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Report on the Ad Hoc Technical Working Group on evaluation of EU legislation as regards ostreid herpes virus 1 μ Var (OsHV-1 μ Var)

An Ad Hoc Technical working Group meeting to evaluate EU legislation as regards OsHV-1 μ Var was held at DG SANCO 11 February 2014. The purpose and frames of this meeting was proposed by the Commission at the Scofcah Animal Health meeting of January 2014.

List of participants:

From the Member States: France (Jaques Beuguel), Ireland (Fiona Geoghegan), Netherlands (Marc Engelsma), The United Kingdom (Edmund Peeler).

Spain was also invited, but was not able to attend.

From EURL for mollusc diseases: Isabelle Arzul

From the Commission: Knut Roenningen

1. Introduction and presentation of the Mandate

The Commission gave a brief update on the background for setting up the Technical Working Group and presented the following mandate to the participants:

- (a). Identify new scientific knowledge on OsHV-1 μ Var and/or other relevant causal agents or cofactors relevant to limit the spread of this disease.
- (b). Evaluate the effect of current EU legislative measures as regards this disease.
- (c). Discuss possible legislative measures as regards this disease including an assessment on whether the disease should be listed in Part II of Annex IV to Directive 2006/88/EC or not.

The participants had no comments to the presented mandate.

2. Information on updated scientific knowledge as regards OsHV-1 μ Var and possible other etiological factors related to increased mortality events in Pacific oysters.

The Commission has asked the EURL for mollusc diseases to prepare a brief report on the scientific status of this disease. This report is based on the conclusions of the EFSA Scientific

Opinion on the increased mortality events in Pacific oysters from November 2010, and presents a review of these conclusions in the light of updated scientific knowledge and practical experience. The conclusions from this report, as presented by Isabelle Arzul, were the following:

- *The oyster production landscape has changed*

The number of collection areas for wild oysters spat in France has increase from 2 to 5 in during this period. The number of hatcheries/nurseries in EU is also significantly higher both in France and the rest of the Union compared to 2008. However, a major part of the production of Pacific oysters in Europe is still based on spat from France.

- *Vibrio aestuarianus is a serious issue*

The bacterium *Vibro aestruarianus* has frequently been detected in mortality events on adult oysters in France in 2012 and 2013 and seems to be of importance as a causative agent. The pathogen has also been detected in Ireland and infection trials carried out at the Ifremer La Tremblade have shown that *V.aestuarianus* isolated from sites with and without mortality have both proven to be pathogenic to *C. gigas*.

- *Diversity of OsHV-1*

OsHV-1 μ Var is detected in most mortality events of spat and juveniles of P. oysters since 2008. Other genovariants of OsHV-1 are currently rarely seen in France both within and outside mortality events. Thus, an apparent decrease of OsHV-1 diversity seems to have developed since 2009. On the other hand, new microvariants of OsHV-1 have now been detected in different parts of the world including Australia, New Zealand and Asia.

- *Mortality outbreak estimation: harmonization is not achieved*

Due to lack of standardized procedure to estimate mortality rates, it still is difficult to compare such rates between years and areas. However, using a same approach in a specific Frenche site (Marene Oléron Bay) over 6 years, mortality of spat seems to have decreased between 2008 – 2012 (80%) and 2013 (57%).

- *C. gigas mortality investigation has improved from 2010 to 2013.*

Investigations are now carried out in most of the mortality events notified in the Member States (MS). However, due to too many notifications in France, investigations are performed for each first event occurring in a geographic zone per age class per year. Presence of OsHV-1 μ Var is checked by PCR in MS producing *C. gigas*, but PCR assays still are different depending on MS. Nevertheless, an Inter laboratory Comparasion test organised in 2011 showed a good agreement between most of participants and a good ability of NRLs ffrom MS producing *C. gigas* to detect the virus under laboratory conditions. Bacterium identification by real time PCR is standardized in France for *Vibrio aestuarianus* and the technique and positive control have been transferred to some NRLs on request in 2013. Histology is also performed in all mortality events to rule out listed/emerging pathogens.

- *Lack of information outside mortality events and surveillance programme.*

Investigation outside mortality events is still limited in Europe.

- *Distribution of OsHV-1 μ Var in EU*

Up till now OsHV-1 μ Var has been detected in several sites in UK (3 in Great Britain, 4 in Northern Ireland), in several bays in France, the Netherlands, Spain (both Atlantic and Mediterranean sides), Portugal and Italy.

3. Effect of current legislative measures – experience gained from relevant Member States

France

France has on-going programmes both on passive surveillance, following up notifications on mortality events from the REPAMO network. In 2013, 43 samples were analysed from this network concerning a majority of the shellfish areas in France. OsHV-1 μ Var was detected in 71% of the batches, mainly in spat and juveniles, while *V. aestuarianus* was detected in 76% of the batches, mainly in adults.

For monitoring of mortalities, the French coast is divided into 120 areas (ZIR). The average mortalities in Pacific oysters in these areas varied in 2013 from 10 – 90% of the stock. However, based on the experience from this programme, some difficulties are identified:

- To characterize the excess mortality
- There is no definition in the regulations
- There are no standard procedures for excessing mortalities
- How should the a mortality event be evaluated

As regards management measures in France, a voluntary regime has been in place since 2012 which is applied when there is a collective mortality in spat and juveniles in an area. This regime requires watchfulness by the professional organisations, confirmation by the local competent authorities and decision aid by the REPAMO network.

Ireland

In Ireland a surveillance programme in accordance with Directive 2006/88/EC has been applied since 2010 starting out with 25 sites in 8 compartments and 2 hatcheries. After four years of surveillance 14 sites have been removed from the programme due to detection of OsHV-1 μ Var. Thus the 2014 programme will consist of 11 sites which at the moment will include approximately 7% of the Irish production of Pacific oysters.

Indications are that the exclusions from the programme may be explained as follows:

- 2010 – virus was historically present (import from France 2007/08) without any reports of mortalities (4)
- Movement to restaurants/ processing plants (1)
- Movement of mussels to depuration units (1)
- Proximity to infected bays (1)

- Biosecurity failures (equipment/personnel) (2)
- Unexplained (4)

In 2013 an additional study as regards the importance of *Vibrio aestuarianus* was carried testing samples from seven different sites. In this study 6 out of 7 samples tested positive for *V. aestuarianus*. However, no pathology was associated with those findings, and 5 out of 6 of the same sites were also positive for OsHV-1 μ Var.

Netherlands

In the Netherlands a programme for early detection of OsHV-1 μ Var was applied in the summer 2010. Two sites (Oosterschelde and Lake Grevelingen) were examined. OsHV-1 μ Var was detected in the Oosterschelde site, but no mortalities was observed among Pacific oysters during the screening.

In 2011 an additional surveillance was carried out at the same sites. At this occasion OsHV-1 μ var was detected in Grevelingen and was associated with spat mortalities. All samples from Oosterschelde turned out negative.

In 2012 a screening for OsHV-1 μ Var was carried out in the Wadden Sea. Here OsHV-1 μ Var was detected in Pacific oysters spat from 3 out of 5 locations sampled.

UK

Just as in Ireland, a surveillance programme in accordance with Directive 2006/88/EC has been carried out since 2010 for the whole territory of Great Britain, the territory of Guernsey and the territory of Northern Ireland.

During the period from 2010 – 2012 two sites in Great Britain and four sites in Northern Ireland was removed from the programme due to detection of OsHV-1 μ Var. In 2013 a third site in Great Britain tested positive, and one site in Northern Ireland has been redrawn from the programme due to operational difficulties.

The remaining sites, including the territory of Guernsey, the whole territory of Great Britain except the tree sites which has tested positive, and one site in Northern Ireland is now recognized as diseases free areas as regard OsHV-1 μ Var in accordance with Article 43 of Directive 2006/88/EC by Commission Implementing Decision of 14 January 2014.

4. Possible options for further Union legislative measures

The Technical Working Group discussed the following options for further Union legislative measures:

- (a) Status quo - National measures according to Decision 2010/221/EC are prolonged for 3 – 5 years.
- (b) National measures according to Decision 2010/221/EC without further limitation in time.
- (c) OsHV-1 μ Var is listed as a non-exotic disease in Part II to Annex IV to Directive 2006/88/EC.

- (d) No further measures are needed – all EU legislative measures as regards this disease are repealed.

Based on the report from EURL for mollusc diseases and the information presented from the participating Member States, the Technical Working Group concluded that current measures have been of some effect on limiting the spread of the disease to new areas in Ireland and UK. Consequently it would be beneficial also in the next years to apply some kind of Union measures as regards this disease.

There are still, however, some uncertainties to be cleared out both concerning the importance of *Vibrio aestuarianus* as a causal agent to mortalities in adult oysters, the potential risk of introducing other mikrovariants of the ostreid herpesvirus 1 detected in Australia and Asia into the Union, and as regards important biosecurity methods to be used to limit the impact of the disease. A final conclusions on whether this disease should be listed or not in Part II to Annex IV of Directive 2006/88/EC or be granted open ended national measures in accordance with article 43 of that directive, should therefore be based on a more comprehensive scientific evaluation of the situation including a new scientific opinion from the European Food Safety Authority (EFSA).

The Technical Working Group concluded therefore that in anticipation of a new EFSA report and further evaluation of the scientific and economic impact of the disease, it would be appropriate to prolong the period of time that certain Member States can apply specific restrictions related to this disease in accordance with Article 43 of Directive 2006/88/EC. This period should be minimum two years.

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