

Cefas Investigations and Enforcement – Fish Health Inspectorate

Risk assessment for Aquaculture Production Businesses

Rationale

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 –

4(1) Regulators should ensure that the allocation of their regulatory efforts and resources is targeted where they would be most effective by assessing the risks to their regulatory outcomes. They should also ensure that risk assessment precedes and informs all aspects of their approaches to regulatory activity, including:

- Data collection and other requirements;
- Inspection programmes;
- Advice and support programmes; and
- Enforcement and sanctions.

4(2) Risk assessment should be based on all available relevant and good-quality data. It should include explicit consideration of the combined effect of:

- The potential impact of non-compliance on regulatory outcomes; and
- The likelihood of non-compliance

4(3) In evaluating the likelihood of non-compliance, regulators should give consideration to all relevant factors, including:

- Past compliance records and potential future risks;
- The existence of good systems for managing risks, in particular within regulated entities or sites;
- Evidence of external accreditation; and
- Management competence and willingness to comply

4(4) Regulators should consult and involve regulated entities and other interested parties in designing their risk methodologies, and publish details of the methodologies.

4(5) Regulators should regularly review and, where appropriate, improve their risk methodologies. In doing so, they should take into account feedback and other information from regulated entities and other interested parties.

**The Cefas FHI policy relating to other Compliance Code obligations, ie economic progress, advice and guidance, inspections and other visits, information requirements and accountability has been developed separately due to additional considerations required under EC Directive 2006/88/EC on Aquatic Animal Health, and corresponding changes to domestic regulations due to be introduced in the Aquatic Animal Health (England and Wales) Regulations 2008 which come into force on 1st August 2008..*

Cefas Risk Assessment – investigations and enforcement

Primary objective – to prevent the introduction and spread of serious fish diseases in England and Wales

<u>Area of non-compliance</u>	<u>Details of risk</u>	<u>Risk assessment/High, Medium/Low</u>
<u>Registration/authorisation</u>		
Failing to register	Introduction/spread of disease through unregulated activity	H
Failing to be authorised	-----“-----	H
Failing to comply with conditions of registration/authorisation	-----“-----	H
<u>Imports</u>		
Importing live coarse fish without a health certificate <ul style="list-style-type: none"> • From other EU member state • From 3rd country 	Introduction of disease/unfair trading advantage Inability to identify source -----“-----	H
Importing live cold water ornamental fish without health certificate <ul style="list-style-type: none"> • From other EU member state • From 3rd country 	Introduction of disease/ Inability to identify source -----“-----	H (open waters) M (closed waters)
Importing live tropical aquatic organisms without health certificate	Introduction of disease/ Introduction of non-native species	L
Importing live temperate shellfish without health certificate	Introduction of disease/ Inability to identify source/ Introduction of non-native species	H
Imports without the correct documentation	Introduction of disease/ Inability to identify source	M
Failing to notify Cefas 24 hours in advance of import	Removes opportunity to inspect the consignment/docs	M
Failing to comply with import licence conditions	Introduction of disease/ Introduction on non-native species	M
Failing to comply with a movement restriction order	Spread of disease	H
<u>Exports</u>		
Exports of live fish and shellfish without health certificate	Spread of disease/ Credibility/reputation of official service	M
<u>Records</u>		
Failing to provide movement records	Prevents effective disease tracing/monitoring	H
Failing to provide mortality records	Prevents prompt identification of disease outbreaks/ epidemiological investigation	H
Failing to provide medicine records	Failure to identify misuse of medicines	M
Failing to provide production figures	Informs policy/EU funding	L
<u>ILFA</u>		
Keeping ILFA species without a licence	Threat to biodiversity through spread of non-native species	H
Failing to comply with conditions of licence	Threat to biodiversity through spread of non-native species	H
<u>Other</u>		
Obstructing a Fish Health Inspector		H

Other influential elements in assessing risk

These elements are likely to affect risk status but will be considered in the context of the prevailing circumstances and the seriousness of the alleged activity.

- Whether animals are for human consumption
- Species and disease susceptibility of animals involved
- Specific information or evidence of offending (subject to the credibility/reliability of information/source)
- Where no attempt is being made to comply (as distinct from those who attempt to comply but fail for some reason).
- Previous convictions, non-compliance or obstruction
- Previous advice/guidance ignored
- Known or suspected non-approved source of imported fish
- Current level of disease threat
- Previous disease outbreaks
- Subject to current monitoring programme
- FHI resources available
- Concerns and views expressed by stakeholders
- Impact of non-compliance on other Aquatic Production Businesses
- External accreditation factors of individual or company involved
- Standard of bio-security in place
- Type of medicines involved
- Public interest factors
- Combination of factors

NB:

- (i) *See also consolidated risk-based surveillance programme which categorises risks for Aquacultural Production Businesses (APBs)*
- (ii) *Non-compliance will be dealt with in accordance with Defra's Enforcement and Prosecutions policy*

High risk - Consequences of non-compliance may result in:

- major or irreversible harm to the aquatic animal health status, biodiversity, or environment of Great Britain, or
- severe economic consequences to industry and/or Government sectors

Medium risk – Consequences of non-compliance may result in:

- manageable or reversible harm to the aquatic animal health status, biodiversity, or environment of GB, or
- tangible economic consequences to industry and/or Government sectors

Low risk – Consequences of non-compliance is unlikely to result in:

- harm to the aquatic animal health status, biodiversity, or environment of GB, or
- tangible economic consequences to Government and industry sectors, or to the political or reputation of Government or Government Agencies.

