Title:	Impact Assessment (IA)
Impact Assessment on the Implementation of Council Regulation 708/2007 concerning the Use of Alien and Locally Absent Species in Aquaculture	**IA No:** Defra 1006
Lead department or agency: Defra	**Date: 01/10/2010**
Other departments or agencies:	**Stage:** Final
	Source of intervention: EU
	Type of measure: Secondary legislation
	Contact for enquiries: Barbara Franceschinis 0207 238 4394

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Alien species have been identified as one of the key causes of the loss of biodiversity in the EU and the world at large. Aquaculture is a fast growing, innovative industry across Europe, constantly looking for new outlets and markets. In order to adapt fully to market conditions and changes, the industry needs to be able to diversify and produce new species. Without regulation, there are insufficient incentives for the industry to take account of the potential environmental cost of the introduction of alien species. The Government is obliged to implement Council Regulation 708/2007, which introduces a framework that will ensure protection from the risks associated with the use of alien and locally absent species in aquaculture.

What are the policy objectives and the intended effects?

The main objective of this proposal is to enable the economic growth of the aquaculture industry, whilst limiting the potential threats to ecosystems posed by alien species. This would be achieved by assessing proposed introductions of novel alien species using science based risk analysis in advance in order to prevent interaction with indigenous species and damage to native ecosystems.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

Option 1 – 'Do Nothing';

Option 2 - Implementation of Council Regulation 708/2007 concerning the Use Of Alien and Locally Absent Species in Aquaculture.

Option 2 is the preferred option. This is a new EU Regulation, hence the Government along with all other Member States is obliged to implement it in its entirety.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 2015
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:..... Date:.....

Summary: Analysis and Evidence

Policy Option 2

Description: Implementation of Council Regulation 708/2007 concerning the Use of Alien and Locally Absent Species in Aquaculture

Price Base Year 2009	PV Base Year 2010	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: N/A**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£0.01		£0.153	**£0.724**

Description and scale of key monetised costs by 'main affected groups'

One-off costs to public bodies to set up the permit system (design of application forms/ setting up of a public register) £10.35k. Costs to public bodies for permit applications (both routine and non-routine) £23.07K on average per year. Costs to the industry for licence applications (both routine and non-routine, inclusive of quarantine facilities) £ 129.63K on average per year.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	-		-	**-**

Description and scale of key monetised benefits by 'main affected groups'

Alien species can be valuable to the aquaculture industry, but current interest in new species in the UK appears to be low. Once established, non-native species can be extremely costly to control. The costs of eradicating an invasive non-native species (e.g. £2.5 million per year on average for a national eradication programme for Topmouth gudgeon) best illustrate the dangers of inadequate controls and the benefits to be derived from having appropriate regulation.

Other key non-monetised benefits by 'main affected groups'

It is impossible to put a precise monetary value on native biodiversity or the loss of an indigenous species. Continued access to varied and disease free fisheries is vital to the three million practising anglers. Healthy fisheries are an important indicator of the good ecological status of rivers under the Water Framework Directive (WFD).

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

It is assumed that anyone starting up a new venture in aquaculture is to carry out a risk assessment analysis in advance if they intend to farm novel non-native species. We have assumed that the industry would be responsible for undertaking and financing the initial risk assessment, whilst the Government would fund the peer review of the risk assessment and the associated costs of the application. It was decided that this scheme would run for a five-year pilot period. Before the end of the pilot period we would conduct a review with a view to possibly introducing charges for permits to cover costs incurred by Government. Both the number of applications by industry and the need for quarantine facilities are uncertain.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB: 0.004	**AB savings:**	**Net:** 0.004	**Policy cost savings:**	No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England and Wales		
From what date will the policy be implemented?			01/10/2010		
Which organisation(s) will enforce the policy?			Cefas/PHSI		
What is the annual change in enforcement cost (£m)?			-		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** -	**Non-traded:** -	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** 0	**Benefits:** 0	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	24
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	21
Small firms Small Firms Impact Test guidance	No	22
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	24
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	24
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	24
Human rights Human Rights Impact Test guidance	No	24
Justice system Justice Impact Test guidance	No	24
Rural proofing Rural Proofing Impact Test guidance	No	24
Sustainable development Sustainable Development Impact Test guidance	No	24

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	
2	
3	
4	
5	
6	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	0.0103									
Annual recurring cost	0.1527	0.1527	0.1527	0.1527	0.1527					
Total annual costs	0.1630	0.1527	0.1527	0.1527	0.1527					
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

Summary of Approach

1. This Impact Assessment is for implementing Council Regulation 708/2007 on the use of alien and locally absent species in aquaculture. The Regulation introduces an EU framework that will ensure adequate protection for the aquatic environment from the risks associated with the use of alien and locally absent species in aquaculture. This would be achieved by assessing proposed introductions of novel alien species using science based risk analysis in advance of any proposed introduction, in order to prevent interaction with indigenous species and damage to native ecosystems. This approach is consistent with Government policy in relation to invasive non-native species, and the need to control the spread of non-native fish and other aquatic organisms.
2. We wish to maintain a 'light touch' and avoid additional administrative burden, where possible. However, the Government is obliged to implement this Regulation.
3. The Evidence Base contains the following sections:
    - Introduction
    - Aquaculture Sector and Scale of the Affected Industries
    - Existing Arrangements
    - Council Regulation 708/2007 on the Use of Alien and Locally Absent Species in Aquaculture
    - Risk Analysis Process
    - Policy Aim
    - Options considered
    - Costs and benefits
    - Competition Assessment
    - Small Business Assessment
    - Annexes

Introduction

4. It has long been recognised that the spread of non-native species can have far-reaching and undesirable ecological consequences for animal and plant communities in rivers and lakes. Introduced non-native species can have direct effects on native species, for example by predation, or can upset the natural balance that operates between native species. Non-native species can also introduce and spread novel diseases and parasites to which our native species may have little or no resistance. Private firms are unlikely to take these issues fully into account since they do not bear the full cost of any spread of non-native species. It is therefore vital that, if we intend to protect native species, their habitat, and conserve the unique diversity of animal and plant life in our rivers and stillwaters, that we are able to regulate introductions of non-native species and restrict their spread in the wild.
5. Invasive non-native species of fauna and flora are considered to be the second biggest threat to biodiversity worldwide after habitat loss and destruction[2]. Releasing such species into the wild or having inadequate measures to prevent their escape can be particularly serious given that the control or eradication of an invasive species, once established, is, at best, extremely difficult and costly, and in many cases unachievable. While not all introduced non-native species will become invasive, they can still have adverse impacts. Given this, and the fact that their precise impact can be unpredictable, a precautionary approach based on a risk-based system for the management and control of such species is deemed to be appropriate.
6. On 28 May 2008, Defra launched the Invasive Non-Native Species Framework Strategy for Great Britain jointly with the Welsh Assembly Government and the Scottish Government. Both the Strategy

[2] Convention of Biological Diversity Invasive Alien Species Introduction: http://www.biodiv.org/programmes/cross-cutting/alien/default.aspx

and implementation plan are available at:
http://www.nonnativespecies.org/02_GB_Coordination/08_Strategy_Working_Group.cfm

7. The Strategy delivers against one of the main Member State measures in the EU action plan for the 2010 biodiversity target. It provides a high-level framework within which the actions of all stakeholders, including government departments and their related bodies can be better co-ordinated and made more effective in minimising the risks posed, and reducing the negative impacts caused by invasive non-native species in Great Britain.

8. The Strategy sets a key objective to minimise the risk of invasive non-native species entering and becoming established in GB, and to reduce the risks associated with the movement of species outside their natural range within GB. It recognises that prevention and early intervention are the most successful and cost-effective approaches for controlling the spread and impact of non-native species, and thus focuses efforts around the three-pronged approach agreed under the Convention on Biological Diversity - i.e. prevention measures, early detection and then carefully considered appropriate action. The Strategy also recognises the crucial need for greater awareness of the issues across all stakeholders, including the public, to achieve this.

Aquaculture Sector

9. Aquaculture in England and Wales is split into the finfish and shellfish sectors, as well as plant sector. The finfish sector is subdivided into fish farmed exclusively for human consumption and those produced for use in recreational fisheries. Both types of business keep and feed juvenile fish, either bred on the farm or supplied by another business, until they are of marketable size. Molluscan shellfish farming is similar, in that juveniles, often supplied by another business or sourced from the wild, are placed in selected areas which promote rapid growth and recovered when they reach a suitable size. There are a handful of farms rearing crustacea, either lobsters for stock enhancement programmes or non-native prawns for human consumption. As far as aquatic plants are concerned, the definition of aquaculture would encompass watercress production, water reed production, algae for industry and the production of ornamental aquatic plants.

Fish and Shellfish Farms

10. In England and Wales there are 518 registered fish and shellfish farms. Of these, 193 are coarse fish farms, the majority of which are located in Southern England, 197 trout and other fin fish farms, and 128 shellfish farms. The number of registered coarse fish farms has increased by 56% since 1997.

11. The main finfish species farmed is rainbow trout (7,294 tonnes). There is also limited production of other species, such as brown trout (441 tonnes), common carp (175 tonnes) Atlantic salmon (63 tonnes), turbot (63.5 tonnes), tilapia (33 tonnes), for a total fish farm production in England and Wales of 8,127 tonnes (2006 figures). Shellfish farm production totalled 15,449 tonnes in 2006, the main species cultivated being mussels (14,553 tonnes) and oysters (880 tonnes).

12. In 2006, the farm gate value of finfish farming in England and Wales was estimated to be £23 million, of which £13 million was salmonids, £0.5 million other food fish and £10 million coarse fish for re-stocking of fisheries and ornamental purposes. The value of shellfish farming is estimated to be around £20 million.

13. Employment figures for 2006 show that the number of people employed by registered fish and shellfish farms were 916 and 414, respectively.

Plant Sector

14. Whilst these industries should be little affected by the implementation of this EU regulation, the value of plants produced in aquaculture is estimated at £0.9 million for water reed production, and less than £1 million for algae (although this may represent a potential for growth for the industry, e.g. as biofuel or waste treatment). In 2004, estimates showed that the production of ornamental plants for ponds and aquaria was in the region of £8 million per year on average. In 2007, the retail value of watercress in the UK was approximately £55 million, much of which is UK produced.

Existing Arrangements

Fish & Shellfish

The Aquatic Animal Health (England and Wales) Regulations 2009

15. These Regulations, which implement European Commission Directive 2006/88/EC, require all aquaculture production businesses (APBs) to be authorised or registered by the competent authority for the purpose of controlling specific fish diseases.

16. Existing or new fish farms and fish dealer businesses have to be authorised, while put and take fisheries (defined as those maintained by the introduction of aquaculture animals) are derogated from the requirement for authorisation and simply require registration by the competent authority.

17. The Fish Health Inspectorate (FHI) at the Centre for Environment, Fisheries and Aquaculture Science (Cefas) is the competent authority for this activity in England and Wales. It maintains a database, which records relevant details of all authorised farms and dealer operations, and is in the process of registering all stocked fishery waters.

Authorised APBs

18. Prospective aquaculture business owners must demonstrate that they are able to operate such a business to appropriate standards, to protect animal health, before they are authorised to farm or trade in such animals.

19. They must apply to Cefas, with full details of their potential aquaculture operation, including confirmation that they have all necessary planning permissions as well as consents to abstract and discharge water as required. The FHI will then arrange an inspection of the potential business site to discuss how the business will operate and establish the requirements of a bio-security measures plan for the business.

20. The authorisation will include specific conditions about the species of animal that can be farmed or traded by the business. The FHI will ensure that the Environment Agency (EA) are content for the proposed species to be held, where the business premises are connected to natural waters or would otherwise require consents from the Environment Agency for stock introduction. Similar procedures will continue to apply under proposed new fish movement controls. Where there is a proposal to farm any species listed in Orders made under the Import of Live Fish Act 1980 (ILFA), then FHI will assess the suitability of the business to keep such animals, and arrange for a licence to be issued following the normal protocols.

21. All authorised aquaculture businesses will be subject to risk-based programmes of compliance checks and disease surveillance according to the species of fish held and the nature of the business operations.

22. If an aquaculture business operator fails to comply with the conditions of authorisation, then the FHI are able to issue enforcement Notices requiring that person to rectify the problem to a specific standard and within a specified timescale. Failure to do so could result in prosecution or in the revocation of the authorisation to carry out that business.

Registered APBs

23. Stocked fishery waters, those cropped occasionally with a view to the sale of live animals and other businesses such as zoos, public aquaria, and scientific research sites, which by the nature of their operations pose a lower risk of disease transmission than farms or dealer premises, are derogated from the requirement to be authorised, but their details are maintained on a register by the FHI.

24. The owners/operators of the businesses operating such lower risk sites must apply to the FHI for registration, supplying details of the nature of the facilities involved and the species that are to be held or traded from the business. In the event that such sites are considered to pose an increased risk of disease transmission due to the nature or scale of their activities, then the FHI may require that the businesses be subjected to authorisation as above. Registered sites are not routinely subject to monitoring by the FHI.

The Import of Live Fish Act 1980 (ILFA)

25. This Act regulates the import, keeping and release of non native fish in England and Wales, by means of Orders relating to specific listed species. Two Orders are in operation at present:

26. The Prohibition of Keeping of Live Fish (Crayfish) Order 1996, prohibits, with one exception, the keeping of any non-native crayfish in England and Wales, other than under a licence issued by the Secretary of State. The one exemption is for the signal crayfish (Pacifastacus leniusculus) kept in areas where it has become established in the southern half of England. The keeping of this species is only controlled in certain no-go areas listed in the Order. Licences under the Order have been issued enabling the keeping of live crayfish in restaurants and markets holding the animals for consumption, and for the keeping of a single species, the redclaw (Cherax quadricarinatus) as an ornamental animal in indoor aquaria.

27. The Prohibition of Keeping and Release of Live Fish (Specified Species) Order 1998, as amended in 2003, prohibits the keeping or release of listed non-native species except under licence. Defra policy restricts the keeping of some of these species to particular trade sectors, with only the least invasive, or those with a long established history of use, being licensed for keeping in natural waters.

28. Applications for licences under the above Orders are administered by the FHI, and subject to scrutiny by the Environment Agency (EA), Natural England (NE), Countryside Council for Wales (CCW) and Cefas Lowestoft laboratory before approval. Enforcement on fish farms and in trade is carried out by the FHI, while EA enforcement officers act in respect of offences at fishery or other inland waters.

29. A revision to the Prohibition of Keeping and Release of Live Fish (Specified Species) Order 1998 was consulted upon in 2010. While Council Regulation (EC) No 708/2007 on the use of alien and local absent species requires Member States to control the use of these species in aquaculture, to prevent impacts on native habitats and species, it makes no provision for the control of such species in other areas, such as the ornamental fish industry. It is therefore important that we act to increase the scope of existing controls on the keeping and release of potentially invasive non-native species outside aquaculture, and this has been addressed through the proposals contained in the Impact Assessment of an amendment to the 1998 Order. Further information is available on the Defra website at http://www.defra.gov.uk/corporate/consult/fish-imports/index.htm

Wildlife and Countryside Act 1981

30. The Wildlife and Countryside Act 1981 (WCA) precludes the release 'to the wild' of any animal not ordinarily resident in GB, and certain established non-native species listed on Schedule 9 of the Act, without an appropriate licence. Thus, fish farms may require a WCA licence to hold non-native species where some or all of the fish farm site qualifies as 'the wild'.

Plants

The Plant Health Order 2005

31. The Plant Health Order implements the EU Plant Health Directive 2000/29 and restricts the entry of plants and plant pests. Any consignment of plants for planting imported from a third country requires a phytosanitary certificate attesting that it meets the import requirements of the UK. Certain plant species are banned from import, as are any plant pests and diseases which are not normally present in Great Britain and which are likely to be injurious to plants in Great Britain. Imports of banned material may be allowed under licence for scientific and trialling purposes

Wildlife and Countryside Act 1981

32. Under the Wildlife and Countryside Act 1981, it is illegal, without an appropriate licence, to plant or otherwise cause to grow in the wild any plant listed on Schedule 9 of the Wildlife and Countryside Act 1981. The schedule includes alien plants which may pose a threat to our native flora.

Council Regulation 708/2007 on the Use of Alien and Local Absent Species in Aquaculture

Background

33. Alien species have been identified as one of the key causes for the loss of biodiversity in the EU and the world at large. They can have significant economic and social impacts, and could undermine the EU's sustainable development objectives. In its Biodiversity action plan for fisheries (COM (2001) 162, Vol.IV), the Commission undertook to evaluate the potential impact of non-indigenous species in aquaculture, and to promote the application of the International Council for the Exploration of the

Seas (ICES) Code of Practice on introductions and transfer of marine organisms, as well as the European Inland Fisheries Advisory Commission (EIFAC) Code of Practice and Manual of procedures for introductions and transfers of marine and freshwater organisms.

34. Aquaculture is a fast growing innovative industry across Europe, constantly looking for new species and markets. In order to adapt fully to market conditions and changes, it is essential that the industry diversifies the species it produces.

35. Building on the existing voluntary ICES and EIFAC rules, Regulation 708/2007 seeks to introduce an EU framework that will ensure adequate protection for the aquatic environment from the risks associated with the use of alien species in aquaculture.

Rationale for Government Intervention

36. Industry is motivated by commercial gain. Without intervention, industry is unlikely to take account of the potential cost of non-native species introduction since the costs will not be borne by an individual company but instead be spread more widely. It is important that the industry considers and addresses the environmental risk associated with the use of new species in aquaculture. Moreover, if the development of aquaculture is to be regulated, then this should be done in accordance with a common European framework that is sufficiently flexible to recognise the variety of aquatic environments and the nature of the risk posed to those environments by proposed aquaculture development.

37. The fact that introductions of alien species for the purpose of aquaculture can have significant adverse environmental impacts is amply demonstrated by the damage caused in England and Wales by the North American signal crayfish. This species was imported in the late 1970s with government support, specifically for the development of small-scale aquaculture, in open ponds, as an agricultural extensification scheme. However, crayfish escaped from such sites and colonised many rivers in England and Wales. The species competes with the native White-clawed crayfish and carries a disease, crayfish plague, to which our native crayfish has no immunity. Native White-clawed crayfish have now all but disappeared in the southern half of England. Signal crayfish is also responsible for a number of other adverse environment impacts. This case highlights the need for prior scientific assessment of the potential impact of species introduced for use in aquaculture.

38. We, therefore, welcomed the Commission's proposal to require Member States to ensure, by means of a rigorous risk assessment process, that aquaculture of non-native species poses no risk to the biodiversity of natural waters or other aquatic environments within the EU. We believe that this regulation largely eliminates the risks posed by aquaculture, and that, in the long term, it will be beneficial to the industry permitting them to diversify and trade in novel non-native species. Also, it endorses the ICES Code of Practice on introductions and transfers of marine organisms, to which the UK already subscribes.

Pre-regulation Consultation

39. An expert group of 46 people, made up of representatives from the Member States, industry, NGO's, ICES, EIFAC, the North Atlantic Salmon Conservation Organisation (NASCO) and other private sector experts, was consulted prior to the drafting of the Regulation. The proposal was also discussed on three occasions in 2004/5 in the Commission's Aquaculture Working Group of the Advisory Committee for Fisheries and Aquaculture.

40. The initial proposal was to include measures for containment of farmed salmon. However, owing to the response from the consultation, it was decided to decouple this aspect so that it could be dealt with separately in the future. Consultees other than the NGOs advised against an over-centralised and heavy handed approach and the proposal was modified to respect the competence of Member States in this field. On the other hand, the requirement for harmonised guidelines for the notification, risk assessment and quarantine was called for and these have been provided to allow for even application of the legislation across Member States.

41. To follow international practice regarding risk analysis, it was decided to separate the risk assessment function (advisory committee) from the risk management function (competent authority). The original option of combining both functions within the competent authority was therefore not advanced.

42. The industry's main concern was that the cost of funding the notification, risk assessment and quarantine would prevent future applications for the introduction of alien species. Consequently, the

Regulation leaves to Member States the option of deciding who should bear the cost of conducting the risk assessment.

43. As regards England and Wales, the general consensus is that the farming of novel non-native species is a fairly specialised area, which only a few will want to consider or have the resources to exploit. By introducing an alien species, operators are risking a potential negative effect and impact on the environment. It is, therefore, of extreme importance that those contemplating the use of alien species in aquaculture take full account of the risks posed by their projected actions and bears the associated costs. Consequently, the burden of minimal risk and of risk mitigation would rest with operators.

Scope

44. Council regulation 708/2007 applies to the introduction of alien species and translocation of locally absent species for their use in aquaculture in the Community.

45. For the purpose of this Regulation, 'alien species' means a species or a subspecies of a non-native aquatic organism, whereas a 'locally absent species' is a species or a subspecies of an aquatic organism that is locally absent from a zone within its natural range of distribution for bio-geographical reasons. Aquatic organisms are defined as any species living in water belonging to the animalia, plantae and protista (i.e. all unicellular organisms lacking a definite cellular arrangement, such as bacteria) kingdoms.

46. Also, for the purpose of this Regulation, aquaculture is taken to include activities such as bottom cultivation of mussels, which use aquaculture techniques as their basis. Ornamental fish and plants are covered by this Regulation only insofar as they are reared, commercially farmed or propagated in the EU for onward sale. While there is a significant trade in non-native organisms, mainly fish species for ornamental use, they are normally kept in pet shops, garden centres and commercial and private aquaria and thus do not fall within the scope of this Regulation[3].

The Competent Authority

47. Member States are required to designate a competent authority, which will take responsibility for ensuring compliance with the Regulation. Each competent authority may also appoint an advisory committee that will incorporate appropriate scientific expertise. The Commission have proposed that anyone intending to undertake an introduction or translocation of an aquatic organism will have to apply for a permit from the competent authority of the receiving Member State.

48. We would anticipate the competent authorities in England and Wales to be Cefas for introductions and translocations of aquatic animals and the Plant Health and Seeds Inspectorate (PHSI) where aquatic plants are involved. The Great Britain Aquaculture Board (GBAB) will act as the advisory committee.

Permits

49. The Regulation provides for a system of permits governing the use of alien and locally absent species in aquaculture, to minimise the possible impact of these and any associated non-target species on the aquatic environment and thus contribute to the sustainable development of the sector. The intention is that such permits will be granted only if the risk associated with the activities proposed by applicants can be considered low, or if the risk can be reduced to a low level by mitigating action on the part of the applicant.

Application process

50. Aquaculture operators intending to undertake the introduction of an alien species or the translocation of a locally absent species will need to 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. Certain species covered by Article 2(5)[4] and listed in

[3] Council Regulation (EC) No. 708/2007, Article 2 (Scope) paragraph 4.

[4] Council Regulation 708/2007, Article 2(5) states that this regulation, except for Articles 3 (definitions) and 4 (measures to avoid adverse effects), shall not apply to the species listed in Annex IV. The risk assessment in Article 9 shall not apply to the 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.

Annex IV[5] , may be exempt from the requirements of the Regulation, although this is subject to interpretation by Member States and thus such exemptions may not apply. In all cases, therefore, clarification will need to be sought from the competent authority.

51. During the initial consultation with the applicant, the competent authority will make a provisional assessment of the proposed venture based on policy guidance documentation, over-arching conservation concerns and the perceived level of risk. This will inform the decision as to whether the venture will involve 'routine' or 'non-routine' movements and the level of associated risk assessment likely to be needed in support of the application. Routine movements are those where the movement of aquatic organisms is from a source where there is low risk of transferring non-target organisms[6] to the open environment. This includes the movement of organisms between two closed facilities. The assessment of risks in defining what constitutes a routine movement must consider the nature of the aquatic organism and/or the method of aquaculture (e.g. a closed system) at the recipient location such that the movement is not likely to result in adverse ecological effects. Non-routine movements are those that do not fulfil these criteria.

52. On the basis of the application and dialogue with the applicant and the advisory committee, the competent authority will establish whether the proposed movement or introduction can be regarded as 'routine' or 'non-routine'. For routine movements, the competent authority will be able to grant a permit, following whatever risk assessment procedures are considered necessary (e.g. in relation to the means of transport and the features of the recipient facility), and where applicable stipulating requirements for quarantine provisions. Non-routine movements will require a full environmental risk assessment as well as a contingency plan before any permit is issued. The risk assessment procedures are outlined in more detail immediately below and in the 'Options Considered' section.

Risk Analysis Process

53. The risk analysis process involves four main components: risk identification, risk assessment, risk communication and risk management. The general principles, or guidelines, to be considered during the risk analysis process were outlined in Annex II of the Regulation, pending the development of a risk analysis framework suited to aquaculture. A risk framework and its various protocols have subsequently been developed for this purpose for the EU in the EC Coordination Action 'IMPASSE' (environmental IMPacts of Alien SpecieS in aquaculturE), which submitted its report to the EC in November 2008. The risk analysis procedures developed by the IMPASSE project have been named the European Non-native Species Risk Analysis Scheme (ENSARS). This consists of a series of risk assessment protocols and management procedures to aid in the decision-making process as regards applications for the use of alien species in aquaculture (Figure 1). The risk analysis process will lead to the ranking of applicant species according to their relative, likely risk (low, medium, high) so as to aid decision makers as regards the issue of permits. The competent authority will only issue permits for non-routine movements where the risk assessment, including any mitigation measures, indicates a low risk to the environment.

54. ENSARS is modular in structure (Figure 1), with the questions used and the assessment of uncertainties being adapted from the GB Non-native Species Risk Assessment Scheme, which is itself adapted from protocols developed by the European Plant Protection Organisation (EPPO). The various ENSAR modules consider all aspects of the aquaculture process, including transport pathways, rearing facilities, infectious agents, non-target organisms, as well as environmental and socio-economic impacts. These modules evaluate the risks of escape, introduction to and establishment in open waters, of any non-native aquatic organism being used in aquaculture. A range of expertise is required to complete the risk assessment modules appropriately. The EC has accepted the final reports from the IMPASSE project, including the report that outlines the ENSARS scheme, and it is assumed that the ENSARS scheme will be incorporated into the Regulation, but this has not yet been confirmed.

[5] Annex IV to Council Regulation 708/2007, as amended by Commission Regulation (EC) No 506/2008 sets out the list of species to which certain provisions of that Regulation do not apply. Member States may request the Commission to add species to that Annex.

[6] For the purpose of Council Regulation 708/2007, '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.

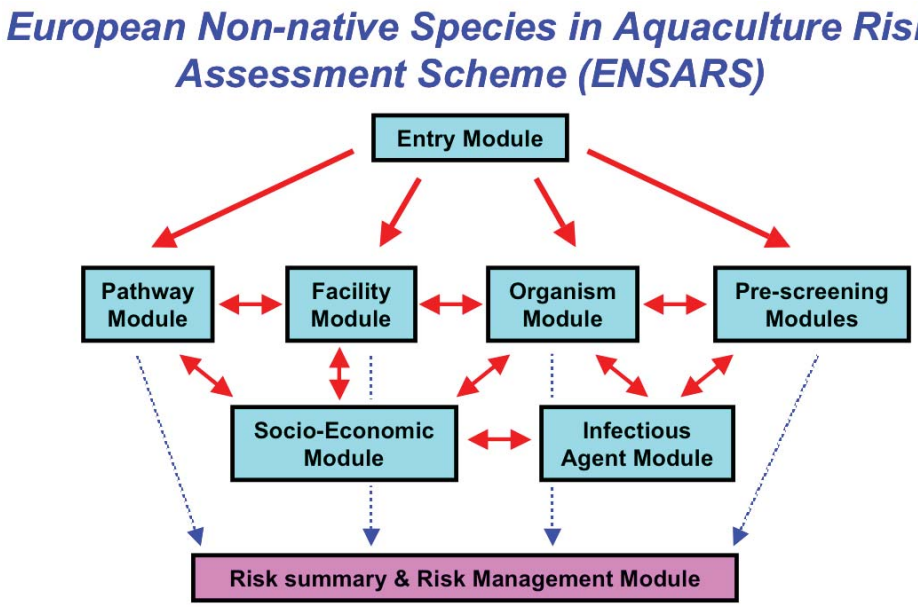

Figure 1. Schematic of the European Non-native Species Risk Analysis Scheme (ENSARS), regarding the Use of Alien and Locally-Absent Species in Aquaculture. The scheme consists of seven risk assessment modules (upper boxes in light blue) and a Risk Summary & Risk Management Module (lower box in light mauve) into which the risk assessment outcomes feed information.

55. Whatever risk analysis scheme is adopted, it is expected that the 'competent authority' will have the task of processing the applications and guiding applicants through the relevant risk assessments. The amount of time required to complete these assessments will depend upon the species involved, the number of assessment modules required[7] and the quantity of information available. It is anticipated that a fish farmer will probably wish to engage a specialist consultant to complete the necessary risk assessment modules, since a range of expertise will be needed to complete all the modules appropriately. However, a basic premise is that efforts will be made to ensure that only essential risk assessment modules are addressed and that decisions are reached as early as possible to avoid unnecessary delays and expenditure on the part of the applicant on risk assessments where these are not needed. Thus, for example, the proposed farming of a new tropical species in a closed aquaculture facility will, most likely, require only limited assessment and could be approved rapidly. In contrast, there is expected to be a general presumption against the farming of novel, temperate species in on-line sites, so applicants could be advised at an early stage that approval in such instances was highly unlikely and detailed risk assessments could be avoided.

56. The Regulation specifies that the applicant should be informed in writing within a reasonable time of the decision, but not longer than six months from the date of application.

Exemptions

57. The UK ensured in negotiations that the Regulation would not apply retrospectively, so that those already farming alien species will not be required to go through the application and risk assessment process. We also argued that where there had been a history of introductions of a proposed species within a Member State, the risk assessment process could be substantially reduced. This would allow applicants to concentrate more on the characteristics of the proposed introduction site and whether this was fit for purpose. However, as set out in Article 2(5), this is not a carte blanche, and Member States still retain the right to impose restrictions and require an environmental risk assessment for any listed non-native species.

58. Probably the most important part of the Regulation from a UK perspective is Article 2(5) and Annex IV, which can be used to exempt certain non-native species from the permitting requirements of the Regulation including the risk assessment process set out in Article 9[8]. These species, while

[7] For example, in the case of a proposed new species, the 'Organism' module could be completed within a day for species about which there is little published information, whereas a number of days could be required for a species about which a large body of literature exists.

[8] Please refer to footnote 4.

technically alien to the Member State, have typically been established in aquaculture (or otherwise) for so long that retrospective regulation would be inappropriate. Of main interest to the UK industry are rainbow trout, common carp, Pacific cupped oyster and Manila clam.

59. Controls on the movement of alien species to be reared in closed aquaculture facilities can be exempted from prior environmental risk assessment, under Article 2(6)[9], except in cases where Member States wish to take appropriate measures. Member States may also make provision for species not listed in Annex IV, which comply with the Annex IV criteria for their country but are not listed in Annex IV. For example, the UK has had ide (Leuciscus idus) in aquaculture for many years. Ide is non-native to the British Isles but is native to numerous countries of the EU. As such, ide is not listed in Annex IV, but in the UK this non-native species appears to comply with Annex IV criteria. Thus, subject to approval by the competent authority, the UK might consider it appropriate to establish a blanket licence for the entire country that would cover the use of such species in aquaculture.

60. As noted previously, Member States retain the right to regulate species on Annex IV. Thus, new species added to the Annex IV list by other Member States, or those already on the list that are not already farmed in the UK or which might pose a risk under conditions of climate change, can effectively be exempted from Annex IV status as it applies in the UK.

Policy Aim

61. The aim of these measures is to allow the economic growth of the aquaculture sector, while protecting the aquatic environment from the potential damage that might arise from the introduction of alien and locally absent species to the wild, where they might result in adverse biological interaction with indigenous populations.

Options Considered

62. Option 1: 'Do nothing'

    This new EU Regulation is binding in its entirety and directly applicable in all Member States. The UK Government is therefore obliged to implement it. In addition, although we already have reasonably comprehensive and robust provisions in place to regulate the use of certain non-native species in aquaculture, as outlined in the 'Existing Arrangements' section of this IA, such measures are deemed to be rigid and not sufficiently risk based. Hence, it is necessary to intervene to ensure that our native aquatic environment is accorded better protection from invasive non-native species, whilst enabling the industry to diversify and exploit new opportunities, within strict controls. Consequently, the 'do nothing' option is not deemed to be a viable alternative.

63. Option 2: Implementation of Council Regulation 708/2007 concerning the Use Of Alien and Locally Absent Species in Aquaculture

    The general thrust of the Regulation is to provide better protection for native flora and fauna across Europe and a level playing field as regards the controls on aquaculture industries in other Member States. The necessity for intervention is based upon the need to better protect native ecosystems from invasive non-native species, which are difficult and expensive to remove and can cause serious and irreversible damage to the aquatic environment. In addition, there is a need to allow the aquaculture and fish farming sector the ability to utilise and harvest new novel fish species. Intervention would also avoid the risk of expensive infractions for not implementing adequately EU legislation.

64. We do not envisage a great impact on the UK's established aquaculture production businesses following implementation of this regulation. Most of the existing businesses that produce non-native species deal in certain, commonly-farmed salmonids, shellfish, molluscs, crayfishes, algae and plants that are already well established in trade. These species have been exempted from the Regulation and there will not be any requirement for retrospective applications. However, those businesses who wish to expand and deal with new species will be required to complete an application form and risk assessment as appropriate

65. For those species that are not exempt from the Regulation, there will be two types of movements or applications to consider:

[9] Council Regulation 708/2007, Article 2(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."

- Routine Movements for established species[10], or where there is unlikely to be any danger of escape etc. and the risks concerned are judged to be minimal; and
- Non-Routine Movements for novel species about which little might be known about their biology a nd possible impact should it escape into the wild.

66. Since there will be some overlap between the requirements of this Regulation and the need for fish farm authorisation under the Aquatic Animal Health Regulations (AAHR) 2009, we assume that a single administration system will apply for authorising sites under both AAHR and this Regulation.

67. As the Regulation requires that the competent authority issues the permits, it is proposed that Cefas[11], which already acts as the competent authority for the AAHR, will also be the competent authority for the purpose of this Regulation. While new responsibilities under this Regulation will entail additional costs for Cefas (i.e. costs of processing and issuing permits, monitoring and inspecting), there will be scope to limit these where they can be combined with other fish health and animal welfare activities. The Plant Health and Seeds Inspectorate (PHSI) will act as the competent authority where aquatic plants are involved.

68. A diagram setting out the application process that we propose to introduce under the Regulation is provided at Annex 3.

Routine Movements

69. With regard to Routine Movements, Cefas or PHSI would register the application. They would then refer the application to the 'GB Aquaculture Board' (GBAB). This body would act as the advisory committee, and would consist of conservation bodies: Natural England (NE), Countryside Council for Wales (CCW)) and the statutory bodies (Cefas (Lowestoft Laboratory), the EA and Defra – fisheries and plant health). The GBAB would consider the application (most likely by correspondence) and prepare a recommendation.

70. On the basis that GBAB considered the application to be a Routine Movement, Cefas or the PHSI would then decide whether to issue a permit. The process for warm water species farmed in secure, closed aquaculture facilities is expected to be relatively straightforward and only requiring completion of few risk assessment modules (i.e. pathway/facility)[12]. However, if the GBAB considered that the application should be regarded as a Non Routine Movement (see below), then a more comprehensive risk assessment would be necessary covering as many modules as necessary.

71. It is not clear how many routine movements might occur, but this is not expected to be great in number.

Non-Routine Movements

72. As with Routine Movements, Cefas or the Plant Health Inspectorate (where aquatic plants are involved) would register a Non-Routine Movement and refer the application to GBAB for initial comment. Assuming that there were no specific over-arching conservation concerns or policy reasons why the application should not be developed in detail, a comprehensive risk assessment would be required to accompany the application. The applicant would normally commission an expert (e.g. consulting firm) to undertake the risk assessment, though in some cases the assessment of particular modules (e.g. pertaining to the facility) may be carried out by the facility manager/owner. The various risk assessments would include, as necessary, assessments of pathways, facilities, species, non-target infectious agents and socio-economic impacts. On the basis of the risk assessments, the applicant will also be required to submit a contingency plan indicating

[10] Regulation of the movement of species currently listed in Annex IV will slightly differ from that for routine movements. However, regulation will be kept to a minimum and, where the competent authority deem this is appropriate, restrictions will simply be imposed by way of notices and associated conditions. In effect, the permitting process will be alike and thus is being considered as part of the Routine Movements section of the IA. Tighter restrictions (or presumptions against use) might apply for some Annex IV species where these have never previously been farmed here, but requirements for operators intending to move a species to submit an environmental risk assessment will be limited to the movement of any new species that might be added to Annex IV at a later date.

[11] The Fish Health Inspectorate at Cefas (Weymouth laboratory) will act as the designated Competent Authority.

[12] It is expected that these assessments will be carried out by facility managers/ owners themselves as part of the application process for routine movements. Representatives of the Competent Authority (i.e. inspectors) will determine during initial inspection visits whether or not such assessments are fit-for-purpose.

how any risks will be mitigated and to detail the actions that would be taken in the event of an escape of the farmed organism from the facility. Once completed, the application, risk assessment dossier and contingency plan would be submitted to the competent authority. The dossiers would then be subject to scientific review to ensure that they are 'fit for purpose'.

73. It is proposed that the competent authority would engage the Non-Native Risk Analysis Panel (NNRAP) for the scientific review of the applications and risk assessments. The NNRAP is an existing committee of experts who report to the Non-Native Species Secretariat (NNSS), which itself reports to the GB Non-native Species Programme Board [13] (http://www.nonnativespecies.org/02_GB_Coordination/04_Risk_Anaysis%20Panel.cfm).

74. Essentially, NNRAP is a core group of risk assessment experts who undertake peer review of non-native species risk assessments and provide advice on the protocols used to assess non-native species risks. The existing NNRAP operation would, therefore, be used to process and evaluate the applications and risk assessments under the Regulation, and would provide for a robust and well established risk assessment mechanism. It is expected that all applications and associated risk assessments related to novel aquaculture species will be peer-reviewed as a matter of course. This will help ensure that the information submitted has a relevant and scientific grounding. In cases where the NNRAP does not possess the necessary taxonomic expertise, the NNSS employs external reviewers with the required expertise as peer-reviewers, complementing the existing risk assessment expertise of the NNRAP. The same procedure would be employed for aquaculture related assessments and would involve one or more peer reviewers (as required) to ensure that the review process is robust and the risk assessment is fit for purpose. The NNRAP would then review the risk assessment in light of the peer review and provide additional comments on whether it has been appropriately completed, is fit for purpose or requires additional input and/ or modification. It is quite likely that on reviewing the risk assessment, NNRAP will want clarification / additional information in some areas. In such circumstances the risk assessment will be sent back to Cefas/ PHSI, and then to the applicant and their appointed risk assessor, to provide additional details.

75. Following their review of the application dossier, the NNRAP would return the application dossier along with their evaluation and recommendations to the GBAB as to the level of risk posed by the species and proposed new venture. Subsequently, the GBAB would consider this advice and prepare a recommendation (which it is expected would normally follow the NNRAP advice) as to whether the application should be approved or rejected (i.e. low or high risk). It is anticipated that any particular concern (e.g. with respect to specific conservation issues) that GBAB might have in respect of an application would be raised prior to the full risk assessment process being initiated. However, the final recommendation from GBAB would ensure that the process is robust and that any conservation aspect arising from the review is taken into account. The GBAB recommendation would then be sent to either Cefas or PHSI who would finalise the application, inform the applicant of the decision and, where appropriate, issue the permit. Any specific concerns that the competent authority had about an application would be raised at the start of any application process and considered as part of the peer review process. It is thus very unlikely that the competent authority would disagree with any GBAB decision. However, in the event that this occurred, the decision would be subject to further dialogue and discussion to seek a resolution.

76. The number of Non-Routine Movement applications is expected to be low, perhaps only 1 a year. This reflects the current low level of interest in novel species and the fact that some previous ventures (e.g. Barramundi) have not always proved successful.

Costs and Benefits

Costs

Option 1: 'Do nothing'

77. This option would preserve the status quo and, therefore, there would be no additional costs compared to the existing baseline scenario. However, there would be the risk of serious and costly infractions if the European Commission considered that we had not suitably implemented the Council Regulation into UK law.

[13] The current peer-review process for non-native species risk assessments is administered by the Non Native Species Sectretariat (NNSS) in York, with peeer-review undertaken by the NNRAP.

Option 2: Implementation of Council Regulation 708/2007 concerning the Use of Alien and Locally Absent Species in Aquaculture (ASR)

78. Alien species can be valuable to the aquaculture industry. Current interest in new species in the UK is currently low, as a consequence of previous animal health rules. It is therefore, not expected that there will be a high immediate demand for evaluating and approving new non-native species, but that may change if the industry decides to exploit new market opportunities. Costs associated with authorising the use of a new species are expected to vary according to whether the application will be a 'Routine Movement' or a 'Non-Routine Movement' (see below).

79. There will be initial 'one off' costs for central Government for the creation of the application form, for the setting up of a public register of alien species introductions and inspection costs. The application form is currently being drafted and we have been quoted £70 per page. The expectation is that the form will be five pages; therefore the cost for the creation of the form would be £350. The costs for creating a public register of alien species introductions which will be located on the Cefas website has been estimated to be around £10,000.

80. There will be additional, more substantial, costs for Government resulting from the evaluation of completed forms and associated risk assessments once these are submitted and these are set out in detail below.

81. For both Routine and Non-Routine Movements, Cefas or the PHSI (where aquatic plants are involved) would initially register the application.

82. Applicants will seek initial advice on the aquaculture of animal species from Cefas, which advises on the fish health standards required for imports, as well as the need for farm authorisation under the new Aquatic Animal Health Regulations (AAHR). For new aquaculture sites, permission under the ASR would be dealt with at the same time as the AAHR authorisation. It is intended that a single administration system for authorising sites under both the AAHR and the ASR would be put in place. While the new duties will entail additional costs for Cefas (i.e. costs of processing and issuing, monitoring and inspection costs), there will be scope to limit these where they can be combined with existing activities related to fish health and animal welfare.

83. It is anticipated that an initial pre-screening will be possible to assess species likely to be of high risk and hence unsuitable for use in open aquaculture facilities. This would be based on simple policy guidelines and would enable a rapid initial response to the applicant on the likely suitability of a potential application, thus avoiding the need for a risk assessment. This would not exclude the applicant from seeking to progress an application and obtaining a full risk assessment for a species, should they so wish. However, it would help provide guidance on the species for which presumption against approval for use in open aquaculture facilities was likely to apply.

84. Where a species is to be held in a bio-secure environment and there is little prospect of the species (or any non-target organisms) escaping, there will not normally be a requirement for the application of comprehensive risk assessment procedures. However, facility and pathway assessments would, most likely, still be required to confirm that the site and associated fish movements to and from it were indeed 'bio-secure'. It is anticipated that this assessments will be undertaken by the facility owner/ manager as part of the standard procedure for routine movements applications[14].

Routine Movement Applications

85. Routine Movement Applications[15] would not be accompanied by a full risk assessment and so registering and checking the application is likely to be more straightforward than for Non-Routine Movements.

86. The expectation is that 17 applications for Routine Movements will be received each year[16]. It is anticipated that the vast majority of the applications received (15) will be for introductions of alien fish species, whereas the number of plant species likely to require assessment under ASR will be very low (2). The cost to the industry for general enquiries under ASR and/ or assistance in

[14] Please refer to footnote no. 12.
[15] Please refer to footnote no.10.
[16] A Cefas/ PHSI estimate based on enquiries received to date from the industry on the farming of non-native species.

completing the application form is expected to amount to £782, based on 17 queries a year, 1 hour per query at an hourly rate of £46[17] (17 x 1 x £46).

87. It is anticipated that it will take 2 hours for a company to complete an application form for a Routine Movement at a cost of £46 per hour, amounting to £92 per application. The total annual cost to industry for completing Routine Applications would therefore be £1,564 (17 x £92)

88. Initial advice from Cefas and/or PHSI related to enquiries under ASR is expected to amount to 1 hour per application at an hourly rate of £68[18]. Therefore the total annual cost would be £1,156 (17 x £68).

89. On the assumption that each application would take, on average, 2 hours to assess and input at an hourly rate of £68, the cost associated with the assessment of 17 application forms would be £2,312 (2 x 17 x £68).

90. Cefas and/or PHSI would then refer the application to the GBAB. Consideration of Routine Movements is expected to require minimal input from GBAB and Cefas and/or PHSI would identify any that might potentially involve any risk. It is expected that consideration would be by correspondence, input would be minimal and therefore additional costs have not been explicitly quantified.

91. Following agreement from GBAB that the application qualifies to be considered a Routine Movement, Cefas and/PHSI would issue a permit. The time required to issue a permit and the associated administrative work is expected to be 1 hour per application at a cost of £46[19] per hour, so the yearly cost would amount to £782 (17 x £46).

Non-Routine Movement Applications

92. For Non-Routine Movements, where the applicant might be applying to establish a fish farm for a novel species, a detailed risk assessment and contingency plan would be required as part of the application. Consequently, for Non-Routine Movement Applications recording and checking the application is likely to be more complicated than with Routine Movements. The number of applications is expected to be low, perhaps only 1 a year, although there may be rather more provisional enquiries (e.g. 20)[20]. This reflects the current low level of interest in novel species and the fact that some previous ventures (e.g. Barramundi) have not always proved successful. The cost to the industry for initial consultation with the competent authority about new species is expected to amount to £920, based on 20 queries a year, 1 hour per query at an hourly rate of £46 (20 x 1 x £46).

93. Initial advice from Cefas/ PHSI related to ASR enquiries related to new species (Non-Routine) is expected to amount to 1hour per query. Therefore the total annual cost would be £1360 (1 x20 x £68).

94. As with Routine Movements, Cefas/ PHSI would receive, register and assess applications for Non-Routine Movements. It is assumed that this process would take 3 hours, on average. At an hourly rate of £68, the cost associated for one application form would be £204.

95. It would be for the applicant to decide who carried out the risk assessment. However, it is expected that GBAB and/or NNRAP might provide a list of potential risk assessors that Cefas/ PHSI would make available to potential applicants. According to NNRAP, risk assessors are currently paid £1,000 (ex VAT), on average, to undertake a simple species risk assessment. This is based on approximately 1 person for 2 days and is for general species risk assessments and not specific to aquaculture. In the case of aquaculture assessments under ASR, which might include potential non-target organisms, a wider range of assessments will be required. Apart from the species and any related non-target organisms (e.g. infectious agents), risk assessments may include facility, pathway and socio-economic modules. On the basis of the risk assessments, the applicant will also be

[17] Industry hourly full economic cost (FEC), with the salary component representing around 40% to 50% of the total. The overhead component comprises the reminder and is made up of accommodation and the costs of support services (e.g. expert advice).

[18] Cefas Pay Band 6 hourly FEC for 2009/10. The salary component represents around 40% to 50% of the total. The overhead component comprises the reminder and is made up of accommodation and the costs of support services (e.g. HR, finance/contracts, Chief Executives office, IT, library, etc.).

[19] Cefas Pay Band 4 hourly FEC for 2009/ 10. The salary component and overhead component are outlined in the above footnote.

[20] Cefas/ PHSI estimation.

required to submit a contingency plan indicating how any risks will be mitigated and the actions that would be taken in the event of an escape of the organism. It is impossible to provide an accurate cost estimate as this will vary from species to species, but a full risk assessment and contingency plan under the scheme might cost £6,000, based on an assessment conducted by one risk assessor in twelve working days. On the assumption that there would be one application per year, this would also be the annual cost to industry. However, it is expected that when embarking on a new commercial venture with a novel species, most operators would commission some form of risk assessment in any case and therefore this figure represents an upper band estimate of the cost incurred by the industry for a full risk assessment.

96. There are also likely to be some administrative costs associated with the completion of the application for a Non-Routine Movement that may be fairly complex. Assuming this would take 8 hours at an hourly cost of £46, the cost to industry would be £368 (on the basis of one application per year, this is also the annual cost to industry).

97. Following registration, and initial discussion with GBAB, Cefas or the PHSI would pass the application and the risk assessments onto NNRAP for peer review.

98. It is quite likely that, on reviewing the risk assessment, NNRAP will want clarification / additional information in some areas. In such circumstances the risk assessment will be sent back to Cefas/ PHSI, and then the applicant and their appointed risk assessor, to provide additional details. This is likely to happen at least once, but may need to be repeated on a number of occasions, with the potential to extend the application assessment process. Applicants and their appointed risk assessors will therefore be encouraged to provide as detailed responses as possible in submitting the original application.

99. Given these factors and the uncertainty about how detailed the dossier of risk assessments might need to be (e.g. the number of possible infectious agents / non-target organisms), and how much information might be available (affecting the complexity of each assessment), it is impossible to provide an accurate estimate of the likely costs associated with the NNRAP peer review of the risk assessment dossier. For indicative purposes, an average cost might be in the region of £13,000. However, costs might vary from around £10,000 to over £15,000. These costs would comprise:

    - Peer review. It is expected that risk assessment dossiers would be subject to an initial thorough peer-review which would be conducted by up to two peer reviewers. Based on 5 days per peer-review per reviewer at an average daily rate of £500[21], the total costs of having a risk assessment peer-reviewed would amount to £5,000. Full review and due consideration of the risk assessment dossier by the NNRAP panel at their quarterly meetings. It is expected that the NNRAP would thoroughly review the risk assessment dossier in light of the peer-review and subsequently scrutinise it following any requested updates/ revisions. The NNRAP panel has 6 members; based on one day and a half per member to complete all the review tasks related to a risk dossier (full assessment meeting, plus catch-all to cover additional reviews following modifications) and on one day travel at £500 per day, this would equate to costs of £7,500 per dossier. These costs are likely to vary dependent on the complexity of the assessment.

    - Administrative costs for NNRAP Secretariat would be £500, based on 1-2 days per assessment at £250[22] per day).

100. Following their analysis, NNRAP would make a recommendation and return the application and risk assessment evaluation to GBAB. Subsequently, GBAB would consider this advice and prepare a recommendation (which is expected to follow the NNRAP advice) as to whether the application should be approved or rejected (i.e. low or high risk). Specific overarching conservation concerns or policy reasons why the application should not be developed would be identified at the start of the application process. The recommendation would then be sent to Cefas to finalise and inform the applicant. The costs of the GBAB operation is expected to amount to £68, based on 1 hour per application at £68 and 1 application per year. It is anticipated that this cost would be met from existing resources. The estimated cost incurred by Cefas in issuing the permits would amount to £46, based on 1 hour per application at an hourly cost of £46.

[21] This figure is based on the full economic cost of a specialist who would carry out a risk assessment or a peer-review and is based on rates currently charged by Universities, Government Agencies, Consultancies, etc.
[22] NNRAP daily full economic cost.

Cost of Site Inspections/ Monitoring

101. It is anticipated that a farm will need to be inspected once an application under the ASR is made to verify whether the premises are bio-secure and, in fish farm cases, that they have means to prevent the escape of fish. A single inspection visit is estimated to cost £230[23]. Consequently, the total cost for inspecting 18 farms will be £4,140, based on the assumption that 17 applications for Routine movements and one for Non- routine movements would be progressed.

102. Routine inspections and any monitoring of conditions will take place at the time of aquatic animal health compliance visits, and so there will be no additional costs for this aspect of the work. It is anticipated that the same procedure will be used for aquatic plants; hence routine inspections and monitoring will be integrated in existing plant health inspection programmes and no additional costs will be incurred. A summary of the costs incurred by the industry and government for dealing with applications for both Routine and Non-routine movements are provided at Annex 4.

Established Businesses

103. The UK ensured in negotiations that this Regulation would not apply retrospectively, so that those already farming alien species will not be required to go through the application and risk assessment process.

New Businesses/Existing Business introducing New Species

104. New aquaculture ventures and existing businesses who wish to expand and deal with new non-native species will be required to complete an application form and, where necessary, a risk assessment.

105. As mentioned in the previous sections, the main cost for the industry will be the completion and submission of the application form, risk assessment and contingency plan. There may be further costs where permits for Non-Routine Movements require the establishment of quarantine facilities, for example as possible mitigation for risks identified during the risk assessment process. Costs have been estimated in some instances to amount to £500 per tonne, for a 400 tonne production unit so the overall cost would be £200,000[24]. However, this estimate is based on a purpose built building and using an existing building might reduce the costs significantly. For the purposes of this analysis costs are therefore based on the cost of a recirculation system and estimated to be in the region of £300 per tonne for a 400 tonne production unit with an overall cost of £120,000 p.a.[25].

106. It is unclear how much of a deterrent such costs might be for the industry. It may restrict their willingness to diversify and invest in new species. However, the new arrangements will allow the facility for new 'start ups', compared to the previous arrangements. It should also be recognised that the cost of the application process should be small relative to the start up costs for a new aquaculture operation and thus should not deter some sectors of the industry from expanding in this new trade.

107. In order to facilitate the process, we intend to establish that, where a proposed species has a long history of introduction in other Member States, the risk assessment procedures can be substantially reduced, allowing the applicant to concentrate on the characteristics of the proposed introduction site and whether this is fit for purpose. In addition, we anticipate that the potential farming of particularly warm-water species in secure, closed aquaculture facilities would only require minimal consideration and accordingly should be processed fairly quickly, with a reduced cost of delivering a risk assessment.

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[23] This figure is based on a half a day inspection at an hourly rate of £46 (Cefas Pay Band 4) plus mileage.

[24] The ratio between the set up costs and production capacity will increase as less fish is produced. Consequently, the cost of setting up a smaller establishment is estimated in the region of –

- £10,000 to £15,000 for a 5 tonne unit (£2-3,000 per tonne);
- £15,000 to £20,000 for a 10 tonne unit (£1,500-2,000 per tonne);
- £50,000 to £100,000 for a medium size 50 tonne outfit (£1,000-2,000 per tonne).

[25] As mentioned in the 'Non-routine Movements' section of this document, the number of applications for such movements is expected to be extremely low, in the region of one a year. Although it is not possible to anticipate whether all permits will be made subject to the full quarantine requirements of the Regulation, the calculation of the present value of all costs arising from the implementation of the ASR reflects a scenario where they all are.

108. Similarly, species such as ide (Leuciscus idus), which is not listed in Annex IV, but which appears to comply with Annex IV criteria, might come under a 'blanket licence', which would apply to the entire country and would cover all farm holdings that trade in the species.

109. Subject to a generic assessment for ide by GBAB, we might be able to introduce a routine permitting system that should pose the minimum burden possible on the Government and the industry.

110. In conclusion, we believe that the volatile market for novel species is likely to be a more significant factor in the industry's decision to diversify than the application process and associated costs.

Funding

111. It is anticipated that the fish farming company who intend to farm the novel species will arrange and pay for the risk assessment (directly to the specialist assessor), including assessments of pathways, facilities, species, non-target infectious agents, socio-economic impacts, as appropriate, and the costs of any ancillary questions/clarification required during the NNRAP peer-review process.

112. Introductions cannot generally be reversed and the cost of containment or control measures, which is very high, usually falls on the public purse. It is thus important that those contemplating the use of alien species in aquaculture take full account of the risks posed by their projected actions and that those actions should be prevented if the wider risks to native species and the environment are unacceptably high. Hence, the precautionary approach and the related costs (as outlined in previous sections) are justified when balanced with the potential damage that might be caused.

113. There is a lot of uncertainty about both the number of applications that might be received following implementation (although we expect these to be very few), and about the cost of evaluating associated risk assessments which is likely to vary considerably depending on the species concerned. Consequently, the best way forward was considered to initiate a five-year pilot period, during which the Government would fund the peer review of the risk assessment and associated costs of the application, whilst applicants would be responsible for undertaking and financing the initial risk assessment and the contingency plan. Before the end of the pilot period we would conduct a review with a view to possibly introducing charges for permits to cover costs incurred by Government. A key advantage of this option is that it would enable us to ascertain clearly the number of applications and risk assessments, hence allowing the Government to gauge the full extent of the costs involved. This option was also deemed to represents a sensible and proportionate response to the issue of cost recovery under this Regulation.

Benefits

Option 1: 'Do nothing'

114. This option would preserve the status quo and, therefore, there would be no additional benefits compared to the existing baseline scenario.

Option 2: Implementation of Council Regulation 708/2007 concerning the Use of Alien and Locally Absent Species in Aquaculture

115. Council Regulation 708/ 2008 is intended to provide greater protection for the native fauna and flora across Member States and a level playing field as regards the controls on aquaculture industries in these countries. Existing controls on the keeping and release of non-native species for aquaculture in England and Wales, although fairly comprehensive, are rigid and not sufficiently risk based. This Regulation introduces EC wide rules which require Member States to ensure, by means of a rigorous risk assessment process, that aquaculture of non-native species poses no risk to the biodiversity of natural waters or other aquatic environments within the EU. Hence, it largely eliminates the risks posed by aquaculture, by introducing a more flexible system which provides a greater emphasis on risk assessment[26].

[26] Recent harmonisation of fish health rules under European Council Directive 2006/88/EC has potentially 'freed up' more species for import, as most fish species can now be imported without any specific health testing. As a result, importers are now able to import most of the world's temperate fish species into the UK, on the basis only of their clinical freedom from disease. Although interest in farming of novel non-native species in the UK has so far proved to be fairly low, imports of non-native

116. Continued access to varied and disease free fisheries is vital to 3 million practising anglers. Healthy fisheries are also an important indicator of the state of the rivers. Protecting native species is of key importance. While assigning monetary values to native biodiversity, or the loss of an indigenous species, are problematic, the costs associated with eradicating invasive non-native species can be very high. This perhaps best illustrates the potential major benefits that are likely to result if effective regulatory controls are in place and the introduction of alien species adequately regulated.

117. By way of illustration, the high costs of eradicating an existing invasive species – topmouth gudgeon – are demonstrated by the following examples:

- Topmouth gudgeon were eradicated from a small infected lake in the Lake District using rotenone in March and April 2005. The capital cost of the rotenone was approximately £6,500. Determination of the total manpower cost was complex as the programme ran over a two year period. During the period of rotenone treatment alone, approximately 70 man-days were required to prepare the water for application and 50 man-days for the actual application. On the basis that 1 man-day costs an average of £260, and then the total cost of manpower just to apply the rotenone was £31,200.
- Topmouth gudgeon were eradicated from another small (<1 ha), infected water in the West Midlands in 2006 and the capital cost alone was in the region of £20,000, with man-power costs estimated at over £20,000. The Environment Agency has borne the cost of such operations to date.
- An economic impact assessment estimated the cost of a national eradication programme for topmouth gudgeon at: ≈£3 million per year initially, decreasing to £2.5 m per year after 10 years, £1.5 m per year after 15 years, and reaching zero at 20 years (assuming successful eradication). This was based on eradication costs only and did not include impacts to local and national economies.

118. Of course, topmouth gudgeon is just one example among many non-native fisheries that pose potential threats. These figures have been used as illustration only and have not been used as the basis for further quantification. It is not appropriate to use the figures for value transfer because:

- The aim of the policy is to reduce the limit the likelihood of the introduction of invasive species. However, it is not possible to quantify the change in probability resulting from the change in policy;
- It is not known if the costs of the eradication of topmouth gudgeon are applicable to the eradication of other potential non-native species;
- The geographical scale of any potential spread of non-native species is unknown.

119. Further guidance on the where value transfer is considered appropriate (or not) can be found at http://defraweb/environment/policy/natural-environ/using/valuation/index.htm

120. Allowing the farming of novel species may also lead to positive socio economic effects and possibly provide a small contribution to food security and maintaining fish stocks.

Competition Assessment

121. It is unlikely that this Regulation will have a major impact on competition within the industry. In the UK, the farming of novel alien species is a fairly specialised area, which only a few will want to consider or have the resources to exploit. The key factor in the decision whether to start up fish farming of a 'novel' non native species is likely to be the volatile nature of the market. Recent expansion of this sector has focussed on high-value, warm-water species reared in secure enclosed facilities, and this is considered to represent the most likely immediate route for further growth. The high cost of funding an application and full risk assessment will constitute a possible deterrent but needs to be viewed against the risk to native species and ecosystems, potential loss of biodiversity and the high costs of ameliorative actions should these prove necessary. It should also be noted that although new aquaculture ventures (or existing businesses that wish to expand and deal with

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species for aquaculture will now be subject to Council Regulation (EC) no. 708/2007, which adequately addresses the risk of their establishment in UK waters.

new non-native species) will have to fund the high costs associated with the application process, these trailblazers will then exploit the monetary opportunities that accrue from those ventures.

122. Also, existing sites are not obliged to apply for permits and species farmed in the UK and listed in Annex IV (i.e. such as rainbow trout and common carp) will not be subject to the full rigour of the Regulation, requiring to show only that the proposed site is secure and that the input species come from “a known and trusted source”.

123. The Ornamental Aquatic Trade Association (OATA) have indicated that they are content with the Regulation. It will have a minimal effect on their industry as it does not apply to the keeping of ornamental aquatic animals or plants in pet shops, garden centres, contained garden ponds or aquaria, or in facilities equipped with appropriate effluent treatment systems.

124. Seafish, whose remit is for marine species, are not aware that the industry has any current plans to invest in novel species, but wishes to retain this option for the future. It is their opinion that the industry is successful today because it has been able to extend production into species other than native species. They therefore believe that the industry needs the option to be able to use as broad a range of species as is possible, including novel (and introduced) species if it is to be able to exploit new market opportunities fully in the future. They also feel that the industry, which is made up by many small producers in the main, is already under pressure in complying with ever increasing regulatory mechanisms. Overall, Seafish consider the Regulation to be a hurdle that the majority of UK businesses would find it hard, if not impossible, to get over without financial support although there was no quantified evidence in support of this view. However, we strongly believe that it is paramount that we place rigorous checks on aquaculture to avoid an ecological disaster that cannot be reversed. The burden of proof of minimal risk should rest with operators and should be taken into account in their business plan operations. We do not believe that the short-term costs for funding application forms and associated risk assessments would deter some sectors of the industry, who are presumably investing for the long term, from expanding into this new trade. Also, this Regulation provides a level playing field as regards the controls on aquaculture industries across Europe. Hence, the measures introduced through this Regulation appear essential to control introductions of new alien species and thus accord greater protection to native biodiversity across Europe.

125. The British Trout Association, a UK wide trade association representing an industry responsible for producing and processing some 14,000 tonnes of rainbow trout per annum, have been supportive of moves to assess the environmental risk associated with the introduction of new species and welcomed a precautionary approach to the such introductions. However, they felt strongly that as far as the rainbow trout is concerned, the long history and disbursement of the species in UK, precludes it from being an exotic species. As mentioned previously in this section, species farmed in the UK and listed in Annex IV, such as rainbow trout, will not be made subject to the full rigour of the Regulation, requiring to show only that the proposed site is secure and that the input species come from “a known and trusted source”.

Small Business Assessment

126. While there are a number of small businesses in the aquaculture sector, the economic climate on fish for the table market has been tough and some businesses have ceased trading. The business representatives that we have contacted have indicated that their members would not be very interested in farming novel species. They appear to be focussing on expanding current markets, rather than looking at new species.

127. New ventures and businesses that decide to expand to new species will have to bear the relatively high costs of the application form and the associated risk assessment. However, we anticipate that some risk assessments may be applicable to subsequent applications, and we also anticipate that a routine permitting system (‘blanket licence’) for certain species established in the UK may be introduced as set out in the ‘Exemptions’ section of this document. In addition, where a proposed species has a long history of introduction in other Member States, the risk assessment procedures can be substantially reduced. Consequently, the costs to the industry would reduce significantly.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added to provide further information about non-monetary costs and benefits from Specific Impact Tests, if relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];

There is nothing in the EU Regulation to suggest that there will be a review. However, the UK proposal is to pilot an approach for 5 years and then review its impact.

Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]

Government will hold a review five years after their implementation to consider to what degree these measures have been successful; both how efficient the process is for reaching permitting decisions and the degree to which the industry has accepted the regulation will be assessed.

Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]

Evaluation of data on number of applications, costs of risk assessments and peer reviews. Collection of stakeholder views on application and permitting process.

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

Measures currently in place to regulate the use of non-native species in aquaculture are rigid and not sufficiently risk based. They cover only a limited number of non-native species and thus do not afford any protection against novel, potentially invasive non-native species. Also, they do not use a robust mechanism for evaluating the risk of invasion and potential to harm the environment that a non-native species may pose.

Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]

- Risk analysis process is performed in a timely and cost effective manner
- Industry is able to diversify into novel species with low risk to the environment
- The policy is accepted by the industry
- No introduction of novel potentially damaging non-native species are registered

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

A public register of alien species introductions will be set up. The database will record information on species and risk assessments undertaken, as well as details of aquaculture facilities and of permits issued. The database will be published on the FHI website - www.**efishbusiness**.co.uk/.

Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]

N/A

Annex 2: Outcome of Impact Tests not referred to in the Evidence Base

Justice System

The proposal does not create any new criminal sanctions or civil penalties aside from those referenced in the evidence base where relevant.

Sustainable Development

The proposal complies with sustainable development principles in that the primary aim of the New Order is to allow Cefas/ PHSI to effectively protect native flora and fauna for future enjoyment.

Greenhouse Gas Assessment

The proposal will have no significant effect on carbon emissions.

Wider environmental issues

The proposals are designed to protect the biodiversity of England and Wales, both aquatic and land based.

Health & Wellbeing

The proposal will have no significant impact on health, well-being or health inequalities.

Statutory Equality Duties

None of the proposals discriminate against either race, disability or gender. The proposals do not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposal.

Human Rights

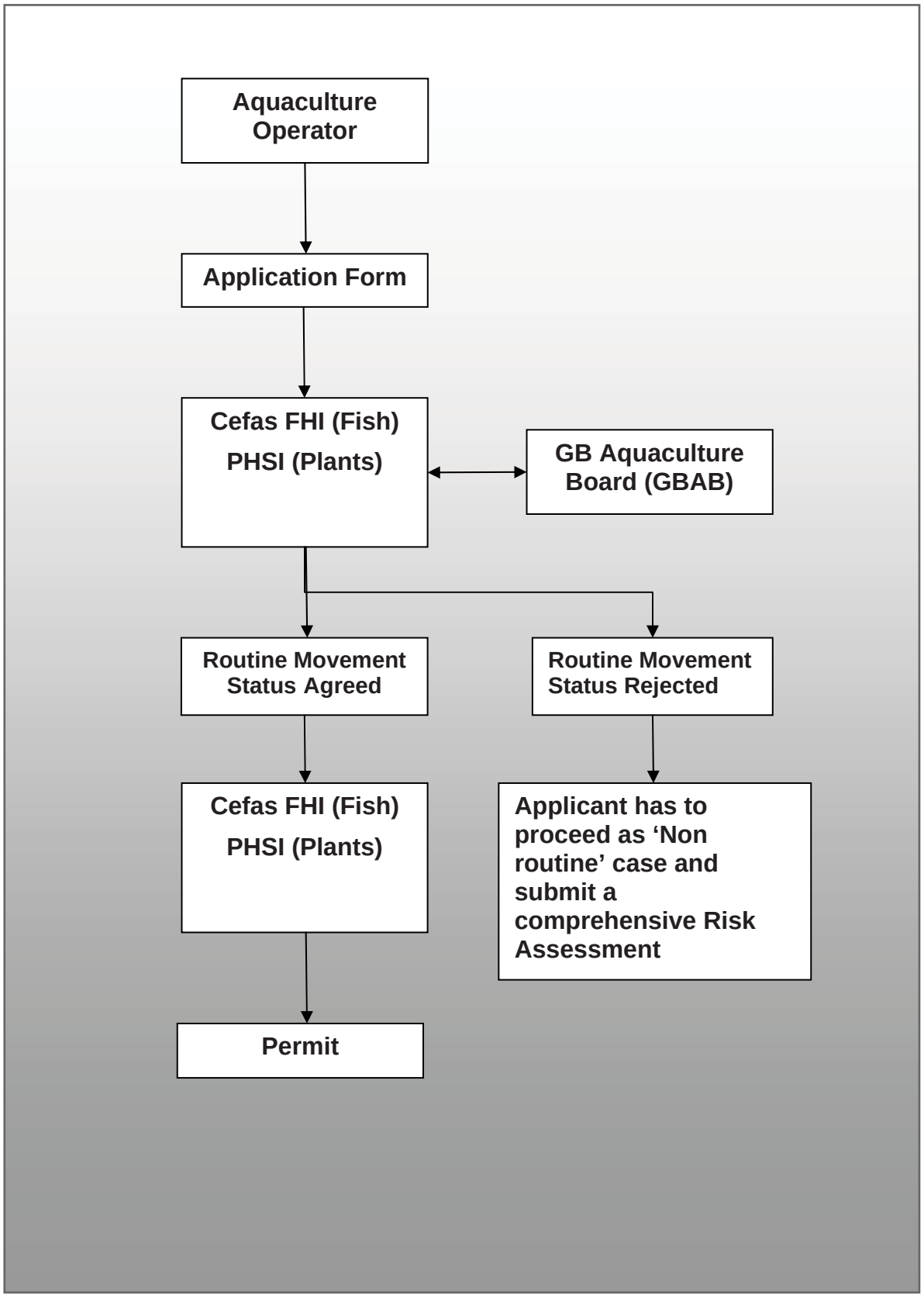
The proposals are consistent with the Human Rights Act 1998.

Rural Proofing

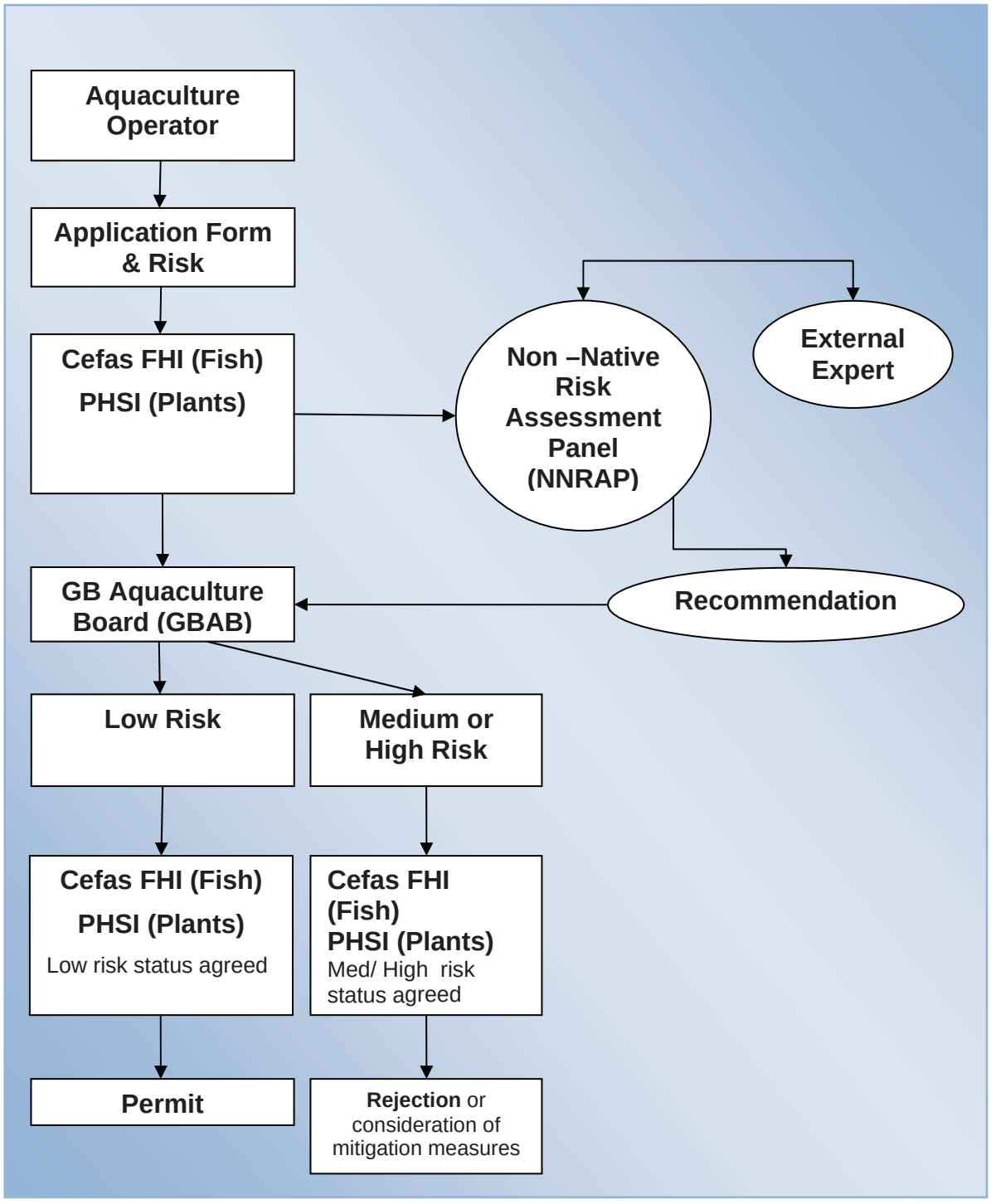
Continued access to varied and disease free fisheries is vital to the 3million practising anglers. The majority of financial benefits that arise from fishing contribute to local communities. As such, the proposals are designed to enhance these benefits and the value of the fisheries to local communities over the long term.

Annex 3 - Application Process under the Alien Species Regulation

Routine Movements



Non Routine Movements



Notes

Cefas (for aquatic animals) and the **Plant Health and Seeds Inspectorate PHSI** (for aquatic plants) will act as the Competent Authorities.

GB Aquaculture Board will act as the Advisory Committee. It will consist of conservation bodies (Natural England, Countryside Council for Wales) and the Statutory Bodies (Cefas (Lowestoft), the Environment Agency and Defra (both fisheries and plant health Divisions)).

The Non –Native Risk Assessment Panel (NNRAP) will act as an independent body tasked with peer-reviewing the Risk Assessments submitted by applicants.

Annex 4 Implementation of EU Regulation concerning use of alien and locally absent species in Aquaculture

Summary of Costs

One-off Costs			
	Cost incurred by	**Estimated cost (£)**	**Comments - Justification**
Design of application form	Govt	£350	£70 per page (form assumed to be 5 pages long - to be confirmed)
Set up of alien species register	Govt	£10,000	Based on the costs of setting up the Register of the Aquaculture Production Business
Annual Costs			
Routine Movements	**Cost incurred by**	**Estimated annual cost (£)**	**Comments - Justification**
Initial advice to applicants	Govt	£1,156	Based on 1 hour per application @£68 per hour and 17 applications per year (Cost per hour based on the full economic charge rate)
Initial consultation with Govt about the ASR	Industry	£782	Based on 1 hour per application @£46 per hour and 17 applications per year (Cost per hour based on the full economic charge rate)
Completion of application forms	Industry	£1,564	Based on 2 hours per application @£46 per hour and 17 applications per year (Cost per hour based on the full economic charge rate)
Registering and preliminary checking of application forms	Govt	£2,312	Based on 2 hours per application @£68 per hour and 17 applications per year(Cost per hour based on the full economic charge rate)
Inspection Costs	Govt	£3,910	Based on a half a day inspection at an hourly rate of £46 (Full economic cost) plus mileage
Final checking and issuing of permits	Govt	£782	Based on 1 hour per application @£46 per hour and 17 applications per year

Annual Costs			
Non-Routine Movements	**Cost incurred by**	**Estimated annual cost (£)**	**Comments - Justification**
Initial advice to applicants (not leading to full application)	Govt	£1,360	Based on 20 queries per year and 1 hour per query @£68 per hour (Cost per hour based on the full economic charge rate)
Initial consultation with Govt about new species	Industry	£920	Based on 20 queries per year and 1 hour per query @£46 per hour (Cost per hour based on the full economic charge rate)
Completion of application forms	Industry	£368	Based on 8 hours per application @£46 per hour and 1 application per year (Cost per hour based on the full economic charge rate)
Registering and preliminary checking of application forms	Govt	£204	Based on 3 hours per application @£68 per hour and 1 application per year (Cost per hour based on the full economic charge rate)
Completion of risk assessment by appointed expert	Industry	£6,000	Average estimate based on need for complex risk assessment dossier from recognised expert. The risk assessment has various modules (e.g. pathway, facility, non-target infectious agents, etc.) and number of modules and complexity of responses is expected to vary widely. Thus, costs will vary, perhaps in the range £2-10k. (Figure based on the full economic charge rate; Figure excludes VAT)
Peer-review of risk assessment and review & subsequent scrutiny by NNRAP	Govt	£13,000	Average estimate based on need for peer review by external risk assessors and review of complex risk assessment dossier by non-native risk assessment panel (NNRAP) (6 members). Costs include peer review by two reviewers, review by NNRAP & subsequent scrutiny and administrative actions by Non-native Species Secretariat, and will inevitably vary, perhaps in the range £10-15k. (Figure based on the full economic charge rate; Figure excludes VAT)
Consideration of NNRAP's advice and issue of recommendation	Govt	£68	Based on 1 hour per application @£68 per hour and 1 application per year
Set up of quarantine facility	Industry	£120,000	This is an estimate of the set up costs for a recirculation system alone based on £300 per tonne for a 400 tonne production unit.
Inspection Costs	Govt	£230	Based on a half a day inspection at an hourly rate of £46 (Full economic cost) plus mileage
Final checking and issuing of permits	Govt	£46	Based on 1 hour per application @£46 per hour and 1 application per year

Summary of estimated average annual costs - Routine and Non-routine Movements			
		Estimated annual cost (£)	**Comments - Justification**
Annual costs for Govt		£23,068	Based on 17 routine and 1 non-routine applications per year and advice on 20 queries from the industry.
Annual costs for Industry (inclusive of quarantine facility)		£129,634	Based on 17 routine and 1 non-routine applications per year and seeking advice on 20 queries from Govt. Assumes average costs for risk assessments and review by NNRAP. Inclusive of set up costs for a quarantine facility.
Annual costs for Industry (exclusive of quarantine facility)		£9,634	Based on 17 routine and 1 non-routine applications per year and seeking advice on 20 queries from Govt. Assumes average costs for risk assessments and review by NNRAP.