Risk Assessment as a decision making tool

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AHAW – EFSA, Scientific Officer
Overview

• EFSA – European Food Safety Authority
• AHAW – Animal Health and Welfare Panel and Unit
• AHAW activities in Aquatic Health and Welfare
• Past opinions
  • Oyster mortality
  • Epizootic Ulcerative Syndrome
  • Infectious Salmon Anaemia HPR0
• Risk Assessment – Risk Management
• Future Work
• Conclusions
European Food Safety Authority

- In answer to a series of Food Crisis
  - Mad Cow Disease (1985-1993)
  - Dioxins (1999)

- Set up in January 2002 as an independent source of scientific advice and communication on risks associated with the food chain (Regulation (EC) No 178/2002)

- Based in Parma (Italy)
- 433 staff members
- 10 Scientific Panels including Animal Health and Welfare
The Authority shall provide *scientific advice and scientific and technical support* for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks."
A process consisting of three components

risk assessment          risk communication          risk management
From mandate to legislation

European Commission
European Parliament
Member States
EFSA (“self tasking”)
The Panel on animal health and welfare deals with questions on all aspects of animal health and animal welfare, primarily relating to food producing animals including fish.
OIE Risk analysis process

- Hazard Identification
- Risk Assessment
  - Entry
  - Exposure
  - Consequence
  - Risk Estimation
- Risk Management

Risk communication
AH main questions

The top three risk question types:

1. The risk of (re)introduction
2. The risk of potential spread to susceptible population, the pathways of transmission and speed of the spread
3. The effectiveness of control measures

Bellet et al 2011
Activities in aquatic animals

- Possible vector species and live stages of susceptible species not transmitting disease as regards certain aquatic diseases (3)
- Aquatic species susceptible to diseases listed in Directive 2006/88/EC
- Scientific Opinion on the increased mortality events in Pacific oysters,
- Scientific Opinion on Epizootic Ulcerative Syndrome
- Infectious salmon anaemia
- DATAQUEST: Inventory of data sources relevant for the identification of emerging diseases in the European aquaculture
- Art 36 grant on Risk categorisation for Aquatic Animal Health Surveillance

- Animal welfare aspects of husbandry systems for farmed fish (5)
- Species-specific welfare aspects of the main systems of stunning and killing (7)
- General approach to fish welfare and to the concept of sentience in fish
Overview of RA in Aquatic Health

Hazard Identification

Oyster

Risk Assessment

Entry
Exposure
Consequence
Risk Estimation

EUS
ISA
Oyster Mortality

SCIENTIFIC OPINION
on the increased mortality events in Pacific oysters,
Crassostrea gigas
Adopted 27/10/10

• Increased mortalities of Pacific oysters in 2008 throughout the **whole French coastline** and a limited number of areas in **Ireland**

• Again detected in 2009 affecting the French coastline and an increased number of areas in Ireland and UK (Jersey)

• The phenomenon was attributed to a combination of factors: **Ostreid herpesvirus-1 (OsHV-1 µvar)**, **Vibrio** species and environmental factors
Oyster Mortality

Historical trends of French oyster production (adapted from Heral 1989).
Oyster Mortality

Mandate

TOR 1: OsHV-1 μvar
TOR 2: Environmental factors
TOR 3: Other molluscs
TOR 4: Age
European production of Pacific oyster in quantity (Tonnes) and value (thousands of USD) (Source FAO 2009)
A “new” disease?
Oyster Mortality - Approach

• Pacific oyster production systems in Europe
• A review of mortality events prior to 2008
• A description of the surveillance methods in place for investigation of abnormal mortality in EU MS
• Mortality events during the period of 2008-2010
• A review of the infectious agents, host and environmental factors that have been associated with increased mortality prior to 2008 and also studied during 2008-2009 outbreaks
Oyster Mortality - Production

- **Spat** - wild caught and hatchery produced.

- **Incomplete description of the Pacific oyster aquaculture industry in Europe** - number of farms, production figures, and movements/transfers.

- **Knowledge of the health status and biosecurity**
Conclusions

TOR 1: OsHV-1 μvar
Predominant necessary cause not sufficient

TOR 2: Environmental factors
Not sufficient, Husbandry practices

TOR 3: Other molluscs
OsHV-1 μvar, no investigation

TOR 4: Age
All ages
• 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.
(31) There is a continuous development in knowledge with respect to hitherto unknown diseases in aquatic animals. It may therefore be necessary for a Member State to apply control measures in the case of such emerging disease. Such measures should be swift and adapted to each individual case, but should not be maintained longer than necessary to achieve their goal. As such emerging diseases may also affect other Member States, all Member States and the Commission should be informed of the presence of an emerging disease and any control measures taken.

Article 41
Emerging diseases

1. Member States shall take appropriate measures to control an emerging disease situation and prevent that disease from spreading, where the emerging disease in question has the potential to jeopardise the health situation of aquatic animals.

Annex I
DEFINITIONS

(...)
(f) ‘emerging disease’ means a newly identified serious disease, the cause of which may or may not yet be established, that has the potential to be spread within and between populations, such as by way of trade in aquatic animals and/or aquatic animal products. It also means a listed disease identified in a new host species not yet included in Part II of Annex IV as a susceptible species;
2010 measures
• Based on Article 41 (*Emerging diseases*)
• New genotype + increased mortality
• **Sampling, testing** and establishment of **containment areas and “surveillance” programmes**
• Movement restrictions
  • out of containment areas
  • into areas with programmes
• Reporting – OCTOBER 2010
• Applies until 30 April 2011

2011-2012 measures
• Based on Article 43 (national measures non listed diseases)
• New genotype
• Sampling, testing for surveillance programmes
• Movement restrictions
  – into areas with programme
• Annual reporting on programmes
• Applies until 30 April 2013
• Measures in infected areas – no detailed EU harmonised measures
Oyster Mortality

EC Action
EU harmonised measures to protect presumably free areas

MS to adopt measures in infected areas, as appropriate, but no detailed EU harmonised rules


EU Re-assessment of the situation in two years

OIE Action

• Mar 2013 - OsHV-1 μvar - propose for listing as an emerging disease
• May 2013 – Propose for adoption
• May 2014 – Review status as a emerging disease
Epizootic Ulcerative Syndrome

Scientific Opinion adopted 15/9/11

• EUS is an epizootic disease in wild and farmed freshwater and estuarine fish.
• The disease has never been reported in Europe.
• The fish species susceptible to EUS include many ornamental fish.

Ornamental aquatic animal (OF)

Closed ornamental facilities (COF): pet shops, garden centres, garden ponds, commercial aquaria or wholesalers keeping ornamental aquatic animals

Open ornamental facility (OOF)
Re-assess the current regulatory regime as regards EUS.
Assess the risks posed by EUS for the EU aquaculture industry.

To assess the **risk of introduction of EUS into EU aquaculture**, by import of live fish from third countries.

To assess the **risk of EUS to spread and persist** within the EU, in particular the risk of spread from closed ornamental facilities.
Aphanomyces invadans

Large number of fresh water and estuarine species.

Ulceration
Map showing the current global distribution of epizootic ulcerative syndrome
(prepared by Jeff Jenness and José Aguilar-Manjarrez, FAO-FIMA; source: African Water Resource Database)

(FAO –2009)
• Total imports of ornamental (2010) : 210 058 725

• Total value of the industry in UK: 400 millions £

• 85% of EU imports arrive at UK and 47% trough Heathrow BIP.
Table 1: Live aquatic animals imported through the Heathrow BIP in 2010.

<table>
<thead>
<tr>
<th></th>
<th>No. consignments</th>
<th>%</th>
<th>No. fish/eggs</th>
<th>%</th>
<th>No. boxes</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-ornamental fish*</td>
<td>40</td>
<td>0.8</td>
<td>20,430,700</td>
<td>42.1</td>
<td>87</td>
<td>0.1</td>
</tr>
<tr>
<td>Ornamental fish</td>
<td>4,864</td>
<td>94.0</td>
<td>27,941,784</td>
<td>57.6</td>
<td>110,371</td>
<td>92.4</td>
</tr>
<tr>
<td>Others**</td>
<td>271</td>
<td>5.2</td>
<td>136,674</td>
<td>0.3</td>
<td>8,936</td>
<td>7.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5,175</strong></td>
<td></td>
<td><strong>48,509,158</strong></td>
<td></td>
<td><strong>119,394</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Trout eggs and one consignment of halibut
**Molluscs, crustaceans, corals, etc.
Quantities in 100 kg
The main exporters of ornamental fish to EU are countries considered not free of EUS.

<table>
<thead>
<tr>
<th>Partner/product</th>
<th>030110 - live ornamental fish(a)</th>
<th>03019 - live fish (excl. Ornamental fish)¹ (a)</th>
<th>EUS Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>SINGAPORE</td>
<td>12666</td>
<td></td>
<td>?</td>
</tr>
<tr>
<td>MALAYSIA*</td>
<td>1350</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>1822</td>
<td>2326</td>
<td>YES</td>
</tr>
<tr>
<td>SRI LANKA*</td>
<td>1915</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>JAPAN</td>
<td>1924</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>THAILAND</td>
<td>1979</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>INDONESIA</td>
<td>4501</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>KENYA*</td>
<td>458</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALDIVES*</td>
<td>601</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRAZIL</td>
<td>620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISRAEL</td>
<td>6789</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td>CHINA (PEOPLE’S REPUBLIC OF)*</td>
<td>750</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COLOMBIA</td>
<td>810</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HONG KONG</td>
<td>816</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>PHILIPPINES</td>
<td>861</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Top exporting countries to the EU (Eurostat 2009 data)

- SINGAPORE: 12666
- MALAYSIA*: 1350
- UNITED STATES: 1822
- SRI LANKA*: 1915
- JAPAN: 1924
- THAILAND: 1979
- INDONESIA: 4501
- KENYA*: 458
- MALDIVES*: 601
- BRAZIL: 620
- ISRAEL: 6789
- CHINA (PEOPLE’S REPUBLIC OF)*: 750
- COLOMBIA: 810
- HONG KONG: 816
- PHILIPPINES: 861

Total: 27018

Ratio: 11:1

1. Top 14 without the group 'COUNTRIES AND TERRITORIES NOT SPECIFIED IN THE FRAMEWORK OF INTRA-COMMUNITY TRADE'
Trade routes of Ornamental fish
Third Countries Import (wild catch & farmed fish)

BIP

Risk of entry

ToR 1

Third Countries

Ornamental non-ornamental fish for market

Ornamental fish in closed facilities

Ornamental fish all others

Closed

Closed

Closed

Non-ornamental farmed fish for market

Incl. Farm

NOT Closed

Farmed non-ornamental fish for market

Regulated

Less regulated
• Limited traceability of the origin of live ornamental fish.
• Imported ornamental fish originate from countries with historic or recent reports of EUS

• No certification of EUS free status for imports to COF - **PROBABILITY**
• The large majority of live fish (>99%) imported into Europe is classed as ornamental fish - **FREQUENCY**.
• There is a greater **RISK** of entry of *A. invadans* into closed ornamental facilities compared to facilities other than closed ornamental facilities.

• It is likely that EUS has repeatedly entered into EU via ornamental fish import from third countries.
Risk of spread

Given introduction...

No ornamentals expected to go to non-ornamental farms

ToR 2

A. invadans

The Wild (Lakes, Rivers)
Risk of establishment/Impact

Given introduction & release ...

What can go wrong & what may happen?

The Wild (Lakes, Rivers)

A. invadans

Risk of establishment/Impact

ToR 3

incl. Farm

NOT Closed

Closed

Closed

Closed

Given introduction & release ...

Risk of establishment/Impact

ToR 3

incl. Farm

NOT Closed

Closed

Closed

Closed

NOT Closed

The Wild (Lakes, Rivers)
• Risk of entry – import is expected
• Climatic conditions and susceptible species do not exclude establishment of *A. invadans* in Europe.

• **However:** So far no report exists?

  – EUS outbreak may not be associated with high morbidity/mortality
    \(<->\) low chance of clinical detection

  – EUS awareness and diagnostic capability in the EU is low (2008)
    \(<->\) low chance of laboratory detection
1. Fish in European waters have never been exposed to *A. ruvadis*.

2. EUS does not establish but fades out after introduction due to unfavourable conditions.

3. EUS epidemics repeatedly establish and spread unnoticed in EU as certain circumstances prevent massive disease expression.

4. EUS is already endemic in EU and regularly misdiagnosed.

No data from monitoring of aquaculture fish in Europe or wild stocks in rivers and other natural water bodies is available to allow for confirmation of either scenario or its likelihood.
Opinion adopted 15/9/2011

The disease was delisted from Annex IV part II, Directive 2006/99 on the 25/10/12


OIE

Mar 2013- Review comments from Member countries on Chapter 10.5.

May 2013 – Propose for adoption
Infectious Salmon Anaemia HPR0 – Risk assessment

• Mandate

Scientific opinion on the HPR0 variant of Infectious salmon anaemia (HPR0 ISA), and in particular to assess:

1. The capability of HPR0 ISA to cause clinical disease

2. The risk of HPR-deleted (Δ) ISA emerging from HPR0 ISA and, if relevant, indicating factors for such an emergence
Risk of $HPR_\Delta$ emerging from $HPR_0$

- **Approach**

Assessment based on review of available published data

**TOR2**

- Genomic structure of ISAV
- Virulence factors
- Evolutionary dynamics
  - Deletion
  - Insertion
  - Consensus

Hypothesis 1 is at the moment the most plausible
Infectious Salmon Anaemia HPR0 – Risk assessment

• **Conclusions**

  Epidemiological and historical data from solitary disease outbreaks indicate that the risk of emergence of virulent ISAV is low but not negligible.

• **Action OIE**
  - Opinion published 20 November 2012
  - Mar 2013 - Review comments from Member countries on Chapter 10.5.
  - May 2013 – Propose for adoption
The European paradigm

• Advantages
• Challenges

Assessment - Management

Question

Assessment

Comunication
Future work

• Data collection
• Surveillance
• Impact assessment
Overview

- EFSA – European Food Safety Authority
- AHAW – Animal Health and Welfare Panel and Unit
- AHAW activities in Aquatic Health and Welfare

- Oyster mortality
- Epizootic Ulcerative Syndrome
- Infectious Salmon Anaemia HPR0

- Risk Assessment – Risk Management
- Future Work

Conclusions
Thank you!

To all members of EFSA – AHAW Panel and expert working groups

To my colleagues

To you for your attention