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# REPORT OF THE MEETING
# OF THE OIE FISH DISEASES COMMISSION

## Paris 11–13 September 2000

The OIE Fish Diseases Commission (FDC) met at the OIE headquarters from 11 to 13 September 2000. The Agenda and the List of Participants are given at Appendices I and II, respectively.

The President of the Commission, Prof. T. Håstein, welcomed the two new Members of the Commission (Dr Eva-Maria Bernoth and Prof. D. Lightner) and congratulated Prof. B. Hill and Dr C. Michel on their re-election.

The Director General of the OIE, Dr J. Blancou, also welcomed the new Members, and then gave a brief account of the OIE Strategic Plan (Agenda item 8.4.), which was agreed in principle at the General Session in May 2000. Dr Blancou requested the Commission to consider the preferred and likely direction of its work over the next five years and emphasised that the Strategic Plan identified the need to strengthen cooperation and partnerships with international and regional organisations. He also advised that, in the future, more attention will need to be directed to the public health aspects of aquatic animal diseases.

The meeting was chaired by Prof. Håstein, and Prof. Hill, Secretary General, acted as Rapporteur.

## 1. *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal diseases*

### 1.1. Final review of the Third Edition of the *International Aquatic Animal Health Code*

The Central Bureau informed the Commission that the new editions of the *International Aquatic Animal Health Code* (the *Code*) and the *Diagnostic Manual for Aquatic Animal Diseases* (the *Manual*) would be published in A4 format, as agreed at the last FDC meeting in February. Hard copies should be available in December 2000.

### 1.2. Final review of the Third Edition of the *Diagnostic Manual for Aquatic Animal Diseases*

The Commission made some final minor editorial corrections to the text and some new information was added for certain diseases as follows:

- **Viral haemorrhagic septicaemia (VHS):** Japan and Finland have been added to the list of countries that have reported VHS, and *Paralichthys olivaceus* has been added to the list of susceptible species. This information was notified to the Central Bureau by the OIE Delegates of both countries in 2000.

- **Infectious salmon anaemia (ISA):** The Faeroe Islands have been added to the list of countries that have reported ISA. This was notified to the Central Bureau by the Chief Veterinary Officer of the Faeroe Islands in May.

## 2. Future amendments to the *International Aquatic Animal Health Code*

The FDC agreed a number of changes to the text of the *Code* chapters on notifiable diseases of crustaceans and Model certificate No. 5 International Aquatic Animal Health Certificate for Dead Crustaceans, and a change to a definition in Section 1.1., for inclusion in the fourth edition. These changes are presented at Appendix III for Member Country comments.

### 2.1. Aim of the *International Aquatic Animal Health Code*

Dr T. Chillaud joined the meeting for this item. He explained that, at the General Session in May, a Member Country had highlighted a significant discrepancy between some of the principles in the aquatic animal *Code* and those in the *International Animal Health Code*. In particular, the aquatic animal *Code* gives no provision to countries that cannot be declared officially free of a disease or that are in the process of conducting a surveillance programme to demonstrate freedom, to require a health certificate for absence of a listed disease when importing from another country, while the *International Animal Health Code* for mammals, birds and bees gives recommendations for avoiding the transfer of pathogenic agents from one country to another irrespective of the health status of the importing country. Dr Chillaud advised that the FDC should establish a dialogue with the International Animal Health Code Commission to resolve such discrepancies. It was agreed to arrange a meeting between representatives of the two Commissions in February 2001. Issues to be addressed will include:

- Measures applicable for emerging diseases,
- Testing for absence of pathogen versus absence of disease,
- Need for active surveillance versus passive surveillance,
- Application for OIE official recognition of freedom from disease for countries or zones.

### 2.2. Chapter on import risk analysis

A draft chapter on import risk analysis had been prepared by Dr S. MacDiarmid, New Zealand. The draft was based on a similar chapter in the *International Animal Health Code* that has been adapted to aquatic animal diseases. The FDC would like to include the chapter in the fourth edition of the *Code*. The amended text is presented at Appendix IV for Member Country comments.

### 2.3. Categorisation of diseases

The FDC discussed various issues relating to aquatic animal disease categorisation. The FDC agreed that any categorisation scheme should be scientifically plausible, consistent and prepared in a defensible manner to support decisions on listing diseases, with the primary aim to obtain and disseminate official information on disease occurrence in OIE Member Countries.

In order to obtain a wider input into these deliberations, the FDC decided to send a questionnaire to OIE Member Countries asking them to list diseases of sufficient concern to their country to require listing by the OIE, and to explain their rationale. In general terms, 'sufficient concern' would mean that the introduction of a disease would lead to public health, socio-economic or ecological damage to an extent that notification of a change in its occurrence in other countries is warranted. The FDC will provide OIE Delegates with a list of criteria to assist in identifying such diseases, and ask for an assessment of the usefulness of these criteria.

## 2.4. Contingency planning

The chapter on and definition of contingency planning that was attached as Appendix III to the report of the FDC meeting in February 2000 was adopted by the International Committee in May 2000 and is included in the Third Edition of the *Code*. The FDC felt that the chapter as written could only serve as guidelines and that it should provide greater detail in the next edition of the *Code*.

## 2.5. Fallowing of sites

The inclusion in the *Code* of text on the principle of fallowing of aquaculture establishment sites was discussed. The FDC thought it preferable to have fallowing included as one of the disease control tools in the chapter on contingency planning. Prof. Håstein will prepare a draft document on fallowing, which will be discussed at the next FDC meeting in February 2001 prior to submission to the OIE Member Countries for comment.

The FDC agreed that fallowing would be applicable for farming of finfish and crustaceans, but not for mollusc farming.

## 2.6. Listing of molluscan pathogens rather than disease names

The FDC reviewed problems concerning perkinsosis, an OIE listed disease of molluscs caused by *Perkinsus marinus* and *P. olseni*. Recent phylogenetic investigations indicate that the genus *Perkinsus* is closely related to the dinoflagellida. Moreover, reports have been published indicating that two species of *Perkinsus* can cohabit in the same area and infect the same host species. An example of this is the case of *P. marinus* and *P. chesapeaki* – diagnostic methods described in the *Manual* will not differentiate the two species. More information is needed on this new species, *P. chesapeaki,* and a request for this will be sent to the OIE Delegate of the country concerned.

Another species of *Perkinsus, P. atlanticus,* infects clams *(Ruditapes decussatus)*. Nucleotide sequences indicate that *P. atlanticus* is probably conspecific to *P. olseni*, but taxonomic relationships between these two species needs to be clarified. Given the geographical distribution of the *P. olseni/atlanticus* complex, occurring from Pacific islands through Australia, New Zealand and South-East Asia to Europe, evaluation of risk associated with transfer of stocks should probably not take into account the unique specification of pathogens, but genotypes of both hosts and pathogens. Within the geographical range of *P. marinus*, differences in virulence between isolates have been demonstrated, suggesting that several strains of the parasite might exist with differences in genetic composition, geographical distribution and virulence.

Molecular taxonomy and epidemiology data are expected to address some of these issues, mainly by clarifying taxa boundaries and providing tools to prevent the transfer of infected stocks in disease-free areas. Listing of pathogens rather than diseases could help to overcome some of these problems. In the case of parasites of the genus *Perkinsus*, some species could be listed as notifiable, some as other significant diseases. It was also suggested that OIE Member Countries should provide annual reports on other significant diseases to facilitate follow up of information on these diseases.

The advantage of listing agents rather than diseases is also illustrated by the case of haplosporidiosis. Pacific oyster, *Crassostrea gigas*, is listed as a susceptible species to emphasise its potential role as a vector of *H. nelsoni*. However, *C. gigas* is not affected by the parasite, and this casts some doubts on the validity of listing it as susceptible to the disease.

A possible solution would be to add a new category of host species to identify those that are vector carriers rather than susceptible species.

Dr F. Berthe was asked to provide a formal proposal on these topics for discussion at the next FDC meeting.

### 2.7. Streptococcosis/Lactococcosis

The FDC discussed recent developments in the occurrence of streptococcosis/lactococcosis and considered whether there was a case for inclusion of the disease on the OIE lists. Knowledge of the disease and the epidemiological situation have changed in the past five years with the recent developments in understanding of the taxonomy and the geographical distribution of two of the causative organisms, *Streptococcus iniae* and *Lactococcus garvieae*. Disease caused by *Streptococcus iniae* remains confined to warm-water fish farming, but it can also cause serious infections in humans, particularly fish handlers. *Lactococcus garvieae* (formerly *Enterococcus seriolicida*), which causes disease in fish at somewhat lower water temperatures, was first reported from Japanese sea-cage facilities, but has since been detected in several other parts of the world and appears to be developing into a threat to salmonid farms in some European countries. Both organisms can have significant detrimental impact on fish production, are difficult to control through chemotherapy, and are difficult to differentiate from other environmental streptococci using routine bacteriological techniques. Vaccines are currently under development, but will have to be subjected to field trials before becoming commercially available. The FDC felt that more information on the distribution and impact of streptococcosis/lactococcosis was needed before considering possible listing of the two bacteria as 'other significant diseases' agents. The situation will be discussed further at the next FDC meeting.

## 3. Future amendments to the *Diagnostic Manual for Aquatic Animal Diseases*

In future editions of the *Manual*, improvements in diagnostic and screening tests are likely to result from further development of molecular techniques, but significant attention needs to be paid to standardisation and validation procedures. Another important point for future reconsideration is sampling. Current specifications require the collection of samples from every susceptible species present on a site. It should be feasible to limit sampling to the most susceptible species so that the chances of detecting a specified agent would be optimal. The FDC will discuss these issues in future meetings.

## 4. International trade in frozen shrimp that may be infected with notifiable diseases and listed pathogens

There is an increasing international awareness that certain viral diseases of marine penaeid shrimp may be transferred from one geographical region to another with frozen commodity shrimp. Recent risk assessments conducted in the United States of America (USA) and Australia have addressed this concern.

White spot syndrome virus (WSSV) may have reached the Western Hemisphere through trade in frozen commodity shrimp, and there is a growing concern that other notifiable and listed shrimp pathogens could be moved and introduced to new regions in the same manner. All three pathogens of the OIE notifiable diseases of shrimp (WSSV, yellowhead virus [YHV] and Taura syndrome virus [TSV]) have been detected (and found to be infectious to the representative American penaeid shrimp species in laboratory studies) in imported frozen penaeid shrimp sampled from the commodity market in the USA. WSSV may have been introduced to the Americas from Asia in frozen *Penaeus monodon*.

The regions where WSSV first appeared in the Western Hemisphere have had no reported history of direct or indirect introduction of live shrimp from areas of Asia where the virus was enzootic. Hence, the introduction of WSSV to the Western Hemisphere cannot be linked to the introduction of live shrimp from Asia. However, each of the affected regions of the south-eastern USA, and the initial epicenter of WSSV in Central America, had a common factor in their history – the importation and reprocessing of thousands of tonnes of Asian shrimp at coastal packing plants. Many of these plants import Asian shrimp and perform value-added processing (i.e. peeling, de-veining, and breading) for the US market. In many cases processing wastes (shells, haemolymph, and tissue scraps) have been discharged directly into coastal waters, which are also the nursery grounds for the marine penaeid shrimp. The use of imported shrimp as fishing bait is another mechanism for a direct route of introduction of these pathogens into the ecosystems of importing countries.

Small-sized shrimp from emergency harvests are commonly found in the commodity imports destined for the US market. The FDC notes that the practice of early or emergency harvest of shrimp infected with WSSV or YHV may result in a commodity product that can serve as a vehicle for the international spread of penaeid shrimp viruses and that this practice should be avoided.

## 5. Closely related pathogens in penaeid shrimp

YHV is an OIE notifiable pathogen and chapter 4.1.3. in the *Manual* describes yellowhead disease caused by YHV and the currently acceptable surveillance and diagnostic methods for YHV. The closely related viruses GAV/LOV (gill-associated virus/lymphoid organ virus), which have been reported from Australia penaeid prawns after the discovery of YHV in South-East Asia, are noted briefly in the chapter on yellowhead disease. GAV/LOV are reported in the scientific literature as being a serious pathogen in the culture of *P. monodon* in Australia. Although GAV/LOV show genomic sequence differences from YHV that are sufficient to consider GAV/LOV as distinctly different strains of virus in the YHV group, they nonetheless cause serious disease in *P. monodon.* Because of the significance of GAV/LOV, this pathogen should either be considered a distinct strain of YHV in the *Manual* and *Code* equal in significance to YHV, or listed and described separately in the *Code* and *Manual*. This issue will be discussed further at the next FDC meeting.

## 6. Ongoing epizootics in American lobsters – possible spread and impact on trade

The FDC discussed the occurrence of epizootics in wild American lobsters that were first noted 3 years ago by lobster fishermen in the north-western USA and south-eastern Canada. Dead and dying lobsters were observed in offshore traps and in lobster pounds. In 1999–2000, a serious epizootic in lobsters was again reported from the region, with the most serious losses being noted in waters off Long Island, New York. In response to the epizootic, a special Lobster Mortality Workshop on the problem was held in the region in mid-2000, and working groups have been formed to study the epizootic and identify its aetiological agent(s). The available information to date suggests that the lobster epizootic has an infectious aetiology. Therefore, the international trade in live lobsters from the affected regions of New England (USA) and Nova Scotia (Canada) could pose a risk to importing countries. The FDC will request copies of the report of the Lobster Mortality Workshop and then consider what action to recommend.

## 7. The role and activities of the OIE in the field of aquatic animals

### 7.1. Representation at international meetings and workshops

As a guest of the Instituto Tecnologico del Salmon, Prof. Hill, Secretary General of the FDC, presented a talk at the International Seminar on Infectious Pancreatic Necrosis, held in Puerto Montt, Chile, 16–17 March 2000, on the SPS Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization) and OIE standards for health conditions applied to international trade in aquatic animals.

Prof. Hill represented the FDC at the Third FAO[1]/NACA[2]/OIE Regional Workshop on Development of Asia Regional Technical Guidelines on Health Management for the responsible Movement of Live Aquatic Animals, held in Beijing, the People's Republic of China, 27–30 June 2000, and gave a presentation on the use of zoning for preventing spread of aquatic animal diseases.

1 Food and Agriculture Organization of the United Nations
2 Network of Aquaculture Centers in Asia-Pacific

Prof. Hill represented the FDC at the APEC[3]/NACA/FAO Regional Workshop on Health Management in Shrimp Aquaculture held in Puerto Vallarta, Mexico, 24–28 July 2000, and presented talks on the *Code* and *Manual* and on zoning for control of aquatic animal diseases.

Dr Michel, Vice-President of the FDC, represented the Commission at the International Symposium on Veterinary Epidemiology and Economics held in Breckenridge, USA, 6–11 August 2000, and presented a talk on risk analysis in aquatic animal diseases. Prof. Hill gave a brief account of the International Database on Aquatic Animal Diseases at the same meeting.

Dr Berthe will represent the FDC at the Annual Meeting of the United States National Shellfish Association to be held in conjunction with the World Aquaculture Society Conference in Orlando, USA, in January 2001.

### 7.2. Publications

#### 7.2.1. Status of diagnostic cards for listed diseases

Completed cards for 27 of the 29 listed diseases of aquatic animals have now been received and most have been scientifically reviewed. On receipt of the final two cards, all cards will be translated into French and Spanish. Hard copies of these cards should be ready to send to OIE Member Countries with the next (February 2001) report of the FDC. At the same time, the cards should be available on the OIE Web Site.

#### 7.2.2. Fish Diseases Commission brochure

The FDC brochure 'Protecting Aquatic Animal Health' was finalised and presented at the 68th General Session in May 2000. The brochure received a good reception by the Members of the International Committee and also at national and international meetings elsewhere in the world.

#### 7.2.3. OIE *Scientific and Technical Review*

The proposal to dedicate an issue of the OIE *Scientific and Technical Review* to aquaculture and related topics has been deferred for this year.

### 7.3. New applications for OIE Reference Laboratory status

One new application for designation as an OIE Reference Laboratory had been received, namely for the two mollusc diseases haplosporidiosis and perkinsosis at the Virginia Institute of Marine Science (VIMS), Virginia, USA, with Dr E.M. Burreson as the proposed expert. The Commission supported this proposal, and will submit it to the International Committee for adoption at the General Session in May 2001.

## 8. Any other business

### 8.1. Cooperation and partnership with other international and regional organisations

Dr R. Subasinghe made a short presentation on the FDC's collaboration with FAO and NACA. He informed the Commission that at the workshop held in Beijing, the People's Republic of China, in June 2000, the 'Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals' were endorsed and adopted in principle by representatives of the regional governments from participating countries. The *Technical Guidelines* are currently being printed. He thanked the FDC for providing assistance to this process and to the other initiatives of FAO/NACA on aquatic animal health management, both in Asia and in Latin America.

3 Asia Pacific Economic Cooperation

Dr Subasinghe also mentioned the new FAO initiative on Shrimp Health Management in the Americas and requested the FDC to actively participate in this regional initiative. While expressing the benefits of such participation, Dr J.E. Pearson suggested that the OIE Regional Representation for the Americas should also be informed. Dr Subasinghe agreed to contact the Regional Representation based in Buenos Aires (Argentina).

Dr Subasinghe said that aquaculture has now been widely recognised as a tool for rural development, poverty alleviation, and improving the livelihoods of poorer sectors of the developing world where aquaculture is feasible. With the ongoing globalisation efforts and rapid trade liberalisation, transboundary pathogen issues would continue to emerge and will have to be further addressed in the future. He said it would be useful to examine the future visions and activities of the FDC and FAO in aquatic animal health management issues and discuss opportunities for closer collaboration between the two organisations. This will also help to avoid duplication of efforts and to find opportunities for better cooperation and collaboration on issues of common interest to the two organisations. The FDC agreed that this would be useful and requested Dr Subasinghe to formally contact the OIE with a proposal for a potential bilateral meeting on opportunities and challenges on collaboration and cooperation between FAO and OIE on aquatic animal diseases.

A request by SEAFDEC[4] for the FDC collaboration with SEAFDEC's aquaculture department (AQD) was also discussed. Professors Håstein and Hill stated that they discussed the issue with SEAFDEC representatives at the General Session in May 2000 and the Commission awaits further communication from SEAFDEC.

### 8.2. Internet activities

The FDC has previously requested the OIE Central Bureau to set up an FDC-specific Web site on the OIE Web page. Dr Pearson informed the meeting that the FDC Web site will be on-line within the next few months. The site will have contact details of FDC Members and Reference Laboratories for aquatic animal diseases, and it will cross-link to the *Code* and *Manual*. FDC reports of the last 2 years will be available, as will be downloadable versions of the Diseases Cards for all aquatic animal diseases listed by OIE.

Importantly, the FDC Web site will provide a link to the International Database on Aquatic Animal Diseases at the OIE Collaborating Centre. A 'News' column may also be included (see 8.5.)

### 8.3. OIE International Conference on Risk Analysis in Aquatic Animal Health

The proceedings of the Risk Analysis Conference are planned to be ready for printing by the end of this year.

The creation of a Working Group on Risk Analysis, as recommended in the conclusions of the Conference, was discussed. Some specialists have been contacted or have expressed their interest to participating in such a group. Terms of reference need to be developed, and means of support and avenues for communication (meetings, electronic conferences) need to be resolved before taking a formal decision. Drs Berthe and Michel were requested to organise contacts and prepare some proposals so that a project plan could be developed and submitted to the International Committee at the next General Session.

### 8.4. OIE Strategic Plan

Dr Pearson introduced the OIE 'Third Strategic Plan 2001–2005'. He briefly presented the outline of the Plan, emphasising the largely unchanged OIE vision and mission statement.

4 South-East Asia Fisheries Development Centre

'*The OIE will strive to become the pre-eminent world reference for animal health by accessing and producing comprehensive scientific knowledge and consensus on it. This knowledge will promote the improvement of international animal health not only for the benefit of animal production and trade world-wide, but also for the protection of public health.*'

'*To convert international scientific data on animal health into information and to transform information into knowledge products that meet the needs of Member Countries.*'

The plan identifies four strategic directions to support the mission:

a) International animal disease information,
b) Development of scientific standards,
c) Guidance on animal and zoonotic disease prevention, control and eradication (including aquatic animals and wildlife),
d) Coordination of research.

Dr Pearson noted that the FDC's work would continue to focus on the first two strategies.

At the time of the FDC meeting, a draft Workplan to implement the Strategic Plan is nearing completion. The Workplan, which translates the strategic directions into specific and measurable goals and objectives, is being developed by the OIE Director General and will be presented to the OIE Administrative Commission for approval prior to submission to the OIE International Committee in May 2001.

### 8.5. Collaborating Centre – database

Prof. Hill provided an update on the International Database on Aquatic Animal Diseases. Pending final clarification of abstract copyright issues, the database will be made freely available via the OIE Web site. There will be a Press release by the United Kingdom's Ministry of Agriculture, Fisheries and Food as the parent organisation of the OIE Collaborating Centre for Information on Aquatic Animal Diseases, which manages the database. The OIE Central Bureau will inform OIE Delegates individually of the availability of the database on-line.

The FDC sought clarification on the definition of 'OIE data' in the context of database entries. This issue arose at the 2000 OIE General Session when the appropriateness of using data from the *Manual* as official 'OIE data' on disease occurrence in a country was questioned for cases where the information in the *Manual* is not supported by the OIE Delegate of that country.

Dr Chillaud confirmed that information in the *Manual* has been endorsed at the OIE General Session and as such is OIE data. However, if discrepancies become apparent, the OIE Central Bureau (as per OIE Administrative Commission decision) will raise this issue with the national Delegate and seek clarification. Where refutations of a disease occurrence are substantiated by the national Delegate, the *Manual* and database will be amended accordingly, and the reasons for refutation be made known via the database entries.

Where no clarification can be reached, the national Delegate's claim will prevail. It is hoped that the incidence of such controversies will decrease in the future. Scientifically published data conflicting with a national Delegate's claims will still be referenced in the database as 'Non-OIE data', but will be removed from the *Manual*.

Prof. Hill reported a recent meeting with Dr C. Zepeda at the OIE Collaborating Centre for Animal Disease Surveillance Systems and Risk Analysis, Fort Collins, USA. Dr Zepeda commended the International Database on Aquatic Animal Diseases; Prof. Hill and Dr Zepeda agreed to increase cooperation in the future, especially on issues of disease information systems and the use of databases to support such systems.

### 8.6. Network on Technology of Aquaculture in the Mediterranean – survey on Mediterranean aquaculture diseases and diagnostic laboratories

The Commission discussed a letter of request from Dr M. Vallas of CIHEAM[5] on the above subject. The letter was accompanied by a questionnaire intended to be sent to different fish diseases laboratories working in fish and shellfish diseases diagnosis. The purpose of the questionnaire is to conduct a large survey, and the OIE was consulted and invited to express an opinion on the questionnaire. The Commission felt that this is a very ambitious epidemiological endeavour which out-passes the fields of Mediterranean aquaculture. TECAM[6] is encouraged to seek further collaboration with FAO, which has already developed large databases, such as AAPQIS[7]. The FDC will follow further developments with interest.

### 8.7. Date of the next Fish Diseases Commission meeting

The FDC agreed to hold its next meeting from 12 to 15 February 2001.

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...../Appendices

5 International Centre for Advanced Mediterranean Agronomic Studies (Centre international de hautes études agronomiques méditerranéennes)
6 Network on Technology of Aquaculture in the Mediterranean
7 Aquatic Animal Pathogen and Quarantine Information System

## REPORT OF THE MEETING OF THE OIE FISH DISEASES COMMISSION

## Paris, 11–13 September 2000

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## Agenda

**1. *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal diseases***

1.1. Final review of the Third Edition of the *International Aquatic Animal Health Code*
1.2. Final review of the Third Edition of the *Diagnostic Manual for Aquatic Animal Diseases*

**2. Future amendments to the *International Aquatic Animal Health Code***

2.1. Aim of the *International Aquatic Animal Health Code*
2.2. Chapter on import risk analysis
2.3. Categorisation of diseases
2.4. Contingency planning
2.5. Fallowing of sites
2.6. Listing of molluscan pathogens rather than disease names
2.7. Streptococcosis/Lactococcosis

**3. Future amendments to the *Diagnostic Manual for Aquatic Animal Diseases***

**4. International trade in frozen shrimp that may be infected with notifiable diseases and listed pathogens**

**5. Closely related pathogens in penaeid shrimp**

**6. Ongoing epizootics in American lobster – possible spread and impact on trade**

**7. The role and activities of the OIE in the field of aquatic animals**

7.1. Representation at international meetings and workshops
7.2. Publications
7.3. New applications for OIE Reference Laboratory status

**8. Any other business**

8.1. Cooperation and partnership with other international and regional organisations
8.2. Internet activities
8.3. OIE International Conference on Risk Analysis in Aquatic Animal Health
8.4. OIE Strategic plan
8.5. Collaborating Centre – database
8.6. TECAM survey on Mediterranean aquaculture diseases and diagnostic laboratories
8.7. Date of the next FDC meeting

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**REPORT OF THE MEETING**

**OF THE OIE FISH DISEASES COMMISSION**

**Paris, 11–13 September 2000**

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# *International Aquatic Animal Health Code*

## Revised texts

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SECTION 1.1.

**DEFINITIONS**

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List of proposed new definitions for the *International Aquatic Animal Health Code*.

***Gametes***

means the *sperm* or unfertilised *eggs* of *aquatic animals [fish]*, that are held or *transported* separately prior to fertilisation.

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CHAPTER 4.1.X.

# NOTIFIABLE DISEASES OF CRUSTACEAN

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Article 4.1.X.4.

**For dead *crustaceans***

In general, the *Competent Authority* of a country importing dead *crustaceans* of a *susceptible species,* for any purpose [human consumption], should require that the consignment be accompanied by an *international aquatic animal health certificate* conforming to the Model Certificate No. 5, issued by the *Competent Authority* in the country of origin that clearly indicates the place of harvest of the product to be imported [if the *crustaceans* of *susceptible species* are to be imported head on].

This *certificate* should declare the health status of the country of harvest in respect of DISEASE NAME and the other *crustacean diseases listed* in this *Code*.

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Model Certificate No. 3

# INTERNATIONAL HEALTH CERTIFICATE

# FOR LIVE MOLLUSCS AND GAMETES

## LIVE MOLLUSCS AND GAMETES

*NOTE: Mark all the relevant items with a cross in the appropriate space.*

### I. Identification

❑ Cultured stocks ❑ Wild stocks

1) Species:
   Latin name:.....
   Common name:.....

2) Age: ❑ Gametes ❑ Unknown ❑ >24 months ❑ 12–24 months ❑ 0–11 months ❑ larvae

3) Total weight (kg):.....
   OR
   Number (×1000):.....

Model Certificate No. 5

# INTERNATIONAL HEALTH CERTIFICATE

# FOR DEAD CRUSTACEANS

## DEAD CRUSTACEANS

*NOTE: Mark all the relevant items with a cross in the appropriate space.*

### I. Identification

❑ Cultured stocks ❑ Wild stocks

1) Species:
Latin name:.....
Common name:.....

2) Quantity (total weight, kg):.....
OR
Number (×1000):.....

3) ❑ Head on animals ❑ Head off animals ❑ Peeled animals

### II. Place of harvest

1) Country::.....

2) Zone:.....

3) Aquaculture establishment/Zone:
Name:.....
Location:.....

### III. Destination

1) Country:.....

2) Zone:.....

3) Company:.....

4) Nature and identification of means of transport:.....
.....

### IV. National crustacean health status and place of harvest

Based on the official health surveillance scheme employing laboratory tests of susceptible species, is the [exporting] country, zone or aquaculture establishment from which the crustaceans were harvested considered to be free of:

| | Country | | Zone | | Aquaculture establishment | |
|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No |
| Taura syndrome | | | | | | |
| White spot disease | | | | | | |
| Yellowhead disease | | | | | | |
| Other serious diseases (to be specified) | | | | | | |

## V. Declaration

I, the undersigned, certify that the dead crustaceans [for human consumption] in the present consignment have as their place of harvest [originate from] a: ❑ Country, ❑ Zone, ❑ Aquaculture establishment subjected to official health surveillance according to the procedures described in the OIE *Diagnostic Manual for Aquatic Animal Diseases*, and that the Country, Zone, or Aquaculture establishment identified in Section II above is officially recognised as being free from the diseases identified in Part IV above, and that the crustaceans have not been subjected to emergency harvest due to the suspicion or the confirmation of the presence of the diseases identified in Part IV above.

Exporting country:.....
Competent Authority:.....

Stamp:

Date:.....
Issued at:.....
Name and address of Health Inspector:
.....
.....
.....

Signature:.....

*IMPORTANT NOTE: This certificate must be completed no more that three days prior to shipment.*

- - - - - - - - - - - - - - -
[] deleted

SECTION 1.4.

# IMPORT RISK ANALYSIS

CHAPTER 1.4.1.

## GENERAL CONSIDERATIONS

Article 1.4.1.1.

**Introduction**

The importation of *animals* and animal products, whether of aquatic or terrestrial origin, involves a degree of disease risk to the *importing country*. This risk, which may be to humans or animals, may be represented by one or several diseases or infections not present in the *importing country*.

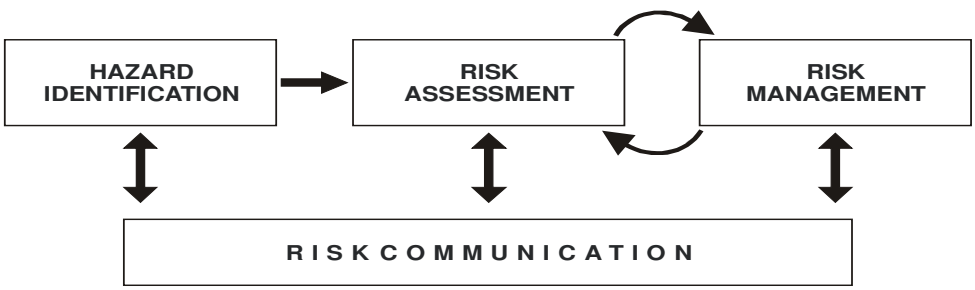
The principal aim of import risk analysis is to provide *importing countries* with an objective and defensible method of assessing the disease risks associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, *biological products* and *pathological material*. The principles and methods are the same whether the commodities are derived from aquatic and/or terrestrial animal sources. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of any import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This Chapter outlines the role of the OIE with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO), provides definitions and describes the OIE procedure for settlement of disputes.

Chapter 1.4.2. provides guidelines and principles for conducting transparent, objective and defensible risk analyses for *international trade*. However, it cannot provide detail on the means by which a risk analysis is carried out as the purpose of the *Code* is simply to outline the necessary basic steps. Nevertheless an outline of some of the processes and skills necessary for conducting import risk analyses are provided in Appendix 1.4.5.1. The components of risk analysis described in Chapter 1.4.2. are hazard identification, risk assessment, risk management and risk communication (Figure 1).

***Fig. 1.*** *The four components of risk analysis.*



The risk assessment is the component of the analysis that estimates the likelihood and consequences associated with a hazard. Risk assessments may be qualitative or quantitative. For many diseases, particularly those listed in the *Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely risks, although the status of some diseases may differ between countries or even between the Northern and Southern Hemispheres. In many cases it is likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import risk analysis on *aquatic animals* and *aquatic animal products* usually needs to take into consideration the results of an evaluation of the *Competent Authorities*, *zoning* and regionalisation, and surveillance systems that are in place for monitoring aquatic animal health in the *exporting country*. These are described in separate chapters in the *Code*.

Article 1.4.1.2.

**The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE**

The SPS Agreement requires WTO Members to base their sanitary measures on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection (the so-called Appropriate Level of Protection, in effect the national acceptable risk level) than that provided by international standards, if the level of protection provided by these standards is considered to be inappropriate.

Nevertheless, adoption of a higher standard **must** be justified scientifically. In such circumstances, Members are subject to obligations relating to risk assessment and to a consistent approach to risk management. Article 5 Paragraph 7 of the SPS Agreement states:

*"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."*

The SPS Agreement requires Governments to make a wider use of risk analysis: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual risk involved.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products, whether aquatic or terrestrial in origin.

Article 1.4.1.3.

**List of terms specific to Section 1.4.**

**Acceptable risk:** Risk level judged by Member Countries to be compatible with the protection of public health, aquatic animal health and terrestrial animal health within their country.

**Consequence assessment:** See point 3 of Article 1.4.2.4.

**Exposure assessment:** See point 2 of Article 1.4.2.4.

**Hazard:** Any pathogen that could produce adverse consequences on the importation of a *commodity*.

**Hazard identification:** The process of identifying the pathogenic agents that could potentially be introduced in the *commodity* considered for importation.

**Implementation:** See point 3 of Article 1.4.2.6.

**Monitoring:** See point 4 of Article 1.4.2.6.

**Option evaluation:** See point 2 of Article 1.4.2.6.

**Qualitative risk assessment:** An assessment where the conclusions on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.

**Quantitative risk assessment:** An assessment where the outputs of the risk assessment are expressed numerically, as probabilities or distributions of probabilities.

**Release assessment:** See point 1 of Article 1.4.2.4.

**Review:** See point 4 of Article 1.4.2.6.

**Risk:** The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to public, aquatic animal or terrestrial animal health in the *importing country* during a specified time period.

**Risk analysis:** The complete process composed of hazard identification, risk assessment, risk management and risk communication.

**Risk assessment:** The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a *hazard* within the territory of an *importing country* (see Articles 1.4.2.3. and 1.4.2.4.).

**Risk communication:** Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties (see Article 1.4.2.7.).

**Risk estimation:** See point 4 of Article 1.4.2.4.

**Risk evaluation:** See point 1 of Article 1.4.2.6.

**Risk management:** The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk (see Articles 1.4.2.5. and 1.4.2.6.).

**Sanitary measure:** Measures such as those described in each chapter of the *Code* that are used for risk reduction and are appropriate for particular diseases.

**Sensitivity analysis:** The process of examining the impact of the variation in individual model inputs on the conclusions of a quantitative risk assessment.

**Transparency:** Comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.

**Uncertainty:** The lack of precise knowledge of the input values, which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed.

**Variability:** A real-world complexity in which the value of an input is not the same for each case because of natural diversity in a given population.

Article 1.4.1.4.

**The OIE in-house procedure for settlement of disputes**

OIE shall maintain its existing voluntary in-house mechanisms for assisting Member Countries to resolve differences. In-house procedures that will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.

2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.

3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.

5. The expert or experts shall submit a confidential report to the Director General, who will transmit it to both parties.

CHAPTER 1.4.2.

# GUIDELINES FOR RISK ASSESSMENT

Article 1.4.2.1.

**Introduction**

An outline of some of the processes and skills necessary for conducting import risk analyses are provided in Appendix 1.4.5.1.

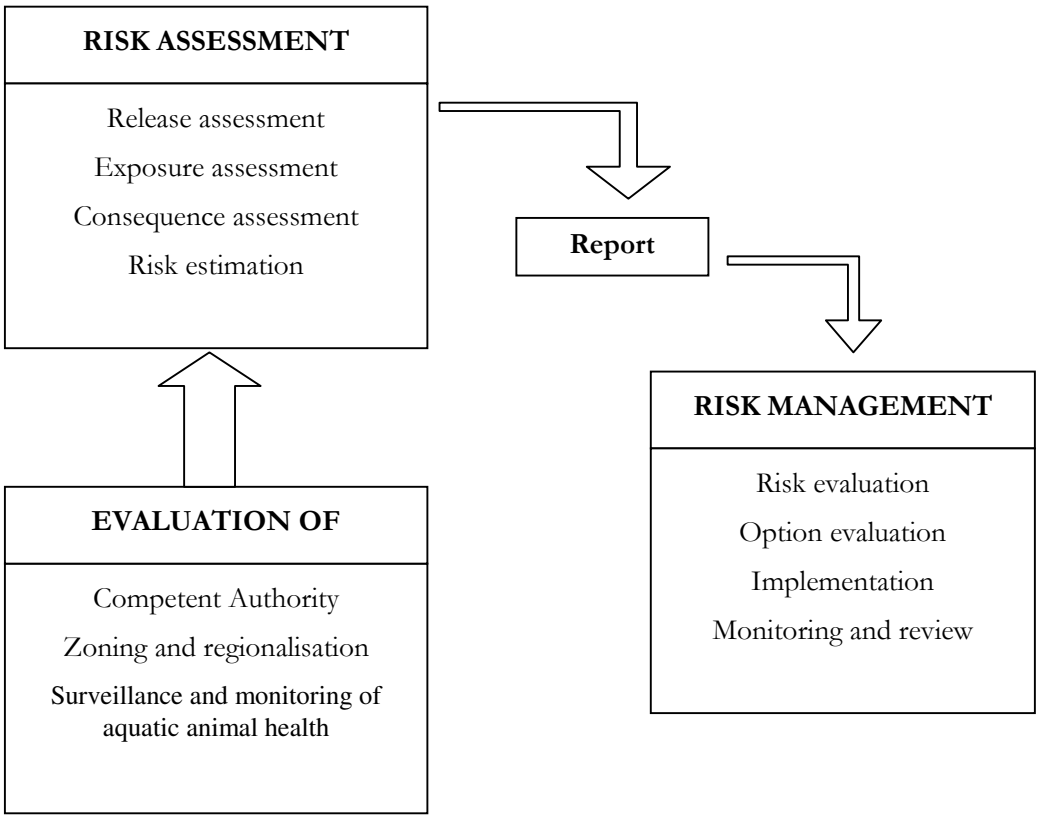
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

Hazard identification is an essential step that must be conducted before the risk assessment.

The risk assessment process consists of four interrelated steps. These steps clarify the stages of the risk assessment, describing them in terms of the events necessary for the identified potential risk(s) to occur, and facilitate understanding and evaluation of the conclusions (or 'outputs'). The product is the risk assessment report which is used in risk communication and risk management.

The relationships between risk assessment and risk management processes are outlined in Figure 1.

***Fig. 1.*** *The relationship between risk assessment and risk management processes.*



Article 1.4.2.2.

**Hazard identification**

Hazard identification involves identifying the pathogenic agents that could potentially produce adverse consequences associated with the importation of a *commodity*.

The hazards identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each hazard is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as hazards or not. The risk assessment should be concluded if hazard identification fails to identify hazards associated with the importation.

The evaluation of the *Competent Authorities*, surveillance and control programmes, and *zoning* and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the aquatic animal population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Code*, thus eliminating the need for a risk assessment.

Article 1.4.2.3.

**Principles of risk assessment**

1. The principles of risk assessment applying to imports of terrestrial animals and their products can, in most respects, be applied to aquatic animals, even though there are features unique to the spread of pathogens between infected and susceptible hosts in the aquatic environment.

2. Risk assessment should be flexible in order to deal with the complexity of real-life situations. No single method is applicable in all cases. Risk assessment must be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.

3. Both qualitative and quantitative risk assessment methods are valid. Indeed, every risk assessment must first be carried out qualitatively. A qualititative assessment is suitable for the majority of risk assessments and is, in fact, the most common type of assessment undertaken to support routine decision making. In some circumstances it may be desirable to undertake a quantitative analysis to gain further insights into a particular problem, identify critical steps, or to compare the effects of sanitary measures. In rare instances a semi-quantitative approach, for example using a subjective scoring system, might be useful to rank risks solely for the purpose of setting initial internal priorities. However, such semi-quantitative methods have significant drawbacks. Semi-quantitative methods are not recommended for external use, particularly in dispute procedures.

4. The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion.

5. Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

6. Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.

7. Risk increases with increasing volume of *commodity* imported.

8. The risk assessment should be amenable to updating when additional information becomes available.

9. Each hazard should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology.

Article 1.4.2.4.

**Risk assessment steps**

1. Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) a *hazard* into a particular environment, and estimating the likelihood of that complete process occurring. The release assessment describes the likelihood of the 'release' of each of the hazards under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

a) Biological factors

- Species, strain or genotype, and age of aquatic animal,
- Strain of agent endemic in the exporting country's environment,
- Tissue sites of infection and/or contamination,
- Vaccination, testing, treatment and quarantine.

b) Country factors

- Incidence/prevalence,
- Evaluation of *Competent Authorities,* surveillance and control programmes, and zoning systems of the *exporting country*.

c) Commodity factors

- Whether the commodity is alive or dead,
- Quantity of commodity to be imported,
- Ease of contamination,
- Effect of the various processing methods on the pathogenic agent in the commodity,
- Effect of storage and transport on the pathogenic agent in the commodity.

If the release assessment demonstrates no significant risk, the risk assessment need not continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of humans and aquatic and terrestrial animals in the *importing country* to the hazards and estimating the likelihood of these exposure(s) occurring, and of the spread or establishment of the hazard.

The likelihood of exposure to the hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and the number, species and other characteristics of the human, aquatic animal or terrestrial animal populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors

- Presence of potential vectors or intermediate hosts,
- Genotype of host,
- Properties of the agent (e.g. virulence, pathogenicity and survival parameters).

b) Country factors

- Aquatic animal demographics (e.g. presence of known susceptible and carrier species, distribution),
- Human and terrestrial animal demographics (e.g. possibility of scavengers, presence of piscivorous birds),
- Customs and cultural practices,
- Geographical and environmental characteristics (e.g. hydrographic data, temperature ranges, water courses).

c) Commodity factors

- Whether the commodity is alive or dead,
- Quantity of commodity to be imported,
- Intended use of the imported aquatic animals or products (e.g. domestic consumption, restocking, incorporation in or use as aquaculture feed or bait),
- Waste disposal practices.

If the exposure assessment demonstrates no significant risk, the risk assessment should conclude at this step.

3. Consequence assessment

Consequence assessment consists of identifying the potential biological, environmental and economic consequences. A causal process must exist by which exposures to a hazard result in adverse health, environmental or socio-economic consequences. Examples of consequences include:

a) Direct consequences

- Aquatic animal infection, disease, production losses and facility closures,
- Adverse, and possibly irreversible, consequences to the environment,
- Public health consequences.

b) Indirect consequences

- Surveillance and control costs,
- Compensation costs,
- Potential trade losses,
- Adverse consumer reaction.

4. Risk estimation

Risk estimation is the process whereby the results and/or conclusions of the release, exposure and consequence assessments are summarised into an estimate of the likelihood of each hazard entering the *importing country*, becoming established or spreading and resulting in adverse consequences. It is not sufficient to conclude that there is a **possibility** of entry, establishment or spread, of adverse consequences. An evaluation must be made of the **likelihood** of each of these occurring.

For a quantitative assessment, the final outputs may include:

- The various populations of aquatic animals and/or estimated numbers of aquaculture establishments or people likely to experience health impacts of various degrees of severity over time;
- Probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- Portrayal of the variance of all model inputs;
- A sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- Analysis of the dependence and correlation between model inputs.

Article 1.4.2.5.

**Principles of risk management**

1. Risk management is the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import *commodities* and fulfil its obligations under international trade agreements.

2. The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions of the standards. Measures in addition to the international standards may be imposed where there is sufficient scientific justification, but should be supported by the risk assessment.

Article 5 Paragraph 7 of the SPS Agreement states:

*"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."*

Article 1.4.2.6.

**Risk management components**

1. Risk evaluation – the process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.

2. Option evaluation – the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation in line with the Member Country's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

3. Implementation – the process of following through with the risk management decision and ensuring that the risk management measures are in place.

4. Monitoring and review – the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.

Article 1.4.2.7.

**Principles of risk communication**

1. Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.

2. A risk communication strategy should be put in place at the start of each risk analysis.

3. The communication of risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in risk communication include the authorities in the *exporting country* and other stakeholders such as domestic aquaculturists, recreational and commercial fishermen, conservation and wildlife groups, consumer groups, and domestic and foreign industry groups.

5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.

6. Peer review of risk analyses is an essential component of risk communication for obtaining scientific critique aimed at ensuring that the data, information, methods and assumptions are the best available.

# 1.4.5. IMPORT RISK ANALYSIS

## APPENDIX 1.4.5.1.

## GUIDELINES ON HOW COMPETENT AUTHORITIES SHOULD CONDUCT IMPORT RISK ANALYSES

As *Veterinary Administrations* and *Competent Authorities* move towards the adoption of formal risk analysis as a basis for making decisions on the importation of aquatic animals and aquatic animal products, there is increasing interest in how to implement the process within existing *Competent Authorities*. The tendency appears to be to focus first on the organisational structure for a risk analysis 'unit'.

However, it is the skills and processes that are far more important than the structure. Structure without appropriate skills and processes is sterile, but if the skills and processes are adequately defined then structures are less relevant and there are a number of ways in which the requirements of good risk analysis can be met. *Competent Authorities* are organised differently depending on national policies on the appropriate role of the State in the formulation of policies and delivery of services. Different resource bases means that some administrations do not have all the necessary skills 'in house'. Different opinions on the appropriate structures of *Competent Authorities* mean that even where resources are adequate, it may not be considered appropriate for certain functions to be carried out 'in house' and so the skills appropriate for carrying out import risk analyses may be distributed across the public and the private sectors. Within the public sector the necessary skills may be distributed within a centralised, traditional public service or may be in a corporatised service-for-fee delivery agency.

Before attempting to prescribe what is an appropriate 'structure' for a risk analysis 'unit', it is appropriate to examine those skills and processes necessary for carrying out import risk analysis on aquatic animals and aquatic animal products.

**Carrying out the risk analysis**

The *International Aquatic Animal Health Code* (Chapter 1.3.2.) describes the four components of import risk analysis as:

- Hazard identification
- Risk assessment
- Risk management
- Risk communication

To conduct these different components adequately requires a range of different skills.

**A team approach**

An aquatic animal health import risk analysis requires the expertise of the epidemiologist, with his or her understanding of the patterns of disease. The analysis is likely to require the input of people specialised in diseases of fish, molluscs or crustaceans and may also require the specialised skills of virologists, microbiologists, mycologists and parasitologists. In some instances it may be necessary to seek advice from experts as diverse as oceanographers, hydrologists, ornithologists, environmental scientists, industry technologists, mathematicians, statisticians, information scientists and economists. Clearly it is unlikely

that all this expertise can be incorporated into a single risk analysis 'unit', even in the most developed countries. It follows, then, that each major risk analysis should be treated as a project and the people with the necessary skills are assembled into the project team as appropriate. Members of the team do not need to be located at the same site.

The key points to remember are:

- Skills are more important than structures.
- The best risk analyses are produced by a multidisciplinary approach.
- Project team approach is best.
- Team composed of risk analyst and other specialists.
- Good risk analyses require adequate time.
- Good risk analyses are not conducted in isolation.
- Quantitative risk analysis requires:
    - Training,
    - A computer,
    - A spreadsheet and/or risk assessment software.

**Hazard identification**

This is the process of identifying the pathogens that could potentially be introduced by the *commodity* considered for importation. To do this requires a good knowledge of aquatic animal diseases, patterns of disease and the properties of the pathogens.

A knowledge of the aquatic animal disease status of the *exporting country* is required. Information of this kind is available from the OIE, from the national *Competent Authorities* of that country and from other competent sources (e.g. OIE International Database on Aquatic Animal Diseases, Food and Agriculture Organization of the United Nation's AAPQUIS [aquatic animal pathogen and quarantine information system]).

Access to sources of information is essential and amongst such sources are libraries, the World Wide Web and a network of specialist contacts.

**Risk assessment**

This phase of the risk analysis comprises:

- Release assessment
- Exposure assessment
- Consequence assessment
- Risk estimation

The release and exposure assessments again call for the skills of the epidemiologist and the specialist in diseases of fish, molluscs or crustaceans. There may also be a need for access to parasitologists, hydrologists and oceanographers. Consequence assessment will require the skills of the epidemiologist and may well call for the skills of the economist.

Where a quantitative risk analysis is to be undertaken, the epidemiologist will need to have appropriate computer skills and, indeed, specialist mathematical skills may be called for. The skills of the biometrician are likely to be needed. The requirement for access to sources of data and information will also call for the skills of the information specialist.

When considering aquatic animal products, the skills of people expert in the processing industries will be required. The exposure assessment may also require information gained from people with an understanding of waste disposal practices and, perhaps, cultural practices.

**Risk management**

The process of managing risks to reduce them to an acceptable level will again call for the expertise of the epidemiologist. However, he or she will need to have access to the specialist knowledge of diagnostic laboratory staff and quarantine staff and those familiar with commodity processing.

**Putting recommendations into practice**

The risk analysis produces recommendations. The recommendations lead to decisions. In import risk analysis, the decisions are translated into conditions for importation.

However, it may not be appropriate for the recommendations of the import risk analysis to be applied directly as a schedule of conditions under which importation may occur. The formulation of import conditions is not always a purely technical process. Indeed, the inputs into the conditions for importation include:

- The risk analysis
- Experience of import/export staff
- Experience of quarantine staff7
- Consideration of SPS Agreement issues
- Perspective of the head of the *Competent Authority.*

The recommendations of the import risk analysis are aids in decision making. The decision maker must also take into account these other factors. Nevertheless, the recommendations of the import risk analysis should be the most significant basis upon which the decision maker makes his or her decision. For this reason, the import risk analysis must be as technically robust as possible.

**Scientific review**

To ensure the technical robustness of the analysis, so that the decision makers can be sure that it will withstand the criticism by stakeholders opposed to importation or in favour of unrestricted importation, it should be subject to a process of:

- Internal scientific review within the *Competent Authority.*
- External scientific review by selected experts with specialised knowledge in risk analysis and its application to the diseases under consideration.

External scientific review can only be carried out subject to reviewers being given adequate terms of reference, as risk analyses are often substantial documents and reviewers must have a clear idea of what is expected of them. One should also expect to pay for the time experts spend reviewing risk analyses.

**Risk communication**

Risk analyses should be subjected to a period of stakeholder consultation. The breadth of groups considered to be 'stakeholders' may vary between countries.

**Relationship between risk analysts and decision makers**

It is said that risk analysis is an 'objective' process. This is debatable, although commendable. The reality is that in animal health risk analysis there are often so few data available that the analyst begins, unconsciously perhaps, to substitute value judgements for facts. Indeed, as consequence assessment is considered to be a component of the risk analysis, an element of subjectivity becomes almost unavoidable.

The risk analysis should precede the decision, rather than being commissioned to support a decision already made.

A close relationship between the risk analysts and the decision makers is essential.

Each needs to appreciate the position of the other, with the analyst appreciating that the decision maker has to take into account a broader range of issues than just the recommendations of the analysis and the decision maker appreciating that the analyst is striving for a 'scientifically objective' outcome.

Nevertheless, risk analyses are seldom truly 'objective' and for this reason transparency is essential.

**Training**

In the absence of a suitable formal course in risk analysis, the best training that can be provided for staff embarking on risk analyses is the discipline of epidemiology. Risk analysis is one of the applications of epidemiology. 'Risk analysis is to epidemiology what weather forecasting is to meteorology'.

**Conclusion**

The skills and processes required for carrying out risk analysis are more important than the structure in which the process is carried out. Without appropriate skills and processes no structure will insure good risk analysis. Where the skills and processes are adequately defined, structures are less relevant and there are a number of ways in which the requirements of good risk analysis can be met.

———————————