

Regulators' Compliance Code

Supporting Economic Progress

Hampton Principle: Regulators should recognise that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.

Regulators' Compliance Code:

- To consider the impact that their regulatory interventions may have on economic progress and adopt an approach if the benefits justify the costs and entails the minimum burden compatible with achieving their objectives.
- To keep under review their regulatory activities and interventions, removing or reducing the regulatory burdens they impose where appropriate.
- To consider the impact that their regulatory interventions may have on the small regulated entities by giving consideration to the size of the entity and the nature of their activities.
- To set standards or provide guidance which allow for reasonable variations in local government priorities as well as those of the devolved administrations.

The High Level Policy/Document

- Council Directive 2006/88/EC enacted through the Aquatic Animal Health (England and Wales) Regulations 2008.

Evidence of changes made to programmes, programmes delivered or ways in which activities are run that reflects the code:

- Regular interactions with trade bodies provide opportunities to review the nature of the regulatory requirements on stakeholders. An example of one of the mechanisms for interaction between Cefas, Defra, and trade bodies is the Committee for Aquaculture Health (CAH) that meets on a quarterly basis and provides an opportunity for industry to exchange views with the regulatory body.
- Regulatory burdens will be reduced to a level appropriate to the achievement of effective and appropriate health controls. For example in the event of a non-exotic notifiable disease outbreak on a fish farm or fishery the Fish Health Inspectorate work with the owners to develop a management plan to eradicate the disease whilst minimising the economic impact on the business.
- Risk assessments are utilised to implement inspection programmes as appropriate to the nature of activity.
- New powers will address non-compliance through enforcement notices, prohibition notices and fines before progressing to prosecution in line with Macrory principles.

Circumstances where the Code's provisions are either not relevant or are outweighed by other relevant considerations

This section sets out why aspects of the code cannot be met [if relevant]

Future work and long term ambitions that will reflect the Code

This sections sets out the forward plans of the regulator to meet the code [if relevant]

Regulators' Compliance Code

Risk Assessments

Hampton Principle: Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources in the areas that need them most.

Regulators' Compliance Code:

- To ensure that the allocation of their regulatory efforts and resources are targeted by assess the risks to their regulatory outcomes. Ensuring that risk assessment precedes and informs all aspects of their approaches to regulatory activity.
- Risk assessment should be based on all available relevant and good quality data.
- All relevant factors should be given consideration when evaluating the likelihood of non- compliance.
- To consult and involve regulated entities and interested parties when designing risk methodologies and publish details of the methodologies.
- To regularly review and where appropriate, improve their risk methodologies taking into account feedback and other information from regulated entities and interested parties.

The High Level Policy/Document

- The new aquatic animal health directive, 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 will be applied on 1 August 2008 through the Aquatic Animal Health (England and Wales) Regulations. This directive introduces a risk based mechanism for surveillance for aquatic animal diseases, and for compliance with statutory requirements associated with authorisation of aquaculture production businesses.

Evidence of changes made to programmes, programmes delivered or ways in which activities are run that reflects the code:

The Fish Health Inspectorate has applied risk based assessment to disease surveillance on fish farms for many years where legislative flexibilities allow. Under the current legislative regime EC Directive 91/67EC surveillance levels on fish farms were based on the risk of spreading diseases, for example farms holding broodstock, or with a hatchery were subject to a higher level of surveillance than fish farms that only grow on fish for the table or for restocking purposes. The new aquatic animal health directive will develop the risk based surveillance further introducing a more rigorous and comprehensive risk assessment methodology to disease surveillance programmes. Enforcement activities have also been risk based, with investigations directed towards areas and businesses/individuals that are considered to be of higher risk in respect of compromising the high aquatic animal health status of the UK.

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Future work and long term ambitions that will reflect the Code

- Surveillance and inspection of Aquaculture Production Businesses (APB's) and Authorised Processing Establishments (APE's) under the new Aquatic Animal Health Directive will be risk based. A risk assessment will be undertaken on each APB and APE, and will determine the surveillance level appropriate for individual businesses.
- Relevant and up to date information will be used in the assessment of risk for each business.
- Details of the methodologies used in the risk assessment of APB's and APE's will be publicly available, and the individual assessments will be transparent and justifiable.
- Cefas Epidemiologists are experienced risk assessors who will establish and regularly review risk assessment methodologies within the constraints of legislative requirements.
- Evidence of non-compliance with statutory requirements will contribute to increased levels of surveillance undertaken on an APB/APE.

Regulators' Compliance Code

Advice and Guidance

Hampton Principle: Regulators should provide authorities, accessible advice easily and cheaply.

Regulators' Compliance Code:

- To ensure that all legal requirements, along with any changes made, relating to regulatory activities are promptly communicated or otherwise made available to relevant regulated entities.
- To provide general information, advice and guidance in a clear and concise and accessible language, using a range of appropriate formats and media.
- To involve regulated entities in developing both the content and style of the regulatory guidance and assessing the effectiveness of their information by monitoring awareness and understanding of legal requirements.
- To provide targeted and practical advice that meets the needs of regulated entities in a range of formats.
- To distinguish between statutory requirements and advice or guidance aimed when offering compliance advice.
- To provide appropriate means to ensure that regulated entities can reasonably seek and access advice without triggering an enforcement action.
- Any charges for advice services beyond the basic advice and guidance necessary to help ensure compliance should be reasonable and take into account of the needs and circumstances of smaller regulated entities.

The High Level Policy/Document

- Council Directive 2006/88/EC to be transposed into UK legislation in 2008 requires that an electronic public register of APB's is developed. This register will be made available to the public in 2009.
- Commission Decision 2004/453/EC implementing Council Directive 91/67/EC as regards measures against certain diseases in aquaculture animals requires that the competent authority provides information to stakeholders to ensure early detection and reporting of unusual disease occurrence.

Evidence of changes made to programmes, programmes delivered or ways in which activities are run that reflects the code:

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All legal requirements, along with changes made, relating to regulatory activity and also more broad based advice such as the dissemination of good practice will be promptly communicated along with information and general advice through:

- The efishbusiness website, a dedicated multi-agency site disseminating information on all aspects of aquatic animal health controls and linked to other appropriate sites
- 24-hour telephone contact
- Information sheets provided to stakeholders covering issues such as new regulations, diseases, trends, and general advice.
- Press articles and TV and radio interviews
- Personal visits and verbal advice where appropriate
- Meetings and communications with representative bodies such as British Trout Association, Coarse Fish Farmers and Traders Association, Shellfish Association of Great Britain, Fisheries and Angling Conservation Trust.
- General correspondence
- Presentations at conferences and meetings with stakeholders, attendance at trade shows.
- The FHI mailbox provides a conduit for stakeholders to provide or request information
- Letters and other correspondence following disease investigations provide practical targeted advice. Tailored advice where non-compliance is found, or advice sought

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The efishbusiness website is currently being re-developed to provide a more modern user-friendly interface.

Cefas are currently developing training programmes for aquaculturists, veterinary surgeons, and those in related industries on aquatic animal health and biosecurity.

Regulators' Compliance Code

Inspection and other visits

Hampton Principle: No inspection should take place without a reason

Regulators' Compliance Code:

- To ensure that inspections and other visits only occur in accordance with a risk assessment methodology except where visits are requested or is acting on relevant intelligence.
- To use only a small element of random inspection in their programme to test risk methodologies or the effectiveness of their interventions.
- To focus their greatest inspection effort where risk assessment shows a compliance breach or breaches that pose a serious risk to a regulatory outcome and there is a high likelihood of non-compliance.
- To give positive feedback following a visit or inspection and share all good practices.
- To make arrangements for joint or co-ordinated inspections and data sharing when visits by two or more inspectors take place on the same regulated entity.

The High Level Policy/Document

- Council Directive 2006/88/EC enacted through the Aquatic Animal Health (England and Wales) Regulations 2008.

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- The underlying principle behind the new Aquatic Animal Health Directive (EC Directive 2006/88/EC) is that inspections and surveillance programmes will be risk based. A clear, transparent and unambiguous risk assessment methodology is currently under development. Aquaculture production businesses will be aware of their risk rating, the methods underlying its calculation, and the means of mitigating risk.
- Inspection effort and random inspection will be concentrated on areas of higher risk, and areas where non-compliance is considered likely to occur.
- The FHI has adopted a whole farm approach for many years, conducting inspection visits on behalf of other Regulators on an 'eyes and ears' principle such as the Veterinary Medicines Directorate, and the Food Standards Agency, and undertaking joint inspections with other Regulatory bodies where appropriate. The FHI strive to conduct single inspections covering all areas of responsibility i.e. fish health, non-native species, veterinary residues thereby reducing the inspection burden on stakeholders.
- Co-ordinated inspections are already conducted between the Environment Agency and the Fish Health Inspectorate when appropriate to do so. Initiatives will be introduced to extend this arrangement into other areas such as the mixing of veterinary medicines licensing.
- Examples of good practice will be disseminated to industry through various means such as recommended codes of practice.
- The FHI are accredited by United Kingdom Accreditation Service (UKAS) to ISO17025 for the inspection of fish and shellfish farms under our aquatic animal health programmes.

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Future work and long term ambitions that will reflect the Code

This sections sets out the forward plans of the regulator to meet the code [if relevant]

Regulators' Compliance Code

Information requirements

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

Regulators' Compliance Code:

- To undertake an analysis of the costs and benefits of data requests to regulated entities giving explicit consideration to reducing costs.
- To share data when two or more regulators require the same information.
- To collect data in a way that is compatible with the processes of regulated entities and those of other regulators who collect similar data.

The High Level Policy/Document

- *This section gives more detail on how the high level policy is meeting the compliance code including key documents, activities etc.*

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Evidence of changes made to programmes, programmes delivered or ways in which activities are run that reflects the code:

- The Fish Health Inspectorate has over several years driven forward the development of the Live Fish Movement/ Fish Health database, this is a shared database with over 300 users in the Environment Agency, Defra, WAG and Cefas, to optimise data use across the two Government Agencies.
- Data collected by the FHI is also used in the discharge of other Government responsibilities e.g. veterinary residues monitoring on behalf of VMD.
- Future developments may also include data collection by the FHI on behalf of other Government Agencies and Local Authorities and a facility for data sharing through the LFMD, thus reducing the burden on regulated entities.
- There are plans for further integration of the database with industry standard farm databases to facilitate electronic submission of data from fish farms directly to the FHI.
- Data requests to regulated entities are in a format that is simple and readily obtained. Any analysis or collation of data is undertaken by the FHI.

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Under the new aquatic animal health directive shellfish depuration plants will need to be authorised by Cefas. These plants are already subject to an inspection regime under food hygiene legislation. We intend to rationalise the two separate inspection requirements and record keeping requirements to reduce the administrative burden on the stakeholder.

Regulators' Compliance Code

Compliance and enforcement actions

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

Regulators' Compliance Code:

- To reward those regulated entities that have consistently achieved good levels of compliance through positive incentives taking account of the circumstances of small regulated entities.
- To discuss the circumstances with those suspected of a breach and take these into account when considering formal enforcement action [Not applicable where immediate action is required].
- To ensure that their sanctions and penalties policies are consistent with the principles set out in the Macrory Review.
- Follow the Macrory characteristics by publishing an enforcement policy; measure outcomes not just outputs; justify their choice of enforcement actions year on year; follow up enforcement actions where appropriate; enforce in a transparent manner; be transparent in applying and determining penalties; avoid perverse incentives that might influence the choice of sanctioning response.
- To give clear reasons, confirmed in writing, for any formal enforcement action being taken. Complaints and relevant appeals procedures for redress should also be explained at the same time.
- To enable inspectors and enforcement officers to interpret and apply relevant legal requirements and enforcement policies fairly and consistently between like-regulated entities in similar situations. To ensure that staff interpret and apply their legal requirements and enforcement policies consistently and fairly.

The High Level Policy/Document

- The Cefas Investigations and Enforcement policy is updated annually and is available on the efishbusiness website

Evidence of changes made to programmes, programmes delivered or ways in which activities are run that reflects the code:

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The Cefas Fish Health Inspectorate's Investigations and Enforcement strategy has for many years been based on risk analysis and prioritisation resulting in the targeting of those persons whose non-compliant activities, identified through intelligence/ information/inspections, pose the greatest threat of introducing and spreading disease. The strategy operates in support of the Defra Enforcement Policy.

Our approach distinguishes between those regulated entities and individuals who try hard but fail in some way to comply with the regulations, and those whose non-compliance is high risk, intentional or persistent. The strategy is published on our website and has been featured in regular angling press publications. It has evolved through experience, common sense and liaison with all of the main angling and fish-farming representative bodies and has received widespread support for many years. For example, fish smuggling is commonly identified by the FHI and the wider angling and fish farming sector as being the highest threat to indigenous fish. For this reason it is our number one priority and all available resources are applied to prosecuting the offender and stopping the illegal trade. This approach creates a fair and equitable environment for all legitimate traders by removing those whose activities are prejudicial to fair trade. It also serves to encourage legitimate traders to identify the non-compliers to the authorities (see also Investigations and Enforcement Risk Assessment for Aquaculture Businesses).

All information is assessed, recorded, collated, and acted upon where possible. A computerised intelligence system is used for this purpose. In this way offenders are identified, their activities risks assessed, and appropriate action taken. Other than in serious cases, or those involving recidivism, advice warnings or cautioning is the preferred course of action.

The measuring of outputs is achieved primarily through the known incidence of offending, and the number of enforcement actions taken to combat it. Cefas does not determine policy, procedures or penalties but provides evidence and advice to Defra for consideration of such action.

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Accountability

Hampton Principle: Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.

Regulators' Compliance Code:

- To create effective consultation and feedback opportunities.
- To identify and explain the principle risks against which they are acting by setting and publishing clear standards and targets for their service and performance. [Local authorities and fire and rescue are exempt]
- To measure their performance against the standards above and regularly publish the results. [Local authorities and fire and rescue are exempt]
- Ensure that employees provide courteous and efficient services to regulated entities and others taking account of any comments received.
- To provide an effective and timely complaints procedure.
- Ensuring the final stage of the complaints procedure includes and independent external person either an Ombudsman, Tribunal or another independent person such as an independent professional body.

Cefas Fish Health Inspectorate polices does achieve the compliance code' provisions for supporting Economic Progress.

The High Level Policy/Document

- The Fish Health Inspectorate and You: Our Code of Practice and Customer Charter is available both as a hard copy and electronically to stakeholders. This document stipulates the delivery standards under which the Fish Health Inspectorate operates, and also includes details of complaints procedure.
- Citizens charter compliance is published annually through the efishbusiness website and in the Cefas publications Finfish News and Shellfish News.

Evidence of changes made to programmes, programmes delivered or ways in which activities are run that reflects the code:

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- The FHI is accountable to Defra under the terms of an annually agreed Memorandum of Understanding.
- It is also committed to the provisions of the Citizens Charter.
- Quarterly and Annual reports are submitted to Defra.
- Reports on Inspectorate Activity are published in Finfish News and Shellfish News available as hard copy or electronically to stakeholders.
- All areas of FHI work are covered in the Annual Report.
- Regular meetings are held with all parties constituting the fish farming, fisheries and angling communities.
- Visits to the Weymouth laboratory are encouraged for fish farming, fisheries groups and other interested parties.
- FHI represented on the Fisheries and Angling Conservation Trust Fish Welfare Group which is comprised of groups from all parts of the fish farming, fisheries, angling, tackle and feed manufacturers, where all issues are open for discussion.
- The FHI has an effective and timely complaints procedure which includes provision of a non-FHI person in appropriate circumstances

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