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Consultation on Aquatic Animal Health – KHV Disease status for England and Wales

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Part I – Rationale for Government involvement

- 1.1 Defra's approach resonates with the aspirations of the Animal Health and Welfare Strategy for Great Britain, which was adopted in June 2004 and set out a number of guiding principles to animal health and welfare – In particular that prevention is better than cure.
- 1.2 Defra works to secure a healthy environment in which we and future generations can prosper. Key to this overall rationale are the Public Sector Agreements (PSAs) which are key cross-Government priorities, and the Departmental Strategic Objectives (DSOs).
- 1.3 In relation to the debate about KHV and the approach to be taken under Directive 2006/88/EC there are elements of the PSAs and DSOs that are relevant. Of particular relevance is the PSA on **“Secure a healthy natural environment for everyone’s well being, health and prosperity, now and in the future”**.
 - A healthy, resilient, productive and diverse natural environment;
 - A thriving farming and food sector, with improving net environmental impact;
 - A strong rural community.
- 1.4 In general therefore, Defra has, at the highest levels, obligations that aim to ensure the maintenance of high animal health across all sectors including the aquatic animal sector. This means not just taking action in the event of disease outbreaks, but also endeavouring to limit the risk of disease incursions.
- 1.5 Where risks have been identified, action will be taken within the framework of activities provided for under relevant legislation, in the case of aquatic animals and KHV more specifically, under the provisions of Directive 2006/88/EC and the Aquatic Animal Health (England and Wales) Regulations 2009.

Part II - Summary

- 2.1 Your views are invited on which health status should be declared for England and Wales in respect of Koi Herpesvirus (KHV) disease. European 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, came into effect in August 2008 and introduced requirements on Member States to control certain non-exotic diseases. Included for the first time under Community legislation is the requirement to control KHV disease.
- 2.2 Member States are required to determine a health status for each of the non-exotic diseases listed in the Directive. For most of the listed diseases, the UK already has a defined health status. However, this is not the case for KHV, which has for the first time come under Community control. We must therefore decide which of the five possible health status options, which are set out in the Directive, is the most appropriate for England and Wales for KHV disease .
- 2.3 Each health status option establishes the level of controls Member States can introduce on movements of KHV susceptible & vector species as appropriate, both when placing them on the market, i.e. movement between different Member States, zones or compartments, and imports from 3rd countries, i.e. from outside the Community.
- 2.4 Certain options when declaring a health status also require the competent authorities in each Member States to undertake different levels of surveillance and controls, thus placing a greater burden on resources within Government and our delivery partners in Centre for Environment, Fisheries and Aquaculture Science (Cefas) and the Fish Health Inspectorate (FHI).

Part III - Background and History

The Virus

- 3.1 Koi herpesvirus (KHV) causes a severe disease with high mortality in populations of common carp (*Cyprinus carpio carpio*) and all varieties, including koi carp (*Cyprinus carpio koi*) and ghost carp (*Cyprinus carpio goi*). KHV disease (KHVD) is temperature dependant, generally expressing itself clinically above 15°C and below 28°C. Most age/size ranges of fish are susceptible to KHVD. The disease course can be rapid with an incubation period as short as 3 days at the higher water temperatures, but is more commonly in the range of 7-21 days. Morbidity of affected populations can reach 100% and mortality is in the range 70-10%. Infected fish produce antibodies against the virus, which have been detected by ELISA-based methods.
- 3.2 It has not been confirmed that survivors of natural outbreaks of KHV disease are persistently infected and for how long the fish may retain the virus or if survivors continue to shed virus. Investigations in experimentally infected fish have shown that virus can persist in common carp infected at a permissive temperature (21°C) and subsequently maintained at a lower than permissive temperature (12°C) for approximately 25 weeks. In the same experiments the virus was also shown to re-activate in these carp when the temperature was raised to 23°C and transmit disease to naïve carp introduced into the same tank.
- 3.3 Studies at Cefas and elsewhere have shown that carp populations with known prior exposures to the virus, and which may include virus carriers, contain high numbers of carp with high titres of detectable antibody to KHV. Repeat testing of such carp populations, where no new introductions of carp have been made, have shown that these high antibody titres can persist for at least 2 years. This may be an indication that antibody titres are being maintained because of a low-level persistent infection but this needs to be confirmed.
- 3.4 Latent KHV infections have not yet been demonstrated in carp. However, to date, every herpesvirus that has been studied in depth, establishes latent infection in a specific population of cells within the host animal. In order to demonstrate true latency it is required to differentiate between a latent and abortive infection. For a true latent state to be present the latent virus must be shown to reactivate either spontaneously or in response to a stressor. Evidence for KHV latency in carp is not substantial. If KHV latency is shown to be difficult to demonstrate in carp this may be because the latent genome is present in low copy numbers and is well hidden in specific cells. Alternatively, the carp may not be the natural host for KHV and a latent state may not be established.

History in the UK

- 3.5 KHV disease poses a serious socio-economic threat to the UK carp industry, affecting in particular the recreational angling and ornamental fish sectors, both of which have significant economic value. From analysis of archive histological material, evidence suggests the presence of KHV in England since 1996 when viral DNA was detected in carp samples from a warm water re-circulation facility in Derbyshire. The facility was importing ornamental fish, including koi carp, and supplying both the ornamental trade and fisheries in the UK.
- 3.6 However, until 2003 KHV had only been detected and isolated from sites in the UK holding imported ornamental carp. In 2003 KHV was detected in common carp for the first time in England, during investigations into large mortalities in angling waters. Further detections of KHV were subsequently made at a small number of angling waters in 2004 and 2005, before the number of outbreaks reported and confirmed increased to 23 sites in 2006. The number of outbreaks has fallen back to earlier levels since then, with only 10 confirmed in 2007 and 12 in 2008.

Affected sectors and groups

- 3.7 A wide range of sectors and groups are affected by KHV. This includes:
- fishery owners;
 - fishery suppliers;
 - coarse fish farmers;
 - anglers;
- and
- ornamental farmers/importers/suppliers.
- 3.8 There are some 4 million regular recreational anglers in England and Wales. The total value of inland recreational fisheries is estimated at over £3 billion per year, with coarse fisheries estimated at £2.3 billion. The Angling industry employs around 10,000 people in the UK, with annual expenditure by coarse anglers, on fishing activities, estimated to be some £2 billion. Expenditure by carp anglers make up a large proportion of this.
- 3.9 The supply and retail of coldwater ornamental fish such as Koi carp (and related dry goods) is estimated to be worth £200 million annually, although not all species traded will be susceptible to KHV. The ornamental trade is estimated to employ 12,000 people. The cost to businesses, both in the ornamental and fisheries sectors, of an outbreak of KHV disease depends on the size and type of business. These costs can be high.

Control and prevalence

- 3.10 KHV disease is an OIE and EU listed disease, and so is of significance for trade of susceptible species between both EU Member States and third

countries. In April 2007 the UK became one of the first EU Member States to introduce controls for KHV, when it became a notifiable disease in England and Wales. This created for the first time a legal obligation to notify the presence or suspicion of the disease.

- 3.11 Although KHV disease was made a notifiable disease, this did not mean that the UK could impose additional restrictions on movements of susceptible species into the country. Consequently, since KHV was first identified, there has been substantial trade in susceptible species from countries where the disease is known or believed to be present. Therefore, it is possible that the virus has been further disseminated widely throughout England & Wales unintentionally, and therefore likely to be present in an undetermined number of waters.
- 3.12 For this reason Defra has funded a KHV prevalence and distribution study carried out by Cefas. This study aimed to determine the geographic distribution and prevalence of KHV in England and Wales. The study examined carp from 82 farm sites, 72 fisheries and 12 consignments of ornamental carp imported from seven different South East Asian countries. Full details of the study can be found in the report at Annex B.

Part IV - Future Controls

- 4.1 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, came into effect on 1 August 2008. This Directive repeals the previous regime under Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products, 93/53/EEC introducing minimum Community measures for the control of certain fish diseases, and 95/70/EC introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs.
- 4.2 Directive 2006/88/EC introduces a number of new features compared with the previous regime. Initial new measures from the Directives introduction; have been implemented through the Aquatic Animal Health Regulations 2009. These include the authorisation of fish farmers, traders and dealers, plus the registration of stocked fisheries and cropping agents.
- 4.3 However, while these measures are not expected to reduce the risk of introducing KHV, it is anticipated to help reduce the scale of outbreaks through quicker background/forward tracing.
- 4.4 Of specific relevance to this consultation are the provisions for declaring the health status of a Member States, zone or compartment, for the non-exotic diseases (including KHV) listed in Annex IV PART 2 of the Directive, whereby Member States are either declaring their freedom from KHV, or through programmes available under category II or IV, looking to achieve this status.
- 4.5 Additionally, the Directive provides the facility for a Member State to self-declare disease freedom either wholly or in terms of zones and compartments. Member States have five possible options to choose from when declaring a health status. These are:-
- Category I Disease free;
 - Category II Surveillance programme;
 - Category III Undetermined (not known to be infected but not subject to a programme for achieving disease-free status);
 - Category IV Eradication programme;
- and
- Category V Infected.
- 4.6 For most of the listed non-exotic diseases the UK already has a defined health status. However, this is not the case for KHV disease, which is being listed as

a non-exotic disease, and so a notifiable disease, in the EU for the first time. The purpose of this consultation is to seek your views on which of these five possible health statuses is the most appropriate for England and Wales for KHV.

- 4.7 Scotland and Northern Ireland will separately assess the KHV status in their respective countries.

Part V - Health Status for KHV

Options for declaring a health status for KHV under Article 12 and Annex III Part A of Council Directive 2006/88/EC

- 5.1 In order to be able to carry out trade with other Member States and certain third countries, the UK needs to establish a health status for each non-exotic disease listed in Annex IV Part II of Council Directive 2006/88. The health status options are set out in Annex III of the Directive, and Annex A to this document.
- 5.2 The health status we declare in England and Wales for KHV disease will determine the level of trade allowed in susceptible species with other Member States and 3rd countries. The status will also impact on trade with other parts of the UK which might have a different health status, plus determine the level of surveillance/eradication programme and control regime, we implement internally.
- 5.3 For example, a farm in a category I area would only be able to receive susceptible species from an area of equal disease free status, whether internally in the UK, another Member State or a 3rd country, but they would be able to dispatch animals to all other health status category areas. Conversely, a farm in a category V area would be able to receive fish from all other category areas, but only dispatch to other infected areas with category V status.
- 5.4 The implications if we were to declare England and Wales category V status and thus infected with KHV disease, includes imports of susceptible species continuing to be traded with little to no controls over where they could be sourced from. This could mean KHV susceptible species being imported from a country, zone or compartment not declared free of disease and therefore potentially KHV compromised.
- 5.5 However, declaring category V status would mean it only possible to export susceptible species to other category V Member States, zone or compartments. This would have implications for movements between England and Wales and other Member states with higher KHV health status, as well as internally in the UK, where, for example, England and Wales might have a different health status to Scotland and/ or Northern Ireland, the Isle of Man and the Channel Islands so restricting trade from England and Wales to theirs.

Option 1

Declaring England and Wales Category I (disease-free) status for KHV disease

- 6.1 By declaring category I (Disease free) status, a Member State, zone or compartment declares disease freedom under Article 49 and 50 of Council Directive 2006/88. This requires the Member State, zone or compartment to either:
- have none of the susceptible species present in their territory;
 - or
 - the disease is known not to be able to survive in the Member State waters;
 - or
 - the area meets certain conditions as laid down in the Directive, including freedom based on historical grounds or following a targeted surveillance programme.

Intra-Community Trade

- 6.2 If a Member States declares category I status for KHV either for the whole country, certain zones or compartments, they may only introduce susceptible species from another category I status Member State, zone or compartment. Under these circumstances where movement of susceptible species is between two category I status areas, the introduction of susceptible species is required to be carried out under appropriate health certification introduced by Commission Regulation 1251/2008.
- 6.3 Susceptible species may be dispatched to all other category (I to V) status areas within the Community. Under these circumstances, health certification is not required when dispatching to category III or V status areas, however health certification is required when dispatching susceptible species from a category I area, to areas under category I, II or IV status.

Third Country Trade

- 6.4 Trade in susceptible species from a country outside the EU can only take place if the country, zone or compartment in question is declared free from KHV in accordance with [the requirements as laid down by Chapter VII (Article 50.4) of Directive 2006/88 or the relevant OIE standard on KHV freedom], and accompanied by a relevant health certificate, introduced by Commission Regulation 1251/2008. Additional requirements that need complying with include:
- the relevant disease being made notifiable to the competent authority;
 - and

- the susceptible species have not been vaccinated against the relevant disease.

Likelihood and impact

6.5 Although this option is listed, we are not in a position to justify declaring this status due to the KHV outbreaks we have seen in certain fisheries, over the past 5 years.

Option 2

Declaring England and Wales Category II (surveillance programme) status for KHV disease.

- 7.1 By declaring category II (under a surveillance programme) status, a Member State, zone or compartment declares that they are operating a surveillance programme in accordance with Article 44 of Council Directive 2006/88/EC. This status would be declared where the area concerned is not known to be infected, but also not able to declare freedom under category I, until an appropriate surveillance programme for achieving disease-free status has been undertaken.

Intra-Community Trade

- 7.2 If a Member State declares category II status for the whole country, certain zones or compartments, KHV susceptible species could only be introduced into the relevant area from a category I status Member State, zone or compartment. Under these circumstances, the movement from a category I status area, to category II is required to be under appropriate health certification. Susceptible species may only be dispatched to category III and V status areas, but this movement does not require health certification.

Third Country Trade

- 7.3 Trade in susceptible species from a country outside the EU can only take place if the country, zone or compartment in question is declared free from KHV disease, in accordance with the requirements as laid down by Chapter VII (Article 50.4) of Directive 2006/88 or the relevant OIE standard on KHV freedom, and accompanied by a relevant health certificate. Additional requirements that need complying with include:
- the relevant disease being notifiable to the competent authority;
 - and
 - the susceptible species have not been vaccinated against the relevant disease.

Likelihood and impact

- 7.4 Option 2 and declaring category II status is more realistic for England and Wales at present than option i, disease freedom. Although we have seen a small number of KHV outbreaks in recent years, these have all been isolated cases in fisheries and to date we have not seen an official outbreak on a farm. This, coupled with the distribution and prevalence study conducted by Cefas, would lead us to believe that with the tighter import controls available under

category II and a surveillance programme meeting the necessary requirements, we could in the future look to reduce the number of KHV outbreaks in fisheries and look to gain category I status.

- 7.5 If we introduced category II status, there could potentially be an initial shortfall in the available third country markets from which imports of KHV susceptible species can currently be imported. Some traditional Koi producing markets would be unable to meet the necessary requirements for import and certify disease freedom to begin with, and would need to introduce specific programmes on surveillance before they could meet this requirement.
- 7.6 However, declaring this status would mean only countries that were able to declare themselves, zones or compartments within those countries, as KHV free, would be able to export to England and Wales. This would provide us with assurances that only KHV-free fish were being imported.

Option 3

Declaring England and Wales Category III (undetermined) status for KHV disease

- 8.1 By declaring category III status, a Member State, zone or compartment declares that it is not known to be infected with KHV at this current time, but also not subject to a programme for achieving a disease-free status. This health status is generally regarded as being of a temporary or transitional state.
- 8.2 The Member State, zone or compartment will be expected to aspire to move to a higher status, i.e. disease freedom via a surveillance programme, or to drop its health status to being infected in the event of significant disease outbreaks in farms or restocking waters.

Intra-Community Trade

- 8.3 A Member State, zone or compartment declaring category III status may introduce KHV susceptible species from category I, II or III status areas. These movements are not subject to health certification. Susceptible species may only be dispatched to category III or V status areas, and again these movements are not subject to health certification.

Third Country Trade

- 8.4 Trade in susceptible species from a country outside the EU can take place without requiring the country, zone or compartment where the fish originated from, to have been declared free of KHV disease, although health certificate is still required. In addition, category III status allows aquatic animals vaccinated against the disease, to be imported.

Likelihood and impact

- 8.5 Similarly to category II, declaring category III is an option for England and Wales. Again, the small number of past outbreaks and evidence about the distribution and prevalence of the disease, would suggest that we are in a position to put in a place a programme for achieving disease free status. However, until such time as we are in a position to implement a surveillance programme to achieve this, declaring category III status for England and Wales is considered to be a starting point, although of course we would wish to implement a surveillance programme to achieve category II status as quickly as possible.
- 8.6 The initial impact in declaring this status is virtually nil, as imports would be able to continue unchanged from current practices and allowed from almost all third countries. Obviously, this would leave England and Wales open to

continuing imports of potentially compromised KHV susceptible species and render any future control regime unrealistic. This would result in an undesirable risk with imports under this scenario. Additionally, costs for carrying out a surveillance programme for this status, are also potentially high.

Option 4

Declaring England and Wales Category IV (eradication programme) status for KHV disease

9.1 By declaring category IV status, a Member State, zone or compartment declares that they are operating an eradication programme in accordance with Article 44(2) of Council Directive 2006/88. A Member State will declare this status and draw up an eradication programme, if they are known to be infected with KHV (see category V below) and believe they can achieve a disease free status through an appropriate eradication programme.

Intra-Community Trade

9.2 A Member State, zone or compartment declaring category IV status may only introduce KHV susceptible species from another category I Member State, zone or compartment. This movement must be carried out under health certification. Susceptible species can only be dispatched to a category V Member State, zone or compartment and again this must be done under health certification.

Third Country Trade

9.3 Trade in KHV susceptible species from a country outside the EU can only take place if the country, zone or compartment in question is declared free of the disease, in accordance with the requirements as laid down by Chapter VII (Article 50.4) of Directive 2006/88 or the relevant OIE standard on KHV freedom, and accompanied by a relevant health certificate. Additional requirements include:

- the relevant disease being notifiable to the competent authority;
- and
- the susceptible species have not been vaccinated against the relevant disease.

Likelihood and impact

9.4 This status is virtually identical to category II status when it comes to impact. Imports would only be possible from known KHV free countries, zone or compartments. With the small number of outbreaks seen in recent years, albeit in fisheries and not farms, this status appears the strongest and most logical starting position for England and Wales. The partial impact assessment, attached as an annex to this consultation, looks at the financial impacts of declaring this status.

Option 5

Declaring England and Wales Category V status for KHV disease

10.1 By declaring category V status, a Member State, zone or compartment declares that they are infected with KHV disease in accordance with Article 39 of Council Directive 2006/88. Under these circumstances, the Member State, zone or compartment must carry out measures to contain the disease, including:

- declaring an infected farm or area;
- establishing a containment area, protection and surveillance zones around the farm or area;
- restricting the movement of aquatic animals from the containment area; and
- the removal and disposal of dead fish.

Intra-Community Trade

10.2 A Member State, zone or compartment declaring category V status, may introduce KHV susceptible species from all the other health categories. This movement can be carried out without the need for health certification. Member States may only dispatch aquatic animals to other category V areas, and this movement must be carried out under appropriate health certification.

Third Country Trade

10.3 Trade in susceptible species from a country outside the EU can take place without requiring the country, zone or compartment of origin to be declared free of disease. However, this movement must be under appropriate health certification.

Likelihood and impact

10.4. Adopting this option will not allow any effective trade controls on imported KHV susceptible species. This would leave any future prospects of controlling KHV disease in England and Wales, under a surveillance or eradication programme (i.e. category II or IV) virtually as minimal. The expectation would also be to see a continuing spread of the disease across fisheries, and eventually it could also enter farms.

10.5 While England and Wales have seen a small number of KHV outbreaks in isolated fisheries, we believe this is by no way seen as enough to warrant us declaring category V status, and so infected. Additionally, none of the recorded outbreaks have occurred in farms and with the evidence from the distribution and prevalence study, concluding that disease freedom is possible

under the right circumstances; we believe declaring this category status would not be the right option at this time.

Part VI – Additional information

- 11.1 As was pointed out in section 2.7 above, the KHV disease virus has been present in England and Wales for some time. During that time, controls on its spread and imports of potentially KHV compromised fish were not possible until April 2007, when the disease was made notifiable and national controls were introduced. This means that the prevalence and distribution of the disease could not be fully estimated with any degree of confidence.
- 11.2 To address this, Defra commissioned Cefas to carry out a study on the prevalence and distribution of KHV in England and Wales. The initial results of this study, “The distribution of Koi Herpesvirus (KHV) in England and Wales 2007 to 2008 Report”, were published in the summer of 2008. These results can be found on the Cefas efishbusiness website at <http://www.efishbusiness.co.uk/news/080902a.pdf>.

KHV Prevalence and Distribution Study

- 11.3 The KHV distribution study was designed to establish the distribution and prevalence of fish exposed to KHV within English and Welsh fish farming, fisheries and ornamental sectors. The study used a diagnostic method of detecting antibodies to KHV, a technique that indicates exposure to the virus rather than the direct detection of the pathogen. This method was adopted, as there is a greater chance of detecting antibodies to KHV as compared with detection of the virus. The main findings of the report were:
- There is good potential for controlling the disease over time;
 - KHV antibody positive fish were detected in each of the geographic regions studied;
 - Around half of the farms currently producing carp in England and Wales were sampled and only 4% were found to be holding KHV antibody positive fish;
 - Six out of eleven consignments of imported fish from Southeast Asia tested positive for the presence of KHV antibody;
 - Over 5000 fisheries are known to hold carp in England and Wales. Because of the large number of fisheries only a small proportion could be sampled. In order to maximise our chances of detection, only those sites at highest risk of receiving KHV exposed fish were sampled. 37% of these high-risk fisheries tested antibody positive;
 - The first recorded outbreak of KHV in a fishery in England and Wales was in 2003. Between then and the end of 2007 there were 39 clinical outbreaks of the disease in fisheries.
- 11.4 While the apparent widespread occurrence of KHV antibody positive fish was not good news, there were positives to take from the results. The status of our farms is very good, with very few sites testing positive and thus a relatively

safe source of fish. Although a high proportion of the fisheries tested were positive, these were fisheries at the highest risk of getting the virus. It is therefore possible that the prevalence in other fisheries is lower than indicated by the study.

11.5 Given these results for England and Wales, information in the report and our past knowledge of KHV, the possibility exists at this time to control the disease. In view of the current situation where the disease has not manifested in the farming sector, and the conclusions of the prevalence study that there is scope for controlling the disease, there is a strong case for England and Wales to declare a category II (surveillance programme) health status in respect of KHV. Alternatively, in view of the presence of KHV infection in England and Wales, albeit currently confined to a limited number of fisheries, this could be interpreted as defining the initial starting condition as being “infected”, i.e. category V, in which case we would want to apply an eradication programme (category IV) in order to achieve disease freedom.

11.6 The eventual goal of the programme would be freedom from the disease. A copy of the prevalence and distribution can be found at Annex B and on the *efishbusiness* website.

Q1. Do you agree that the results of the prevalence study offer hope of controlling and eventually eradicating the disease from England and Wales?

11.7 In the light of the conclusions of the prevalence study there is an opportunity to control and over time to eradicate KHV from England and Wales. In order to take advantage of this opportunity England and Wales would need to enter into an eradication programme under Article 44 of Directive 2006/88/EC as soon as possible. A prolongation of the lack of import controls on KHV susceptible species would in time make controlling and eradication harder.

Q2. Do you agree that adoption of a programme designed to control KHV and seek to eradicate it from England and Wales, is to a large extent time critical, so the sooner such a programme is adopted the less hard such control would be ?

11.8 As has been pointed out earlier, there are a number of consequences that automatically derive from the application of any programme introduced to seek eventual freedom from KHV. These include :

- Fish of susceptible species could only be sourced from areas declared free from the disease; and
- Imports of fish vaccinated against KHV would no longer be permitted.

11.9 In combination, these factors are likely to have an impact on the availability of certain categories of KHV susceptible species, for restocking and ornamental purposes. Specifically, the need for fish to come from free areas and the loss of vaccinated fish imports would leave a significant gap in the availability of certain sizes of Koi carp. This has led to concern by the industry.

- Q3 Do you consider the combination of only sourcing fish from KHV free areas and the loss of vaccinated fish imports, will lead to sourcing problems and a drastic drop in imports?**
- Q4 Could the potential unavailability of certain sized Koi carp, from previously traditional import markets, be made up through UK production sources? If so, what time period is considered appropriate, before UK production is able to meet any shortfall?**
- 11.10 In terms of the loss of access to fish that have been vaccinated against KHV, a study carried out by Cefas in 2008 concluded that, although the risk of intruding KHV into a water through stocking with KHV vaccinated fish was low, there was nevertheless a risk. A copy of this study can be found at Annex C, and is available on the *efishbusiness* website.
- Q5 Do you agree with the findings and conclusions of this study? If not, what data do you have to support your view?**
- Q5. Do you agree that in light of the information currently available that we should adopt a programme designed to control and eventually eradicate KHV from England and Wales?**

Conclusion

- 11.11 In the final analysis, taking into consideration the conclusions of the prevalence and distribution report and other information, the initial presumption is that for England and Wales the most appropriate KHV health status is either category II - surveillance programme or more likely category IV – eradication programme. This will offer the opportunity to control KHV nationally whilst also providing protection from imports of potentially KHV compromised or at risk imports. Over time, therefore, there is potentially scope for eradicating the disease.
- 11.12 A final decision on the most appropriate health status will be made taking into account the responses from this consultation and all relevant scientific and other information. As has been pointed out above, there would be little to no difference as far as the various industry sectors are concerned in declaring certain statuses, such as category II and IV; and category III and V. The brunt of any difference would be borne by the competent authority in terms of the degree of surveillance that would be needed to be carried under the different categories.

IMPACT ASSESSMENT

- 12.1 In conjunction with this consultation, we are drawing up an assessment of the likely impact on businesses and others of the various options in terms of the health status category which may be adopted. Realistically the ranges of categories open to England and Wales are category IV (eradication programme) or category V (infected).
- 12.2 A partial impact assessment is enclosed with this consultation document. To help inform the decision-making process I would be grateful if you could provide information about likely impacts to your businesses should we adopt any of the possible options, but in particular category IV or category V, as these are seen as the only real options available to us at this moment in time.
- 12.3 If you support or disagree with any element of the partial impact assessment, we would very much welcome your views, along with supporting data on why you think this is the case.

ANNEX A

Council Directive 2006/88 - Annex III PART A - Health status of aquaculture zones or compartments to be considered for the application of Article 12 Aquaculture animals for farming and restocking.

Category	Health status	May introduce animals from	Health certificate		May dispatch animals to
			Introduction	Dispatching	
I	Disease-free (Articles 49 or 50)	Only category I	YES	NO when dispatching to category III or V YES when dispatching to categories I, II or IV	All categories
II	Surveillance Programme (Articles 44(1))	Only category I	YES	NO	Categories III and V
III	Undetermined (not known to be infected but not subject to a programme for achieving disease-free status)	Categories I, II, or III	NO	NO	Categories III and V
IV	Eradication Programme (Article 44(2))	Only category I	YES	YES	Only category V
V	Infected (Article 39)	All categories	NO	YES	Only category V

