Title: The Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 **IA/PIR No: 2011/2292** **Lead department or agency:** Defra **Other departments or agencies:** Fish Health Inspectorate **Contact for enquiries:** John Manning 020 8026 3388	Post Implementation Review **Source of intervention:** Domestic **Type of regulation:** Secondary legislation **Type of review:** Statutory - other **Date of implementation:** 10/10/2011 **Date review due (if applicable):** 10/10/2016

Summary

1a. What were the policy objectives and the intended effects? (If policy objectives have changed, please explain how).

The policy objective was to enable the economic growth of the aquaculture industry whilst limiting the potential threats to our native ecosystems posed by the introduction of new alien species. This was to be achieved by assessing the 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.

The Government also wanted to fully implement Council Regulation 708/2007 concerning the use of Alien and Locally Absent Species in Aquaculture [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l28179#amendingact] , which introduced a framework throughout the EU to ensure protection from the risks associated with the use of alien and locally absent species in aquaculture.

1b. How far were these objectives and intended effects expected to have been delivered by the review date? If not fully, please explain expected timescales.

The objectives and effects were expected to have been delivered by the statutory October 2016 review date for England-only.
The success criteria were listed as:

- 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

2. Describe the rationale for the evidence sought and the level of resources used to collect it, i.e. the assessment of proportionality.

In 2011, we did not envisage a significant impact on the UK's established aquaculture production businesses following implementation of the regulations. Most of the existing businesses that produced non-native species dealt in certain commonly-farmed salmonids, shellfish and molluscs that were already well established in trade. These species were exempt from the regulations with no requirement for retrospective applications. However, the regulations did require those businesses who wished to expand and deal with new species to complete an application form and risk assessment as appropriate.

The original expectation, that only a low number of applications would be made under the regulations has been borne out, with 10 routine movement applications (species farmed in a closed environment or using species established before the 2011 regulations), 10 enquiries into non-routine movement applications (using novel species post-2011 and farmed in an open environment) and 0 non-routine movement applications. Consequently, the regulations have undergone a light-touch review, with a low level of evidence sought by seeking views from aquaculture businesses and key stakeholder organisations. We also emailed officials from other UK administrations and EU member states to check how they were implementing Council Regulation 708/2007 concerning the use of Alien and Locally Absent Species in Aquaculture. This approach is proportionate due to ex-ante and ex-post assessment of a low impact on businesses.

3. Describe the principal data collection approaches that have been used to gathering evidence for this PIR.

This PIR has been informed through the implementation of a light touch process evaluation informed by stakeholder surveys and discussion with the implementing body, the Fish Health Inspectorate, and a high-level review of impacts.

The main source of monitoring data is from data on the number of applications made under these regulations from the public register of Alien Species in Aquaculture in England and Wales, held and made available by the Fish Health Inspectorate http://www.cefas.defra.gov.uk/alienspecies/default.aspx.

In order to inform this PIR's process evaluation and review of impacts, we approached five key stakeholder organisations by email and telephone to seek their views on the regulations through a questionnaire. We also distributed the questionnaire to members of Seafish's Aquaculture Common Issues Group, whose mailing list includes representation from the main producer associations, food and fish feed processors, retailers, environmental NGOs, Crown Estates, Government Departments and regional development organisations, as well as Seafish. The questionnaire asked respondents the following questions to inform both the process evaluation and review impacts:
1) if they believed these regulations were achieving their objective
2) their experiences in relation to operating in other Member States
3) whether these regulations could be acting as a significant barrier to the introduction of new aquaculture species in England & Wales and/or the establishment of new businesses
4) how these regulations might be improved, bearing in mind UK legal obligations in relation to Council Regulation 708/2007 (Alien and Locally Absent Species in Aquaculture).

We received two responses to the questionnaire (one from a trade group, one from the industry levy body) which have informed the findings of this PIR. This small response was despite following up with organisations by telephone and email several times.

Out of the ten organisations which made enquiries into farming novel species in open environments, we had contact details for two organisations, who we contacted to seek their views on why they decided not to go ahead with their enquiries. Of the two organisations contacted, one responded, saying that they were not able to raise the funds required to establish the business and subsequently developed another business; however it still remained a future interest.

As part of the process evaluation, we also emailed officials from EU member states who had attended an aquaculture seminar on 18-19 November 2015 organised by the European Commission to check how other member states had implemented Council Regulation 708/2007 concerning the use of Alien and Locally Absent Species in Aquaculture. The email included details of how 708/2007 was implemented in England and requested similar information on how member states had implemented the Council Regulation. We separately emailed administrations within the UK to enquire how they had implemented the Regulation and its effects on their aquaculture sectors.

We received responses from eight member states (Belgium (Flanders and Wallonia), Croatia, Germany (national environmental ministry and Schleswig-Holstein region), Greece, Hungary, Slovakia, Spain, and Sweden) and one UK administration (Scotland).

As part of this PIR's process and impact evaluation, we also spoke to officials from the Fish Health Inspectorate, who described how the regulations had been implemented. This also helped to inform the impact evaluation by describing whether officials had received any initial expressions of interest in using new alien species by new aquaculture businesses which may have been discouraged by either the introduction of these regulations or in their implementation.

4. To what extent has the regulation achieved its policy objectives? Have there been any unintended effects?

Please set out conclusions and supporting evidence.

The policy objective in 2011 was to enable the economic growth of the aquaculture industry whilst limiting the potential threats to our native ecosystems posed by the introduction of new alien species.

As there have been no recorded threats since 2011 to local ecosystems posed by new alien species used for aquaculture in England, then this part of the policy objective is considered to have been successful.

There have only been ten initial enquiries and no formal applications to introduce novel alien species not presently farmed in open-environment systems since the introduction of these regulations in 2011. The limited response received from stakeholder engagement would suggest that these regulations have had little or no positive or negative effects on existing aquaculture businesses, which take place either in closed-environment systems or using alien species introduced before the regulations came into effect (and listed in Annex IV of the regulations), as they have not held back the profitability of the industry by imposing an additional burden in terms of application costs.

This PIR also looked at whether these regulations could have held back the growth of the sector by deterring applications to introduce new alien species in new aquaculture businesses. One stakeholder suggested that this may have been the case, but there is insufficient evidence to suggest how large this effect may be. However, an initial enquirer to the Fish Health Inspectorate reported that they did not pursue an application due to business reasons, an inability to raise the necessary funds to establish a new aquaculture production facility, and that it still remained an interest. It is therefore likely that the absence of any formal applications for introducing new alien species is associated with a lack of suitable market conditions and demand for such species rather than the introduction of the regulations.

The introduction of the regulations is driven by the very high potential costs to society if alien species are introduced to the environment. Evidence shows that there have been no recorded ecosystem threats from introduction of alien species to the environment from aquaculture businesses since the introduction of alien species (Cefas, pers. comm. 2015). However, this may also have occurred without implementation of the Regulations, as evidence also suggests that the demand for using novel species in aquaculture businesses has been low.

5a. Please provide a brief recap of the original assumptions about the costs and benefits of the regulation and its effects on business (e.g. as set out in the IA).

Costs

In 2011, one-off costs to public bodies to set up the permit system (design of application forms/ setting up of a public register) were expected to be £10.35k. Costs to public bodies for permit applications (both routine and non-routine) were expected to be £23.07k on average per year. Costs to the industry for licence applications (both routine and non-routine, inclusive of quarantine facilities) were expected to be £129.63k on average per year.

Benefits

In 2011, the interest in new aquaculture species for the UK appeared to be low. However, the costs of eradicating an invasive non-native species was illustrated by the £2.5m per year on average for a national eradication programme for Topmouth gudgeon, highlighting the dangers of inadequate controls and the benefits to be derived from having appropriate regulation.

In 2011, it was considered 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 was considered vital to the three million practising anglers; healthy fisheries were considered an important indicator of the good ecological status of rivers under the Water Framework Directive (WFD).

5b. What have been the actual costs and benefits of the regulation and its effects on business?

Costs

All costs are presented in 2011 prices. The one-off costs to public bodies have been estimated as £10,350 for setting up the permitting system, with ongoing annual costs of £9,400 for operating the system. There are costs to private businesses of £400 per year for submitting routine movement applications (those involving species farmed in a closed environment or introduced before the 2011 regulations) and making non-routine movement enquiries (those involving novel alien species in an open environment) into applications, using the regulations. These costs are significantly lower than those expected in the Impact Assessment, as no businesses applied for or were granted a non-routine movement of alien species and therefore no businesses have incurred the substantial costs of adapting their aquaculture operations to comply with a license.

Benefits

Evidence shows that there have been no recorded ecosystem threats from introduction of alien species to the environment from aquaculture businesses since the introduction of alien species (Cefas, pers. comm. 2015). However, this may also have occurred without implementation of the Regulations, as evidence also suggests that the demand for using novel species in aquaculture businesses has been low.

The potential costs from new invasive species being introduced into the natural environment remain high; for example costs of £2.7m per year from signal crayfish which were introduced to the UK in the 1970s. Hence these regulations are considered to form part of an overall system which has prevented such costs from occurring, aiming to ensure a successful sustainable and responsible aquaculture industry both now and in the future.

6. Assessment of risks or uncertainties in evidence base / Other issues to note

- What are the main limitations to the evidence base for the PIR?
- Are there any other issues which should be considered when this PIR is reviewed?

There are two main limitations to the evidence base in this PIR. Firstly, the absence of any non-routine movement applications under these Alien Species in Aquaculture Regulations (ASR) has meant that it is difficult to judge how effectively the process works and how well the regulations achieve their objectives. Secondly, a limited response from the aquaculture sector to our data collecting tools has meant that it has been difficult to judge whether the regulations have deterred businesses from introducing alien species into aquaculture businesses.

7. Lessons for future Impact Assessments

- Are there any significant lessons for future IAs arising from this PIR, e.g. were any costs or benefits substantially mis-estimated and, if so, how can better estimates be obtained in future?

The original Impact Assessment substantially over-estimated interest in introducing new alien or non-native species into aquaculture businesses, leading to over-estimated costs. The assumptions in the original impact assessment were not based on sound evidence regarding the future interest in alien species. Future Impact Assessments should adopt a more cautious approach and attempt to gather more intelligence from businesses regarding their future intentions, in this case to introduce new alien species or if other innovative changes into the aquaculture sector were proposed.

8. What next steps are proposed for the regulation (e.g. remain/renewal, amendment, removal or replacement)?

Please summarise rationale and provide evidence below.

In summary, since the Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 came into effect, there have to date been no new potential threats to native ecosystems posed by newly introduced alien species, with only very limited evidence suggesting that these regulations are restricting the economic growth of the aquaculture sector.

In addition to these regulations which apply to England and Wales, there are equivalent regulations applying to Scotland and Northern Ireland:

Alien and Locally Absent Species in Aquaculture (Scotland) Regulations 2015

[http://www.legislation.gov.uk/ssi/2015/103/contents/made]

Alien and Locally Absent Species in Aquaculture Regulations (Northern Ireland) 2012

[http://www.legislation.gov.uk/nisr/2012/335/made]

Having these alien species in aquaculture regulations (ASR) remain in place ensures that the UK Government meets its legal obligations under Council Regulation 708/2007 [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l28179#amendingact] , which introduced a Europe-wide framework to ensure protection from the risks associated with the use of alien and locally absent species in aquaculture. Responses from other EU states and UK administrations indicated that they have implemented the Council Regulation in a similar way to England and the rest of the UK.

The most important factor, however, is that the potential costs arising from new invasive species being introduced into the natural environment would be high. For example, costs of £2.7m per year are estimated to have arisen from one particular invasive species, signal crayfish, introduced into the UK in the 1970s.

Therefore, these regulations are considered to form part of a proportionate overall system which has prevented costs arising from the introduction of new invasive species into the local environment. The regulations help to ensure a successful sustainable and responsible aquaculture industry both now and in the future.

As a result, it is proposed that these Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 remain in place in England in their current form, subject to further review in England in 2021.

Sign-off For Post Implementation Review:

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the policy.

Signed: John Manning (Fisheries & Conservation) Date: 09/08/2016

Evidence Base

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1. Introduction and Summary of Approach

1.1 Introduction

1.1.1 These Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 implemented Council Regulation 708/2007 on the use of alien and locally absent species in aquaculture. Regulation 708/2007 introduced a framework within the EU to ensure adequate protection for the aquatic environment from the risks associated with the use of alien and locally absent species in aquaculture. This is 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 was and continues to be 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.

1.1.2 The original objective was to maintain a 'light touch' and avoid additional administrative burden, where possible, whilst implementing Regulation 708/2007 and so meet UK legal obligations.

1.1.3 The Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 cover England and Wales, but the scope of this PIR only covers implementation of this Regulation in England.

1.2 Background on the Aquaculture Sector[1]

1.2.1 Aquaculture in the UK contributed £194m to the economy in GVA in 2012.[2] However, production is dominated by the Scottish salmon sector; Scottish aquaculture accounted for 92% of production in the UK in 2012. However, this regulation only covers aquaculture in England and Wales, where the industry is much smaller scale and is made up of small businesses.

[1] All statistics in this section on production, employment and number of businesses are from 2012 and sourced from Cefas: Aquaculture Statistics for the UK, with a focus on England and Wales (2012). Available here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/405469/Aquaculture_Statistics_UK_2012.pdf

[2] European Commission: Annual Economic Report on the Economic Performance of the EU Aquaculture Sector (2014). Available here: https://stecf.jrc.ec.europa.eu/documents/43805/839433/2014-11_STECF+14-18+-+EU+Aquaculture+sector_JRC93169.pdf

1.2.2 Aquaculture in England and Wales is split into the finfish, shellfish, and plant sectors. 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, aquaculture encompasses watercress production, water reed production, algae for industry and the production of ornamental aquatic plants.

1.2.3 In England and Wales there are 356 registered finfish and shellfish farms. Of these, there are 278 finfish farms, and 78 shellfish farms. Finfish farms employed 923 people in 2012 in England and Wales, and shellfish farms employed 292 people.

1.2.4 The main finfish species farmed is rainbow trout, with 8400 tonnes of rainbow trout produced and 800 tonnes of other finfish species in England and Wales. Total finfish production was worth £23m in revenue in 2012.

1.2.5 The main shellfish species farmed is mussels, with 15000 tonnes of mussels produced in 2012 in England and Wales, and 1000 tonnes of other molluscan species. Total molluscan shellfish production was worth £19m in revenue in 2012. There is also a small amount of crustacean production, but this is not valued.

1.2.6 Whilst the plant sector 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.

2. Policy Options Considered

2.1 Rationale for Intervention

2.1.1 Alien species have been identified as one of the key causes of the loss of biodiversity in the EU and the world at large. The costs of damage to the environment caused by alien species are incurred by society as a whole. This is an example of an external cost, as the individual actor responsible for the release of an alien species will not bear the full costs of damage from the release of the species.

2.1.2 The aquaculture sector is motivated by commercial gain. Without intervention, the aquaculture sector 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.

2.1.3 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.

2.1.4 The UK Government supports Council Regulation 708/2007, which provides a framework throughout the EU to ensure protection from the risks associated with the use of alien and locally absent species in aquaculture. We believe that this regulation largely eliminates the risks posed by aquaculture, and that it is beneficial to the businesses by ensuring that they can trade responsibly 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.

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

2.2.1 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.

2.2.2 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 biogeographical 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.

2.2.3 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.

The Competent Authority

2.2.4 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.

2.2.5 The competent authority in England and Wales is the Fish Health inspectorate at Cefas for introductions and translocations of aquatic animals with input from the Plant Health and Seeds Inspectorate (PHSI) at the Animal and Plant Health Agency (APHA) where aquatic plants are involved.

Permits

2.2.6 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 are 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

2.2.1 Aquaculture operators intending to undertake the introduction of an alien species or the translocation of a locally absent species 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) and listed in Annex IV 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.

2.2.2 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.

2.2.3 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.

Exemptions

2.2.4 The UK ensured that the Regulation would not apply retrospectively, so that those already farming alien species were 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 allows applicants to concentrate more on the characteristics of the proposed introduction site and whether this is 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.

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

2.2.6 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), 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.

2.2.7 As noted previously, Member States retain the right to regulate species on Annex IV, managing them in all circumstances if they choose. Thus, any new species subsequently added to the Annex IV list in future, 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.

2.3 Baseline before The Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011

2.3.1 The following legislation applicable to the aquaculture sector was in place before the 2011 regulations:

2.3.1.1 The Aquatic Animal Health (England and Wales) Regulations 2009

2.3.1.2 Authorised Aquaculture Production Businesses (APBs)

2.3.1.3 The Import of Live Fish Act 1980 (ILFA)

2.3.1.4 Wildlife and Countryside Act 1981

2.3.1.5 The Plant Health Order 2005

2.3.2 The scope and implications of these regulations are discussed in Annex B. All of these regulations continue to apply to the aquaculture sector in England, with the exception of the Import of Live Fish Act, where the relevant provisions of the Act were superseded by implementation of the ASR in 2011.

2.4 Policy Aim and Objectives

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

2.5 The Regulations Implemented in 2011

2.5.1 The Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 implemented Council Regulation (EC) No 708/2007 concerning the use of alien and locally absent species in aquaculture. Council Regulation 708/2007 is described more fully in paragraphs 2.2 above.

2.5.2 Regulation 4 requires the Secretary of State to review the operation and effect of these Regulations in England and lay a report before Parliament within five years after they come into force and within every five years after that.

2.5.3 Part 2 of the Regulations deals with permits (regulation 5), environmental risk assessments (regulation 9), contingency plans (regulation 10) and monitoring (regulation 11). It also makes provision for the movement of species listed in Annex IV to Council Regulation 708/2007 and locally absent species from within the United Kingdom to be restricted (regulations 6 to 8).

2.5.4 Part 3 gives enforcement powers to inspectors and makes provision for appeals. A person found guilty of an offence under these Regulations is liable on summary conviction to a fine not exceeding the statutory maximum or on conviction on indictment to an unlimited fine (regulation 23).

3. Costs and Benefits

3.1 Costs and Benefits in Impact Assessment

3.1.1 The ex-ante impact assessment identified several potential impacts on businesses, government and wider society from implementation of the Alien Species Regulation, which are summarised below.

Costs to Government

3.1.2 The Impact Assessment estimated that there would be one-off costs to Government of introducing the Regulation, which included costs of drafting an application form (£350) and developing a public register of alien species introductions (£10,000), leading to an estimated one-off cost to Government of £10,350.

3.1.3 The Impact Assessment also estimated costs for applicants and Government of applications. The method used in the IA to estimate these costs was based on the distinction between routine and non-routine movement applications, as explained in paragraph 2.2.2.

3.1.4 For routine movement applications, the IA assumed that it would take the Fish Health Inspectorate (FHI) or the Plant Health and Seeds Inspectorate (depending on whether the application was for a fish or shellfish species or a plant species) 1 hour to provide initial advice on an application at a cost of £68 per hour, 2 hours to assess and process each application at £68 per hour, and 1 hour to issue the permit at £46 per hour. This leads to a total cost to the FHI and/or the Plant Health and Seeds Inspectorate (PHSI) of £250 per application, or a total annual cost of £4250.

3.1.5 For non-routine movements, the IA assumed it would take 1 hour to respond to initial queries at a cost of £68, resulting in a total cost of £1360 per year.

3.1.6 The IA assumed it would take the FHI or the PHSI 3 hours at a cost of £68 to review a non-routine application, followed by 1 hour at £68 to prepare a recommendation from an Aquaculture Advisory Board (consisting of Cefas, the Environment Agency and Natural England) and a further one hour at £46 to issue the permit for a successful application. This results in annual admin costs of £318.

3.1.7 The IA also assumed that the Government would also be liable for the costs of peer reviewing the risk assessment provided by the applicant. These were estimated at £13,000, including paying for the costs of peer reviewers' time, for the time of members of a Non-Native Risk Assessment Panel (NNRAP) to attend a meeting to discuss the application, and for the time of the NNRAP secretariat to undertake the associated administrative tasks.

3.1.8 For both routine movement and non-routine movement applications, the FHI and PHSI would also inspect the site to ensure that there was a low-risk of escape and that the premises were secure. The estimated costs of an inspection were £230, leading to an annual cost of inspections of £4,140 for the 17 routine movement cases and one non-routine movement case.

3.1.9 This leads to total annual costs to Government of £23,100 (rounded to the nearest £100).

Costs to Businesses

3.1.10 For routine movement applications, the applicant may have to contact the FHI or PHSI for guidance with their application, and will also have to spend time filling in the application form. The IA estimated that it will take each applicant one hour to make enquiries and read guidance on filling in an application, and two hours to fill in the form, all costed at a rate of £46 per hour. This therefore results in expected costs to business of £138 per application, or total annual costs to business of £2,346 for the 17 routine movement applications.

3.1.11 For enquiries into non-routine movement applications, the IA assumed that it would take each business one hour to make an enquiry and read the guidance provided by the FHI or the PHSI. This is costed at a rate of £46, resulting in a total annual cost to business of £920 for the expected 20 enquiries.

3.1.12 There will also be costs to businesses which choose to make a full non-routine movement application. The applicant will have to undertake a risk assessment for the proposed species, which the IA estimated would cost £6,000. In addition, there would also be some administrative work in relation to the risk assessment and application, which the IA estimated would take 8 hours costed at £46. An applicant may also have to install quarantine facilities for the new alien species.

3.1.13 The IA acknowledged that these costs are very uncertain and depend on the type of facility required and existing buildings on the site, but estimated that additional costs to the applicant for installing quarantine facilities to comply with the Regulation would cost £120,000. This results in a total annual cost to business for making a non-routine movement application of £126,368.

3.1.14 This results in total annual costs to businesses of £129,600 (rounded to the nearest £100). The profile of costs to the public and private sector over the course of the five year appraisal period is shown in Table 1.

Table 1: Costs to public and private sector estimated in Impact Assessment

Year	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Costs to Government						
One-off Costs of Setting up System	£0.010m	0	0	0	0	£0.010m
Annual Costs for routine movement applications	£0.004m	£0.004m	£0.004m	£0.004m	£0.004m	£0.021m
Annual Costs for non-routine movement enquiries	£0.001m	£0.001m	£0.001m	£0.001m	£0.001m	£0.007m
Annual Costs for non-routine movement applications	£0.013m	£0.013m	£0.013m	£0.013m	£0.013m	£0.067m
Annual costs for inspections	£0.004m	£0.004m	£0.004m	£0.004m	£0.004m	£0.021m
Total Costs to Government	**£0.033m**	**£0.023m**	**£0.023m**	**£0.023m**	**£0.023m**	**£0.126m**
Costs to Businesses						
Annual Costs for routine movement applications	£0.002m	£0.002m	£0.002m	£0.002m	£0.002m	£0.012m
Annual Costs for non-routine movement enquiries	£0.001m	£0.001m	£0.001m	£0.001m	£0.001m	£0.005m
Annual Costs for non-routine movement applications	£0.126m	£0.126m	£0.126m	£0.126m	£0.126m	£0.632m
Total Costs to Businesses	**£0.130m**	**£0.130m**	**£0.130m**	**£0.130m**	**£0.130m**	**£0.648m**
Total Costs	**£0.163m**	**£0.153m**	**£0.153m**	**£0.153m**	**£0.153m**	**£0.774m**

Benefits

3.1.15 The Impact Assessment expected there to be interest from the UK aquaculture sector in introducing new alien species into aquaculture farms, despite a lack of evidence and low levels of interest at the outset of the policy's implementation. This is shown in the estimated number of applications discussed in costs.

3.1.16 The Impact Assessment predicted that successful implementation of the policy would reduce the risks of new alien species released from aquaculture businesses damaging the environment. This was expected to be of high value to society, particularly with regard to users of the environment such as anglers.

3.1.17 The Impact Assessment noted that it is very difficult to value changes in the state of the environment and native biodiversity. It indicated the scale of the potential benefits from reducing the risks of alien species entering the environment through the estimated costs of eradicating topmouth gudgeon, an invasive species which damages the freshwater environment. The IA cited an economic impact assessment of the costs of eradicating topmouth gudgeon as in the range £1.5m-£3m per annum over a 20 year period.

3.1.18 However, these benefits were only presented indicatively, as it's difficult to estimate the reduction in risk from implementing the Alien Species Regulation, or the potential costs of any new alien species outbreak, which may be different from the costs of eradicating topmouth gudgeon.

3.1.19 In addition, the IA also noted the potential benefits to the aquaculture sector of greater certainty in being able to introduce alien species with a low risk of escape. These benefits were not quantified.

3.2 Methodology

3.2.1 This PIR has involved both a process evaluation and a high-level review of impacts. The process evaluation has been undertaken in order to understand how the regulation has been implemented, and if implementation can be improved, how it can be improved. This includes investigating how European Council Regulation 708/2007 has been implemented in other EU member states.

3.2.2 The review of impacts has been undertaken in order to understand the costs and benefits of the regulation, including comparing them to the impacts estimated in the ex-ante impact assessment.

3.2.3 In order to undertake both the process and review of impacts it is necessary to collect evidence. The available guidance for conducting Post Implementation Review states that the level of evidence collected should be proportionate to the expected impact and risk of a policy.[3]

3.2.4 In the case of this policy, the ex-ante Impact Assessment estimated that the total Present Value costs to business and Government were £0.72m over the course of five years. However, much of these costs were made up of application costs for businesses for submitting full applications to introduce alien species into aquaculture production sites. An initial review of the available data on applications showed that no full applications had been made over this period, and therefore costs would be expected to be much lower than this.

3.2.5 Furthermore, the UK was required to introduce this regulation by European Council Regulation 708/2007, which is still binding. As a result of the expected low impact and ongoing requirement to implement regulation on alien species in aquaculture, this PIR has sought to collect a low level of evidence to support its conclusions, in line with existing guidance on proportionality in PIRs.

3.2.6 Data collection has been informed by creating a logic model for this policy. The logic model is shown in Section 3.3. The evidence collection methods used are listed below:

3.2.6.1 **Use of available monitoring data:** This includes data collected by the Fish Health Inspectorate in Cefas on the number of applications for non-routine movements of alien species in aquaculture[4], and the outcomes of these applications.

3.2.6.2 **Survey of industry stakeholders:** Defra designed and distributed a survey asking aquaculture membership organisations for their experiences with these alien species in aquaculture regulations (ASR), and costs incurred as a result of the ASR. The survey is shown in Annex A. The survey was directly sent to four industry associations the British Trout Association, the Ornamental Aquatic Trade Association, Shellfish Association of Great Britain and the Seafish Industry Authority (henceforth referred to as Seafish), with two reminders to participate issued to stakeholders. In addition, the survey was sent to members of the Aquaculture Common Issues Group, which includes aquaculture production businesses, and other stakeholders. There were two responses to this survey from Seafish and another trade body.

[3] Cross Government Evaluation Group, Regulatory Policy Committee Secretariat and Better Regulation Executive: Guide for Conducting Post Implementation Reviews V6, August 2015.

[4] Available here: http://www.cefas.defra.gov.uk/alienspecies/default.aspx

3.2.6.3 Follow-up contact with enquirers: Defra has also contacted businesses which enquired into non-routine movement applications to ask about their experiences with the Regulation and why they chose not to proceed with an application. There were two enquiries for which the FHI were able to provide contact details, of which one responded to a request for information.

3.2.6.4 **Interviews with Cefas' Fish Health Inspectorate (FHI):** the FHI is responsible for implementing these regulations which apply to England and Wales. As part of the evidence collection for this PIR, Defra officials conducted an interview with the FHI in order to understand how these regulations were implemented, the costs to Government of their implementation, and their impacts on the aquaculture sector and the environment.

3.2.6.5 **Evidence from other member states and UK administrations:** Defra also collected evidence by email from 32 officials from EU member states[5] who had attended an aquaculture seminar on 18-19 November 2015 organised by the European Commission. The email included details of how Council Regulation 708/2007 was implemented in England and Wales and requested similar information on how other member states had implemented the Council Regulation. Further to this, we also contacted other UK administrations to ask how they had implemented the Regulation and its effects on their aquaculture sectors. We received responses from eight member states and one UK administration, which have also fed into the results of this PIR.

3.3 Logic Chain

3.3.1 Logic chains are a frequently used tool in evaluation to demonstrate how a policy would achieve its intended objectives. The logic chain also helps to identify the assumptions which are required to be fulfilled for a policy to achieve its objectives. This can help to identify indicators to track whether the policy is achieving its objectives, and identify possible reasons why it may not be achieving them or how implementation can be improved. A logic chain shows:

3.3.1.1 **Objectives**: what the policy is designed to achieve

3.3.1.2 **Inputs**: the resources which are allocated to achieving the policy's objectives

3.3.1.3 **Activities**: the activities which the inputs are used to undertake

3.3.1.4 **Outputs**: the direct results of the activities of the policy

3.3.1.5 **Outcomes**: the short- and medium-term benefits from the policy's outputs

[5] Some member states had more than one official attending.

3.3.1.6 **Impacts**: the wider and long-term benefits of achieving the policy's objectives

3.3.2 Figure 1 shows a logic chain for the Alien Species in Aquaculture which has been developed as part of the analysis to support development of this PIR.

Figure 1: Logic Chain for the Alien Species in Aquaculture Regulations (ASR)

Objective: to enable the economic growth of the aquaculture industry, whilst limiting the potential threats to ecosystems posed by alien species					
Group	**Inputs**	**Activities**	**Outputs**	**Outcomes**	**Impacts**
Aquaculture Businesses	Time for aquaculture businesses to understand ASR, costs of additional time and expertise to make an application	Familiarise with ASR; make applications under ASR	Able to introduce alien species where risks to environment are low	Greater certainty on ability to introduce alien species	Economic growth in the aquaculture sector
Government	Time spent by officials to implement and manage ASR, costs of developing applications database	ASR implemented; database operational; process applications under ASR	Regulation is in line with EU Council Regulation	Avoiding costly programmes to deal with alien species	-
Society	-	-	Alien species not introduced where there is a medium or high risk to the environment	Threat from alien species introduced via aquaculture reduced	Biodiversity within the marine & freshwater environment is protected
Indicators	1. Costs to applicants of making applications 2. Costs to Government of processing applications, maintaining database	3. Number of applications received under ASR 4. Proportion of aquaculture businesses deterred from introducing alien species by ASR	5. Number of applications accepted / rejected	6. Industry perceptions of certainty under ASR 7. Alien species used by aquaculture businesses	8. Industry perceptions of whether ASR has stimulated or held back industry 9. Recorded threats to ecosystems from alien species used in aquaculture

3.4 Process Evaluation: Evidence gathered in the UK

3.4.1 The process evaluation aimed to address whether these regulations have been implemented as intended, and whether implementation could be more effective. The survey of stakeholders and interviews with the Fish Health Inspectorate have provided data to inform the process evaluation.

3.4.2 The FHI provided evidence on how these regulations had been implemented, including describing the process which applications go through. A summary of this is provided below in Figure 2.

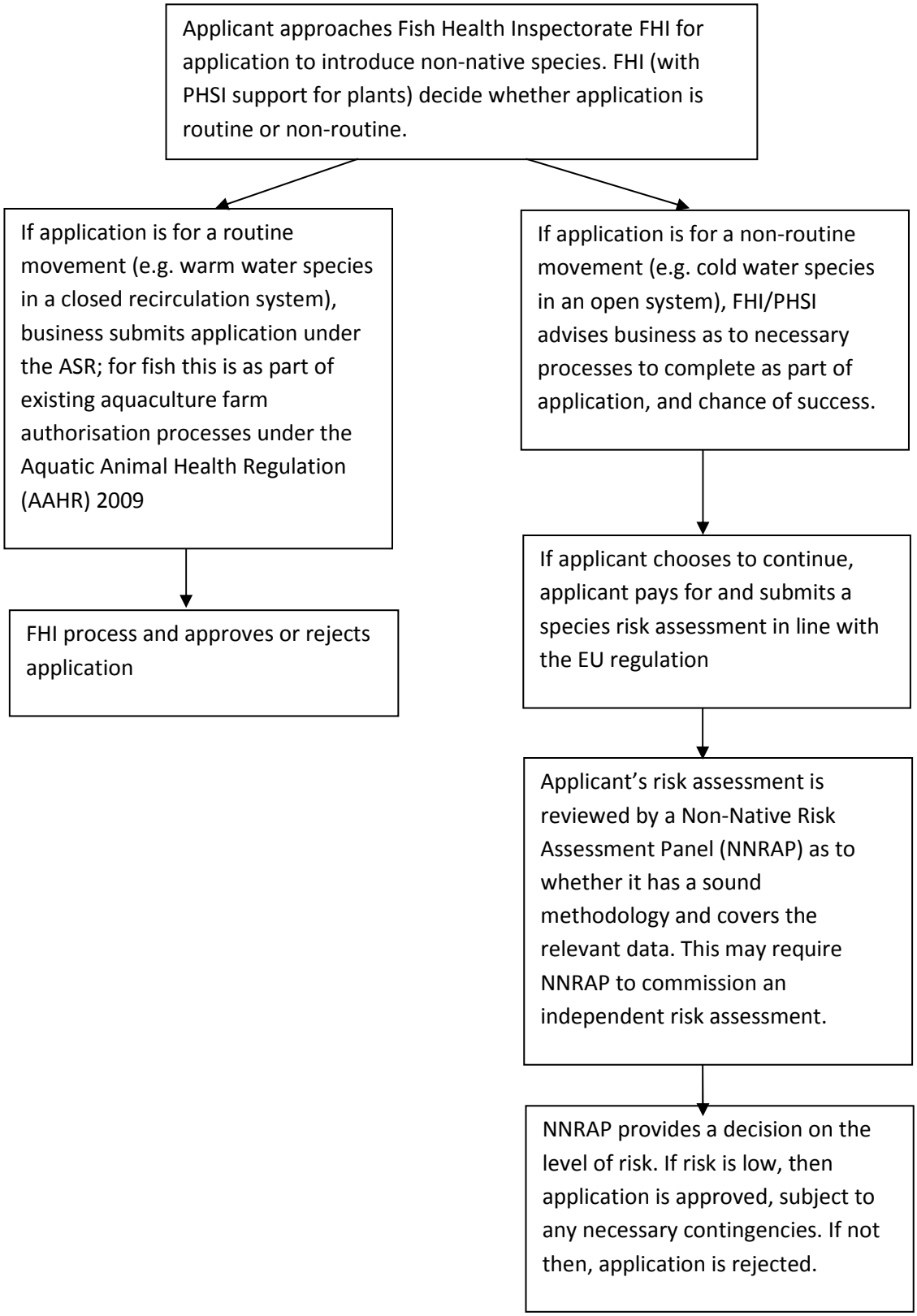
3.4.3 Figure 2 shows that the process for applications has been implemented as intended and set out in the Impact Assessment, with two exceptions. Firstly, for routine movement applications of fish, the application process has been merged with the process for authorising aquaculture farms under the Aquatic Animal Health Regulations 2009 (AAHR), a regulation which is in the baseline. The FHI suggested that this has helped to reduce costs to the public sector of implementing the measures, and reduced the administrative burden on businesses.

3.4.4 Secondly, the FHI also emphasised the role of advice to potential applicants ahead of submitting an application for a non-routine movement. While this was included in the original process, the FHI emphasised that this advice is an important part of the process which informs potential applicants regarding the potential costs and chances of success of the application process for non-routine movements.

3.4.5 The two responses received from the stakeholder survey did not indicate any problems or potential improvements with how the regulations had been implemented. The lack of response to the stakeholder survey also suggests that none of the potential respondents considered the way the regulations had been implemented to be a significant burden or factor holding back the growth of the sector. The FHI suggested that a further potential reason for the lack of response was the move to merge the processes for the ASR with those for the AAHR, which meant that applicants for new aquaculture farms would not be aware that they were fulfilling the requirements under the ASR.

3.4.6 In conclusion, the ASR regulations have been broadly implemented as intended, with some small changes. There is no evidence which points to how the implementation of these regulations has led to a failure to achieve their objectives, or how their implementation could be improved.

Figure 2: Process Chart for applications to introduce non-native species into aquaculture sites under the Alien Species Regulations ASR



3.5 Process Evaluation: Implementation in other EU member states and UK administrations

3.5.1 As part of the process evaluation, we also investigated how other EU member states and UK administrations had implemented Council Regulation 708/2007 concerning the use of Alien and Locally Absent Species in Aquaculture. In response to our request to officials in EU member states we received eight responses, and one response from Scotland. Of these responses, Germany and Spain were the two responding countries with the most similar population sizes relative to the UK; they implemented Council Regulation 708/2007 as follows:

3.5.2 We received responses from the following countries: Belgium (both Flanders and Wallonia), Croatia, Germany (both the national environmental ministry and Schleswig-Holstein region), Greece, Hungary, Slovakia, Spain, and Sweden.

3.5.3 Most of these countries had set up their systems in a similar way to England and Wales, including in some countries where implementation of the regulation is devolved to sub-national regions. As with England and Wales, several countries have set up a register of applications. There are some remaining member states which are yet to implement the Regulation. Where the Regulations has been limited, responses from member states and investigation of online registers of applications show that there has been no or a small number of applications in each case.

3.5.4 The respondents who gave the most detailed answers were those from Spain and Schleswig-Holstein in Germany. These are discussed below.

3.5.5 In Germany, every federal state is responsible for inland fisheries and aquaculture. In the state of Schleswig-Holstein, a special state regulation was enacted in April 2010 to implement 708/2007. To date, Schleswig-Holstein has not received any proposals to use the relevant species covered by 708/2007. The state also implements a spot check system on 10% of all aquaculture companies per year to supervise compliance with 708/2007. To date, it has not identified any infringements.

3.5.6 In Spain, 708/2007 is directly applied by its regional authorities which have competences on aquaculture management: they are implementing the regulation in terms of issuing permits and performing inspections. At a national level, a register has been created and published in a website which includes a list of closed aquaculture facilities. Spain is also developing an aquaculture act that would include a section on the use of alien species in aquaculture. The draft law also includes improving the national register and the coordination of the various administrations involved.

3.5.7 The response from Scotland indicated that the Scottish Government had implemented the Regulation in 2015. Since this point, the Scottish Government has received no applications to introduce or translocate alien species covered by the Regulation, with the Scottish Government explaining that the main alien species of interest to the industry are exempted from the provisions of the ASR.

3.5.8 In conclusion, the findings from the survey of other EU member states and UK administrations indicate that while in other member states the regulation has been implemented at different legislative levels, the systems remain similar. The cases of Schleswig-Holstein and Scotland have particular similarities with England, as there have also been no applications to introduce alien species.

3.6 Impacts: Estimated Outturn of Costs

3.6.1 The aim of the review of impacts is to estimate the impacts of the implementation of the ASR. This section estimates the costs caused by the implementation of the ASR, and the next section considers the benefits.

3.6.2 The logic chain in Figure 1 identified several negative and positive impacts from implementing the ASR, and several indicators for monitoring these impacts. These indicators are individually discussed below as part of estimating the costs and benefits of the regulation.

3.6.3 Indicators 3 and 5 track the number of applications received and then approved or rejected by the FHI under the regulations, which is necessary to then estimate costs to businesses. This information is sourced from historic data collected by the Fish Health Inspectorate, including the database on non-routine movements, available here: http://www.cefas.defra.gov.uk/alienspecies/default.aspx

3.6.4 There are 18 existing aquaculture firms which have been authorised to farm non-native species. Of those, 10 firms are farming species which are in Annex IV of the regulations, and therefore exempt from controls, as these species were established in the UK's aquaculture sector before the regulations came into force. There were also two applications to farm other species, resulting in 10 approved routine movement applications. These farms all used closed production systems, and were therefore treated as routine movement applications.[6]

[6] FHI, pers comm.

3.6.5 For non-routine movement applications, i.e. those involving the introduction of novel species in an open environment, since the ASR was implemented there have been a further 10 initial enquiries into such applications. As shown in Figure 2, after these enquirers were provided with advice by the FHI, they did not proceed in making full applications for non-routine movements of novel aquaculture species.

3.6.6 There have been many fewer applications than were expected at the point of implementation, as was set out in the Impact Assessment. Both the stakeholder surveys and interview with the FHI suggested that this was largely due to a lack of demand from industry, with the alien species for which there is a demand to farm already contained in Annex IV, and therefore excluded from the regulations.

3.6.7 Indicator 2 tracks the costs to Government of implementing the regulations. The Impact Assessment identified a one-off cost of setting up the regulations, and annual costs of processing applications, including providing initial advice on non-routine movement applications.

3.6.8 The IA identified an initial cost of setting up the systems to support the Regulations of £10,350. The FHI said that they were unable to find any information on the initial costs of setting up the system that were actually incurred. However, the figures provided in the Impact Assessment were sourced from quotes given to the FHI. As a result, £10,350 is considered to be a reliable estimate of the actual costs incurred.

3.6.9 The IA also estimated an annual cost to Government of £23,000 for implementing the Regulations. However, the FHI have advised that the actual expenditure on ASR in 2015-6 was just £10,000. This has been converted into 2011 prices (in line with the other cost estimates in this PIR), giving an annual cost of £9449. The lower than expected expenditure occurred in part because of efficiencies realised through merging the ASR processes with those for the AAHR, and in part due to lower than expected demand for introducing alien species.

3.6.10 Indicator 1 monitors quantified costs to applicants. The IA estimated annual costs of £129,600. These costs are expected to arise from staff time to make applications, and paying for risk assessments in the case of non-routine movement applications.

3.6.11 Evidence from the survey of aquaculture stakeholders did not suggest a significant burden on applicants, but provided no evidence on the unit costs for making applications. As a result, in estimating the costs incurred by businesses we use the assumed unit costs from the Impact Assessment, which are described above. The FHI have advised that these may be an overestimate, given that the merging of processes with the AAHR processes will have likely meant the amount of time applicants need to spend on their application is lower than expected.

3.6.12 The IA estimated that businesses would incur a unit cost of £138 per routine movement application, £46 per enquiry into non-routine movement applications and £126,368 per non-routine movement application. As there have been 10 routine movement applications, 10 enquiries into non-routine movement applications and 0 non-routine movement applications, this result in an estimated total cost since implementation of the Regulations of £1840, or an estimated annual cost of £368.

3.6.13 There may also be costs to business through deterring businesses from introducing alien species. Indicator 4 aims to monitor the proportion of aquaculture businesses which have been deterred from introducing alien species. This could either happen through aquaculture businesses which make an enquiry into a non-routine movement application, but choose not to follow through with the application, or where a business is deterred from even making an enquiry due to the perceived costs and chances of success.

3.6.14 We approached two of the enquirers into non-routine movement applications for which we had contact details, seeking their views on why they decided not to go ahead with their enquiries. One enquirer responded, saying that they were not able to raise funds for the proposal and subsequently developed another business; however it still remained a future interest. This indicates the number of external factors which affect whether an enquirer may choose to proceed with an application beyond having to apply for a permit under the ASR; for example the costs of the application process for introducing novel species farmed in an open environment are only a small part of the total cost of establishing such a new business. It may also be the case that realisation of the enquirers' these proposals were realised the costs to society would exceed the benefits if there is a high risk of alien species escaping to the surrounding native environment.

3.6.15 In addition, it's worth noting that a high ratio of enquiries to actual full non-routine movement applications was expected in the Impact Assessment, which assumed 20 enquiries into non-routine movements for each full application.

3.6.16 This is not possible to quantify, due to a lack of evidence. For example, it may be that some of the prospective enterprises seeking to introduce alien species would also have been restricted by existing regulations in the baseline, such as the Import of Live Fish Act. In addition, it is not possible to estimate the number of businesses which have been deterred from even making an enquiry into a non-routine movement application.

3.6.17 The responses to the survey of stakeholders and aquaculture businesses were divided on the subject of deterrence, with one respondent saying that "the regulations appeared not to have made a significant impact on the UK's established aquaculture production businesses", while the other argued that "It believed that the regulations may have deterred those considering the profitable aquaculture of certain non-native species such as the Noble Crayfish (*Astacus Astacus*)"[7].

3.6.18 In conclusion, it is not possible to provide a quantitative estimate of the costs of deterring businesses from introducing alien species due to a lack of evidence. Given the 10 enquiries into non-routine movements, it's likely that the implementation of the ASR has led to some benefits to businesses being foregone, but it is not possible to estimate these benefits.

3.6.19 Table 2 below shows a summary of costs to business and government from the regulations.

[7] Responses to Stakeholder Survey, 2015.

Year	2011	2012	2013	2014	2015	Total
Costs to Government						
One-off Costs of Setting up System	£10,400	0	0	0	0	£10,400
Estimated Annual Costs of processing applications	£9,400	£9,400	£9,400	£9,400	£9,400	£47,200
Total Costs to Government	**£19,800**	**£9,400**	**£9,400**	**£9,400**	**£9,400**	**£57,600**
Costs to Businesses						
Annual Costs for routine movement applications	£300	£300	£300	£300	£300	£1400
Annual Costs for non-routine movement enquiries	£100	£100	£100	£100	£100	£500
Costs of deterrence	Unquantified					
Total Costs to Businesses	**£400**	**£400**	**£400**	**£400**	**£400**	**£1800**
Total Costs	**£20,200**	**£9,800**	**£9,800**	**£9,800**	**£9,800**	**£59,400**

3.7 Impacts: Estimated Outturn of Benefits

3.7.1 The Impact Assessment identified two potential benefits from implementing the regulations, which include greater certainty for aquaculture businesses and reduced risk of escape by alien species into the environment.

3.7.2 Indicator 6 monitors the degree of certainty for aquaculture businesses by aiming to measure their perceptions. Survey respondents suggested that existing businesses farming non-native species which were established in UK aquaculture prior to the regulations coming into force had benefitted from the certainty of being allowed to farm these species. Respondents did not offer any evidence indicating that certainty had increased for businesses seeking to introduce new species.

3.7.3 This is evident from Indicator 7, which aims to monitor the variety of species being used in UK aquaculture. The Fish Health Inspectorate reported that there has been no new non-native species being farmed in the UK since implementation of the regulations. However, both the FHI and respondents to the survey indicated that this is most likely to be due to a lack of demand from industry, with most of the non-native species which industry are seeking to farm already established in the UK before 2011 (and therefore exempt from the regulations) or species which could be treated as a routine movement due to the low chance of escape.

3.7.4 Indicator 8 sought to provide an overall indication of whether the regulations have stimulated or held back the aquaculture industry. Both of the respondents to the stakeholder survey suggested that the regulations had established businesses to continue farming established alien species, but had probably also had a small effect in disincentivising the introduction of new alien species. In summary, the low level of evidence available cautiously suggests that the regulation has had a marginal impact on the development of the industry.

3.7.5 Indicator 9 sought to track the threats to ecosystems posed by the escape of alien species from aquaculture farms. Expert opinion from the FHI has advised that there have been no recorded ecosystem threats from the escape of alien species from aquaculture farms.

3.7.6 However, it is likely that such threats would have been limited in the baseline due to the industry's limited desire to use alien species. There have only been ten enquiries into non-routine movements since the implementation of the regulations, and other factors such as the costs of developing an aquaculture production site are likely to have meant that at least some of these new farms would not have progressed even without the regulations. Furthermore, it's possible that some of these alien species could have been used in aquaculture without escape to the environment, even in the case where a risk assessment may have found there to be a high risk of escape.

3.7.7 The costs of escape of alien species remain high – for example, a 2010 paper estimated that the invasive signal crayfish cost the UK £2.7m annually, which is likely to be an underestimate given the negative effects the species has on angling and the high value obtained from angling by recreational fishermen.[8]

3.7.8 As a result, the regulations are likely to have had some benefits in preventing the release of alien species in the environment, but it is not possible to quantify these due to difficulties establishing the risks posed by alien species in the baseline without the regulations. Where the regulations have reduced the risk of alien species escaping from aquaculture, the benefits to society could be very high given the high cost of invasive species. Despite this, the benefits from the regulations are likely to be lower than expected in the original Impact Assessment, due to a lower than expected interest from the aquaculture sector in introducing alien species.

3.7.9 **Table 2** summarises the results of the indicators which have been used to help evaluate the impact of the regulations.

Table 2: Estimated indicators from implementation of Alien Species Regulations

Indicator	**Result**	**Source**
1. Costs to applicants of making applications	Annual cost of £400	FHI monitoring data; Defra analysis
2. Costs to Government of processing applications, maintaining database	One-off cost of £10,350 Annual cost of £10,000	FHI, pers. comm
3. Number of applications received under ASR	10 routine applications, 10 Expressions of Interest in non-routine applications, 0 non-routine applications	FHI monitoring data
4. Proportion of aquaculture businesses deterred from introducing alien species by ASR	Unquantified - see discussion	Survey results; FHI, pers. comm
5. Number of applications approved / rejected	10 routine applications approved, 0 non-routine applications received	FHI monitoring data

[8] http://www.cieem.net/data/files/Resource_Library/Sections/Section_Event_Resources/Invasive_Non-Native_Crayfish_in_Britain_-_Paul_Bradley_-_27032014.pdf

6. Industry perceptions of certainty under ASR	See discussion	Survey results; FHI, pers. comm
7. Alien species used by aquaculture businesses	No change since implementation of ASR	FHI, pers. comm
8. Industry perceptions of whether ASR has stimulated or held back industry	See discussion	Survey results; FHI, pers. comm
9. Recorded threats to ecosystems from alien species used in aquaculture	0	FHI, pers. comm

3.8 Small and Micro Business Assessment

3.8.1 The aquaculture sector in England and Wales is almost exclusively made up of small and micro enterprises (SMEs). For UK aquaculture, the UK's Business Population Estimates suggest that only 10 aquaculture businesses employ more than 50 people[9]. These medium or large sized businesses are likely to be in the Scottish salmon sector, which has 50 businesses employing 1387 people, compared to 366 shellfish and finfish aquaculture enterprises in England and Wales employing 1215 people[10]. This means that the scope of the regulations (which applies to England and Wales) is likely to cover almost exclusively small and micro enterprises. These businesses are likely to incur the majority, if not all, of the burden on businesses from these regulations.

3.8.2 Providing an exemption to the regulations for small and medium enterprises would not be feasible, as it would mean that the regulations would not apply to the vast majority of the aquaculture sector in England and Wales and the regulations would be unable to achieve its objectives to limit the threat to ecosystems from alien species introduced into aquaculture businesses. Furthermore, if an exemption for SMEs were introduced, then England and Wales would be in breach of Council Regulation 708/2007, risking infraction from the European Commission.

[9] https://www.gov.uk/government/statistics/business-population-estimates-2015 . See table 7.

[10] Cefas aquaculture statistics, available here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/405469/Aquaculture_Statistics_UK_2012.pdf

4. Conclusions and Next Steps

4.1 Conclusions

Summary of Policy Objective

4.1.1 The policy objective was to enable the economic growth of the aquaculture industry, whilst limiting the potential threats to our native ecosystems posed by the introduction of new alien species. This was to be achieved by assessing the 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.

4.1.2 The Government also wanted to fully implement Council Regulation 708/2007 concerning the use of Alien and Locally Absent Species in Aquaculture [http://eur-lex.europa.eu/legal content/EN/TXT/?uri=URISERV:l28179#amendingact], which introduced a framework throughout the EU to ensure protection from the risks associated with the use of alien and locally absent species in aquaculture.

4.1.3 These objectives continue to remain current and valid following this PIR.

Success criteria

4.1.4 The success criteria were originally as follows:

- The risk analysis process for introducing an alien species in England is performed in a timely and cost effective manner
- The aquaculture industry is able to diversify into novel species with low risk to the environment
- The policy is accepted by the aquaculture industry
- There is no registered introduction of novel but potentially damaging non-native species

4.1.5 Following this PIR, these success criteria continue to remain valid.

Results from Process Evaluation

4.1.6 These regulations have been broadly implemented as intended, with some small changes. Firstly, for routine movement applications for fish and shellfish, the application process was merged with that for authorising aquaculture farms under the Aquatic Animal Health Regulations 2009 (AAHR). This is believed to have helped reduce costs to the public sector of implementing the regulations' measures, whilst preventing new administrative burdens on businesses. Secondly, for non-routine movements there has been a greater emphasis on providing advice to potential applicants before submitting an application, informing on potential costs and the chances of success.

4.1.7 There is no evidence arising from this PIR which points to how the implementation of these regulations has led to a failure to achieve their objectives, or how their operation could be improved for either industry or the public sector.

Results from Review of Impacts

4.1.8 This PIR has produced evidence to show that the actual costs and the actual benefits of these regulations were both lower than expected, This is primarily believed to be as a result of a lower than expected demand for introducing new alien species

4.1.9 The one-off costs to public bodies have been estimated as £10,400 for setting up the permitting system, with ongoing annual costs of £9,400 for operating the system. There are costs to private businesses totalling £400 per year for submitting routine movement applications and making non-routine movement enquiries into applications using the regulations.

4.1.10 Regarding benefits, it is estimated that even without these regulations there would have been limited interest in introducing new alien species. This means that the estimated benefits of these regulations are also low, as they are unlikely to have prevented the introduction of any new invasive species into the natural environment. However, it is important to note that the potential costs from invasive species being introduced into the natural environment remain high, e.g. £2.7m per year from signal crayfish. Hence these regulations are considered to form part of an overall system prevents such costs from occurring where there is a risk that aquaculture business will introduce alien species into the environment, and aiming to ensure a successful sustainable and responsible aquaculture industry both now and in the future.

4.2 Next Steps for the regulations

4.2.1 Since the Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 came into effect, there have to date been no new potential threats to native ecosystems posed by newly introduced alien species, with only very limited evidence that this Regulation is holding back the development of the aquaculture sector.

4.2.2 In addition to these regulations which apply to England and Wales, there are equivalent regulations applying to Scotland and Northern Ireland: Alien and Locally Absent Species in Aquaculture (Scotland) Regulations 2015 and Alien and Locally Absent Species in Aquaculture Regulations (Northern Ireland) 2012

4.2.3 Having these alien species in aquaculture regulations (ASR) remain in place ensures that the UK Government continues to meets its legal obligations under Council Regulation 708/2007, which introduced a Europe-wide framework to ensure protection from the risks associated with the use of alien and locally absent species in aquaculture.

4.2.4 As a result, it is proposed that these Alien and Locally Absent Species in Aquaculture (England and Wales) Regulations 2011 remain in place in England in their current form, subject to further review in 2021

5. Annexes

5.1 Annex A: Survey distributed to key stakeholder organisations

5.1.1 Did you or your member organisations expend time or resources to understand the Alien Species Regulations when they were implemented in England? [http://www.legislation.gov.uk/uksi/2011/2292/contents/made]

5.1.1.1 *If yes:* Measured in total number of person hours, how long do you think this took?

5.1.2 Has the introduction of the Alien Species Regulations deterred or encouraged you to look into introducing alien species in England? Can you explain why?

5.1.3 When considering whether to introduce alien species in England, did you or your member organisations expend time or resources to understand the Alien Species Regulations?

5.1.3.1 *If yes:* Measured in total number of person hours, how long do you think this took?

5.1.4 Do you think the introduction of the Alien Species Regulations has deterred or encouraged new entrants to the aquaculture sector in England? Have they affected competition within the sector in other ways? Can you describe how?

5.1.5 Do you think the introduction of the Alien Species Regulations has increased or decreased the certainty for aquaculture businesses regarding the management of introducing alien species into England? Can you describe how?

5.1.6 Do you think the introduction of the Alien Species Regulations has been a good or bad thing for aquaculture in England? Have they achieved their objective? Why do you think this is?

5.1.7 Do you have any experience or knowledge of how Council Regulation 708/2007 concerning the use of Alien and Locally Absent Species in Aquaculture has been implemented in other countries within the European Union? [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l28179#amendingact]

5.1.7.1 *If yes:* What do you know about it and how has this been different to England?

5.1.8 How could implementation of the Alien Species Regulations in England have been improved?

5.2 Annex B: Baseline Regulations before implementation of ASR

5.2.1 This Annex summarises the provisions and implications of baseline regulations which were in place in 2011 before implementation of the ASR in 2011. All of these regulations continue to apply to the aquaculture sector in England, with the exception of the Import of Live Fish Act, which was superseded by the ASR.

Fish & Shellfish

The Aquatic Animal Health (England and Wales) Regulations 2009

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

5.2.2 Existing or new fish and shellfish 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.

5.2.3 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 Aquaculture Production Businesses (APBs)

5.2.4 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.

5.2.5 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.

5.2.6 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.

5.2.7 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.

5.2.8 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

5.2.9 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.

5.2.10 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)

5.2.11 This Act regulates the import, keeping and release of non-native fish in England and Wales for any purpose, by means of two Orders relating to specific listed species:

5.2.12 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.

5.2.13 The Prohibition of Keeping and Release of Live Fish (Specified Species) Order 1998, as amended in 2003, prohibited 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.

5.2.14 Applications for licences under the above Orders are administered by the FHI, and subject to scrutiny by the Environment Agency (EA), Natural England (NE), Natural Resources Wales (NRW) 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.

5.2.15 The Prohibition of Keeping and Release of Live Fish (Specified Species) Order 1998 was subsequently revoked and replaced in England by The Prohibition of Keeping Or Release Of Live Fish (Specified Species) (England) Order 2014. This included a schedule of fish at the taxonomic level (rather than at an individual species level). It provides for licences for new species capable of surviving in UK waters being issued only following an assessment of the risk they pose to native species and habitats

5.2.16 The provisions of this Act affecting aquaculture businesses in England were superseded by the implementation of the Alien Species Regulation in 2011.

Wildlife and Countryside Act 1981

5.2.17 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 (England) Order 2005

5.2.18 The Plant Health (England) Order implements the EU Plant Health Directive 2000/29, substantially amended by Council Directive 2002/89/EC, 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

5.2.19 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.