

The Fish Health Inspectorate

A Hampton Implementation Review Report

July 2009

Fish Health Inspectorate

This review is one of a series of reviews of regulatory bodies focusing on the assessment of regulatory performance against the Hampton principles and Macrory characteristics of effective inspection and enforcement. It was carried out by a review team drawn from the Better Regulation Executive, from the Gambling Commission and Natural England, in December 2008.

Further information about the reviews can be found at:

<http://www.berr.gov.uk/whatwedo/bre/inspection-enforcement/implementing-principles/reviewing-regulators/page44054.html>

EXECUTIVE SUMMARY AND CONCLUSIONS

Key findings from the review:

The Fish Health Inspectorate (FHI) already demonstrates good compliance with the Hampton criteria and this will be strengthened when the new Aquatic Animal Health Directive comes into force.

Key findings are:

- The FHI places a strong emphasis on guidance, information and advice and enjoys good relations with the industry it regulates;
- It takes considerable efforts to minimise the burden of data collection and has established good data-sharing arrangements with other agencies;
- The FHI is developing a sophisticated risk-assessment tool, which will help it to take a more risk-based approach to inspection;
- It strives to minimise the impact of inspection, including conducting inspections on behalf of other agencies.

Issues for follow-up identified during the review:

The key follow-up issues identified during the Review are:

- The need for FHI to be fully integrated into the policy development process;
- The FHI should put in place systems for measuring the effectiveness of its advice and guidance to business;
- When its new enforcement powers come into effect under the new Directive, the FHI should publish an enforcement policy indicating when it is likely to use the powers at its disposal;
- The FHI has a clear sense of purpose but should develop some underlying performance measures and report on these annually.

INTRODUCTION

Introductory background information about the regulator such as the rationale for establishing it:

The Fish Health Inspectorate is part of the Centre for Environment Fisheries and Aquaculture Science (Cefas), an executive agency of Defra.

The FHI's mission is to maintain and improve fish and shellfish health in England and Wales. It regulates the fish and shellfish farming industries and licenses and monitors imports and exports of live fish and shellfish.

The United Kingdom has a long history of fish disease controls dating back to 1937. The Fish Disease Act 1937 was introduced to control 'furunculosis', a bacterial disease that was causing serious losses in wild salmonid (i.e. salmon and trout) populations. These controls have been extended to other 'notifiable diseases' and where outbreaks of such diseases occur, the Act provides for controls of movement of live fish to prevent further spread of the disease.

Notifiable diseases are generally untreatable and are likely to have significant economic impact on aquaculture (such as the loss of fish stocks) and an economic or environmental impact on wild fish populations.

As a result of these controls, the UK is currently regarded as having a high health status in the EU.

The legislation establishing the regulator:

The original legislation governing fish health is the Fish Disease Act 1937.

Other subsequent legislation includes the Sea Fisheries (Shellfish) Act 1967, the Import of Live Fish Act, the Import of Live Fish (England and Wales) Act 1980 and the Fish Disease Act 1983.

In order to facilitate trade between EU Member States and to limit the spread of the most serious diseases, a new EU Fish Health Regime was established in 1992. This was based on Council Directive 91/67 EEC and subsequent Directives and Decisions.

The current regime is about to change considerably as a result of a new Aquatic Animal Health Directive (EC Directive 2006/88/EC) implemented into legislation in England and Wales through the Aquatic Animal Health Regulations, due to come into force in early 2009. This will require most fish and shellfish farms to be authorised (they are simply registered at the moment) and encourages a much more risk-based approach to surveillance.

The regulator's statutory remit or objectives:

The FHI's principal remit is to maintain and improve fish and shellfish health in England and Wales.

It is the competent authority for the diagnosis and control of notifiable diseases of fish and shellfish in England and Wales. This review has concentrated on FHI's control functions, rather than the diagnosis functions.

The regulator's budget:

£2 million per annum funding from Defra.

Number of staff (including breakdown of policy and frontline staff):

The FHI employs 22 staff, all of whom are based at the Cefas facilities in Weymouth. The staff are split between field staff and support staff (in charge of licensing, authorisation/registration, data collation, etc.). There is no policy team, but there are specialist policy advisers within the FHI. Policy responsibility lies formally with the Aquatic Animal Health Unit, Food and Farming Group, in Defra.

The sectors and number of businesses regulated either directly or indirectly:

There are over 400 fish and shellfish farming businesses in England and Wales operating on some 524 sites and employing 1,300 people. The sector is dominated by trout production, although the farming of coarse and ornamental species is on the increase.

THE HAMPTON VISION

Both the Hampton and Macrory reports are concerned with effective regulation – achieving regulatory outcomes in a way that minimises the burdens imposed on business. Key to this is the notion that regulators should be risk-based and proportionate in their decision-making, transparent and accountable for their actions and should recognise their role in encouraging economic progress.

Any findings relevant to whether the regulator is risk-based:

Under its current statutory framework the FHI is required to visit every registered fish or shellfish farm at least once a year. This restricts the extent to which it can take a risk-based approach to inspection, although those businesses that are higher risk, such as those that have poor record keeping, can expect to be inspected more frequently.

The position will change, however, when the new Directive comes into force. This encourages a more risk-based approach to surveillance and inspection and lower risk farms may only be inspected every four years. The FHI has developed a sophisticated risk-assessment model and this should provide a good basis for changing its approach to inspection.

Any findings relevant to whether the regulator is transparent and accountable:

The FHI is relatively transparent. Its inspectors enjoy a good, close and open relationship with the industry and it publishes a large amount of information through its website, bi-annual newsletters and leaflets.

It has no published enforcement policy as it follows the Defra enforcement policy. However it plans to issue one when it acquires new powers under the new Directive.

This report also recommends that the FHI should develop some underlying performance measures and report on these annually and put in place systems for measuring the effectiveness of its advice and guidance to business. These steps would further enhance FHI's transparency and accountability.

Any findings relative to whether the regulator encourages economic progress:

The FHI regulates a number of SMEs, many of which are one or two employee businesses. It is keen to minimise the impact of regulation on the industry, for example through its 'whole farm' approach to inspections, its data-gathering/sharing with other agencies and its flexible approach to collecting data. It has also encouraged new areas of the industry, such as those farming coarse fish and exotic species, to form their own trade associations to help develop this part of the industry.

DESIGN OF REGULATIONS

Hampton Principles

All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all parties should be consulted when they are being drafted

When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.

Key findings on
Design of
Regulations:

The statutory framework within which FHI operates will change considerably when the new Aquatic Animal Health Directive comes into effect (likely to be January 2009). There is, however, uncertainty about when the changes will be introduced, arising from a delay in secondary legislation to be published by the European Commission. There is also uncertainty within the industry about what the changes will mean in practice. While Defra consulted on the new Directive in December 2007, this was at an early stage in the process when much of the underlying detail was unknown.

FHI has had some input to the regulations that will transpose the Directive but in our view should have had greater involvement.

Changes within the Defra policy team suggest a more positive relationship with FHI. However, there needs to be greater clarity in roles between Defra and FHI in terms of developing new policy, particularly in relation to consultation and guidance. FHI and Defra are in the process of redrafting the Memorandum of Understanding (MoU) between them and should take this opportunity to bring such clarity to their relationship.

Background information such as the regulator's role in developing regulations:

Given its size, FHI has no central policy team, though senior inspectors provide advice to Defra on the requirements for policy decisions in respect of new business activities and on the potential implications of new legislation and policies both from the perspective of burdens on industry, and on the practicalities of regulation. Policy responsibility lies instead within Defra. Discussions with the review team suggest that the FHI was drawn into the process for drafting the regulations relatively late in the day, despite the fact that it is clearly the leader in this field and will be responsible for implementing the new Directive in practice.

It also seems that the FHI is limited in the role it can play in influencing policy in Europe. Again this needs to be addressed.

Examples of good regulatory practice:

FHI has very good relations with the industry and has brought the new Directive to the attention of the industry through advice and more formally through mailshots.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principles:

FHI has been keen to ensure regulations are proportionate and easy to enforce and has lobbied Defra hard on these points. In spite of a public consultation (which was relatively early in the process) there have been no real mechanisms for feedback from the industry. Responsibility for this appears to lie with Defra, rather than FHI, but there are clearly issues to be addressed here.

ADVICE AND GUIDANCE

Hampton principle

Regulators should provide authoritative, accessible advice easily and cheaply

Key findings on
Advice and
Guidance:

The FHI places a large emphasis on advice and guidance. Its website, eFishBusiness, is well regarded by business and Cefas has two bi-annual publications, Finfish News and Shellfish News, which are very well received. FHI also publishes a range of informative leaflets and its inspections are seen by the industry as a valuable source of advice.

Although the trade associations felt that information was reaching their members, FHI has no formal mechanism in place for monitoring this. We recommend that the FHI should put such systems in place.

While FHI has done its best to bring the changes that will be brought about by the new Directive to the attention of the industry through mailshots and advice, Defra is not planning to issue guidance to the industry 12 weeks in advance of implementation. This is in breach of the Code of Practice on Guidance and may mean that some sectors of the industry are not made aware of the changes in advance of the new regime coming into effect (particularly those sectors that are outside the current arrangements). Defra should consider whether to delay implementation to allow such guidance to be issued. Another approach might be to phase in full compliance with the new regime and to combine this with guidance. There has been some consideration of phasing in compliance but nothing has been formalised.

Background information such as the means by which the regulator provides advice and guidance:

The key source of FHI information is the eFishBusiness website. This is easy to use and text is written in plain English. It is well regarded by the industry, although the FHI is planning further improvements to it.

Cefas also publishes twice a year 'Finfishnews' and 'Shellfishnews', which are mailed to registered fish farms. The FHI regularly contributes to these publications. Again, these are very well regarded, with one stakeholder describing Shellfish News as an 'excellent publication'.

The FHI benefits from a close relationship and obvious synergies with research teams at the Cefas Weymouth laboratory, ensuring that technical advice provided to stakeholders is always up to date and apposite.

Inspections are also a good source of information. FHI does not currently charge for its services because its focus is on maintaining and improving fish and shellfish health in England and Wales. But some of its services, which can take up a disproportionate amount of an inspector's time, may lend themselves to levying a charge, such as approving live fish exports.

Examples of good regulatory practice:

In addition to the above methods of communication, FHI staff regularly attend stakeholder conferences and trade shows. This increases the visibility of the organisation and has helped to establish and maintain good relations with the industry and to promote the need for those who deal with fish and shellfish to adopt practices that maintain fish and shellfish health.

The FHI has also invited industry groups to visit the Cefas laboratories in order to get a better understanding of their work.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The FHI has demonstrated strong compliance with this principle, although we recommend that it put systems in place to monitor the effectiveness of its communications.

DATA REQUESTS

Hampton principle

Businesses should not have to give unnecessary information or give the same piece of information twice.

Key findings on Data Requests: The FHI is conscious of the need to collect only that information that is relevant or necessary. It is flexible in the format that data returns must take and allow information to be submitted electronically. It also collects information on behalf of other organisations, thereby reducing the burden on business.

The FHI has established a database incorporating a wide range of information including Environment Agency (EA) data. This has allowed the EA to share information internally as well as with the FHI – previously each EA regional office had operated separate databases in different formats. This too has helped to minimise the burden on business.

Background information such as the data required by the regulator; the means by which business can return data, etc:

The FHI collects a range of data on fish health and fish movements. This enables it to act quickly in the case of a disease outbreak. The FHI is very flexible in the format that the data return can take and merely specifies the minimum information requirements. This allows businesses to maintain their own records, such as Excel spreadsheets, or to complete the FHI stock movement forms. Data is collected annually and business seems to understand the need for this data.

The FHI also collects data on behalf of others, thereby minimising the burden on business. This includes information about employees, collected on behalf of the EC. The only downside of this is that it may be less clear to business why this information is needed.

The FHI has reviewed not only the information it collects to ensure that it is still relevant, but has also challenged others for whom it collects data, such as the EA and the Veterinary Medicines Directorate (VMD). This has led to simplification of the information requirements.

Examples of good regulatory practice:

The FHI database (see above) is an excellent example of best practice and has only been possible because of the resilience and expertise of FHI staff.

The FHI's flexibility in the format and method of data collection is also an example of good practice and appears to work well.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The FHI has shown very strong compliance with this principle. Any question marks are minor and relate to information it collects on behalf of other regulators.

INSPECTIONS

Hampton principle

No inspection should take place without a reason.

Key findings on Inspections:

Under the current regulatory framework, businesses are currently visited on an annual basis or more frequently if there are concerns about how they are operating. With the new Regulations, the FHI will move towards a more risk-based approach system and has developed a sophisticated, yet easy to use, risk assessment methodology.

Any relevant background information such as the number of inspections and the number of businesses inspected; the regulator's risk model etc

FHI regulates over 400 fish and shellfish farms. Under the current statutory framework, it is required to inspect each business on an annual basis. Businesses that are considered to be higher risk, because for example there are concerns over their record-keeping, may be inspected more frequently.

FHI also operates a 'whole farm approach' whereby it conducts inspections on behalf of other agencies, such as the EA and the VMD, thereby reducing the burden on business.

Businesses do not find these inspections to be a burden. On the contrary, inspections are seen as a good source of advice.

Under the new Regulations, the FHI will move to a more risk-based system of inspections. The FHI is awaiting secondary legislation from the EU on the terms of the surveillance arrangements, but it is likely that low-risk businesses will be inspected only every 4 years.

The FHI has developed a risk-based methodology for use when the Directive comes into forces. This takes account of issues such as the breeds of fish and their susceptibility to disease, the sourcing of eggs or live fish and the risk of contamination from water sources.

The FHI intends to publish its methodology. We recommend that they go a step further and publish information about the number of inspections undertaken and the findings from those inspections. This does not need to identify the individual farms, but could be totals for England and Wales.

Examples of good regulatory practice:

Good examples in this area are FHI's 'whole farm' approach to inspection and its new risk-assessment methodology (see above).

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The current statutory framework limits FHI's ability to operate in a truly risk-based manner. The new Regulations and their emphasis on a more risk-based system of inspection will strengthen the FHI's compliance with this principle.

SANCTIONS

Hampton & Macrory principles

The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.

Regulators should be transparent in the way in which they apply and determine administrative penalties.

Regulators should avoid perverse incentives that might influence the choice of sanctioning response.

Regulators should follow up enforcement actions where appropriate.

Key findings on Sanctions:

The FHI is clearly focused on how it enforces its regulations. Its enforcement powers are limited under the current regulations, but it will gain additional powers under the new Directive. The FHI has no published enforcement policy at present, but intends to publish one when the new Directive comes into effect. We urge them to do so.

There also needs to be greater clarity about who takes the final decision on whether to prosecute an offence – FHI or Defra. Again this could be clarified in the revised MoU and in the enforcement policy.

Background information such as a summary of sanctions available to the regulator and any data on sanctions imposed by the regulator:

The FHI's current powers are limited to advice, warning letters and prosecution. There is a strong emphasis on advice and guidance, with prosecution only taken in the more serious cases, such as illegal importation of live fish, or following repeat offences.

When the new Directive comes into force, farms will have to be authorised rather than simply registered. The FHI will have the power to suspend or even withdraw authorisation, which will be very powerful tools in their own right. For more minor breaches of the regulations, the FHI will have access to improvement/enforcement notices. With criminal prosecution remaining an option for the more serious offences, this will give the FHI access to a range of powers.

The FHI falls within scope of Part 3 of the Regulatory Enforcement and Sanctions Act 2008 and so could have access to an even wider range of civil sanctions, such as monetary penalties and compliance and restoration notices. The FHI can see no need for these additional powers at this stage, although it proposes to keep this under review.

Examples of good regulatory practice:

The FHI makes good use of its dedicated enforcement officer to warn businesses of potential breaches of Regulations. This, coupled with a formal follow-up letter, helps to avoid the need for prosecution.

Review findings:

The FHI is generally compliant with this principle. Its compliance will be strengthened by the new powers available under the Directive and by publishing an enforcement policy.

The extent to which the review team believes the regulator is acting in line with the Hampton principles and Macrory characteristics:

FOCUS ON OUTCOMES

Hampton principle

Regulators should measure outcomes and not just outputs.

Key findings on Focus on Outcomes: The FHI has a very clear focus on its primary objective – keeping England and Wales free from outbreaks of notifiable diseases. It is less clear on how its underlying activities contribute to this. These should be stated in its MoU with Defra and FHI's performance against them published on its website.

Background information such as the regulator's key objectives: The FHI as an organisation has a clear sense of purpose and this is understood by the industry. Its aim is to keep England and Wales free from notifiable diseases and it has been very successful in doing so. However, it lacks underlying performance measures or targets, which mean it might not be receiving the credit that it deserves. It may also be less clear to businesses how FHI's inspections and data collection contribute to this overall aim.

As part of renegotiating its MoU with Defra, FHI should take this opportunity to agree some underlying performance measures, which should be published on its website and reported against each year.

The extent to which the review team believes the regulator is acting in line with the Hampton principle: The FHI is broadly compliant with this Hampton principle but needs to consider how best to link its activities to achieving its desired outcome.

Appendix 1: Review team membership

Beryl Brown was the Director of Policy and Communications at the Gambling Commission (regulator of the gambling industry) to the end of October 2008. She has previously been the Head of Competition Policy at Ofwat (economic regulator of the water industry) and a Principal Economic Consultant with Ernst & Young in New Zealand.

Dr Tim Hill is Director of Regulatory Services & Access in Natural England (Government's independent wildlife, farming and landscape adviser). He has previously worked for English Nature and the Joint Nature Conservation Committee in a range of roles that focus on regulation, protected areas and marine ecology.

Dominic Smales is an Assistant Director in the Better Regulation Executive in the Department for Business, Enterprise and Regulatory Reform. He has previously worked in the Ministry of Justice and Home Office in a range of positions, with a strong focus on developing policy and legislation.

Better Regulation Executive
Department for Business, Enterprise and Regulatory Reform
3rd Floor
1 Victoria Street
London SW1H 0ET

Website: www.berr.gov.uk/bre

URN: 09/1112

© Crown copyright 2009

The text in this document may be reproduced free of charge in any format or media without requiring specific permission. This is subject to material not being used in a derogatory manner or in a misleading context. The source of the material must be acknowledged as Crown copyright and the title of the document must be included when being reproduced as part of another publication or service.