

**EXPLANATORY MEMORANDUM TO
THE DISEASES OF FISH (ENGLAND AND WALES) ORDER 2007**

2007 No. 864

1. This explanatory memorandum has been prepared by Defra and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 The Order makes notification of suspicion that inland waters have become infected with Koi Herpesvirus Disease, to Defra, compulsory. This obligation to report outbreaks of Koi Herpesvirus Disease falls on any person entitled to take fish from inland waters, or employed for the purpose of care of any inland waters (including fisheries owners and staff). Anyone required to notify, who fails to do so, would be guilty of an offence under the Diseases of Fish Act 1937 (as amended).

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 The Order is being made in response to increased incidence of Koi Herpesvirus disease, experienced during the summer of 2006.

4.2 Ben Bradshaw announced his intention to make KHV disease notifiable, subject to consultation, during Oral Questions in the House on 20 July 2006 (Hansard Column 445).

5. Territorial Extent and Application

5.1 This instrument applies to England and Wales.

6. European Convention on Human Rights

The Minister of State for Local Environment, Marine and Animal Welfare has made the following statement regarding Human Rights:

In my view the provisions of the Diseases of Fish (England and Wales) Order 2007 are compatible with the Convention rights.

7. Policy background

7.1 Koi Herpesvirus disease affects common and koi varieties of carp and can be highly pathogenic. During the summer of 2006, 23 outbreaks of the disease were reported in recreational fisheries in England. Due to the historic absence of any formal controls and ability of the disease to become latent within an infected host and, therefore

difficult to detect using current testing techniques, the current distribution of the disease is unknown. The disease has no implications for human health.

7.2 In partnership with affected sectors (recreational angling and ornamental trade interests), Defra has developed an approach aimed at determining the current distribution of the disease, and encouraged the elaboration of guidance on reducing the risk of spread through industry codes of practice. The approach has been designed to minimise the impact on industry and public sector resources while information is gathered to further refine the policy response to this disease.

7.3 A formal notification requirement is needed to ensure that all suspected outbreaks are investigated. Industry will be made aware of all sites that are confirmed as infected with the disease to reduce the risk of introducing infection when restocking fish at other sites. Guidance on how best to reduce the risk of becoming infected and what to do in the event of infection, including the obligation to notify, will be made available to all affected sectors by relevant industry bodies.

7.4 This policy has also been designed to assist transition to a new EU aquatic animal health regime (Council Directive 2006/88/EC). This Directive, which will be applied from in August 2008, will require that measures are taken to prevent the spread of Koi Herpesvirus disease.

7.5 A formal consultation exercise has been conducted. There were no comments on the draft order or objections to making KHV notifiable. The majority of responses (8 out of 14) were supportive of our preferred policy option of making KHV notifiable and adopting an industry/government partnership approach to control pending establishment of the distribution of KHV in the UK.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum

8.2 The impact on the public sector is hard to determine due to the difficulty in predicting the number of future outbreaks. Investigations into outbreaks would cost approximately £1600 per site. There were 23 outbreaks during 2006.

9. Contact

David Mullin at Defra Tel: 020 7904 6540 or e-mail: David.Mullin@defra.gsi.gov.uk can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSEMENT

1. Title of proposal

1.1 The Diseases of Fish (England and Wales) Order 2007

2. Purpose and intended effect

Objectives

2.1 The purpose of the Diseases of Fish (England and Wales) Order 2007 will be to require any person entitled to take fish from inland waters, or employed for the purpose of care of any inland waters to report any reasonable grounds for suspecting that fish in the waters are infected with Koi Herpesvirus (KHV) disease.

2.2 The intended effect of the measure would be to help determine the incidence and prevalence of KHV disease in fish stocks in England and Wales by making it a legal requirement to notify suspected outbreaks of the disease at farms, fisheries and other sites. The location of confirmed outbreaks of the disease would be made public to help industry sectors avoid further transmission of the disease through trade or other contact with known infected stocks.

Background

2.3 KHV disease affects common and koi varieties of carp and it has been found to occur in a number of countries. It is temperature dependent, only expressing itself clinically above 15°C and below 28°C. Mortality rates can be very high. However, even within that temperature range clinical signs of the disease may not occur for an assortment of reasons including good environmental or stock management conditions acting as a counter to the effects of temperature and/or possibly higher resistance to the disease in some genetic strains of carp. KHV disease has no implications for human health.

2.4 Like many other herpesviruses, KHV can become latent within an infected host and difficult to detect using current testing techniques but easier to detect when clinical signs are present. Up to 2006 only relatively few outbreaks of the disease had been reported in carp populations in England over a number of years. However, during the summer of 2006, possibly as a result of hot weather and corresponding high water temperatures, KHV disease was confirmed in carp on a total of 23 sites with some of them reporting dead fish numbering in the thousands. The Environment Agency adopted a precautionary position in not consenting movements from affected or contact sites.

2.5 There are currently no specific EU or national controls in respect of KHV disease, which limits the ability of the UK to place restrictions on trade. However, Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (the new Aquatic Animal Health Directive) lists KHV as a disease for control on a Community wide basis. In addition, the World Organisation for Animal

Health (the OIE) decided at its General Session in May 2006 to include KHV disease in its list of notifiable diseases.

Rationale for government intervention

2.6 The disease primarily affects the recreational angling and ornamental carp sectors. If the number of outbreaks of the disease and associated high mortalities experienced in 2006 are repeated or increase in intensity in subsequent years, there could be significant adverse economic impact on those sectors and the businesses and communities that depend on them.

2.7 Industry sectors affected by the disease have actively sought government intervention to assist them to limit the impact of outbreaks on businesses.

2.8 Little information currently exists on the extent of distribution of KHV disease in England and Wales. Making the disease notifiable will assist research work in hand to assess the extent of infection in trade and in the natural environment. This will contribute towards the development of UK policy on KHV disease in preparation for implementation of the new Aquatic Animal Health Directive. It will also provide a formal mechanism for recording the occurrence of the disease for notification to the OIE in accordance with the UK's obligation as a member country of that organisation.

3. Consultation

Within government

3.1 Policy options have been discussed and developed with fish farm and fisheries interests within the Devolved Administrations and the Environment Agency.

Public consultation

3.2 Full consultation has taken place on a draft order to make KHV disease notifiable and on the possible options for controlling confirmed outbreaks once the disease is made notifiable.

3.3 Representations were received from a number of organisations and individuals. Those representing a majority of the affected industry sectors were generally in favour of making KHV disease notifiable and on complementing that status with control arrangement based on Option 3 below.

4. Options for controlling KHV Disease

4.1 The following provides an outline of options upon which stakeholders were invited to comment:

Option 1

No direct Government intervention. Industry itself would be free (as it is now) to take a number of positive steps to reduce the risk of spread of the disease. It would be possible to control the disease at the individual site level, although, due to the interdependence of many businesses at risk from the disease, it would be more

effective if there were broad consensus on an overall approach between different commercial interests within the industry. Measures for further consideration and development could include:

- application of improved biosecurity, including quarantine to keep new introductions of fish separate from existing stock until KHV freedom is confirmed; and
- demanding suitable health attestation from suppliers, as part of commercial agreements, especially from areas where KHV infection is endemic.

Option 2

The Government would make KHV disease notifiable and consider applying control measures on the same basis as the statutory controls that currently apply in respect of a number of serious notifiable fish diseases (e.g. Spring Viraemia of Carp and Viral Haemorrhagic Septicaemia). This would involve extensive surveillance monitoring and testing on a regular basis at sites holding susceptible species either in furtherance of an eradication programme for a disease such as SVC, or monitoring to confirm free status in respect of a disease such as VHS.

When an outbreak of one of these diseases occurs, movement restrictions are applied and, where possible, the infected site is de-stocked and disinfected. Contact sites, implicated through movements of live fish, on or off infected sites, are identified, placed under movement controls and tested. These controls have operated on the assumption that diseases are not normally present in England and that any outbreak is likely to be due to an introduction of the disease through trade in fish or by another route.

Option 3

The Government would make KHV disease notifiable and any control arrangements to complement notifiable status would be on the basis of a partnership approach between industry and government. Under this option the Government would investigate clinical outbreaks of the disease and identify infected sites or areas of high risk so that industry could take precautionary steps to reduce the risk of further spread of the disease. The approach would allow for a gradual build up of information on the distribution of the disease to enable further consideration to be given to an effective long-term strategy in preparation for implementation of the new Aquatic Animal Health Directive.

Industry would be expected to develop Codes of Practice in each of the three stakeholder groups - anglers, fishery owners and live fish suppliers. The purpose of the Codes would be to ensure that all concerned could take robust voluntary measures to minimise spread of KHV disease through good biosecurity and trade in health assured fish.

5. Costs and benefits

Sectors and groups affected

5.1 The following are the main sectors and groups affected by outbreaks of KHV disease:

- Fisheries owners (fisheries stocking susceptible species numbering 11,000 sites with 2,000 movements of live carp consignments per year)
- Coarse fish farmers and suppliers (there are 176 registered farms and 107 significant suppliers)
- Anglers (there are some 4 million regular recreational anglers with carp anglers forming the majority)
- Ornamental farmers/importers (there are 75 ornamental fish farms, 114 importers)

Overview of costs and benefits

5.2 The total value of inland recreational fisheries is estimated at over £3 billion per year, with coarse fisheries estimated at £2.3 billion and carp angling representing the majority of this figure. The coarse fish angling industry is estimated to employ some 15,000 people.

5.3 The supply and retail of coldwater ornamental fish (and related dry goods) is estimated to be worth £200 million annually, although not all species will be susceptible to KHV. The ornamental trade is estimated to employ 12,000 people.

5.4 The cost to businesses, both in the coarse/ornamental supply and fisheries sectors, of an outbreak of KHV disease depends of the size and type of business. These costs can be highly significant. During the summer of 2006, some of the affected fisheries had mortalities numbering in the thousands. Some businesses might, in addition to culling and disposing of affected stocks in accordance with animal by product legislation, choose to disinfect their sites before restocking. The number of such business would probably be very few but a rough estimate of the total costs based on a site culling 20 tonnes of susceptible species might be up to £100,000. However, even minor losses of fish could have an adverse impact on businesses if anglers stop using fisheries as the result of an outbreak. Moreover, in certain types of 'specimen' fishery, large individual fish can be highly valuable and their loss could cause significant damage to a business.

5.5 It is not possible to predict, with any degree of certainty, the number of outbreaks of KHV disease that are likely to arise in the future because of limited information currently available about the distribution of the disease in England and Wales (making the disease notifiable and research underway to try and establish the extent of distribution will assist the process). In the meantime Defra, WAG and the Environment Agency are working with industry representatives to produce comprehensive advice on how to minimise the risk of an outbreak of KHV, in time for the late spring and summer when water temperatures rise to 15C and above.

5.6 The field work, diagnostic tests and administrative work associated with an investigation into a reported outbreak of KHV disease is, according to conservative estimates, likely to cost in the region of £1600 for each incident. The Government has

made it clear during consultation that currently no additional Government funding is available for the operation of future control arrangements for KHV disease and the cost of any regime may have to be borne largely by the sectors of industry benefiting from the measures.

Costs and benefits of the options

Option 1

Benefits

5.8 Industry itself would be free to determine its level of response to the disease and therefore the degree of its financial commitment to voluntary control. This could vary from

- doing nothing and living with the likelihood of more frequent disease outbreaks;
- adopting a de-minimis approach of self regulation involving, for example, trading around known infection; to
- the development, with all affected sectors and groups, of robust voluntary controls based on accredited standards of biosecurity to assist with the gradual elimination from trade of fish capable of causing outbreaks of KHV disease.

Costs

5.9 The do nothing option would involve costs because industry would have to continue to factor into their business plan the unpredictability of outbreaks and high losses that they could sustain from large scale mortalities. The adoption of de-minimis or more robust risk mitigation should at least help to limit such losses and generally improve biosecurity standards.

5.10 Without firm agreement between the different sectoral interests on the approach to control there would be no coherent overarching command and control structure for a voluntary disease containment or eradication policy.

5.11 Any industry initiative would in any event have to be replaced or augmented upon application of the new Aquatic Animal Health Directive before application of that measure in August 2008

Option 2

Benefits

5.12. This option could provide reasonable protection to affected industry sectors against spread of the disease through tighter containment and progressive eradication of pathogen from the supply chain. It would also help to provide more definitive information on the distribution of the disease.

Costs

5.13 The option would be extremely costly (currently estimated at some £2.5 million per annum) because it would, in practice, require regular inspection and surveillance of several thousand fishery and farmed sites. Surveillance represents one of the most expensive elements of this type of control. In order to sample a relevant number of sites costs could be prohibitive. However, these could be reduced if that surveillance were combined with other statutory duties.

5.14 A commitment to this level of control and associated cost before determining the extent of distribution of KHV disease in England and Wales might be regarded as irresponsible and wholly impracticable if the disease is subsequently found to be widely distributed. There has been trade in potentially infected carp since the 1990s and the disease is likely to be present in an undetermined number of waters. Moreover, it can be difficult to confirm its presence or guarantee its absence because of the tendency of the virus to become latent in recovered fish, its dependence on temperature for clinical expression, and the need for development of more sensitive and specific diagnostic techniques.

5.15 Many movements of live fish at risk from KHV disease may be taking place without valid consenting permissions or records, making complete contact identification and any potential control operation difficult. In addition it is likely to be totally impractical to eradicate the disease from most waters at risk from KHV through disinfection, although most supply premises (from which there is the greatest risk of spread) can be disinfected.

5.16 In the absence of any additional government funding, the high costs associated with such a regime would have to be borne largely by the sectors of industry benefiting from the measures. Those sectors would, in addition, have to operate under potentially very restrictive conditions which could in themselves prove extremely disruptive to businesses across all sectors.

5.17 There would be no guarantee that this option would be effective in terms of controlling within, and eradicating the disease from, England and Wales. There could also be legal difficulty in seeking to apply statutory measures at this level in advance of implementation of the new Aquatic Animal Health Directive

Option 3

Benefits

5.18 This joint industry/government partnership approach would provide a “light touch” first step to gaining a better understanding of the disease situation and the measures that might be applied to control it in the future under the new Aquatic Animal Health Directive. It would allow sufficient time to enable an assessment to be made of the significance of the disease in terms of its distribution within England and Wales and would deliver an interim mechanism to control spread of the disease with minimal disruption to all sectors of the industry.

5.19 Long term co-operation between affected industry sectors and groups would lead to a greater appreciation of the economic benefits of engaging in trade founded on high biosecurity standards and health-assured fish.

Costs

5.20 There could be negative economic impacts for sites identified as infected with KHV disease as part of the notifiable disease requirement. In practice this is likely to impact more on fishery rather than farm sites because control and eradication at the latter is less difficult. It may through publicity, be possible to counter adverse impact on fishery sites by making it clear to anglers that it may be perfectly possible for them to continue fishing at such sites providing appropriate measures have been taken to deal with an outbreak and advice on ongoing biosecurity is strictly observed.

6. Small Firms Impact Test

6.1 The majority of the businesses involved in recreational angling and the trade in ornamental fish can be described as small enterprises. Although all options will impact on small businesses within the different sectors, there would be no disproportionate impact, as compared with larger enterprises. Fisheries or live fish suppliers will either be free of the disease or infected.

6.2 The industry sectors involved are predominantly made up of small enterprises but are represented by a number of organisations who deal with their needs at national level. Early consultation on the future policy options will include bodies representing all sectors of the industry.

7. Competition assessment

7.1 The simple competition assessment indicated that there was unlikely to be a significant market effect from the measures. However, industry codes of practice, identification of infected sites or movement controls could potentially limit the choice and location of businesses, and have an adverse impact on them depending on the distribution of the disease.

8. Enforcement, sanctions and monitoring

8.1 If KHV disease becomes notifiable, failure to notify on suspicion of clinical sign of the disease would become an offence. Enforcement of movement controls on premises confirmed to be infected could be implemented through voluntary industry codes of practice or government regulation such as Environment Agency section 30 consents or Defra Designated Area Orders. The latter two options would make unauthorised movements of fish an offence.

9. Implementation and delivery plan

9.1 KHV disease will become notifiable on clinical expression on the common commencement date of 6 April. Any incidences of clinical expression are unlikely before late spring early summer and industry codes of practice should have been agreed before then offering advice to at-risk businesses on how best to protect themselves from the disease.

10. Post-implementation review

10.1 The KHV disease policy will be reviewed in early 2008. This will allow the experience gained from the disease being notifiable throughout the summer of 2007 to be analysed and the effectiveness of the policy to be assessed. The research project aiming to establish the current distribution of KHV disease expected to deliver a final report early in 2008. This also coincides with the final stages of the implementation of the new Aquatic Animal Health Directive, which will require a response to the disease from all Member States.

11. Summary and recommendation

11.1 The three options presented each would have a very different impact on the affected industry and, potentially, the distribution of the disease. Option 1 (the zero option) places all the responsibility with industry and does nothing to help determine the extent of distribution. It is low cost in terms of regulatory burden and cost to the taxpayer, but could lead to high costs to industry and wild carp fisheries in the future, if latent infection is spread and environmental conditions occur which promote expression of the disease.

11.2 Option 2, the traditional regulatory approach to diseases such as Spring Viraemia of Carp and Viral Haemorrhagic Septicaemia, reduces the risk of spread but at a potentially very high cost that might have to be borne by industry itself. Collateral impacts on business would be high, as controls would be placed on contacts to sites with outbreaks, pending confirmation of infection or freedom. This approach would not solve the problem of the spread of latent infection.

11.3 Option 3 combined with making KHV disease notifiable is a proportionate approach to gaining greater knowledge of the disease situation within the country and the measures that might be applied to control it in the future. There might be some adverse impact on those sites identified as being infected but the industry codes of practice in development to complement notifiable status should help to mitigate collateral impact by encouraging higher biosecurity standards and quantifying advice to at-risk businesses for avoiding spread from known infected sites.

Recommendation

11.4 Notifiable status complemented by controls in accordance with Option 3 is recommended at this stage

Summary costs and benefits table

- Due to the difficulty in predicting the number of future outbreaks of KHV disease, because of the unknown distribution and the dependency on temperature and other environmental factors, three different outbreak scenarios are being considered. Examining the costs and benefits for the three options (10 outbreaks, 25 outbreaks and 75 outbreaks) will give an indication of how the costs, in particular, of the three options would breakdown.
- In order that the models are relatively simple and easy to assess, the following assumptions have been made:

The diagnostic test is accurate, with negligible risk of giving false positives or negatives;

Where option 2 is examined, 3 contacts will be investigated for each site notifying an outbreak;

Of the 10,000 plus sites holding susceptible species, a sample would be subject to surveillance on an annual basis. When considering option 2, the surveillance scheme will cover 2000 sites, to reflect the numbers of sites potentially involved in the movement of live fish.

| Option | Total benefit per annum: economic, environmental, social | Total cost per annum: - economic, environmental, social - policy and administrative |
|--------|---|---|
| 1 | Dependent on the effectiveness of any industry action. No regulatory impact on business. | <p>Economic, environmental, social No controls on spread, potential for increased outbreaks.</p> <p>Policy and Administrative No cost</p> |
| 2 | No further risk of spread from sites where there have been outbreaks or from contacts identified as positive. | <p>Economic, environmental, social Sites impacted by controls: 10 outbreaks – 40 sites 25 outbreaks – 100 sites 75 outbreaks – 300 sites</p> <p>Probable loss of stock, customers, cost of disinfection and disposal.</p> <p>No effect on latent infection, the risk of further spread would still exist.</p> <p>Policy and Administrative Surveillance costs: £2 million Investigation/control: £64,000 – 10 outbreaks £160,000 – 25 outbreaks £480,000 – 75 outbreaks</p> |
| 3 | <p>Dependent on industry codes of practice, but the risk from sites suffering from outbreaks will be clearly identified.</p> <p>Minimal regulatory burden as a result of Government intervention.</p> | <p>Economic, environmental, social Possible risk of spread from sites epidemiologically connected to each outbreak site.</p> <p>Impact on custom at sites notifying outbreaks.</p> |

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| | | No effect on latent infection, the risk of further spread would still exist. Policy and Administrative Investigation: £16,000 – 10 outbreaks £40,000 – 25 outbreaks £120,000 – 75 outbreaks |
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Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed Ben Bradshaw

Date 15th March 2007

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