

EXECUTIVE NOTE

THE AQUATIC ANIMAL HEALTH (SCOTLAND) REGULATIONS 2009

2009 No.85

Purpose of the instrument

1. These Regulations modernise the legislation to protect fish and shell fish from serious disease. They introduce a system of authorisation for businesses involved, amend and update measures used in the event of outbreaks of serious disease, and implement common EU rules on trade in these animals and their products. They do not apply to fish caught from the sea.

Legislative Context

2. The Regulations implement Council Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals. A transposition note is attached.

3. The Directive requires that all businesses keeping these animals must be authorised. This will be done by the Fisheries Research Services (FRS), Aberdeen. At the discretion of the Member State, organisations such as angling clubs can be merely registered. We are generally, where the Directive permits, requiring only registration, subject to a provision in the Regulations that authorisation will be required where necessary to prevent or limit the spread of disease.

4. The Directive sets out circumstances under which different animal health certificates are required when animals are moved within or imported from outside the EU. This element is further elaborated by Commission Decision 2004/453/EC and Commission Regulation (EC) 1251/2008. We have avoided replicating these lengthy provisions in the Regulations. Instead, regulation 17 provides the references and imposes an overarching requirement to comply.

5. The Directive requires Member States to ensure that the movement of ornamental fish does not increase the risk of serious disease of other fish or shell fish. The Regulations require that all ornamental import enterprises must be authorised by FRS.

6. The Directive specifies measures Member States must take in response to suspicion or confirmation of certain named diseases. It requires Member States to take action to control situations relating to serious, newly-identified diseases, though the steps are not specified. It also allows Member States to take protective measures against diseases important to them but not across the EU. The Regulations implement these measures to control disease through flexible powers in Part 4 and lists the three diseases important here in Schedule 1.

Territorial Extent and Application

7. This instrument applies to Scotland
8. Similar and parallel Regulations are required in England, Wales and Northern Ireland.

European Convention on Human Rights

9. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

Policy background

- *What is being done and why*

10. Directive 2006/88/EC updates and expands the existing European Community regime for aquatic animal health. The main theme of the Directive is to enhance aquaculture industry (farming of aquatic animals for food and products) in the Community. It does so in three ways: authorisation of industry to encourage reasonable standards of bio-security, harmonised trade rules and effective disease control measures. The regime also covers measures for the protection of the wild environment and fish for angling and to guard against the spread of disease from ornamental fish.

11. The aquaculture industry in Scotland is worth around £400 million per year, making it second to beef (£467m) and ahead of fish catches (£370m).

12. Authorisation is the biggest single change affecting industry. A form of licensing, authorisation is granted subject to conditions on bio-security, record keeping and participation in disease surveillance. As required by the Directive, authorisation will not be granted where there is an unacceptable risk of disease spread from a business.

13. Regulations were seen as the most suitable vehicle for implementation. A number of the aquaculture industry sectors have codes of practice, which cover areas such as bio-security and trading practices. Compliance with these may be used, on a case-by-case basis, to play a part in assessment for authorisation. But they do not cover the entire set of enterprises involved or implement the full range of authorisation requirements. The other main areas - trade rules and statutory disease controls - can only be implemented through regulation.

14. The changes are important to those involved in aquaculture, trade in fish and, to a lesser extent, angling. They do not have implications beyond these sectors.

- ***Consolidation***

These Regulations consolidate the legislation in this area and repeal pieces of redundant legislation. Although the 1937 Act is repealed, one of its important provisions is not for technical reasons included in these Regulations. The Act contains a provision enacted by the Aquaculture and Fisheries 2007 Act for Scottish Ministers to make a scheme for payments necessary for any outbreak of *Gyrodactylus salaris* (Gs), a parasite of salmon in freshwater which could have a devastating impact on our stocks. Because of the rules on sub-delegation we are unable to include that provision in these Regulations. We will however prepare as soon as possible a scheme for Gs payments under separate Regulations. We will of course assure stakeholders of our intention.

Consultation outcome

15. There was a full public consultation on modernisation of the aquatic animal health regime between December 2007 and March 2008. Fifteen responses, from affected consultees were received. There was strong support for the broad themes of the Directive and the outlined policy direction proposed. A summary of the consultation responses was published on our website.

Guidance

16. Guidance for aquaculture production businesses is being developed. This will be placed on the FRS website.

Impact

17. The impact of these Regulations is set out in the Final Regulatory Impact Assessment.

Monitoring & review

18. The success of the legislation lies in reduced disease outbreaks, compared with estimates if no rules were in place. Monitoring on their success lies in continuing dialogue with stakeholders.

**Marine Directorate
Scottish Government
February 2009**

Transposition Note

Council Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

The Aquatic Animal Health (Scotland) Regulations 2009 implement this Directive. The animals covered are finfish and shellfish. The aim is to reduce disease in farming of these animals, in the wild environment, and in fish for angling. Fish kept for ornamental purposes are also covered because of their potential interactions with the target sectors.

Directive Article	Objective of Article	Transposition in Scotland
Chapter I of the Directive sets out subject, scope and definitions.		
1	<p>Aims of Directive:</p> <ul style="list-style-type: none"> • health requirements for movement and trade in the animals to minimise risk of disease spread; • preventative measures and preparedness for disease; • control measures in the event of disease outbreaks. 	<p>The Regulations, especially:</p> <ul style="list-style-type: none"> • Part 3; • Part 2; • Part 4.
2	Excludes certain types of these animals from the scope of the Directive or ornamental animals if certain conditions are met.	Regulations 2 and 4.
3 and Annex I	Defines terms used in the Directive.	Regulation 3.
Chapter II of the Directive requires authorisation of certain enterprises that keep or process the animals. The aim is implementation of good hygiene practice and disease surveillance to minimise introduction and spread of serious disease; and good record keeping, to aid the authorities in tracing disease in the event of an outbreak.		
4	<p>Requires authorisation of:</p> <ul style="list-style-type: none"> • all aquaculture production businesses; 	Regulation 5.

	<ul style="list-style-type: none"> processors who handle animals from diseased areas. <p>Provides an option for Member States to derogate, so that certain classes of aquaculture production businesses can be registered instead of authorised. Registration is a simpler process.</p>	<p>Regulations 8-11 set out processes for application, amendment, suspension and revocation. Regulation 14 provides a transitional provision to allow for interim authorisations.</p> <p>Regulation 12.</p>
5	<p>Requires authorised businesses to comply with conditions and cooperate with the competent authority.</p> <p>Authority may not grant authorisation if there is an unacceptable risk of spreading disease.</p>	<p>Regulations 6, 7, 10, 11 and 39.</p> <p>Regulation 6 (1) and 7(1).</p>
6	<p>Requires that certain information on authorised aquaculture production businesses and processing establishments is available on a public register.</p>	<p>Regulation 13.</p>
7	<p>Links supervision of aquaculture production businesses and authorised processors with the official food and feed controls established under Regulation (EC) No 882/2004.</p>	<p>Regulation (EC) No 882/2004 is directly applicable in Scotland and is already in force.</p>
8	<p>Sets out details of record keeping obligations for authorised aquaculture production businesses and processors, and transporters of aquaculture animals.</p>	<p>Regulations 6, 7 and 20.</p>
9	<p>Sets out some detail of good hygiene practice (that is, biosecurity) required by</p>	<p>Regulations 6 and 7.</p>

	authorised aquaculture production businesses and processors.	
10	Sets out some detail on the animal health surveillance required at authorised aquaculture production businesses.	Regulation 6.
Chapter III of the Directive provides a framework of requirements for movement of these animals within the Community. The aim is to reduce the risk of the spread of serious disease.		
11	Allows Member States to derogate from the provisions on movement when undertaken for research under the supervision of the competent authority.	Regulation 15.
12	Emphasises importance of controls on movements of animals and products between defined areas (eg zones, Member States) and requires Member States to ensure that movements do not increase disease risk at destination.	Regulations 12 (which includes registration of specialist transporters), 17 and 18.
13	Requires disease prevention measures for the transport of aquaculture animals, including any water exchange.	Regulation 19.
14	Imposes health and certification requirements for movements of animals for farming, restocking or for processing before human consumption. Details given in Commission Decision (EC) 2004/453/EC and Commission Regulation (EC) 1251/2008, which establish model certificates, lists of vector species, and 3 rd countries approved to trade with the Community.	Regulation 17. Guidance will be available from the Fisheries Research Services to both importers and exporters of aquaculture animals.
15	Imposes general health requirements which	Regulation 16.

	<p>must be met before aquaculture animals can be moved.</p> <p>Includes a discretionary power allowing Member States to ensure animals being released into the wild have a very reduced risk of spreading disease.</p>	Regulation 18 (1).
16	Aquaculture animals for farming or restocking in disease-free areas must come from disease-free areas.	Regulation 17.
17	Animals for farming or restocking in disease-free areas, which are vectors for the listed diseases, must come from disease-free areas or go into quarantine. Vector means an animal which can pass on the disease even if unaffected itself.	Regulation 17.
18	Aquaculture animals for temporary storage or processing for human consumption in disease-free areas are subject to restrictions to minimise risk of spreading disease.	Regulation 17.
19	Exemption for animals for human consumption which are pre-packed.	Regulation 17 and Regulation (EC) 853/2004.
20	Wild animals for farming from areas not declared disease-free must go into quarantine before they can be moved to disease-free areas.	Regulation 17.
21	Requires that the trade in ornamental aquatic animals does not jeopardise the health status of other aquatic animals.	Regulations 4 and 16 (3).
<p>Chapter IV of the Directive provides a framework of requirements for import of these animals into the Community. The aim is to reduce the risk of serious disease.</p>		

22 & 24	Aquaculture animals and products may only come from non-EU countries if the country is on the EU list and they must be accompanied by the right documents.	Regulation 17.
23 & 25	Places obligations on the Commission on drawing up the list and provides the procedure to amend the EU rules.	Not applicable.
Chapter V of the Directive set out Member States' obligations on systems to identify serious disease and to control outbreaks.		
26	People who manage or look after these animals must report suspicion of disease or increased mortality.	Regulation 23.
27	Requires notification of the Commission, other Member States and EFTA States of confirmation of exotic diseases or non-exotic diseases in an area previously considered free of that disease.	This obligation is not transposed in the Regulations and will be met administratively.
28	Sets out initial measures required when a listed disease is suspected, including controls on movement of animals and an obligation for samples to be tested for disease.	Regulations 24 to 26.
29	Requires Member States to conduct an epizootic investigation, on suspicion of a listed disease, to establish the source and any onward spread.	Regulation 24 (2).
30	Determines the circumstances under which controls placed, due to suspicion of disease, can be lifted.	Regulation 27.
31-36	Establishes the minimum control measures to eradicate an outbreak of an exotic disease.	Regulations 28 to 30.

37	Determines the circumstances under which controls placed, due to confirmation of disease, can be lifted.	Regulation 31.
38-39	Sets out the possible controls for an outbreak of a non-exotic disease: eradication or containment.	Regulations 28 to 30.
40	Establishes minimum controls for diseases suspected or confirmed in wild aquatic animals.	Regulations 24 to 30.
41	Sets out steps to be taken when an emerging disease is suspected or confirmed. The intention is to control the new situation before it becomes a more difficult problem. Member States must notify the Commission, other Member States and EFTA states.	Regulations 24 to 30. Notifications will be implemented administratively.
42	Allows the use of 'ad-hoc' epidemiological measures to be adopted, where general measures are ineffective.	Regulations 24 to 30.
43	Allows Member States to take controls for diseases of national concern not listed in the Directive. Controls that restrict trade need to be approved by the Community.	Schedule 1 lists the diseases for control in Scotland. These have been approved by the Community under Commission Decision 2004/453/EC. Regulations 32 to 34 make specific provision in relation to one of these diseases.
Chapter VI of the Directive sets out the administrative framework for Member States to gain recognition for their surveillance and eradication programmes, and rules on vaccination.		
44-46	Establishes procedures for Member States to	This will be implemented

	become recognised for implementation of surveillance and eradication programmes for listed diseases.	administratively.
47	Sets out requirements for national contingency plans for emerging and exotic diseases.	Contingency plans will be implemented administratively.
48	Sets out controls on the use of vaccines.	Regulation 44.
Chapter VII of the Directive sets out the administrative framework for Member States to gain recognition that they are free of disease in part or the whole of their territories.		
49-50, 52-53	Establishes a procedure for the declaration, maintenance and suspension of disease free Member States, zones and compartments.	This will be implemented administratively.
51	Requires Member States to establish and maintain a list of zones and compartments declared free under Article 50 (2).	Regulation 45.
Chapter VIII of the Directive sets out Member States' and Community obligations on competent authorities and laboratories to be used for enforcement of the Directive.		
54-57	Sets out principles for scientific cooperation between Member States, provision of Community and national reference laboratories and diagnostic services.	These requirements will be implemented administratively.
Chapter IX of the Directive provides the basic framework for Community and Member States activity on provision of information and enforcement.		
58	Sets out circumstances when the Commission may conduct inspections and audits of implementation of this Directive.	These requirements will be implemented administratively.

59	Establishes a requirement for Member States to maintain and publicise certain records and information in an electronic form.	These requirements will be implemented administratively.
60	Requires Member States to take measures to ensure requirements of the Directive are implemented, including effective, proportionate and dissuasive penalties for non-compliance.	Regulations 10 and 11 and Part 6.
Chapter X of the Directive sets out the EU procedures for detailed amendments and implementing regulations.		
61	Sets out areas of the Directive that can be amended by Committee procedure.	Not applicable.
62	Establishes the Committee procedure.	Not applicable.
Chapter XI of the Directive sets out consequences for current and future legislation.		
63-67	Final provisions setting out repeals of existing EC legislation, transposition timetables and entry into force.	Not applicable.

FINAL REGULATORY IMPACT ASSESSMENT (RIA)

1. Title of proposal

Impact assessment of the modernising aquatic animal health project, established to transpose an updated European aquatic animal health regime (Directive 2006/88/EC).

2. Purpose and intended effect

The aim of the new Directive is to act as a framework within which standards in aquaculture can be raised across the community. Specifically this means closer supervision of aquaculture producers and a flexible risk based approach to disease surveillance and inspection. Implementation is intended to reduce the risk of outbreak of serious disease, while minimising the burden of the new regime on aquaculture producers. The regulations will come into effect on 27 March 2009, as will comparable regulations for England and Wales

3. Consultation

Consultation within government has been achieved through a Project Board comprising representatives of all the UK administrations. Wider consultation through the Aquaculture Health Joint Working Group has included representatives of the aquaculture industry, wild fisheries interests, fish veterinarians and the Scottish Environment Protection Agency.

4. Summary of approach

The main objective of the new EU legislation is reducing the impact of serious disease on the aquaculture sector whilst facilitating safe trade in aquaculture animals and their products. The main feature is better management of aquaculture production businesses (APB).

In order to evaluate policy approaches, analysis of the costs and benefits is required. Identification of costs is straightforward. Using standard cost model approach, the impact of each administrative cost can be estimated with a degree of confidence. Benefits are somewhat harder to estimate, as they accrue from the prevention or curtailment of disease

outbreaks, complex situations with many uncertainties around cause and effect. We will use a number of methods to estimate the benefit of policy approaches.

This evidence section will be split into 4 main sections:

1. Background

- Summary of the industries affected
- Existing disease risks
- Justification of Government intervention
- Comparison of the new and existing regimes
- Aim of Government intervention: outbreak prevention and curtailment

2. Explanation of the options

- Minimum application
- Processor options
- Surveillance options
- Preferred option

3. Cost analysis

- Identification of information requirements
- Administrative cost vs. administrative burden
- Estimates of administrative burdens

4. Benefit analysis

- Disease outbreak under existing regime
- Assumed benefits of Authorisation of APBs
- Cost benefit analysis of disinfecting processors effluent
- Comparison of surveillance options

5. Justification for Government intervention

- Aquaculture generates economic value, particularly in rural communities. This should be safeguarded where the activity's benefit outweighs the costs.
- Maintenance of high health status allows the UK to require that imports come from similarly high health status countries, reducing the risk of importing pathogens with live fish. Loss of this status would also limit the freedom of UK industry to export to other high health status countries.
- The activities of aquaculture and recreational fisheries can pose a disease risk to wild populations of aquatic animals. Such populations should be protected.

- Recreational angling has important social benefits. Disease outbreaks can also impact on access to the country.
- Fish and shellfish can play an important nutritional role. A thriving domestic industry provides security of supply and fewer food miles, compared with alternative sources.

6. Background

The aquaculture, recreational fisheries and ornamental industries

The new Directive has updated and drawn together existing EC legislation on the control of certain diseases in farmed fish and shellfish and the conditions for the placing aquaculture products on the market. It takes a more holistic approach than the existing regime in that it brings recreational fisheries, ornamental and wild fish into its ambit. The existing regime only laid down rules for fish and shellfish farms. The new regime also includes disease of crustaceans.

Aquaculture in Scotland is split into the finfish and shellfish sectors. The finfish sector is fish farmed predominantly for human consumption but with some production for recreational fisheries.

Shellfish farming is similar, in that juveniles, often supplied by another business, are reared in conditions which promote rapid growth and recovered when they reach a suitable size. No feeding is required.

There are 461 active fish farms in Scotland. Finfish aquaculture is dominated by the production of salmon. Finfish production produces around 150,000 tonnes annually, worth over £280 million in first sales.

There are 333 mollusc farms in Scotland. Shellfish farming generates £5.4m. The farmed shellfish species tend to be oyster and mussel. Wild shellfish stocks are at risk from diseases that could potentially be imported through the activities of mollusc farms. Wild shellfish harvesting is an important industry, shellfish landings were worth £23,915,041.

Crustacean farming is very small scale in Scotland, with only one active farm.

The fish and shellfish farming industries employ over 8,500 people, largely in rural areas. It is expected that the importance of aquaculture will increase further as an alternative to declining capture fisheries.

Existing disease risks

There are a number of serious diseases of aquatic animals, due to the nature of the industry in Scotland, some diseases are of more importance than others. The diseases are addressed in the Directive in terms those exotic to the Community (outbreaks must be eradicated), present in the Community (can be eradicated if part of or entire Member State is seeking freedom, or contained if not) and those diseases of importance at a national level (controls are decided by the Member State, approval of the Community is needed if measures impact on trade).

Diseases of finfish

Exotic diseases	Sector at risk
Epizootic haematopoietic necrosis	Trout and the wild environment

Epizootic ulcerative syndrome	Coarse fish farmers, dealers, stocked fisheries and ornamental suppliers
Non exotic diseases	
Spring viraemia of carp (SVC)	Coarse fish farmers, dealers, stocked fisheries and ornamental suppliers
Viral haemorrhagic septicaemia (VHS)	Trout
Infectious haematopoietic necrosis (IHN)	Trout and Salmon
Koi herpes virus (KHV) disease	Coarse fish farmers, dealers, stocked fisheries and ornamental suppliers
Infectious salmon anaemia (ISA)	Salmon
Diseases of national importance	
<i>Gyrodactylus salaris</i> (Gs)	The wild environment, Atlantic salmon in particular
bacterial kidney disease (BKD)	Trout and Salmon

Diseases of Molluscs

Exotic diseases	Sector at risk
<i>Bonamia exitiosa</i>	The wild environment and oyster farming
<i>Perkinsus marinus</i>	The wild environment and oyster farming
<i>Microcytos mackini</i>	The wild environment and oyster farming
Non exotic diseases	
<i>Bonamia ostreae</i>	The wild environment and oyster farming
<i>Martellia refringens</i>	The wild environment, oyster and mussel farming

Diseases of Crustaceans

Exotic diseases	Sector at risk
Taura syndrome	None
Yellowhead disease	None
Non exotic diseases	Sector at risk

Great Britain is currently free of IHN, Gs, *Bonamia exitiosa* and *Martellia refringens*. There is currently a programme to re-establish freedom from VHS, after a limited outbreak in England in 2006 and from ISA which was discovered in South West Shetland in December 2008. There are also on-going programmes for the eradication of SVC in England and BKD. The majority of the UK is free of *Bonamia ostreae*, although there are some infected areas.

VHS and Gs are highly significant diseases for finfish in Scotland. VHS is a threat to farmed stocks of trout, Gs impacts on wild populations. It has been seen that Gs is capable of decimating wild populations of Atlantic salmon, a species with no resistance to the effects of the parasite. Due to the difficulty of controlling disease in the wild environment and the potential impact of this disease, Gs is one of our highest risks.

Shellfish diseases, such as *Bonamia ostreae* are difficult, if not impossible to eradicate once introduced. They can be spread through inappropriate handling of shellfish by restaurants and consumers, relaying infected molluscs in free areas.

In all disease situations, the control policy itself can have a heavy impact on industry. Movement restrictions, while suspicion of disease is investigated can cause, can impact both the businesses under suspicion and industry relying on supplies of fish from those farms. Wherever possible, a flexible approach to disease control is taken, where financial impacts are minimised without increasing the risk of disease spread.

7. Explanation of the options

Minimum application

This represents the cost of implementing the bare minimum of measures required under the new Directive. Authorisation, the record keeping and basic biosecurity required by it, a basic once per year combined surveillance and supervision visit by the Fish Health Inspectorate is the only other significant cost.

Processor options

At a minimum, no processing plants are required to be authorised. However, with no authorised processors available, there is no option to process unaffected animals from infected farms, leading to increased industry costs during outbreaks of disease.

Authorisation of processors could involve substantial costs, as authorised processors would have to treat effluent to a specified standard. These increased costs could affect the supply of processing capacity to the aquaculture industry. Three options for the authorisation of processors are being considered:

1. All processors have to be authorised and effluent treatment is required.
2. Processors are risk assessed and those posing a significant risk have to be authorised and employ effluent treatment.
3. Appropriate numbers of processors are licensed for operation during disease outbreaks (those posing the least risk of disease spread). Appropriate biosecurity measures would be required, possibly including effluent treatment when processing from infected farms.

Surveillance options

The Directive devolves responsibility for the design of disease surveillance schemes to individual Member States. The scheme has to be based on and reflect the relative risk of different aquaculture businesses of getting or spreading disease. There will therefore be a shift towards a risk-based surveillance system. This means we can target our resources much more effectively, visiting those sites with a high perceived risk often and those that pose lesser risk infrequently. The overall cost of surveillance is not expected to increase.

Old Regime	New Regime
Applied to fish and mollusc farms.	Applies to all aquaculture production types (including crustacean), processors ¹ , stocked fisheries, ornamental and wild aquatic animals ² .
Simple registration of fish and mollusc farms.	Authorisation of aquaculture production businesses ³ , which requires: <ul style="list-style-type: none"> • Record keeping; • Biosecurity measures; • Participation in disease surveillance. Registration of stocked fisheries.
For disease status purposes, the Community is broken down into zones, (geographically and epidemiologically separate unit) and approved farms.	The concept of disease-free Member States and compartments has been introduced in addition to zones. These are deemed to be equivalent.
General provisions on reducing risk of diseases spread through transport.	In addition, specific obligations on record keeping.
Diseases reflect salmon and trout based aquaculture	New diseases included to reflect the diversity of EU aquaculture

8. Aim of Government intervention

The main aim of government intervention is to limit the impact of disease on both farmed and wild aquatic animals. This can be split into two main areas: disease prevention and outbreak curtailment.

¹ When processing aquatic animals from an infected farms.

² Stocked fisheries, ornamental owners and dealers are derogated from much of the Directive, apart from provisions on disease control. There are also disease control obligations with regard to wild aquatic animals.

³ This includes fish and shellfish farms, depuration and dispatch centres. Some of the conditions apply to processors processing aquatic animals from infected farms.

Disease prevention

The first priority for Government intervention is to prevent the introduction of disease. The UK has a high aquatic animal health status and is free of many of the more serious diseases. The key area of risk, in this respect, is trade in live, and to lesser extent dead aquatic animals.

The main line of defence here is the control of movements of live animals between zones and compartments. Live aquatic animals can only be introduced to UK waters if they come from an area of equivalent health status. All animals coming in have to be accompanied by the appropriate certification, with officials of the exporting country making statements about the health status of the consignment. The same applies nationally, where live fish from the ISA infected area of Shetland cannot be moved elsewhere in the UK, due to their health status.

Outbreak curtailment

In the event of introduction of disease, efficient procedures to discover that introduction, control and eradicate infection will reduce the impact of an outbreak. These measures require that certain systems are in place in order to reduce the impact of an outbreak. Disease control consists of the following elements: detection of an outbreak, controls to prevent further spread, assessment into current spread, eradication or containment of disease outbreak.

Surveillance is key to detecting an outbreak. Although surveillance and testing is necessary for the maintenance of disease free status, an outbreak of a disease exotic to the UK has never been detected through an active surveillance programme. Passive surveillance, that is notification of suspicion of disease by a vet or farmer, has been the route almost all disease outbreaks have come to the attention of the authorities.

Initial controls, to prevent further spread of disease, include an immediate ban of movement of aquatic animals from the premises where disease is detected. A blanket ban on movements from other sites in the same water catchment, or further might be appropriate.

Assessment of disease spread is largely supported by record keeping at aquaculture production facilities. All movements of all animals on or off the facility should be recorded and are used to determine sites that have potentially been infected or the possible source of infection. The local hydrological conditions are also assessed for source of infection and spread.

Depending on the disease and production type, decisions are made about destocking and disinfection of the affected facility. In some cases, all aquatic animals have to be destroyed and disposed of, in others, clinically unaffected animals can be harvested for human consumption. Once facilities are depopulated, they undergo disinfection followed by a period of fallow, to ensure infection does not reoccur, before resuming operation. Where it is not possible to eradicate the disease, as is the case with most diseases of molluscs, a policy of containment is employed to minimise the risk of spread to areas free of disease.

9. Cost analysis

Sectors and groups affected

- Fish and shellfish farmers
- Put and take fisheries

- Fish and shellfish processors
- Depuration centres
- Transporters

Baseline administrative costs

The Standard Cost Model (SCM) provides a framework methodology for measuring administrative costs. By identifying obligations within new legislation and estimating the costs to businesses of meeting them, gives an indication of the administrative costs of the measure.

The basic standard cost formula is as follows:

$$\text{Activity cost} = \text{Price (tariff x time)} \times \text{Quantity (population x frequency)}$$

Tariff, the hourly cost of the person likely to be undertaking the activity. The most suitable category, from the Annual Survey of Hours and Earnings⁴, is managers and proprietors in agriculture and services. The median hourly rate is £12.49. It is standard practice to add 30% to the tariff to cover overheads.

Time, the amount of time taken to complete an administrative task.

Population, number of businesses required to carry out activity.

Frequency, number of times a year the activity must be conducted.

Identification of information obligations

Activities	
Application for authorisation	Familiarisation with obligations, assessment of business premises and practices. Providing information to inspectorate staff.
Maintenance of authorisation information	Updating information on ownership, species held, disease status, etc
Keeping of mortality records	Recording mortalities for each epidemiological unit, as practical for each production type. Records will have to be kept in a standard format.
Completion of movement records	Farms and croppers will need to record all movements on and off business premises. Processing plants and depuration centres will need to record inward movements. The records are required in a standard format.
Cooperation with inspections and surveillance	Inspection visits for surveillance and to ensure authorisation conditions are being met are required. Such visits will have to be supervised by the business owner
Record keeping during transport	When aquaculture animals are transported, the transporter must keep records of farms, mollusc farming areas or processing establishments visited, mortality

⁴ Office of National Statistics 2006 (UK figures)

	levels, as practical for the type of transport, and any water exchange.
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Administrative cost vs. Administrative burden

It is important to understand the difference between administration costs and administrative burden. The analysis above covers all administrative activities required to meet the obligations of the new regime. Many of these administrative tasks would be undertaken in the course of normal business. Through discussion with the affected industries bodies, we have estimated the split between activities undertaken as part of good business practice and those which actually impose a new burden. The results are used to modify the costs in the table below.

Estimates of administrative burden

Activities	Price		Quantity			Annual cost/burden		
	Time (Hours)	Tariff	Population		Frequency	Activity Cost	% of cost to burden	Admin burden
Application for authorisation	2.5	£16.24	Fish farms	461	One off	£33.6k	100	£33.6k
			Mollusc farms	333				
			Crustacean farms	1				
			Depuration centres	32				
Maintenance of authorisation	0.02	£16.24	Fish farms	461	Twice a year	£537	100	£537
			Mollusc farms	333				
			Crustacean farms	1				
			Depuration centres	32				
Completion of movement records	0.02	£16.24	Farm to farm ⁵		2,800	£2.5k	25	£624
			Fish farm to processor		2,000			
			Mollusc farm to Depuration centre ⁶		0			
			Movements to stocked fisheries		3,000			
Cooperation with article 7 inspections	8	£16.24	Fish farms	461	Once per year ⁷	£25.8k	100	£25.8k
			Mollusc farms	333				
			Crustacean farms	1				
			Depuration centres	32				
Record keeping during transport	0.02	£16.24	7,800 movements per year			£2.5k	100 ⁸	£2.5k
Total (excluding one off costs)							£29.5k	
% of industry turnover (estimated at £285.4m)							0.01%	

⁵ Will require 2 records, one for movement off site another for introduction to the new site. This also applies to mollusc farms to mollusc farm movements.

⁶ Depuration centres are already obliged to keep these records under food hygiene rules.

⁷ For minimum application, one visit per year, for a combined surveillance and supervision inspection is expected. The cost of different surveillance options is discussed in the benefits section.

⁸ Documentation is already required, for journeys over 65km, under welfare in transport legislation.

Compliance costs

Activities	
Good hygiene practice activities	Good hygiene practice will consist of a number of activities, specific to the type of production, designed to reduce the introduction or spread of disease. These could include disinfection activities
Animal health certification	When exporting to third countries or trading with areas of the Community with a high health status, animal health certification needs to be completed. This requires that an inspector examines stock before despatch.
Biosecurity measures for specialist transporters	A number of measures will be required, principally disinfection of vehicles and equipment prior to loading..

Estimates of compliance costs

Activities	Price		Quantity		Annual cost			
	Time (hours)	Tariff	Population		Frequency	Activity cost	% of industry	Industry cost
Good hygiene practice activities	2	£16.24	Fish farms	461	Weekly	£1.4m	5 ⁹	£279k
			Mollusc farms	333				
			Crustacean farms	1				
			Depuration centres	32				
Animal health certification	1	£16.24	150 certificated movements per year			£2.5k	100	£2.5k
Biosecurity for transporters	1	£16.24	7,800 per year			£127k	5 ¹⁰	£6k
Total						£287.5k		

10. Benefit analysis

Disease outbreak under existing regime

Disease outbreaks can follow many different paths and have wildly differing impacts. A great deal depends on when a disease is detected but other factors such as geography, industry practices or even the time of year can all have an effect on how a disease outbreak runs its course.

An economic evaluation of the control of notifiable diseases in the UK was undertaken by the Scottish Agricultural College and a paper was published in 2006¹⁰. This evaluation compared

⁹ Takes account of reported compliance with voluntary codes of practice

the public cost of surveillance and control measures with the benefits of avoided costs of unregulated disease outbreaks. It concluded that for Infectious Salmon Anaemia the yield for every £1 of public expenditure was £3.20 to £4.30 for a range of scenarios; and for Viral Haemorrhagic Septicaemia the yield was £5.70 to £6.80.

Assumed benefits of new regime

Some of the new regime's improvements are hard to quantify, in terms of risk reductions. Such elements all have a downward effect on risk. Individually, these measures might not prevent an outbreak, but they could all contribute to reducing the impact of an outbreak and improve the yield described above.

Authorisation of APBs

Closer supervision of aquaculture businesses, through the authorisation system, delivers a number of important elements which will aid early detection of disease and limit the impact of outbreaks. Minimum biosecurity measures, such as registration with a vet, will improve businesses' ability to protect themselves from introduction of disease and recognise signs of disease, should it be introduced. Standardised record keeping will aid identification of source and potential spread if disease does break out and mortality records could help early identification of a problem.

Authorisation can also be refused or withdrawn if a business represents unacceptable risk of disease spread. This, however, is a last resort.

Benefits also could include a general increase in health for farmed species, a reduction in diseases, other than those addressed by the Directive. This will lead to a reduction in the use of veterinary medicines and an increase in fish welfare.

Wild aquatic animals, in particular wild shellfish beds, benefit from a reduction of disease risk from aquaculture. Recreational angling will also benefit, from a safe supply of fish for restocking and reduction in outbreaks of disease, caused by restocking.

Implementation of this regime also contributes to the delivery of other legislation, such as control of non-native species, control of stocking of wild fisheries and protection for habitats.

Comparison of surveillance options

The Directive introduces new methods for risk based animal health surveillance. The specific approach to implementation of this feature has been left to Member States to decide. We have developed a surveillance scheme where the frequency of visits to farms is determined by an assessment of the risk of the farm acquiring and spreading disease.

11. *Small/Micro Firms Impact Test*

We have engaged with key industry representatives of large and small companies both during the negotiation of the Directive and since, seeking their views on our proposals. Consultation took the form of regular meetings of the Aquaculture Health Joint Working Group where papers outlining our proposals were discussed. The proposed measures have attracted broad support

¹⁰ An economic evaluation of the control of three notifiable fish diseases in the United Kingdom. Available online at www.sciencedirect.com

12. ***Legal Aid Impact Test***

The proposals include a right of appeal against the serving of enforcement notices where non-compliance with the regulations has been established. We do not feel that this will have any significant implications for Legal Aid as the compliance requirements will be based on accepted good practice.

13. ***Test Run of Business Forms***

FRS are involved in the preparation of new business forms and these will be tested with appropriate business organisations to ensure they are easily accessible, clear, simple and easy to complete.

14. ***Competition Assessment***

The proposals will not distort or restrict competition.

15. ***Enforcement Sanctioning and Monitoring***

The regulations will be enforced by the Marine Directorate and the Fish Health Inspectorate of the Fisheries Research Services. Proposed sanctions include enforcement notices and revocation of authorisation. Monitoring for compliance with the regulations will be undertaken by the Fish Health Inspectorate.

16. ***Declaration***

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed Date

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