OsHV-1

μ var

Annual Meeting NRLs for mollusc diseases La Rochelle, March 2011
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Background
Overview of the presentation

- Measures adopted 2010
- EFSA opinion
- Measures adopted 2011
Commission Regulation (EU) No 175/2010 implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species Crassostrea gigas in connection with the detection of Ostreid herpesvirus 1 \(\mu\) var (OsHV-1 \(\mu\) var)

- Based on Article 41 (Emerging diseases)
- Expire 31 December 2010 30 April 2011
- Applicable to Pacific oysters
Why EU harmonisation?

- **Level playing field:**
  - Prevent further spread whilst not imposing unnecessary restrictions on movements
- **Knowledge collection**
- **Transparency**
Movement restrictions
Regulation (EU) No 175/2010

Increased mortality occurs

Sampling and testing

- Negative
- Positive

Establish Containment measures + Restrict movements

Mortality decreases

Measures according to Directive 2006/88/EC as appropriate

General movement restrictions Lifted.

BUT restrictions on movements into areas with programme

Compartment tested negative.

All movement restrictions lifted
OsHV-1 $\mu$ var status
– listed on MS web pages

1. Containment areas

2. Compartments where the absence of OsHV-1 $\mu$ var has been demonstrated in areas previously subjected to containment measures

3. Areas previously subjected to containment measures

4. Areas under programme for the early detection of OsHV-1 $\mu$ var
The Annexes to Regulation (EC) No 175/2010

- **Annex I**
  - Sampling requirements
  - Diagnostic methods
  - Factors for defining containment areas

- **Annex II**
  - Model animal health certificate
## Surveillance 2010

<table>
<thead>
<tr>
<th>Country</th>
<th>Sampling points</th>
<th>Positive OsHV-1 uvar</th>
<th>Mortalities</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td>22</td>
<td>3/22</td>
<td>1 of 3</td>
<td>All farming areas which were not affected by the increased mortalities in 2008 and 2009 were included in the program</td>
</tr>
<tr>
<td>UK England Wales</td>
<td>30</td>
<td>1/30</td>
<td>1</td>
<td>All negative, except one bay</td>
</tr>
<tr>
<td>UK Northern Ireland</td>
<td>4</td>
<td>1/4</td>
<td>None</td>
<td>4 oysters from the 150 sampled were positive</td>
</tr>
<tr>
<td>UK Scotland</td>
<td>13</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>6</td>
<td>2/6</td>
<td>None</td>
<td>86 oysters from the 450 sampled were positive</td>
</tr>
<tr>
<td>Spain</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Detections in 2010

<table>
<thead>
<tr>
<th>Country</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>Whole coastline.</td>
</tr>
<tr>
<td>Ireland</td>
<td>Same bays as in 2009, with a few exceptions.</td>
</tr>
<tr>
<td>UK</td>
<td>One containment area.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>One compartment.  <em>No increased mortality</em> recorded</td>
</tr>
<tr>
<td>Italy</td>
<td>Three farms.  <em>No increased mortality</em> recorded</td>
</tr>
</tbody>
</table>
European Food Safety Authority (EFSA)

SCIENTIFIC OPINION
on the increased mortality events in Pacific oysters, *Crassostrea gigas*

Adopted 27/10/10

**DG SANCO:**
Assess the role and importance of infectious agents with special focus on the role of the new biotype of Ostreid herpesvirus-1 (OsHV-1) named OsHV-1 µvar as possible aetiological agents

**EFSA:**
OsHV-1 (reference strain and µvar) has been *predominantly demonstrated* in Pacific oysters spat and juveniles from events of increased mortality. The available evidence suggests that OSHV-1 infection is a *necessary cause but may not be sufficient* by itself as other factors appear to be important. OsHV-1 µvar has not been sufficiently characterised to be defined as a new genotype but may be considered as a different strain. OsHV-1 µvar seems to be the *dominant viral strain* in the 2008-2010 increased mortality outbreaks but it is not clear if this is a result of *increased virulence or other epidemiological factors*. The sensitivity and specificity of current diagnostic methods for OsHV-1 is not known. The role of other pathogenic agents such as *Vibrio* spp. has not yet been resolved.
EFSA:
Climatic and seasonal factors alone are not likely to be a sufficient cause for the increased Pacific oyster mortality reported in France, United Kingdom and Republic of Ireland in 2008-2009 although these events are seasonal in their occurrence. An increase or a sudden change in the temperature of the water around oysters has been shown to be an important risk factor predisposing for the disease. Up to now no outbreaks have been reported when the water temperature is below 16ºC. Husbandry practices such as introduction of non certified possibly infected spat, movements and mixing of populations and age groups are probably important risk factors.

DG SANCO:
Assess the role and importance of climatic, seasonal or other environmental factors in their occurrence
DG SANCO:
Assess the role and importance of other mollusc species which could be involved

EFSA:
In addition to *C. gigas*, there is evidence of susceptibility to OsHV-1 in *Ostrea edulis*, *Pecten maximus* and *Ruditapes philippinarum*. There was no investigation on susceptibility to OsHV-1 µvar made on other mollusc species other than *C. gigas*. 
**DG SANCO:**
Assess the scientific background that may justify the authorization to transfer adult Pacific oysters older than 18 months old when they are sourced from an area affected by the increased mortality event.

**EFSA:**
OsHV-1 (reference strain and µvar) was detected by PCR in Pacific oyster older than 18 months associated with increased mortality. Therefore it is concluded that oysters older than 18 months can be a source of virus and it is **not safe to transfer oysters older than 18 months** from affected areas to areas not affected by increased mortality events.
A clear case definition for “increased mortality” in Pacific oyster needs to be developed. An acceptable baseline mortality and “increased mortality” in Pacific oyster needs to be defined where unit of concern (population, lease area, batches and/or production units), season, age/size, observation period should be taken into account as well as a description of an appropriate method for mortality estimation.

A description of the Pacific oyster aquaculture industry in Europe namely regarding number of farms, production figures, and traceability on movements/transfers both on hatchery and grow out sites should be achieved in accordance to the requirements by CD 2006/88.
To best promote and preserve high health status and in particular to prevent and/or control increased mortality, measures are **urgently needed to improve the general level of biosecurity in the oyster aquaculture industry in Europe.**

To minimize the risk of subsequent transfer of infectious agents from hatcheries and wild-caught spat, there is a **need to establish the health status of oyster spat at source.** An assessment of the health status should include results of regular batch laboratory testing (at least in regards to OsHV-1, ref strain and uvar, *Vibrio* species, and histopathological examination) and epidemiological assessment.
Improved diagnostic methods should be developed to check for the presence of OsHV-1 μvar and other strains. The methods for detection of OsHV-1 (including different strains) need to be validated and harmonized.

Relevant genomic information of the OsHV-1 μvar virus should be obtained for a better characterization of the strain in order to i) perform phylogenetic studies, ii) improve diagnosis iii) investigate potential for increased infectivity and virulence.

The phylogenetic relationship of OsHV-1 strains should be investigated.
Clear criteria for viral strain differentiation taking in account genotype and epidemiological criteria are necessary.

To better understand existing and emerging health problems, a robust health surveillance system for Pacific oyster production in Europe is needed.

Well designed epidemiological research studies, including comparison studies, in order to determine the potential importance of infectious agents and other environmental factors on increased mortality in Pacific oyster are necessary.
Commission Regulation (EU) No 175/2010 implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species Crassostrea gigas in connection with the detection of Ostreid herpesvirus 1 μ var (OsHV-1 μ var)

Decision 2011/??/EU amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μ var (OsHV-1 μ var) into certain areas of Ireland and the United Kingdom
Movement restrictions
Regulation (EU) No ??/2011

Increased mortality occurs

Sampling and testing

Negative

Establish Containment measures + Restrict movements

Mortality decreases

General movement restrictions Lifted.

BUT restrictions on movements into areas with programme

Compartment tested negative.

All movement restrictions lifted

Measures according to Directive 2006/88/EC as appropriate
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In case of increased mortality
- Sampling and testing
  - Negative
    - Measures according to Directive 2006/88/EC as appropriate
  - Positive
    - Establish Containment measures + restrict movements
    - Mortality decreases
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      - BUT restrictions on movements into areas with programme
      - Compartment tested negative.
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Commission Regulation (EC) No ???/2011 amending Regulation (EC) No 1251/2008 as regards the placing on the market requirements for consignments of Pacific oysters intended for Member States or parts thereof with national measures regarding ostreid herpes virus 1 μ var (OsHV 1μ var) approved by Decision 2010/221/EU.

Commission Decision 2011/??/EU amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μ var (OsHV 1μ var) into certain areas of Ireland and the United Kingdom.

Compartment tested negative.

All movement restrictions lifted.
Movement restrictions
Regulation (EU) No ??/2011


- Increased mortality occurs
  - Sampling and testing
    - Negative
    - Positive

- General movement restrictions lifted.
  - BUT restrictions on movements into areas with programme

- Measures according to Directive 2006/88/EC as appropriate
- Commission Decision 2011/??/EU amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μ var (OsHV 1 μ var) approved by Decision 2010/221/EU
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- Compartment tested negative.
  - All movement restrictions lifted
Commission Decision 2011/??/EU amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μ var (OsHV-1 μ var) into certain areas of Ireland and the United Kingdom

- Based on Article 43 (national measures)
- Approves surveillance programmes established by UK Ireland
- Allow UK and Ireland to apply restrictions on movements of Pacific oysters
- Until 30 April 2013
Surveillance programmes

- Guidance document on the establishment of surveillance programmes as regards ostreid herpesvirus 1 μvar (OsHV-1 μvar) (SANCO/7004/2011/rev5)

OsHV-1 $\mu$ var status
- listed on MS web pages

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**New** Annex III to Decision 2010/221/EU:
Areas in UK and Ireland under surveillance programme
Movement restrictions

- Into areas covered by surveillance programme (UK, parts of Ireland)

Scope:
- Further farming, relaying
- Dispatch centres, purification centres or similar businesses which are **NOT** equipped with an effluent treatment system validated by the competent authority that:
  - inactivates enveloped viruses; or
  - reduces the risk of transmitting diseases to the natural waters to an acceptable level.
What about movement out of infected areas?

- Art 15(1) of Directive 2006/88/EC
  - Member States shall ensure that animals placed on the market for farming are:
    - Clinically healthy
    - Do not come from a farm or mollusc farming area where there is any unresolved increased mortality
translated into the model health certificate:

I, the undersigned official inspector, hereby certify that the aquaculture animals referred to in Part I of this certificate:

II.1.1 either [have been inspected within [72][24] hours of loading, and showed no clinical signs of disease.]

or [in the case of (...) molluscs, come from a farm or mollusc farming area where, according to the records of the farm or mollusc farming area, there is no indication of disease problems.]

or [in the case of wild aquatic animals, according to the best of my knowledge and belief are clinically healthy];

II.1.2 are not subject to any prohibitions due to undefined increased mortality;
Summary

- EU harmonised measures to protect presumably free areas
- MS to take adopt measures in infected areas, as appropriate
- EU Re-assessment of the situation in two years
Merci pour votre attention!