World Animal Health Organisation (Office des International Epizooties) and European Union (EU) standards for trade in live aquatic animals and their products

Kanchanakhan@yahoo.com
Senior Fishery Biologist, OIE Expert on EUS
Inland Aquatic Animal Health Research Institute (OIE Reference Laboratory)
Bureau of Inland Fishery Research and Development
DOF, Thailand

THE URUGUAY ROUND established the World Trade Organization (WTO).

• It is recognised as a reference organisation by the World Trade Organization (WTO) and as of April 2009, had a total of 174 Member Countries and Territories.
• 1st January 1995 establishment of WTO
• The Uruguay Round (1986-1994) Agreements represent
  • a multilateral trading system that incorporated agriculture and food under operationally effective rules and regulations.
  • To protect the health of their consumers, animals and plants could become hidden barriers to trade as well as being unfair.
• 1 Agreement Establishing the WTO
• 2 General Agreement on Tariffs and Trade 1994
• 3 Uruguay Round Protocol GATT 1994
• 4 Agreement on Agriculture
• 5 Agreement on Sanitary and Phytosanitary Measures
• 6 Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least-Developed and Net Food-Importing Developing Countries
• 7 Agreement on Textiles and Clothing
• 8 Agreement on Technical Barriers to Trade
• 9 Agreement on Trade-Related Investment Measures
• 10 Agreement on Implementation of Article VI (Anti-dumping)
• 11 Agreement on Implementation of Article VII (Customs Valuation)
• 12 Agreement on Preshipment Inspection
• 13 Agreement on Rules of Origin
• 14 Agreement on Import Licensing Procedures
• 15 Agreement on Subsidies and Countervailing Measures
• 16 Agreement on Safeguards
• 17 General Agreement on Trade in Services
• 18 Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods
• 19 Understanding on Rules and Procedures Governing the Settlement of Disputes
• 20 Decision of Achieving Greater Coherence in Global Economic Policy-Making

Agreement on Sanitary and Phytosanitary

To protect from

• HUMAN HEALTH / LIFE
• Risks of food additives, contaminants, toxins, disease causing organisms in food
• disease carried by animals, plants, products
### SPS measures

<table>
<thead>
<tr>
<th>To protect</th>
<th>from</th>
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<tbody>
<tr>
<td>• ANIMAL HEALTH / LIFE</td>
<td>• The entry, establishment or spread of disease, disease-carrying or disease-causing organism</td>
</tr>
<tr>
<td>• PLANT HEALTH / LIFE</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>To protect</th>
<th>from</th>
</tr>
</thead>
<tbody>
<tr>
<td>• a country</td>
<td>• Damage within the territory from entry or establishment or spread of diseases or pests</td>
</tr>
</tbody>
</table>
Other measures

- Environment protection
- Consumer interests other than health related
- Animal welfare

- Are not covered by the SPS agreement....
- ....but rather by the TBT Agreement

BASIC RIGHT

- Right to apply measures to protect human, animal or plant life or health.
- Necessary to protect health and life
- based on scientific principles and shall not be maintained without sufficient scientific evidence.
- not to be arbitrary(biased), discriminatory, unjustified, unnecessary or disguised barriers to trade.
### HARMONIZATION

- International standard-setting organisations recognised by WTO
  - Office International Epizooties (OIE) in animal health / zoonoses
  - International Plant Protection Convention (IPPC) in plant health
  - Codex Alimentarius Commission in food safety
- Referenced standards are codes, guidelines and manuals produced by these organisations.

### RISK ASSESSMENT

- MEASURES MUST BE BASED ON
  - RISK ASSESSMENT
  - using internationally accepted risk assessment techniques
- Development of acceptable level of protection (ALOP)
  - avoid arbitrary, unjustifiable
Setting health SPS measures

• The SPS Agreement allows WTO members two options:
  1. To base their health measures on the OIE standards
     This is the strongly encouraged option.
  2. To conduct a scientific risk analysis
     … where there is no relevant standard, or when a member
     chooses to adopt a higher level of protection than that
     provided by the OIE standards.
• In reality, the setting of health measures always involves some
  form of risk analysis, and the resulting measures may be a
  combination of the OIE standards and additional measures
  acceptable to the importing country and its trading partners.

SPS-KEY POINTS

• Right to apply measures to protect life and health
• SPS measures based on Science/risk assessment
• notify each other of SPS measures in the course of
  preparation
• adhere to international standards where they exist
• should seek to accept the SPS measures of other
  countries as equivalent
• procedures should be undertaken in similar manner
  for imported products and domestic products
Challenge to ASEAN and APEC

- SPS controls of import/export among members
- SPS measures based on science and risk assessment

About

- The OIE is an intergovernmental organisation created by the International Agreement of 25 January 1924, signed by 28 countries. In year 2009 has 174 members.
- In 1960, the OIE established the Fish Diseases Commission (FDC)
- In 1988, the scope of the FDC was extended to include diseases and pathogens of molluscs and crustaceans.
- In 2008, the scope of the FDC has extended to cover amphibians.
- Disease outbreaks cause significant losses in aquaculture production and trade and are having an impact on the economic development of some countries.
How to prepare for disease control system in the country

1. Special law for disease control
2. List of diseases to be controlled
3. Manual for disease diagnosis
4. Manual for disease surveillance

- 5. Disease surveillance and reporting system
- 6. Import control of aquatic animals (based on IRA)
- 7. Import/export control at the port of entry
- 8. Disease diagnosis laboratory improvement
How to prepare for disease control system in the country

- 9. Disease information centre
- 10. Contingency planning
- 11. Aquatic animal movement control
- 12. Treatment control of diseases
- 13. Training

OIE reporting system

Competent Authority → National Delegate

 Measures:
1. Temporary stop importation
2. Risk management
3. Import requirements
4. Quarantine measures

OIE – WAHID system
- Internet Web
- Electronic mail
4 August 2009

What are the OIE aquatic standards?

• Aquatic Animal Health Code (Aquatic Code)

Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual)
1. The OIE aquatic standards

- The OIE standards are documents relating to rules that Members can use to protect themselves from diseases.
- The value of the OIE standards is twofold:
  - The measures published in the standards are the result of consensus among the veterinary authorities of OIE Members.
  - The standards constitute a reference within the SPS Agreement for international standards for animal health and zoonoses.
- This means that by applying the OIE standards, Members can be assured that their measures do not represent unjustified sanitary barriers, because the OIE normative documents are recognised as ‘international standards’ under the agreements of the WTO.

2. The OIE Aquatic Manual

- Aims to provide a uniform approach to the diagnosis of the diseases listed in the Aquatic Code and of other diseases that may be of importance to international trade.
- This is achieved through the detailing of pathogen identification methods that are suitable for the diagnosis of isolated cases of disease as part of national aquatic animal health surveillance or control programmes, or as part of a programme to underpin claims of freedom from a specific disease.
- Contains general provisions as well as recommendations applicable to specific diseases.
- Also lists the 30 OIE Reference Laboratories for aquatic animal diseases.
2.1 Diseases covered by the Aquatic Manual

- **Diseases of fish** (viruses, oomycete and parasite origin)
  - Epizootic haematopoietic necrosis
  - Infectious haematopoietic necrosis
  - Spring viraemia of carp
  - Viral haemorrhagic septicaemia
  - Infectious salmon anaemia
  - Epizootic ulcerative syndrome *(oomycete)*
  - Gyrodactylosis *(Gyrodactylus salaris)* *(parasite)*
  - Red sea bream iridoviral disease
  - Koi herpesvirus disease *(year 2007)*

- **Diseases of molluscs** (parasites, bacterium and virus)
  1. Infection with *Bonamia ostreae*
  2. Infection with *Bonamia exitiosa*
  3. Infection with *Marteilia refringens*
  4. Infection with *Perkinsus marinus*
  5. Infection with *Perkinsus olseni*
  6. Infection with *Xenohaliotis californiensis* *(an intracellular bacterium in the family Rickettsiaceae)*
  7. Abalone viral mortality *(virus)*
     - Abalone herpes-like virus disease
Diseases of crustaceans (viruses, oomycete, bacterium)

1. Taura syndrome
2. White spot disease
3. Yellowhead disease
4. Tetrahedral baculovirosis (*Baculovirus penaei*)
5. Spherical baculovirosis (*Penaeus monodon* type baculovirus)
6. Infectious hypodermal and haematopoietic necrosis
7. Crayfish plague (*Aphanomyces astaci*) (oomyete)
8. Infectious myonecrosis (year 2008)
9. White tail disease (year 2008)

Milky haemolymph disease (MHD) of spiny lobsters (*Panulirus spp.*) is an emerging disease and now is under study for removal from emerging disease.

Diseases of amphibian (2008)

- Infection with *Batrachochytrium dendrobatidis*
- Infection with ranavirus
• A new disease ulcerative disease of cultured tiger frog\cite{Kanchanakhan et al., 1999}

CPE and viral particle of ranavirus
2.2 Disease-specific chapter template

Aquatic Manual disease chapter template
CHAPTER XXX.

DISEASE NAME
1. Case definition
2. Information for the design of surveillance programmes
   a) Agent factors
   b) Host factors
   c) Disease pattern
   d) Control and prevention
3. Diagnostic methods
   a) Field diagnostic methods
   b) Clinical methods
   c) Agent detection and identification methods
4. Rating of tests against purpose of use
5. Corroborative diagnostic criteria
   a) Definition of suspect case
   b) Definition of confirmed case
6. Prescribed diagnostic/detection methods to declare freedom

2.3 Rating of tests against purpose of use for specific aquatic diseases

A = the method is the recommended method for reasons of availability, utility, and diagnostic specificity and sensitivity;
B = the method is a standard method with good diagnostic sensitivity and specificity;
C = the method has application in some situations, but cost, accuracy, or other factors severely limits its application; and
D = the method is presently not recommended for this purpose.
### WSV surveillance, detection and diagnostic methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Surveillance</th>
<th>Presumptive</th>
<th>Confirmatory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Larvae</td>
<td>PLs</td>
<td>Juveniles</td>
</tr>
<tr>
<td>Gross signs</td>
<td>D</td>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td>Bioassay</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Direct LM</td>
<td>D</td>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td>Histopathology</td>
<td>D</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Transmission EM</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Antibody-based assays</td>
<td>D</td>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td>DNA Probes in situ</td>
<td>D</td>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td>PCR</td>
<td>D</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Sequence</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
</tbody>
</table>

### EUS surveillance, detection and diagnostic methods (2006)

<table>
<thead>
<tr>
<th>Method</th>
<th>Surveillance to declare freedom from infection</th>
<th>Presumptive diagnosis of infection or disease</th>
<th>Confirmatory diagnosis of infection or disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross signs</td>
<td>D</td>
<td>B</td>
<td>D</td>
</tr>
<tr>
<td>Direct observation of the oomycete hyphae in muscle or internal organs under microscope</td>
<td>C</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Histopathology of tissues and organs</td>
<td>B</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>Isolation of A. invadans and confirmatory identification</td>
<td>C</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Antibody based assays to detect A. invadans antigen (IFAT, ELISA)</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Transmission EM of tissues</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>PCR of tissue extracts</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>PCR of pure isolate of A. invadans</td>
<td>D</td>
<td>D</td>
<td>A</td>
</tr>
</tbody>
</table>
### EUS surveillance, detection and diagnostic methods (purposed for 2009 version; unapproved table)

<table>
<thead>
<tr>
<th>Method</th>
<th>Targeted surveillance</th>
<th>Presumptive diagnosis</th>
<th>Confirmatory diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fish fry</td>
<td>Juveniles</td>
<td>Adults</td>
</tr>
<tr>
<td>Gross signs</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Direct LM; observation of the oomycete hyphae in tissues, fresh squash</td>
<td>d</td>
<td>d</td>
<td>d</td>
</tr>
<tr>
<td>FISH; observation of the oomycete hyphae in tissues</td>
<td>d</td>
<td>d</td>
<td>d</td>
</tr>
<tr>
<td>Histopathology</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Isolation of A. invadans and confirmatory identification by bioassay or PCR</td>
<td>d</td>
<td>d</td>
<td>d</td>
</tr>
<tr>
<td>PCR of tissue extracts</td>
<td>d</td>
<td>d</td>
<td>d</td>
</tr>
<tr>
<td>Sequence analysis</td>
<td>d</td>
<td>d</td>
<td>d</td>
</tr>
<tr>
<td>Transmission EM of tissues</td>
<td>d</td>
<td>d</td>
<td>d</td>
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### SVC surveillance, detection and diagnostic methods 2006

<table>
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<tbody>
<tr>
<td>Gross signs</td>
<td>D</td>
<td>B</td>
<td>D</td>
</tr>
<tr>
<td>Histopathology of tissues and organs</td>
<td>D</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Isolation of SVCV in cell culture</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Antibody-based assays to detect SVCV antigen (IFAT, ELISA)</td>
<td>D</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>Transmission EM of tissues</td>
<td>D</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>PCR of tissue extracts</td>
<td>C</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>PCR - sequence analysis</td>
<td>NA</td>
<td>C</td>
<td>A</td>
</tr>
</tbody>
</table>
Model Health Certificate of the OIE

- Model HC year 2008
- Model HC year 2009

EU standards for trade in live aquatic animals and their products
• COUNCIL DIRECTIVE of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (91/67/EEC)


• Since the adoption of Directive 91/67/EEC, the Community has ratified the WTO SPS Agreement. The SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE).

• The animal health requirements for placing live aquaculture animals and products thereof on the market within the Community set out in Directive 91/67/EEC are more stringent than those standards.

• Therefore, this Directive (COUNCIL DIRECTIVE 2006/88/EC) should take into account the Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aquatic Animals of the OIE.
COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006
on animal health requirements for aquaculture animals and products
hereof, and on the prevention and control of certain diseases in aquatic
animals


Scope (1/3)

1. This Directive shall not apply to:
   - (a) ornamental aquatic animals reared in non-commercial aquaria;
   - (b) wild aquatic animals harvested or caught for direct entry into the food chain;
   - (c) aquatic animals caught for the purpose of production of fishmeal, fish feed, fish oil and similar products.
Scope (2/3)

2. Health requirements shall not apply where ornamental aquatic animals are kept in pet shops, garden centres, garden ponds, commercial aquaria, or with wholesalers:
   - (a) without any direct contact with natural waters in the Community; or
   - (b) which are equipped with an effluent treatment system reducing the risk of transmitting diseases to the natural waters to an acceptable level.

Scope 3/3

3. This Directive shall apply without prejudice to provisions on the conservation of species or the introduction of non-native species.
Limitation of imported countries

- For imports into the EU, the over-riding rule is that aquaculture animals intended for farming, relaying areas, put and take fisheries and open ornamental facilities shall only be imported into the Community from third countries, territories, zones or compartments listed in the Regulation. No consignments will be permitted entry if they originated from a country not listed. There are many Asian countries that are not listed.

Conditions for imports of cold-water ornamental fish or farming fish

- Member States shall authorise imports of cold-water ornamental fish or farming fish into their territory only if:
  - (a) the fish originate from a country listed in:
    - (i) Annex I to Decision 2003/888/EC (page 9):
COMMISSION REGULATION (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species

- List of possible vectors (page 11)
- List of countries allow to export ornamental fish for close ornamental facilities (page 22)
- HC page 24 (Annex IV Part A)
- HC page 29 (Annex IV Part B)

Susceptible spp.

- List of diseases and susceptible spp.
3. Summaries

- The OIE Aquatic Code and Aquatic Manual have a major role to play not only in the prevention and control of aquatic animal diseases, but also more generally in the improvement of aquatic animal health worldwide.
- Member Countries and Territories
  - can use to protect themselves from diseases without setting up unjustified sanitary barriers.
  - shall improve their aquatic disease diagnostic capabilities.
- EU standards have been adjusting to comply with the OIE standard.
- Achievement of the OIE standard shall be first priority of all members.

Thank You for Attention

List of EUS susceptible species