on alien species to cover all possible sources of environmental threat

To avoid proliferation of legislation on closely related subjects, the possibility of bringing all issues relating to alien species under one instrument was examined at two inter-service meetings (on 6/2/2004 and 8/7/2004). Despite the desirability of coordinating efforts on the alien species front, no immediate solution was forthcoming. As the environmental threats are very varied in nature, and especially in the kind of sectoral industrial activity which may be the source of such threats, extensive consultation and preparation will be necessary in order to be able to deal comprehensively with this issue. Formal contacts between the Commission services led to the conclusion that it was preferable to proceed with a proposal in the field of aquaculture, as the sector is expanding rapidly and as there are solutions, based on current experience, to anticipate and remedy any negative environmental consequences

Since reliance on the Habitat Directive had been ruled out, the next question to address was whether legislation on alien species in aquaculture could be dovetailed with the implementation of the IMO (International Maritime Organization) Ballast Water Convention. This new international IMO Convention to prevent the spread of harmful aquatic organisms carried by ships' ballast water, adopted in February 2004, has no overlap with the draft proposal. The main tenet of the Convention is that ballast water is to be exchanged in offshore waters over 200 metres deep (whenever possible over 200 nautical miles from land, but at least 50 miles). The change-of-water requirement is obligatory when the concentration of biota in the ballast water exceeds a given threshold. The Convention is to enter into force 12 months after ratification by 30 states, representing 35 percent of world merchant shipping tonnage. The Energy and Transport DG and the Environment DG have informed the Member States about this Convention and plan to implement it in EU law at the same time as it enters into force generally. The Community cannot determine when that time will

be, and for this reason the alien species in aquaculture proposal cannot readily be integrated with the ballast water legislation.

3.3. Going it alone

Owing to the uncertainly about timing of the implementation of the Ballast Water Convention and to the fact that there was no specific initiative ongoing in this area in the short term, it was decided that a proposal for a Council Regulation in the context of the CFP was required in order to meet the policy objectives. Within this policy the following three sub-options were considered:

- **Light legislation**. Adoption of legislation which would simply oblige Member States to abide by the **ICES and EIFAC Codes** on introductions The issue of how non-ICES members would participate in the ICES decision making process would have to be resolved. Member States would be required to report on implementation every five years.
- Stronger legislation. Adoption of the essential elements of the ICES and EIFAC codes as a new EU Code for Introductions and Translocations in aquaculture, with very detailed provisions for the marine environment and more general rules for freshwater, plus provision for decentralised decision making linked to an application system similar to the current procedures for notification of technical regulations under Directive 98/34 laying down a procedure for the provision of information in the field of technical standards and regulations. When a proposed movement is liable to affect other Member States, the Member State dealing with the permit application would notify a proposed introduction and decision to the Commission and other Member States. The matter would be referred for an opinion to a working group established under STECF, which would assist the Commission with risk assessment prior to the Commission deciding to confirm, cancel or amend it.
- Very strong legislation. Adoption of the ICES and EIFAC codes as above to include detailed regional or site-specific and species-type requirements with centralised decision making under the control of the Commission. A full Environmental Impact Assessment would be required for the introduction of a non-indigenous species. Member States would be required to report annually on developments regarding introduced species. Translocations would be permitted within the same biogeographical zone to be determined with the assistance of EU environment experts. A permit mechanism would be devised for transfers beyond such zones. Introductions could only take place via EU-approved quarantine facilities located in isolated areas. A list of non-native species would be drawn up to help in implementing the legislation.

3.4. Choice of policy option taking account of proportionality and subsidiarity

One of the strong messages taken from the December 2003 Consultation meeting was the need for proportionality and the need to ensure that the new legislation will be embraced by industry and not regarded as just another unworkable legislative burden. This, together with the additional permanent workload that option (3) above would entail for the Commission services, makes option (3) less attractive. The subsidiarity principle does not apply in this case, since aquaculture falls within the

CFP - a policy where the Community has exclusive competence. However, in order to cope with regional differences, which can be technically difficult to deal with at EC level, Member States are given responsibility for taking decisions on permits.. The requirements for translocations are not as onerous as those for introductions of alien species, and the overall screening to establish whether the movement is routine or not is left to the Member States, as is the initial decision on whether a permit should be granted for non-routine movements which do not affect other Member States.

4. IMPACTS – POSITIVE AND NEGATIVE

The main positive impact expected is a more sustainable European aquaculture sector in which the introduction and translocation of alien species will not cause wanton damage to biodiversity.

On the negative side, a high proportion of aquaculture farms will be affected by this regulation, since nowadays most of them use alien species (rainbow trout, Pacific oyster, carp) and introduce these regularly. However, it is felt that these introductions will in most cases be considered as routine movements, which will greatly simplify the procedure. In the case of non-routine movements, a considerable amount of work will be required in the risk analysis process at Member State level and, in the event that a movement would be likely to affect other Member States, work would need to be done in a short period of time as part of the Community procedure. Industry has objected that they will be obliged to pay for the process and that movements of alien species will come to a standstill as a result. As it is not the aim of the measure to bring such movements to an absolute halt, the proposal gives Member States discretionary power to decide about the allocation of the costs which would normally be met by industry. (Article 4(6)). Moreover, operators can form associations to share the costs of obtaining the information required both for drawing up the application and, where applicable, for the risk analysis. The proposal also provides for the issuing of permits for successive movements within a period of up to five years, which will also simplify costs and procedures. The maximum cost of drawing up the application and the risk assessment is estimated at €10,000 based on the retention of consultants for one month. (in response to RTDs request)

5. MONITORING AND EVALUATION OF THE RESULTS AND IMPACTS OF THE PROPOSAL FOLLOWING IMPLEMENTATION

The proposal contains a requirement under Article 22 for Member States to keep a register of introductions and translocations in aquaculture and the documentation gathered in the process. Under Article 17 alien species must be monitored for a period of not less than two years following release into the environment. This monitoring will allow the implementation of the policy to be monitored. Analysis of these results would also facilitate ex-post evaluation of the policy.

6. STAKEHOLDER CONSULTATION

Formal consultations were held with an expert group of 46 persons representing Member States (15 government experts from EU15 and seven from EU10); EEA-EFTA (three

government experts), industry (six nominated by the Aquaculture Working Group of the Advisory Committee for Fisheries and Aquaculture), NGOs (two persons from the UK and one from the Netherlands) and ICES (five person with experience of the Working Group on Introductions and Transfers), EIFAC (one expert), NASCO (one form head office and one from the industry liaison group) together with four additional private sector experts (more detail given on experts as requested by SG). A one-day meeting held in Brussels in December 2003 considered a previously circulated discussion paper, and written comments were obtained on the draft legislation during 2004. The proposal was presented and discussed on three occasions in 2004/5 in the Aquaculture Working Group of the Advisory Committee for Fisheries and Aquaculture.

The initial proposal was that measures for containment of farmed salmon should be incorporated in the proposal. In view of the response to the consultation it was decided not to deal with containment in the current proposal. Consultees other than NGOs, and especially the representatives of the aquaculture industry, advised against an over-centralised and heavy-handed approach, and so the proposal was modified to acknowledge the competence of Member States in this field. On the other hand, there was a call for harmonised guidelines for the application, risk assessment and quarantine, and these have been provided so as to allow even application of the legislation across the Member States.

7. COMMISSION DRAFT PROPOSAL AND RATIONALE

The final policy is along the lines of strong legislation as advocated in section 3.3(2) rather than following the options described under 3.3(1) or 3.3(3) above for introductions and translocations. The same provisions apply for marine as for freshwater movements, but more rigorous requirements are to be applied to introductions from outside the natural range than to translocations within it. Much of the decision-making is decentralised to Member State level as outlined in section 3.4. Despite the desirability of joining forces with other Commission departments to develop a single regulation covering all related aspects of the alien species issue in the interest of better regulation, this was not possible for the reasons stated above (unsuitability of existing instruments, new instruments planned by other Commission departments but with a long time horizon).

The decision not to include the containment aspect was a trade-off which reflected the reluctance to introduce mandatory rules in an area for which voluntary guidelines exist, and at a time when these guidelines are being evaluated in the light of experience and scientific progress. On the principal issue of alien species it was felt that delaying action to wait for a better body of knowledge on this topic would be undesirable. Amendment of the annexes via comitology procedures will enable them to be updated in line with technical progress in this area of biology. There is sufficient evidence to show that the biodiversity of aquatic ecosystems will be threatened if there is no regulation in this area.