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REPORT OF THE MEETING
OF THE OIE FISH DISEASES COMMISSION

Paris 12–15 February 2001

The OIE Fish Diseases Commission (FDC) met at the OIE headquarters from 12 to 15 February 2001. The Director General of the OIE, Dr B. Vallat, welcomed the FDC Members and gave a brief review of the OIE Work Plan for the next 5 years. He commented that the OIE Member Countries recognised the importance of the work the Commission had done on aquatic animal diseases. Dr Vallat then stated that the OIE strongly supports the work of the FDC on aquatic animal diseases and that the Commission should have more means made available in order to better facilitate its efforts in this important field. The FDC Members highly appreciate this recognition of the importance of aquaculture and aquatic animal diseases.

The meeting was chaired by Prof. T. Håstein, and Prof. B. Hill, Secretary General, acted as Rapporteur. The Agenda and the List of Participants are given at Appendices I and II, respectively.

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

1.1. Schedule for preparation of Fourth Edition of the *International Aquatic Animal Health Code*

The FDC discussed the timetable for the different stages involved in the preparation of the fourth edition of *International Aquatic Animal Health Code* due to be published in 2003 and agreed the schedule shown in Appendix III.

In addition to preparing new editions (every 3 years) the FDC gives continuous consideration to improvements to the *International Aquatic Animal Health Code* through discussion at its biannual meetings. Any proposed changes are presented as updates to the International Committee at the OIE General Session each year, and if agreed, such amendments are distributed to OIE Delegates and consolidated into the electronic version on the OIE Web site. However, the latter does not show where the amendments have been made, and the FDC recommends that the Central Bureau considers how to achieve this to ensure that users of the *International Aquatic Animal Health Code* on the Web site are aware of the updates.

1.2. Schedule for preparation of Fourth Edition of the *Diagnostic Manual for Aquatic Animal Diseases*

The FDC discussed the timetable for the different stages involved in preparation of the 4th edition due to be published in 2003 and agreed the schedule shown in Appendix III.

2. Discrepancies between the *International Aquatic Animal Health Code* and *International Animal Health Code*

The FDC was joined for this item by Dr Th. Chillaud, Head of the OIE Department of Information and International Trade.

2.1. Measures required by importing countries – *Code* recommendations and the SPS[1] Agreement (e.g. health status of importing country)

Dr Chillaud advised the FDC that the *International Aquatic Animal Health Code* should be as consistent as possible with the *International Animal Health Code*, bearing in mind the SPS Agreement. There is a need to facilitate international trade but the *International Animal Health Code* approach was to reduce the risk of disease or pathogen transfer even to a country where the disease/pathogen is already enzootic. There is no provision for this in the current *International Aquatic Animal Health Code*, and it was suggested that a new article should be inserted along the lines that any country importing aquatic animals should request the exporting country to provide health certification of freedom from a (specified) disease without there being a requirement for the importing country to be officially declared free of that disease.

The FDC decided that such a change to the *International Aquatic Animal Health Code* would be a big shift in the principle of 'equivalence' that has been applied over many years and that it would need careful discussion with the International Animal Health Code Commission (Code Commission). It was agreed that a meeting should be arranged between the President and Secretary General of the FDC and the President of the Code Commission together will Dr Chillaud and Dr J.E. Pearson at the Central Bureau as soon as possible.

2.2. Link between category of disease and requirements for health certification

The FDC was advised by Dr Chillaud to retain the present system requiring an international health certificate for notifiable diseases and possibly for other significant diseases (if appropriate) rather than to combine the lists and propose the same requirement for both notifiable and other significant diseases.

2.3. Measures applicable for emerging diseases

The FDC pointed out that the *International Animal Health Code* makes no provision nor gives any guidance for dealing with new emerging diseases, and that this is an important issue in the expanding aquatic animal health area. The rapid global increase in farming of aquatic animals and the associated international trade in live animals and products have led to the emergence of many new major diseases in recent years. Some provision needs to be made in the *International Aquatic Animal Health Code* for countries to protect themselves against the risk of introducing such diseases before there is agreement from OIE Delegates for their inclusion in the list of notifiable or other significant diseases. Dr Chillaud informed the FDC that there will be a Technical Item on emerging diseases at the General Session in May 2001, which would likely lead to a resolution being presented to the International Committee to add a provision for such diseases to the *International Animal Health Code*. The FDC agreed to await the outcome of this and to discuss it further at their next meeting in September.

1 Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization

2.4. Testing for absence of pathogen versus absence of disease

For the *International Animal Health Code*, there is a trend toward testing for the absence of a pathogen rather than the historical approach of absence of observed clinical cases. A new chapter is in preparation for the *International Animal Health Code* to describe methods of surveillance for clinical disease and for presence/absence of the pathogen.

An Ad hoc Group appointed by the Foot and Mouth Disease and Other Epizootics Commission/Code Commission has considered the issue of 'historical freedom' from specific diseases as an OIE category for all listed diseases rather than just for Aujeszky's disease as at present. The Group made recommendations to the Code Commission who have agreed to include a new chapter on this in the next edition of the *International Animal Health Code.*

The President of the FDC agreed to prepare a similar general chapter providing guidelines on various categories of 'freedom' and how these can be demonstrated. This will be considered by the FDC at its next meeting.

2.5. Need for active surveillance versus passive surveillance

See Agenda Item 2.4.

2.6. Application for OIE official recognition of freedom from disease for countries or zones, including 'provisional freedom'

Article 1.4.4.4. of the *International Aquatic Animal Health Code* describes how OIE Member Countries may apply for recognition by OIE of a disease free zone. This is not limited to any specific diseases but includes all the diseases listed in the *International Aquatic Animal Health Code*. This is in contrast to the *International Animal Health Code,* which provides this for only three specified diseases. In its co-ordinated response to the Central Bureau on the Report of the FDC meeting of September 2000, the European Community requested that the *International Aquatic Animal Health Code* should give more provisions for encouraging Member Countries to apply for official OIE recognition of freedom from disease for countries or zones. The FDC agreed to develop guidelines for Member Countries to apply to OIE and to include these in the next edition of the *International Aquatic Animal Health Code.* The procedure for scrutinising applications will have to be decided, but final agreement to add a country or zone to the official OIE list will have to be via a Resolution put to the International Committee at the General Session.

2.7. How to list diseases with closely related agents (Asian YHV and Australian GAV)

The FDC discussed whether the virus (YHV) causing yellowhead disease in cultured black tiger prawns *(Penaeus monodon)* in Asian farms and the closely related gill-associated virus (GAV), that has been described to cause a similar disease in cultured *P. monodon* in Australia, should be listed in the same or different chapters in the *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*.

YHV is an OIE notifiable pathogen, and chapter 4.1.3. in the *Diagnostic Manual for Aquatic Animal Diseases* describes yellowhead disease and the currently acceptable surveillance and diagnostic methods for YHV. The closely related viruses GAV/LOV (lymphoid organ virus), which have been reported from Australia in penaeid prawns after the discovery of YHV in South-East Asia, are noted briefly in the chapter on yellowhead disease. GAV has been reported in the scientific literature as being a serious pathogen in the culture of *P. monodon* in Australia. Recently, Australian scientists have reported that GAV and LOV are the same virus, and have suggested to discontinue to refer to LOV as a non-pathogenic strain of GAV.

Authorities on GAV and YHV have recently proposed that these closely related yet distinct viruses are members of the 'yellowhead virus complex'. Because YHV and GAV are morphologically indistinguishable, cause clinically similar disease in *P. monodon*, and are genetically similar, the Commission agreed to recommend to the OIE General Session that GAV and YHV be treated as similar agents in the same chapters on the yellowhead complex in the *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*. This will require revision of these chapters.

This is not a unique situation in the OIE *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*. Chapter 4.2.2. Nuclear Polyhedrosis Baculoviroses (*Baculovirus penaei* and *Penaeus monodon*-type baculovirus) provides an example where two distinctly different yet closely related pathogens that cause similar disease in infected host species are considered in the same chapter. Another example is Chapter 2.2.8. (New World and Old World Screwworm) in the *International Animal Health Code* and *Manual of Standards for Diagnostic Tests and Vaccines* where closely related but distinctly different agents are considered in the same chapter.

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

3.1. Proposed changes to the *International Aquatic Animal Health Code* including chapter on import risk analysis

The draft chapter on risk analysis prepared by Dr S. MacDiarmid had been appended to the report of the September 2000 meeting. Member Countries reviewed it and proposed further adjustments to fit with aquatic animal diseases specificity. Drs F. Berthe and C. Michel were asked to consider these comments and prepare an amended version of the text to support general discussion and detailed examination by the Commission. The newly amended chapter is found at Appendix IV and will be submitted to the International Committee at the General Session in May 2001 for approval. Preparation of the zoning and regionalisation chapter, which will require further consultations and discussions, is delayed until complete agreement on the concepts has been reached.

3.2. Categorisation of diseases

Dr E.-M. Bernoth introduced this subject by presenting a draft questionnaire previously circulated within the FDC. The purpose of the questionnaire – which is to be sent out to OIE Member Countries – is to gain wider input into improvements to the current categorisation criteria used, with the view to better reflect the global situation regarding the aquatic animal diseases listed by the OIE.

The current standards support disease notification as well as health certification: for *Diseases Notifiable to the OIE*, notification requirements are detailed in the *International Aquatic Animal Health Code*, however, there is currently no mechanism to gather official data on the *Other Significant Diseases*. FDC Members viewed this as a gap in the information gathering and disseminating function of the OIE.

Regarding health certification, the *International Aquatic Animal Health Code* recommends for *Diseases Notifiable to the OIE*, that importing countries should require *an International Aquatic Animal Health Certificate*, whereas it suggests that for *Other Significant Diseases*, countries may wish to require such certification.

FDC Members felt that the concept of two disease lists may not be the only option for the future, especially if disease status data on all listed diseases are sought.

The FDC endorsed the draft letter and questionnaire and agreed that they be circulated to OIE Member Countries, requesting replies by 1 August 2001 in time for consideration at the next FDC meeting.

The FDC also noted that deliberations on aquatic animal diseases are currently taking place within the European Commission and will consider the results of those discussions.

3.3. Contingency planning – extension of existing chapter

The existing chapter on contingency planning was approved at the last OIE General Session, and after brief discussion, the FDC decided that there was no need to extend the existing paper at the present time. However, as the FDC intended to provide more details in the chapter for the fourth edition of the *International Aquatic Animal Health Code*, the Commission will seek advice on this topic from the OIE Member Countries.

3.4. Fallowing of sites

The President of the FDC had prepared a draft chapter and a definition of fallowing for aquaculture establishments. There was general agreement that the principles of fallowing are an important tool for improving disease control on a given site. However, the practice cannot be applied equally to all aquaculture situations.

The topic was discussed thoroughly and it was decided that FDC Members should supply written proposals for amendments to the draft chapter to Prof. Håstein by no later than 1 June 2001. An amended draft chapter will be prepared taking into account these comments. The FDC will discuss this new draft at length at its meeting in September.

3.5. Listing of pathogens rather than disease names

Dr Berthe questioned the appropriateness of using disease names as opposed to pathogen names for the listed mollusc diseases. Clinical disease is only one form of manifestation of an infection with a pathogen. The OIE aims to limit the spread of pathogens because they have the potential to cause disease. Thus, it may appear more accurate to list pathogens rather than diseases. Also, some animal species may serve as carriers of pathogens without ever establishing clinical disease. The example of molluscs was used to discuss this point. In addition, the use of genus name (e.g. *Marteilia*) to designate the disease (i.e. marteiliosis) may not always be appropriate because not all species of a genus (i.e. *Marteilia*) cause diseases of concern. The FDC agreed to use disease names followed by pathogen name in brackets for all appropriate listed diseases of aquatic animals (see Appendix V).

3.6. Streptococcosis/Lactococcosis

Little new information has been recorded on distribution of streptococcosis in fish since the last FDC meeting, but data collected from several sources confirm that for the present there is insufficient justification for this disease and its agent to be added to the OIE lists. *Streptococcus iniae* is a tropical and subtropical agent which is probably widely distributed, and clinical impact on farmed and wild fish is associated with environmental and husbandry factors. The disease has caused some concern because it can cause infections in susceptible human beings. This does not appear more critical than infections with certain other fish-borne agents (*Mycobacteria* and *Vibrio* species).

Although *Lactococcus garvieae* has caused serious disease in some affected fish farms, and has probably increased significantly its geographical distribution through active trade exchanges in recent years, it does not seem to have the potential to spread much further. Moreover, vaccination trials are presently in progress to protect fish against these two forms of bacterial disease and these could result in positive control methods in the near future. It was decided to delay a decision on listing of these diseases for the present.

3.7. Consistency throughout articles in the health certificates

The FDC closely scrutinised the current five model health certificates, and changes made are reflected in Appendix VI to this report.

The FDC also examined the Articles in the *International Aquatic Animal Health Code* chapters that make reference to the model aquatic animal health certificates. Editorial changes were made to these Articles in accordance with changes to the model certificates. These changes are required throughout the chapters on diseases notifiable to the OIE and are reflected in Appendix VII to this report.

Furthermore, the FDC noted a lack of clarity in the wording of Articles 2.1.X.8. and 4.1.X.8., dealing with trade in dead fish and crustaceans, respectively, and the use of a health certificate in such trade. The current wording leaves room for an importing country to request a health certificate regardless of its own health status, which is in contrast to the guidelines for live fish and crustacean imports. The FDC will be guided in resolving this issue by the International Animal Health Code Commission in the context of more fundamental discussions on consistency between the *International Aquatic Animal Health Code* and the *International Animal Health Code* (see Agenda Item 2.1.).

4. Future amendments to the *Diagnostic Manual for Aquatic Animal diseases*

4.1. Approval of new or improved diagnostic methods for aquatic animal diseases

The question of approval of new or improved diagnostic methods for aquatic animal diseases was discussed at length. It was agreed that it would be important to have information on new or improved methods as soon as possible in order to provide an update of the chapters in the *Diagnostic Manual for Aquatic Animal Diseases* for approval at the OIE General Session. The FDC recommends that the *Diagnostic Manual for Aquatic Animal Diseases* should be made available in electronic form as is currently the case for the *International Aquatic Animal Health Code* on the OIE Web site and requested the Central Bureau to implement this recommendation. It was agreed that it would be beneficial to have a more rapid method for updating the existing methods and introducing new diagnostic techniques in the *Diagnostic Manual for Aquatic Animal Diseases*. It was decided that the Central Bureau should write to the authors of the specific disease chapters (the designated experts at the relevant OIE Reference Laboratory) to ask whether they could recommend any improvements to the current methods. The FDC agreed that this should be done annually to allow consideration of any proposals at the following FDC meeting. When an updated chapter has been approved by the OIE International Committee, information on the update(s) will be placed on the FDC home page and will be incorporated and noted on the Web site version of the *Diagnostic Manual for Aquatic Animal Diseases.*

4.2. Sampling schedules and numbers (general information chapters)

The FDC noted that sampling procedures as described in the *Diagnostic Manual for Aquatic Animal Diseases* are increasingly being questioned. Issues of concern to OIE Member Countries include, for example, whether it is justified in all cases to require continued targeted active surveillance once freedom from a disease has been established.

FDC Members discussed this particular issue at length and agreed that maintenance of a free status should rather be reached by a combination of testing and biosecurity measures. If, at one end of the scale, previous sampling and testing have established freedom from the disease, biosecurity measures are in place to safeguard against introduction, and a surveillance system ensures that suspicion of disease is immediately investigated, then continued targeted active surveillance (in the absence of disease suspicion) could cease. The resources thus freed could usefully be transferred to higher priority areas of aquatic animal health.

At the other end of the scale, i.e. in the absence of sufficient biosecurity measures, targeted active surveillance would have to continue to maintain a disease free status. In such cases, the statistical basis for dropping to lower sample numbers (as currently suggested in the *Diagnostic Manual for Aquatic Animal Diseases* for fish diseases in Chapter I.1.) will need to be reconsidered.

Another issue discussed was whether it is justified to request sampling and testing of all species susceptible to a particular disease, as currently stipulated in the *Diagnostic Manual for Aquatic Animal Diseases* for fish diseases (Chapter I.1.). FDC Members felt that sampling and testing the most susceptible species would present a better use of resources, but that a grading of species for susceptibility would be required for each disease.

The FDC concluded that a more in-depth review of the pertinent chapters is required. Drs Bernoth and Hill agreed to draft a new sampling chapter for fish, and Drs Lightner and Berthe agreed to prepare the chapters for crustaceans and molluscs, respectively. The FDC will review these drafts at their next meeting in September 2001.

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

5.1. Issue of labelling of actual country of origin in international trade for shipments of dead crustaceans

The issue of indicating on International Aquatic Animal Health Certificates the actual country of origin for shipments of dead crustaceans was discussed by the Commission. For example, it was noted that frozen crustacean products harvested and exported from country A to country B may be shipped from country B to country C for value-added processing and then re-imported by country B for domestic distribution and marketing. In this example, the competent authorities of country C may be provided with documents indicating country B as the source of the consignment and be unaware that country A was the actual country where the dead crustacean product was cultured and harvested. It was further noted by the Commission that the status of OIE notifiable and listed pathogens in countries A, B, and C may differ, and that country C may wish to have protection from the notifiable diseases likely to be present in crustaceans from country A. Therefore, the Commission agreed to recommend to the OIE International Committee that the International Aquatic Animal Certificate for Dead Crustaceans (Model Certificate No. 5, pp. 150 –151 in the *International Aquatic Animal Health Code*, third Edition, 2000) be amended to require exporters to indicate the actual place of harvest of the dead crustaceans if it is different from the country of origin of the consignment (see also Appendix VI).

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

6.1. Representation at international meetings and workshops

Dr Berthe attended the annual conference of the World Aquaculture Society (WAS) from 21 to 25 January 2001 in Orlando, Florida, United States of America. A special session was devoted to *Perkinsus* spp., causative agents of perkinsosis of molluscs.

6.2. Publications – status of diagnostic cards for listed diseases

All cards except one have been completed (a total of 28) and will be sent out together with the FDC report.

6.3. Annual reports of Reference Laboratories

Reports had been received from 17/20 Reference Laboratories. The Commission commented once again on the impressive range of activities by the Reference Laboratories towards the objectives of the OIE, and the continuing support provided by individual experts to the work of the Fish Diseases Commission. A small number of annual reports for 2000 have not been received so far and a reminder letter will be sent to those concerned.

The full set of reports will be supplied to Member Countries and to all the Reference Laboratories and Collaborating Centres. The international activities relevant to the work of the OIE are summarised below:

	International activities	Percentage of Laboratories carrying out these activities
(a)	Diagnostic testing	95%
(b)	Production/testing/distribution of diagnostic reagents	90%
(c)	Research	95%
(d)	International harmonisation/standardisation of methods	35%
(e)	Preparation and supply of international reference standards	70%
(f)	Collection, analysis and dissemination of epizootiological data	35%
(g)	Provision of consultant expertise	75%
(h)	Provision of scientific and technical training	65%
(i)	Organisation of international scientific meetings	15%
(j)	Participation in international collaborative studies	55%
(k)	Publications	90%

7. Any other business

7.1. Cooperation and partnership with other international organisations

A letter from NACA[2] sent to the Director General of OIE was circulated. The letter acknowledges the technical support provided by the OIE and the FDC to the joint FAO[3]/NACA/OIE Asia Regional Programme of Aquatic Animal Health Management, which was successful in developing the 'Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy'. These Technical Guidelines were adopted in principle by 21 participating governments in the Asian region in July 2000. The letter affirmed that the collaborative efforts between NACA, FAO, and OIE helped in laying an important foundation for the future improvement of aquatic animal disease control in the Asia-Pacific region. NACA hopes that the collaboration could be further strengthened, in particular, towards efforts in assisting the regional countries on implementing the provisions given in the Technical Guidelines.

In the letter, NACA also informed the OIE that an Asia-Pacific Regional Advisory Group on Aquatic Animal Health would be established and a small preparatory expert meeting is scheduled for July/August 2001 in Bangkok. NACA invites OIE representative (FDC or the Regional Representation for Asia-Pacific) to participate in the meeting. It was agreed that FDC should participate in this important regional initiative, and OIE will send a reply to NACA on the issue in due course.

A communication received by the President of the FDC from Dr Y. Inui of the SEAFDEC[4] Aquaculture Department was discussed. Dr Inui invited two FDC Members to participate in the proposed Regional Workshop on Disease Control in Fish and Shrimp Aquaculture in South-East Asia – Diagnosis and Husbandry Techniques, to be held in Iloilo, Philippines, in December 2001. While acknowledging the importance of FDC participation in the proposed workshop, the Commission is of the opinion that there should be a clear benefit to OIE of such participation, especially if the expenses are to be met by the OIE. The Commission also noted that it is more cost effective and beneficial to the Member Countries if major regional agencies and organisations involved in aquatic animals health management issues collaborate closely in such activities. The President of the Commission will communicate with Dr Inui requesting more information and a formal invitation to OIE.

2 Network of Aquaculture Centers in Asia-Pacific
3 Food and Agriculture Organization of the United Nations
4 South-East Asia Fisheries Development Centre

Dr R. Subasinghe presented to the Commission the importance and benefits of closer collaboration of FDC, FAO Fisheries Department and other relevant regional/national institutions and organisation in achieving the objectives of the *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*. He elaborated that there is a need to examine the provisions of the *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases* with respect to their compliance in different regions and countries under different circumstances (infrastructure, socio-economic, human capacity, etc.). Need for regional and national level awareness building on the provisions of the *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*, assistance to Member Countries on implementation/compliance with the *International Aquatic Animal Health Code's* provisions, harmonisation of FDC activities with various regional initiatives and activities - particularly Asia Regional Aquatic Animal Disease Reporting activities, were also mentioned. Dr Subasinghe informed the FDC that a meeting between OIE and FAO is being planned in June/July 2001 in Rome, to discuss the issues on collaboration between the two agencies. He will communicate with the OIE and FDC in due course on the meeting arrangements.

7.2. Status of FDC Internet activities

Ms Caroline Malotaux, OIE Information Systems Correspondent, joined the meeting to explain progress in developing the FDC Web pages. A prototype version had been sent to Prof. Hill for comment, and his suggested amendments are being incorporated. During an on-line demonstration of the pages via the Internet, the FDC discussed possible further improvements and requested the Central Bureau to make some changes. The FDC page will be ready to go on-line soon after these changes have been incorporated.

7.3. Status of booklet on OIE International Conference on Risk Analysis in Aquatic Animal Health

Ms Gill Dilmitis, Head of the OIE Publications Department, gave a status report on the Proceedings of the Risk Analysis Conference. Several authors and rapporteurs did not send their texts on time, so that editing work was delayed. All but one paper is now available, eight papers out of 54 are ready for printing. It is hoped that work will be completed by June 2001. Based on previous sales of aquatic animal health publications, the FDC anticipate strong demand.

7.4. Status of Collaborating Centre database

Prof. Hill gave an update on attempts to resolve the problem of obtaining copyright clearance for the electronic abstracts in the International Database on Aquatic Animal Diseases. The copyright holder, an electronic abstracting company in the United States of America, had not responded to three communications explaining the public service purpose of the database and requesting permission for retaining the abstracts when the database is made available publicly on-line via the internet. Prof. Hill suggested that a letter to the company from the OIE Director General may help to resolve this impasse. If permission is not forthcoming, Prof. Hill has obtained funding for having all the abstracts paraphrased to avoid the copyright issue. It is envisaged that the database will be available on-line via the FDC Web page by the end of March 2001.

7.5. Listing of amphibian diseases

The FDC discussed a request received by a Member of the OIE Working Group on Wildlife Diseases to consider the listing by the OIE of two newly emerging diseases of amphibians, namely amphibian chytridiomycosis (caused by the fungus *Batrachochytrium dendrobatidis*) and infections with ranaviruses. The FDC felt that it was premature to list these diseases; on the evidence presented, it is unclear whether they have implications for international trade in frogs and thus fall within the remit of the FDC.

7.6 Date of the next Fish Diseases Commission meeting

The FDC agreed to hold its next meeting from 17 to 19 September 2001.

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REPORT OF THE MEETING OF THE OIE FISH DISEASES COMMISSION

Paris, 12–15 February 2001

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Agenda

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

1.1. Schedule for preparation of Fourth Edition of the *International Aquatic Animal Health Code*
1.2. Schedule for preparation of Fourth Edition of the *Diagnostic Manual for Aquatic Animal Diseases*

2. Discrepancies between the *International Aquatic Animal Health Code* and *International Animal Health Code*

2.1. Measures required by importing countries – *Code* recommendations and the SPS Agreement (e.g. health status of importing country)
2.3. Link between category of disease and requirements for health certification
2.3. Measures applicable for emerging diseases
2.4. Testing for absence of pathogen versus absence of disease
2.5. Need for active surveillance versus passive surveillance
2.6. Application for OIE official recognition of freedom from disease for countries or zones, including 'provisional freedom'
2.7. How to list diseases with closely related agents (Asian YHV and Australian GAV)

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

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3.2. Categorisation of diseases
3.3. Contingency planning – extension of existing chapter
3.4. Fallowing of sites
3.5. Listing of pathogens rather than disease names
3.6. Streptococcosis/Lactococcosis
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4. Future amendments to the *Diagnostic Manual for Aquatic Animal diseases*

4.1. Approval of new or improved diagnostic methods for aquatic animal diseases
4.2. Sampling schedules and numbers (general information chapters)

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

5.1. Issue of labelling of actual country of origin in international trade for shipments of dead crustaceans

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

6.1. Representation at international meetings and workshops
6.2. Publications – status of diagnostic cards for listed diseases
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7. Any other business

7.1. Cooperation and partnership with other international organisations
7.2. Status of FDC Internet activities
7.3. Status of booklet on OIE International Conference on Risk Analysis in Aquatic Animal Health
7.4. Status of Collaborating Centre database
7.5. Listing of amphibian diseases
7.6 Date of the next Fish Diseases Commission meeting

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OF THE OIE FISH DISEASES COMMISSION
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Timetable for preparation of the fourth editions of the OIE *International Aquatic Animal Health Code* and OIE *Diagnostic Manual for Aquatic Animal Diseases* by the Fish Diseases Commission 2001–2003

Time	Meetings and important dates, etc.	Tasks
February 2001	Fish Diseases Commission (FDC) meeting	Review *International Aquatic Animal Health Code* (the *Code*)
March 2001	Letter to Reference Laboratories	Ask experts to review the chapters for the fourth edition of the *Diagnostic Manual for Aquatic Animal Diseases* (the *Manual*).
March 2001	Send to OIE Delegates for comment: Annual report of FDC meeting (including proposed changes to the *Code*)	
May 2001	OIE General Session	Ask for approval of: • FDC reports • *Code* updates
December 2001	Reference Experts' deadline	Receive *Manual* chapter updates
January 2002	FDC meeting	Review updated *Manual* chapters
February 2002	Send to OIE Delegates for comment: Annual report of FDC meeting (including any proposed changes to the *Code*) and updated *Manual* chapters	
September 2002	FDC meeting	Review Member Country comments on *Manual* chapters. Make appropriate changes
January 2003	FDC meeting	Finalisation *Code* and *Manual* chapters
May 2003	OIE General Session	Ask for approval of *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*
June/July 2003	Print the fourth editions of the *Code* and *Manual*	

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*.

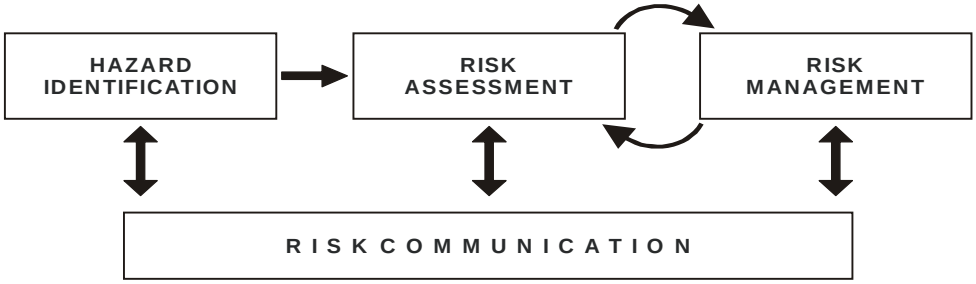
The principal aim of import risk analysis is to provide *importing countries* with an objective and defensible method of assessing the disease risks associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, *biological products* and *pathological material*. The 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 encourages [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 texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to risk assessment and to a consistent approach of risk management. [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 encourages [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.

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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.]

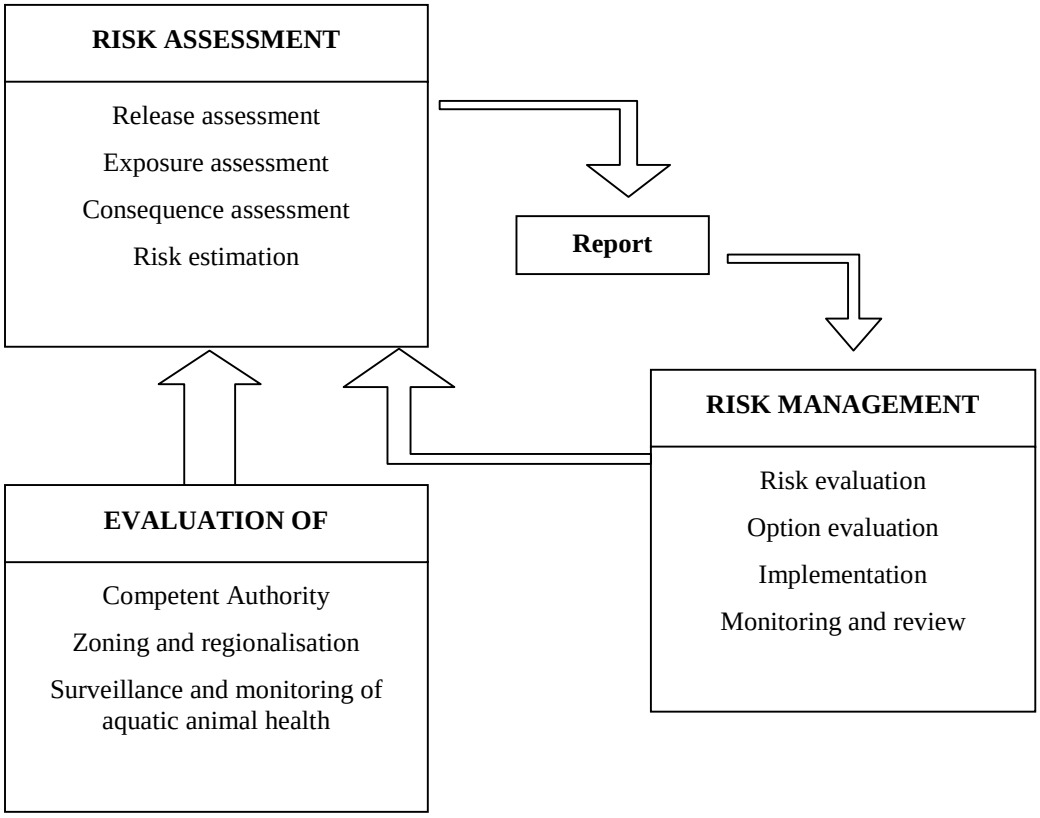
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available,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

1.[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.

2.[3] Both qualitative and quantitative risk assessment methods are valid, although quantitative analysis is recognised to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited as is often the case with aquatic species. [Indeed, every risk assessment must first be carried out qualitatively. A qualitative 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.]

3.[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.

4.[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.

5.[6] Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.

6.[7] Risk increases with increasing volume of *commodity* imported.

7.[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.]

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

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 or other recommendations of the SPS Agreement. [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.

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[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 staff
- 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.]

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List of diseases included in the *International Aquatic Animal Health Code*

Part 2: Diseases of Fish

Section 2.1. Diseases Notifiable to the OIE

2.1.1. Epizootic haematopoietic necrosis
2.1.2. Infectious haematopoietic necrosis
2.1.3. *Oncorhynchus masou* virus
2.1.4. Spring viraemia of carp
2.1.5. Viral haemorrhagic septicaemia

Section 2.2. Other Significant Diseases

2.2.1. Channel catfish virus disease
2.2.2. Viral encephalopathy and retinopathy
2.2.3. Infectious pancreatic necrosis
2.2.4. Infectious salmon anaemia
2.2.5. Epizootic ulcerative syndrome
2.2.6. Bacterial kidney disease *(Renibacterium salmoninarum)*
2.2.7. Enteric septicaemia of catfish *(Edwardsiella ictaluri)*
2.2.8. Piscirickettsiosis *(Piscirickettsia salmonis)*
2.2.9. Gyrodactylosis *(Gyrodactylus salaris)*
2.2.10. Red sea bream iridoviral disease
2.2.11. White sturgeon iridoviral disease

Part 3: Diseases of Molluscs

Section 3.1. Diseases Notifiable to the OIE

3.1.1. Bonamiosis *(Bonamia ostreae, B. sp.)*
3.1.2. Haplosporidiosis *(Haplosporidium costale, H. nelsoni)*
3.1.3. Marteiliosis *(Marteilia refringens, M. sydneyi)*
3.1.4. Mikrocytosis *(Mikrocytos mackini, M. roughleyi)*
3.1.5. Perkinsosis *(Perkinsus marinus, P. olseni)*

Part 4: Diseases of Crustaceans

Section 4.1. Diseases Notifiable to the OIE

4.1.1. Taura syndrome
4.1.2. White spot disease
4.1.3. Yellowhead disease

Section 4.2. Other Significant Diseases

4.2.1. Baculoviral midgut gland necrosis
4.2.2. Nuclear polyhedrosis baculoviroses
(*Baculovirus penaei* and *Penaeus monodon*-type baculovirus)
4.2.3. Infectious hypodermal and haematopoietic necrosis
4.2.4. Crayfish plague *(Aphanomyces astaci)*
4.2.5. Spawner-isolated mortality virus disease

Model Certificate No. 1

INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATE FOR LIVE FISH AND GAMETES

LIVE FISH AND GAMETES

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

I. Identification

❑ Cultured stocks ❑ Wild stocks ❑ Fish ❑ Sperm ❑ Unfertilised eggs
❑ Fertilised eggs ❑ Larvae

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

2) Age (years): ❑ Unknown ❑ 0+ ❑ 1+ ❑ 2+ ❑>2+

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

II. Place of production [Origin]

1) Country:.....

2) Zone:.....

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

III. Destination

1) Country:.....

2) Zone:.....

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

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

[IV. National fish health status

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

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Epizootic haematopoietic necrosis						
Infectious haematopoietic necrosis						
Oncorhynchus masou virus disease						
Spring viraemia of carp						
Viral haemorrhagic septicaemia						
Other serious diseases (to be specified)						

IV [V]. Declaration

I, the undersigned, certify that the live fish and/or fish larvae, fish gametes, ova and fertilised eggs in the present consignment have as their place of production [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 is officially recognised as being free from the pathogens causing the diseases listed in the *Code*, as identified in the table below [Part IV above].

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Epizootic haematopoietic necrosis						
Infectious haematopoietic necrosis						
Oncorhynchus masou virus disease						
Spring viraemia of carp						
Viral haemorrhagic septicaemia						
And any of the following if required by the importing country						
Channel catfish virus disease						
Viral encephalopathy and retinopathy						
Infectious pancreatic necrosis						
Infectious salmon anaemia						
Epizootic ulcerative syndrome						
Bacterial kidney disease *(Renibacterium salmoninarum)*						
Enteric septicaemia of catfish *(Edwardsiella ictaluri)*						
Piscirickettsiosis *(Piscirickettsia salmonis)*						
Gyrodactylosis *(Gyrodactylus salaris)*						
Red sea bream iridoviral disease						
White sturgeon iridoviral disease						

[In addition:

❑ no unexplained mortality has been observed during the three months prior to shipment

❑ no other diseases/pathogens have been detected

OR

the following diseases/pathogens have been detected during the past two years (give dates):
.....
.....]

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

Stamp:

Date:.....
Issued at:.....
Name and address of Certifying Official [Health Inspector]:
.....
.....
.....

Signature:.....

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

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Model Certificate No. 2

INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATE FOR DEAD UNEVISCERATED FISH

DEAD UNEVISCERATED FISH

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 (years): ❑ Unknown ❑ 0+ ❑ 1+ ❑ 2+ ❑>2+

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

II. Place of production [Origin]

1) Country:.....

2) Zone:.....

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

III. Destination

1) Country:.....

2) Zone:.....

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

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

[IV. National fish health status

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

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Epizootic haematopoietic necrosis						
Infectious haematopoietic necrosis						
Oncorhynchus masou virus disease						
Spring viraemia of carp						
Viral haemorrhagic septicaemia						
Other serious diseases (to be specified)						

IV [V]. Declaration

I, the undersigned, certify that the dead fish and/or fish products in the present consignment, have as their place of production [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 is officially recognised as being free from the pathogens causing the diseases listed in the *Code*, as identified in the table below [which has been recognised to be free from the above diseases].

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Epizootic haematopoietic necrosis						
Infectious haematopoietic necrosis						
Oncorhynchus masou virus disease						
Spring viraemia of carp						
Viral haemorrhagic septicaemia						
And any of the following if required by the importing country						
Channel catfish virus disease						
Viral encephalopathy and retinopathy						
Infectious pancreatic necrosis						
Infectious salmon anaemia						
Epizootic ulcerative syndrome						
Bacterial kidney disease *(Renibacterium salmoninarum)*						
Enteric septicaemia of catfish *(Edwardsiella ictaluri)*						
Piscirickettsiosis *(Piscirickettsia salmonis)*						
Gyrodactylosis *(Gyrodactylus salaris)*						
Red sea bream iridoviral disease						
White sturgeon iridoviral disease						

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

Stamp:

Date:.....
Issued at:.....
Name and address of Certifying Official [Health Inspector]:
.....
.....
.....

Signature:.....

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Model Certificate No. 3

INTERNATIONAL AQUATIC ANIMAL 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):.....

II. Origin of consignment

1) Country:.....

2) Zone:.....

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

III. Place of harvest (if different from II)

1) Country:.....

2) Zone:.....

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

IV [III]. Destination

1) Country:.....

2) Zone:.....

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

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

[IV. National mollusc health status

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

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Bonamia ostreae						
Bonamia sp.						
Haplosporidium costale						
Haplosporidium nelsoni						
Marteilia refringens						
Marteilia sydneyi						
Mikrocytos mackini						
Mikrocytos roughleyi						
Perkinsus marinus						
Perkinsus olseni						
Other serious diseases (to be specified)]						

IV [V]. Declaration

I, the undersigned, certify that the live molluscs 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 is officially recognised as being free from the pathogens causing the diseases listed in the *Code*, as identified in the table below [Section IV above].

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Bonamia ostreae						
Bonamia sp.						
Haplosporidium costale						
Haplosporidium nelsoni						
Marteilia refringens						
Marteilia sydneyi						
Mikrocytos mackini						
Mikrocytos roughleyi						
Perkinsus marinus						
Perkinsus olseni						

[In addition:

❑ no other pathogens have been detected

OR

the following pathogens have been detected during the past two years (give dates):

.....
.....

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

Stamp:

Date:.....
Issued at:.....
Name and address of Certifying Official [Health Inspector]:
.....
.....
.....

Signature:.....

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

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Model Certificate No. 4

INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATE FOR LIVE CRUSTACEANS

LIVE 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) Age: ❑ Fertilised eggs or nauplii ❑ Postlarvae ❑ Juveniles ❑ Broodstock

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

II. Place of harvest [Origin]

1) Country:.....

2) Zone:.....

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

III. Origin of consignment if different from II

1) Country:.....

2) Zone:.....

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

IV [III]. Destination

1) Country:.....

2) Zone:.....

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

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

[IV. National crustacean health status

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

	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 live crustaceans 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 Sections II and III above is officially recognised as being free from the diseases identified in the table below [Part IV above].

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Taura syndrome						
White spot disease						
Yellowhead disease						
And any of the following if required by the importing country						
Baculoviral midgut gland necrosis						
Nuclear polyhedrosis baculoviroses (*Baculovirus penaei* and *Penaeus monodon*-type baculovirus)						
Infectious hypodermal and haematopoietic necrosis						
Crayfish plague *(Aphanomyces astaci)*						
Spawner-isolated mortality virus disease						

[In addition:

❑ no unexplained mortality has been observed during the three months prior to shipment

❑ no other diseases/pathogens have been detected

OR

the following diseases/pathogens have been detected during the past two years (give dates):
.....
.....

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

Stamp:

Date:.....
Issued at:.....
Name and address of Certifying Official [Health Inspector]:
.....
.....
.....

Signature:.....

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

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Model Certificate No. 5.

INTERNATIONAL AQUATIC ANIMAL 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
❑ Block frozen ❑ Individually quick frozen ❑ Other processing method

II. Place of harvest [Origin]

1) Country:.....

2) Zone:.....

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

III. Origin of consignment if different from II

1) Country:.....

2) Zone:.....

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

IV [III]. Destination

1) Country:.....

2) Zone:.....

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

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 country, zone or aquaculture establishment from which the crustaceans were harvested considered to be free from:]

	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 in the present consignment have as their place of harvest 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 Sections II and III above is officially recognised as being free from the diseases identified in the table below [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 the table below [Part IV above].

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Taura syndrome						
White spot disease						
Yellowhead disease						
And any of the following if required by the importing country						
Baculoviral midgut gland necrosis						
Nuclear polyhedrosis baculoviroses (*Baculovirus penaei* and *Penaeus monodon*-type baculovirus)						
Infectious hypodermal and haematopoietic necrosis						
Crayfish plague *(Aphanomyces astaci)*						
Spawner-isolated mortality virus disease						

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

Stamp:

Date:.....
Issued at:.....
Name and address of Certifying Official [Health Inspector]:
.....
.....
.....

Signature:.....

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

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CHAPTER 2.1.X.

NOTIFIABLE DISEASES OF FISH

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Article 2.1.X.6.

When importing live *fish* of any *susceptible species*, or their *sexual products* (*eggs* and *gametes*), the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official fish health *surveillance* scheme comprising inspection and laboratory tests on *susceptible species* conducted according to the procedures described in the *Manual*, whether or not the place of production of the consignment [originates from] is a country officially declared DISEASE free.

If the place of production of the consignment is not a country [of origin is not] officially declared DISEASE free, the certificate must state whether the place of production of the consignment [originates] is:

1. [from] a zone officially declared DISEASE free, or

2. [from] an *aquaculture establishment* officially declared DISEASE free.

The certificate shall be in accordance with Model Certificate No. 1 given in Part 6 of this *Code*.

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Article 2.1.X.8.

The *Competent Authorities* in countries officially declared DISEASE free should demand that dead *fish* for importation from countries not free from DISEASE be *eviscerated* before transit.

In general, the *Competent Authority* of a country importing uneviscerated dead *fish* should require that the consignment be accompanied by an *international aquatic animal health certificate*, conforming to the Model Certificate No. 2, issued by the *Competent Authority* in the country of origin.

This certificate should declare the health status of the place of production [country] in respect of DISEASE and the other *fish diseases* listed in this *Code*.

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CHAPTER 3.1.X.

NOTIFIABLE DISEASES OF MOLLUSCS

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Article 3.1.X.6.

When importing live *molluscs* of all age groups of any susceptible host species for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country.*

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual*, whether or not the place of harvest of the consignment [originates from] is a country officially declared DISEASE free.

If the place of harvest of the consignment is not a country [of origin is not] officially declared DISEASE free, the certificate must state whether the place of harvest of the consignment [originates] is:

1. [from] a zone officially declared DISEASE free, or

2. [from] an *aquaculture establishment* officially declared DISEASE free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

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Article 3.1.X.8.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* listed as DISEASE NAME susceptible host species have as their place of harvest [originate from either] a country, a zone or an *aquaculture establishment* free from DISEASE .

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* listed as susceptible host species originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

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CHAPTER 4.1.X.

NOTIFIABLE DISEASES OF CRUSTACEANS

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Article 4.1.X.6.

When importing live *crustaceans* (fertilised eggs/nauplii, postlarvae, juveniles and/or broodstock) of any *susceptible species*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official crustacean health *surveillance* scheme comprising inspection and laboratory tests on *susceptible species* conducted according to the procedures described in the *Manual*, whether or not the whether or not the place of harvest of the consignment [originates from] is a country officially declared DISEASE free.

If the place of harvest of the consignment is not a country [of origin is not] officially declared DISEASE free, the certificate must state whether the place of harvest of the consignment [originates] is:

1. [from] a zone officially declared DISEASE free, or

2. [from] an *aquaculture establishment* officially declared DISEASE free.

The certificate shall be in accordance with Model Certificate No. 4 given in Part 6 of this *Code*.

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Article 4.1.X.8.

In general, the *Competent Authority* of a country importing dead *crustaceans* belonging to the susceptible host species listed in Article 4.1.X.1 and destined for 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 if these *crustaceans* are to be imported head on.

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

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