Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals (FWG 01/2002)

Report of the Joint
APEC/FAO/NACA/OIE/DOF – THAILAND/ INP/ CONAPESCA/SAGARPA Workshops
Bangkok, Thailand 1-6 April 2002 and Mazatlan, Sinaloa, Mexico 12-17 August 2002
Report prepared by:
J. Richard Arthur and M.G. Bondad-Reantaso (editors)

Network of Aquaculture Centres in Asia-Pacific (NACA)
Suraswadi Building, Department of Fisheries
Kasetsart University Campus
Ladyao, Jatujak, Bangkok, 10900, Thailand
Tel: + 66 2 561 1728 (to 29)
Fax: + 66 2 561 1727
E-mail: naca@enaca.org
Website: http://www.enaca.org

Report prepared for:

Asia-Pacific Economic Cooperation

APEC Secretariat
35 Heng Mui Keng Terrace
Singapore 119616
Tel: (65) 6775 6012 / Fax: (65) 6775 6013
E-mail: info@apec.org
Website: www.apec.org

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Network of Aquaculture Centres in Asia-Pacific (NACA)
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Department of Fisheries
Kasetsart University Campus
Ladyao, Jatujak
Bangkok, 10900
Thailand
Tel: + 66 2 561 1728 (to 29)
Fax: + 66 2 561 1727
E-mail: naca@enaca.org
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APEC Secretariat
35 Heng Mui Keng Terrace
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Tel: + 65 6775 6012
Fax: + 65 6775 6013
E-mail: info@mail.apecsec.org.sg
Website: http://www.apecsec.org.sg

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1 EXECUTIVE SUMMARY

The Asia-Pacific Economic Cooperation, Fisheries Working Group project APEC FWG 01/2002 "Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals", proposed in 2000 during the 12th Meeting of the APEC FWG, was successfully implemented in 2002-2004. This project is a follow-up of two recently concluded APEC FWG projects - 03/2000 "Joint APEC/FAO/NACA/SEMARNAP-Mexico Ad-Hoc Expert Consultation on Trans-boundary Aquatic Animal Pathogen Transfer and Development of Harmonised Standards on Aquaculture Health Management" and 02/2000 "Development of a Regional Research Programme on Grouper Virus Transmission and Vaccine Development". Both projects identified the need to build capacity and awareness on import risk analysis (IRA) for movement of aquatic animals in APEC economies. The objectives of the project are: (a) to organize the first Asia-Pacific/Americas training course/expert workshop on IRA for aquatic animals, (b) to develop a manual on IRA for aquatic animals, (c) to establish a network of people involved in conducting IRAs for aquatic animals, and (d) to facilitate exchange of experience and expertise on IRA.

The Department of Fisheries (DOF) of Thailand served as Project Overseer, with the Network of Aquaculture Centres in Asia-Pacific (NACA) (supported by three technical consultants) as project contractor/implementor. Three local government institutions in Mexico, the Instituto Nacional de la Pesca (INP), the Comisi□n Nacional de Acuacultura y Pesca (CONAPESCA) and the Secretaria de Agricultura, Ganader□a, Desarrollo Rural, Pesca y Alimentaci□n (SAGARPA), organized the training/workshop in Mazatlan, Mexico. A number of collaborating partner institutions supported the implementation of this project. The Office International des □pizooties (OIE) Regional Representation for Asia-Pacific (based in Tokyo, Japan) provided support for an IRA expert (at that time based in Switzerland). OIE also supported the participation of one Fish Diseases Commission (FDC) member and an FDC expert, and the Food and Agriculture Organization of the United Nations (FAO) provided support to representatives from 13 countries in Latin America, as well as translation services during the event in Mazatlan. A number of other regional institutions/organizations (e.g., the Mekong River Commission (MRC), the Secretariat of the Pacific Community (SPC), the Danish International Development Agency (DANIDA/SUMA-Vietnam), the Bangladesh Global Environment Facility (GEF) Project, Intervet Singapore, and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA)) also supported additional participants. APEC economies supported their own participants (e.g., Australia, Canada, Chinese Taipei, Hong Kong China, Japan, Korea RO and the United States of America), while NACA provided travel and subsistence support to seven NACA member governments.

The two training/workshops were successfully conducted in Bangkok, Thailand (1-6 April 2002) and Mazatlan, Mexico (12-17 August 2002). A total of 130 participants comprised of regulatory authorities, administrators and aquatic animal health specialists responsible for trade of live aquatic animals participated in the two training/workshops. The participants represented 37 countries in the Asia-Pacific (i.e., Australia, Bangladesh, Cambodia, Canada, China, Chinese Taipei, Hong Kong China, India, Indonesia, Japan, Korea RO, Malaysia, Myanmar, Nepal, New Zealand, Pakistan, Philippines, Singapore, Sri Lanka, Thailand and Vietnam) and the Americas (i.e., Belize, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru, the United States of America and Venezuela). These training/workshops not only provided a venue to raise awareness and enable better understanding of the concepts of IRA, they also fostered better communication between government representatives and aquatic animal health specialists on issues related to aquatic animal movement, and enhanced subregional, regional and international cooperation on issues related to aquaculture health and trade of aquatic animals.

The number of economies taking part in the two workshops and the participation of non-APEC economies, FAO and NACA member governments and collaborating partner organizations such as OIE, MRC, SPC, DANIDA, OIRSA and private-sector representatives demonstrate the great value of this APEC initiated activity and APEC's important role in supporting responsible aquaculture, trade and health management practices for better productivity, increased and stable contribution to food security, promotion of sustainable aquaculture and preservation of biodiversity.

This report, which contains 26 technical presentations, is divided into four parts: (a) Background for Risk Analysis, (b) The Risk Analysis Process, (c) Risk Analysis and the World Trade Organization: Country Experiences and (d) National Strategies for Aquatic Animal Health. Four annexes are also included containing the (a) Workshop Programs, (b) Lists of Participants, (c) Working Group Recommendations and (d) List of Acronyms and Abbreviations.

2 BACKGROUND TO THE PROJECT AND WORKSHOP

Background

During recent years, the Asia-Pacific Economic Cooperation (APEC) through its Fisheries Working Group (FWG) has intensified support to activities relating to aquatic animal health management in the Asia-Pacific.

The project APEC FWG 01/2002 "Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals" is a follow-up activity to one of the major recommendations of two recently concluded APEC FWG projects - 03/2000 "Joint APEC/FAO/NACA/SEMARNAP-Mexico Ad-Hoc Expert Consultation on Trans-boundary Aquatic Animal Pathogen Transfer and Development of Harmonised Standards on Aquaculture Health Management" (APEC/FAO/NACA/SEMARNAP 2001) and 02/2000 "Development of a Regional Research Programme on Grouper Virus Transmission and Vaccine Development" (APEC/AAHRI/FHS-AFS/NACA 2001). Both projects identified the need to build capacity and awareness on import risk analysis (IRA) for movement of aquatic animals in APEC economies.

A comprehensive "Puerto Vallarta Action Plan[1]" resulted from APEC FWG 03/2000, an expert consultation held in Puerto Vallarta, Jalisco, Mexico on 24-28 July 2000. The plan incorporated a wide range of recommendations for short, medium and long-term implementation to control the spread of serious aquatic animal pathogens, and was adopted by the 49 workshop participants representing 17 APEC economies and FAO and NACA member governments. One major emphasis was on the special need for capacity building on risk analysis, procedures for monitoring and disease surveillance, standardization and validation of diagnostics methods, extension services, and contingency planning for emergency disease situations. The recommendations considered an important role for APEC in capacity building and support for harmonization of aquatic animal health standards between member economies in the Asia-Pacific Region. The need for FAO, along with OIE, to promote broader international cooperation in aquatic animal health management, and a role for NACA in supporting further development of aquatic animal health capacity building within the Asia-Pacific Region were also recognized. The workshop requested that APEC support the implementation of the "Puerto Vallarta Action Plan" by developing suitable projects.

The second project, APEC FWG 02/2000 "Development of a Regional Research Programme on Grouper Virus Transmission and Vaccine Development", held in 18-20 October 2000 in Bangkok, Thailand and attended by 37 participants from 12 economies including representatives from the private sector, developed a "Regional Research Program on Grouper Health and Production" that strongly recommended two related subprojects on (a) development of regional standards, including establishment and harmonization of import/export protocols, health certificates and general health certification requirements and (b) import risk assessment processes and hazard identification, under Component 5 on Responsible Trans-boundary Movement of Live Groupers.

Both projects emphasized the importance of effective cooperation between countries within APEC, between states and the private sector, and within and between regions to harmonize aquatic animal health management measures and promote responsible trans-boundary movement of aquatic animals, ultimately contributing to improvements in the trade of aquatic animals and their products and to social and economic development through aquaculture.

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[1] APEC FWG 03/2000 "Joint APEC/FAO/NACA/SEMARNAP-Mexico Ad-Hoc Expert Consultation on Trans-boundary Aquatic Animal Pathogen Transfer and Development of Harmonised Standards on Aquaculture Health Management" was held in Puerto Vallarta, Jalisco, Mexico in July 24-28, 2000. It was hosted by the Government of Mexico and attended by participants from 17 APEC economies, FAO and NACA member countries.

Recognizing the importance of the recommendations from the two APEC FWG projects in realizing the APEC objectives for trade liberalization and sustainable development in APEC economies, this project was developed in 2001 and successfully implemented as a step forward in translating APEC project recommendations into national development policies. The project responds well to APEC priorities of strengthening and facilitating trade in aquatic animals and their products and improving public health and environmental protection in APEC member economies. Specifically, it addresses the following goals of the APEC FWG:

1) Promoting conservation, management and sustainable utilization of fisheries resources through expert workshops that will facilitate information exchange, policy development and formulation of recommendations and implementing on a regional basis broader global initiatives arising from the work of the FAO.
2) Assisting APEC in enabling economies to reap the benefits of trade and investment liberalization by undertaking and promoting sector-specific work relating to trade and investment liberalization and facilitation.
3) Assisting APEC in broadening its outreach to the business community and increasing the involvement of business in APEC development activities by taking a lead role in collaborating with other regional organizations and agencies within the Asia-Pacific Region to progress the FWG work program and broader APEC policy outcomes.
4) Assisting APEC's Economic and Technical Cooperation (ECOTECH) goals through activities that will promote sustainable and responsible management of both fisheries resources and aquaculture, develop human capital, enhance food safety and quality of fish and fisheries products, and safeguard the quality of life through environmentally sound growth.

After three years of consensus building and development, 21 countries in Asia (i.e., Australia, Bangladesh, Cambodia, China PR, Hong Kong China, India, Indonesia, Iran, Japan, Korea DPR, Korea RO, Lao PDR, Malaysia, Myanmar, Nepal, Pakistan, Philippines, Singapore, Sri Lanka, Thailand and Vietnam) in the Asia-Pacific adopted in principle the *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy*[2] (FAO/NACA 2000).

The **"**Technical Guidelines", developed through a consultative process and based on a set of 15 guiding principles, describe a number of health management measures aimed at minimizing the risk of disease spread via aquatic animal movements and were developed to:

a) Assist countries in the Asia-Pacific to move live aquatic animals in a way that minimizes the risks associated with pathogen transfer and disease spread, both within and across boundaries;
b) Enhance protection of the aquatic environment and biodiversity, as well as the interests of aquaculture and capture fisheries;
c) Provide a mechanism to facilitate trade in live aquatic species and avoid unjustifiable trade barriers based on aquatic animal health issues; and
d) Implement relevant provisions of FAO's Code of Conduct for Responsible Fisheries (CCRF) and other international treaties and agreements (e.g., the World Trade Organization's (WTO) Sanitary and Phytosanitary (SPS) Agreement applicable to the Asian Region.

One of the guiding principles used in the development of the Technical Guidelines was that *"the role of health management is to reduce the risks arising from the entry, establishment or spread of pathogens to a manageable level with the view to protecting animal, plant and human life. Health management should also protect living aquatic resources, the natural aquatic environment and aquatic biodiversity, as well as support the movement of aquatic animals and protect trade".* The Technical Guidelines were devel-

[2] The Technical Guidelines are one of the major outcomes of FAO Regional Technical Cooperation Project TCP/RAS 6714 and 9605 "Assistance for the Responsible Movement of Live Aquatic Animals" implemented by NACA in cooperation with the OIE and a number of regional bodies and institutes. The project, which involved the participation of 21 governments, commenced in 1998 and completed in 2001.

oped, among others, "*to provide a mechanism to facilitate trade in live aquatic species and avoid unjustifiable trade barriers based on aquatic animal health issues"*. The *Beijing Consensus and Implementation Strategy* indicated that because import risk analysis (IRA) is a new concept for many countries in the region, there is a need to build awareness among policy-makers and administrators, and the capacity to understand and implement risk analysis at national and regional levels. It strongly recommended effective partnership with APEC and other concerned regional and subregional bodies and organizations in assisting countries to effectively implement the Technical Guidelines.

The APEC project became an opportunity to assist economies in the implementation of the Technical Guidelines and to directly supported global and regional efforts on aquatic animal health management, such as:

- FAO's *Code of Conduct for Responsible Fisheries* (CCRF),
- WTO's Sanitary and Phytosanitary (SPS) Agreement,
- the Asia Regional Aquatic Animal Health Management Programme of NACA and its partners,
- the FAO/NACA/OIE Asia-Pacific Quarterly Aquatic Animal Disease Reporting System,
- the World Bank (WB)/World Wildlife Fund(WWF)/FAO/NACA Consortium on Shimp and Environment, and
- the Regional Technical Cooperation Programme (TCP) of FAO in the Americas "Assistance to Health Management in Shrimp Aquaculture in Americas, with Special Reference to Improving Post-larval Quality".

APEC's value stems from its important role in providing opportunities for assisting, building and improving countries' capacity to implement, monitor and evaluate the agreements reached at regional and international levels, particularly through assistance to APEC economies with very little resources or capability. APEC also plays a significant role in building subregional, regional and international cooperation through joint strategies/approaches, stressing complementarities and enhancing consultation and information exchange in order to effectively respond to the growing needs for aquatic animal health strategies in support of responsible aquaculture, trade and health management practices for better productivity, increased and stable contribution to food security, promotion of sustainable aquaculture and preservation of biodiversity.

The project provided a venue for relevant expert administrators and aquatic animal health scientists to be involved in an exercise that will enable them to interact and jointly frame common approaches and solutions to aquatic animal health problems, including development of an IRA manual for aquatic animals. The project also allowed different participating economies with varying levels of political and socio-economic development to exchange experiences, information and expertise in finding common approaches to an important issue through effective cooperation, consultation, and confidence and consensus-building activities.

Governments are the primary users of import risk analysis for the purpose of making and implementing import/export policy decisions based on international standards that affect international trade. The direct involvement of key expert government officials was critical to the success of the project in terms of ensuring awareness of, and support for, the process, both at a national level and with respect to IRA processes instigated by trading partners. The implementation of national quarantine policy is often complicated by practical considerations. The input of key expert officials was essential, and enabled the presentation of case studies regarding their national systems and experiences that provided valuable guidance in formulating and refining the IRA manual, and provision of expert input in order to ensure that the manual is a pragmatic document relevant to regulatory authorities.

The ultimate beneficiaries of the project are the business sectors and the rural farming communities. They will benefit from effective legislation and policies on aquatic animal health that will contribute to increasing aquaculture production through measures that will safeguard the livelihoods of farmers and the industry sector from disease incursions.

Project Purpose

The project's purpose was to strengthen and facilitate trade in aquaculture products in the APEC Region and improve public health protection in APEC economies through improving human capacity, standardizing approaches, and establishing networking that will facilitate exchange of information, experience and expertise. The specific objectives of the project are to:

- ***Organize the first Asia-Pacific/the Americas training courses and expert workshops on import risk analysis for aquatic animals*** to bring together regulatory authorities and administrators responsible for trade in live aquatic animals and aquatic animal health specialists to share experience, raise awareness, contribute to development of an IRA manual for aquatic animals and build capacity.
- ***Develop a manual on IRA for aquatic animals*** that will support economy IRAs and standardize approaches (by defining criteria, trade issues, and regional and international issues). This will enable harmonization of IRA procedures and processes, including health certification requirements for importation/exportation of aquatic animals across countries and regions and their implementation.
- ***Establish a network of people involved in conducting IRAs for aquatic animals*** in APEC economies that will further facilitate exchange of information of epidemiological and surveillance data on aquatic animal diseases having significance to trade of aquatic animals.
- ***Facilitate further exchanges of experience and expertise on IRA for aquatic animals*** between countries such as Australia, Japan, New Zealand and USA that have wide ranging experience in the conduct of IRA, and thereby assist and supplement the existing capacities of other APEC economies.

Project Development and Implementation

The project proposal, developed by the Thailand Department of Fisheries (DOF), with technical assistance from NACA, was presented during the APEC FWG 12th Meeting held in Hong Kong SAR China in May 2001. The project was approved, funding was secured and implementation commenced in January 2002. Dr. Maitree Duwangsawasdi of Thailand's DOF served as Project Overseer and NACA was the implementing agency. The project involves a training/workshop format held at two venues, the first in Asia (Bangkok, Thailand) and the second in Latin America (Mazatlan, Mexico). The second workshop was locally co-organized by the Instituto Nacional de la Pesca (INP), the Comisionado Nacional de Acuacultura y Pesca (CONAPESCA) and the Secretaria de Agricultura, Ganader□a, Dessarrollo Rural, Pesca y Alimentaci□n (SAGARPA). Regulatory authorities, administrators and aquatic animal health specialists and regional/global consultants and experts on risk analysis, epidemiology and aquatic animal health management provided the technical know-how for the training/workshop. A number of regional and international organizations and the private sector supported project implementation through provision of travel support to experts and participants. These include the Office International des Epizooties (OIE) Regional Representation for Asia-Pacific, the Mekong River Commission (MRC), the Secretariat of the Pacific Community (SPC), the Danish International Development Agency (DANIDA/SUMA), the Bangladesh Global Environment Facility (GEF) Project, Intervet Norbio, the Aquatic Animal Health Research Institute (AAHRI), FAO, OIE, and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

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FAO. 1995. Code of Conduct for Responsible Fisheries. Food and Agriculture Organization of the United Nations, Rome, 41 p.

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3 SUMMARY WORKSHOP REPORT

The First Training/Workshop was held from 1-6 April 2002 in Bangkok, Thailand and brought together a total of 59 regulatory authorities/administrators responsible for trade of live aquatic animals and aquatic animal health specialists (see Annex II(A)). Sixteen APEC economies (Australia, Canada, China, Hong Kong China, Chinese Taipei, Indonesia, Japan, Korea RO, Malaysia, Mexico, New Zealand, Philippines, Singapore, Thailand, United States of America and Vietnam) participated in this activity, with an additional representation from seven Asian governments (Bangladesh, Cambodia, India, Myanmar, Nepal, Pakistan and Sri Lanka) and representatives from regional and international organizations such as the Network of Aquaculture Centres in Asia-Pacific (NACA), the Office International des □pizooties (OIE) Regional Representation for Asia-Pacific, the Mekong River Commission (MRC), the Secretariat of the Pacific Community (SPC), the Danish International Development Agency (DANIDA/SUMA) and the Bangladesh Global Environment Facility (GEF) Project.

The Second Training/Workshop was held from 12-17 August 2002 in Mazatlan with the assistance of Mexican authorities (the Instituto Nacional de la Pesca (INP), the Comisionado Nacional de Acuacultura y Pesca (CONAPESCA), and the Secretaria de Agricultura, Ganader□a, Dessarrollo Rural, Pesca y Alimentaci□n (SAGARPA)), NACA, the Food and Agriculture Organization of the United Nations (FAO) and the OIE Fish Diseases Commission. Seventy-one regulatory authorities and administrators responsible for trade of live aquatic animals and aquatic animal health specialists came together to share experience, raise awareness, build capacity and contribute to the development of a practical manual for risk analysis in aquatic animal movements (see Annex II (B)). Delegates came from five APEC economies in the Americas (Canada, Chile, Mexico, Peru and USA) and two economies in Asia (Australia and Thailand). An additional representation from 12 countries in Latin America (Belize, Brazil, Costa Rica, Colombia, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, and Venezuela) was supported by FAO.

The training sessions were presented during the first three days (see Annex I) and the workshops followed where participants were divided into three working groups with specific terms of reference to discuss issues related to three broad thematic areas. These are:

- **Working Group 1**: Policies/regulatory frameworks governing trade, health certification, quarantine, competent authority, as part of aquatic animal health management.
- **Working Group 2**: National-level requirements for implementing IRA for aquatic animals: research, diagnostics, surveillance/reporting, zoning, information0, epidemiology, networking.
- **Working Group 3**: Outline/framework for an IRA manual for aquatic animals.

After fruitful deliberations the working groups presented the results in plenary and provided recommendations (see Annex III).

The number of economies that took part in the two workshops, and the participation of non-APEC economies, FAO and NACA member governments, organizations such as OIE, MRC, SPC, DANIDA and OIRSA, and private-sector representatives are a clear indication of the value of this APEC-initiated activity. This broad interest also recognizes APEC's significant role in supporting aquatic animal health projects that benefit both APEC member economies and non-member economies. The commitment of partner organizations in working with APEC to achieve the common goals of finding resolutions and appropriate strategies for dealing with the aquatic animal problems currently facing the Asia-Pacific Region and in achieving economic and social development through support to aquaculture-related projects/activities has also been clearly demonstrated. A networking of people with certain skills and an increased level of awareness on IRA for aquatic animals in some 40 countries in the Asia-Pacific and the Americas is now in place.

4 TECHNICAL PRESENTATIONS

4.1 BACKGROUND FOR RISK ANALYSIS

A Brief Review of International Trade in Live Aquatic Animals

J. Richard Arthur

6798 Hillside Drive
Sparwood, B .C., Canada V0B 2G3

J.R. Arthur. 2004. A brief review of international trade in live aquatic animals. p. 1-7. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

Information on the world trade in live aquatic animals is fragmentary, widely scattered, and generally very imprecise. Reasons for international movements of aquatic species include their intentional introduction into aquaculture facilities or the natural waters of the importing country, the ornamental and live restaurant trades, and those movements that are the unintentional results of trade (e.g., movement via the ballast waters of ships). It appears that freshwater ornamental finfish account for the vast majority of the routine trade. Shipments for aquaculture development may be extremely high for some species/countries/time periods. They are probably responsible for most pathogen introductions, and many of the most serious disease problems faced by aquaculturists are a result of these poorly considered movements.

Introduction

Live aquatic animals (finfish, crustaceans and molluscs) are traded internationally for a variety of reasons. These include the movement of species for intentional introduction or transfer into aquaculture facilities or the natural waters of the importing country; the movement of species that are intended for use in the importing country, but not destined for aquaculture or release (e.g., ornamental fishes and the live restaurant trade); and those movements that are the unintentional results of trade (e.g., movement via the ballast waters of ships).

Information on the world trade in live aquatic animals is fragmentary and widely scattered, and such data are generally very imprecise. While the Food and Agriculture Organization of the United Nations (FAO) provides exhaustive production statistics by species or species group for both capture fisheries and aquaculture on both a world wide and country basis, data are not provided for export/import nor for live aquatic animals vs. their products (see FAO 2000a,b). Industry information can be found for some countries for some exported aquaculture commodities (e.g., live oysters) and for the ornamental fish trade (e.g., OATA 2002). FAO also maintains the Database on Introduced Aquatic Species (DIAS), which provides information on the introduction and transfer of live aquatic animals (FAO 1998), while information on introduced finfishes for individual countries can be found in FishBase (Froese and Pauly 2002).

Introductions and Transfers

Introduced species are highly important to the success of today's aquaculture industries, accounting for some 17% of the total world aquaculture production. Chilean aquaculture of salmon, for example, accounts for 20% of world production and employs 30,000 people, while Asia, where tilapias (*Oreochromis* spp.) have been widely introduced for both aquaculture and capture fisheries, currently produces some 700,000 metric tonnes (mt) of tilapia (FAO 2002).

FAO's Database on Introduced Aquatic Species (DIAS, FAO 1998) shows that aquaculture development is by far the primary reason that live aquatic animals are introduced into new areas, accounting for some 38.7% of all records in DIAS (Table 1).

Table 1. DIAS statistics by reason of introduction (modified from FAO 1998).

Reason	No. of Records	%
Aquaculture	1386	38.7
Fisheries	299	8.3
Angling/sport	283	7.9
Accidental	267	7.5
Ornamental	263	7.3
Diffused from other countries	139	3.9
Research	104	2.9
Other reasons	286	8.1
Unknown	552	15.4

Examination of data summarized by period of introduction shows that introductions of aquatic animals have increased dramatically during the past six decades, with 54.7% of all records in DIAS being since 1940. During the forty-year period 1940 to 1979, 35.5% of all records were established, an average rate of 27.8 new records/year (Table 2). In the most recent period (1980-1998), an additional 19.2 % of all recorded introductions have been made, an annual average rate of 31.7 records/year. These figures would appear to indicate, that despite increased concerns about the possible negative environmental, genetic, ecological and disease effects of transfers and introductions, the rate of new introductions of aquatic animals has not slackened, and indeed, may have even increased slightly.

Finfishes are the most frequently introduced species group, comprising 81.9% of all DIAS records, followed by molluscs (9.4%) and crustaceans (6.0%) (Table 3). According to DIAS, the most frequently introduced finfishes are common carp (*Cyprinus carpio*), with 124 records, rainbow trout (*Oncorhynchus mykiss*), with 99 records, and Mozambique tilapia (*Oreochromis mossambicus*), with 92 records (Table 4). The most often introduced crustaceans include the giant river prawn (*Macrobranchium rosenbergii*), with 43 records; the red swamp crayfish (Procambarus clarkii), with 24 records; and the giant tiger prawn (*Penaeus monodon*), with 13 records. For molluscs, the Pacific cupped oyster (*Crassostrea gigas*) leads in the number of introductions (45 records), followed by the top shell (Trochus niloticus), with 15 records and the American slipper-limpet (Crepidula fornicata), with 12 records.

When the data are grouped by importing region, Europe accounts for 25.1% of the records, while Asia is second, with 16.4%, and Africa third, with 14.7% (Table 5). Although there are no supporting data available in DIAS, it seems likely, given the rapid growth of aquaculture in Asia and Latin America, that the majority of recent introductions and transfers have occurred in these regions.

Table 2. DIAS statistics by year of introduction (from FAO 1998).

Year	No. of Records	%
Before 1800	47	1.5
1800-1899	136	4.3
1900-1939	314	10.0
1940-1979	1114	35.5
1980-1998	603	19.2
Multiple introductionsin different periods	90	2.8
Unknown	837	26.6

Table 3. Statistics by species group (from FAO 1998).

Group of Species	No. of Records	%
Fishes	2574	81.9
Molluscs	294	9.4
Crustaceans	191	6.0
Algae and plants	35	1.1
Other invertebrates	29	0.9
Other vertebrates	18	0.6

Table 4. Most frequently introduced fish, crustaceans and molluscs (modified from FAO 1998).

Scientific Name	Common Name	No. of Records
Fish		
Cyprinus carpio	Common carp	124
Oncorhynchus mykiss	Rainbow trout	99
Oreochromis mossambicus	Mozambique tilapia	92
Ctenopharyngodon idella	Grass carp	91
Oreochromis niloticus	Nile tilapia	80
Hypophthalmichthys molitrix	Silver carp	79
Gambusia affinis	Mosquitofish	67
Micropterus salmoides	Largemouth black bass	64
Hypophthalmichthys nobilis	Bighead carp	55
Carassius auratus	Goldfish	54
Crustaceans		
Macrobrachium rosenbergii	Giant river prawn	43
Procambarus clarkii	Red swamp crawfish	24
Penaeus monodon	Giant tiger prawn	13
Penaeus japonicus	Kuruma prawn	12
Pacifastacus leniusculus	Whiteleg prawn	11
Molluscs		
Crassostrea gigas	Pacific cupped oyster	45
Trochus niloticus	Top shell	16
Crepidula fornicata	American slipper-limpet	12
Pomacea canaliculata	Golden apple snail	11
Tridacna derasa	Smooth giant clam	11

Table 5. Statistics by recipient continent (from FAO 1998).

Continent	No. of Records	%
Europe	787	25.1
Asia	517	16.4
Africa	470	14.9
Oceania	464	14.7
South and Central America	442	14.1
Middle East	263	8.4
North America	198	6.3

Two Countries with Different Trading Situations

The situations of individual countries differ considerably with regards to international trade in live aquatic animals. These differences are related to such factors as:

- historical trading patterns,
- local culture (fish eating vs. red meat eating traditions),
- extent of aquaculture development,
- past and current government policy, and
- affluence

Namibia, a relatively new country in southwestern Africa with a small population (approximately 1.7 million people), provides an example of a country with a very small trade in live aquatic animals. Although Namibia has least 72 species of finfish with aquarium trade potential (see Froese and Pauly 2002), the country does not export any domestically produced cultured or wild ornamental fishes. Namibia has a small but developing marine aquaculture industry for oyster that is totally based on the importation of spat from Chile and South Africa. Currently some 400 mt (shell on) of live Pacific cupped oysters are exported to South Africa.

There are only two licensed aquarium fish importers for the entire country (Arthur 2002), and during the past six months only one importer brought in fish. The importer chooses from a list of 200-300 species available from sellers in South Africa, importing a total of 15 consignments with a total value of about $US 3,360. Nevertheless, three of the seven exotic species that have established self-sustaining populations in Namibian fresh waters are aquarium fishes (guppy, swordtail and gourami) (see Froese and Pauly 2002).

Australia provides an example of a country with a medium-size trade in live aquatic animals. Domestic production of freshwater ornamental fishes is valued as some A$ 25 million/year, while the entire ornamental fish industry has been valued at A$ 135-150 million/year (see Khan *et al.* 1999). In 1997-98, the country exported a total of 79,428 marine and freshwater ornamentals, valued at A$ 1.3 million. About 74% of the fish exported are native Australian species, the primary importers being the United States, Japan and Hong Kong.

Some 40% of the ornamental fish sold in Australia are imported (Table 6), with 80% of the imports coming from Singapore, Hong Kong and Malaysia. In 1997-98, the total estimated number of freshwater fish imported was 6.3 million, while the total estimated cost to importers was A$ 1.97 million, of which some $1.76 million was for freshwater species (Khan *et al.* 1999). Australia prohibits the importation of live aquatic animals destined for aquaculture development or release in natural waters.

Reasons Live Aquatic Animals are Traded Internationally

Live aquatic animals are traded internationally for many reasons, the primary being for:

- live food markets,

Table 6. Total number of ornamental finfish supplied to the Australian ornamental finfish industry (modified from Khan *et al.* 1999).

Source	Marine Fish	Freshwater Fish	Total Fish
Imports	68,700	6,999,000	7,067,700
Commercial breeders	0	4,916,100	4,916,100
Collectors/divers	63,900	0	63,900
Totals	132,600	11,915,100	12,047,700

- live food markets,
- aquaculture development or sustainment,
- the ornamental fish trade, and
- for other reasons (e.g., development of capture and sport fisheries, use as bait and as biological control agents)

Examples of fish, crustaceans and molluscs traded to supply live food markets include the movement of live oysters from producing countries to consuming countries (e.g., to Europe, North America, South Africa); and the intra-regional trade in Asia involving live finfish and shellfish (e.g., grouper, seabass, shrimp, cockles etc.) for consumption in seafood restaurants.

Grouper fry, for example, are collected mainly from the wild in developing countries such as Sri Lanka, the Philippines, Thailand and Indonesia (see Arthur and Ogawa 1996). They are shipped to more highly developed countries such as Singapore, Malaysia and China (Hong Kong) for grow-out in cages. Market-sized fish are then consumed locally or shipped to restaurants in Singapore, Hong Kong, Chinese Taipei and mainland China. The grow-out to consumer aspect of this trade generally represents little risk of disease transfer due to the high value of these species and their quick turnover; however, some concerns exist related to potential pathogen transfer via shipping water, improperly disposed slaughter wastes and via occasional releases of live finfish.

Movements of live aquatic animals for aquaculture development involves the shipment of gametes or fertilized eggs: Fry, fingerlings or spat; and of broodstock. The international movement of eggs and gametes is infrequent (particularly in Asia); however, this method is recommended by international codes of practice for species introductions (e.g., the International Council for the Exploration of the Sea (ICES), and the European Inland Fisheries Advisory Commission (EIFAC)), as it generally involves a lower risk of pathogen transfer (see Turner 1988, ICES 1995).

Fry, fingerlings and spat of aquatic animals are frequently moved across international borders, particularly in Asia and Latin America. This trade often involves large numbers of an individual species (e.g., prawn postlarvae, oyster spat). Such movements are characteristic of new industries, those hampered by non-existent or temporarily insufficient national production (e.g., milkfish fry, oyster spat, prawn postlarvae) or industries involving species whose the life cycles has not been completed to a commercial level (e.g., groupers, tiger prawn). An example of the magnitude of this trade is given by Hossain (1997), who estimated that in 1995, 50 million nauplii and postlarvae of giant tiger prawn were imported into Bangladesh, primarily from Thailand, India and Myanmar, to support the country's developing shrimp culture industry. Such movements often involve a relatively high risk of pathogen transfer.

The international movement of broodstock is less frequent and typically involves only a few animals at a time. Such movements are seen for species without closed life cycles (prawns), for new aquaculture species, and to avoid delays in aquaculture start up due to the time needed for maturation of juveniles to broodstock. They often involve a high risk of pathogen transfer.

Ornamental Fish Trade

The international trade in marine and freshwater fishes for tropical fish hobbyists involves more than 2,000 species (see Khan *et al*. 1999, Davenport 2001), and millions of fish are moved annually. According to the Ornamental Aquatic Trade Association (OATA), some 10 million ornamental marine fish with an estimated total weight of 70-100 mt are imported annually throughout the world (OATA 2002). Data for imports of aquarium fishes into the European Union for the period 1993 to 1997 show a value of ECU 67,583,000 for 1993, which had risen to ECU 90,987,000 by 1997 (OATA 2002).[1] Marine fish comprised approximately 10% of the value of imported ornamental fish during this period.

The culture and trade of aquarium fishes is an important source of foreign exchange earnings for some countries. For example, in 1988, Malaysia produced some 58.9 million aquarium fish valued at $M 5.18 million (Siow and Nagaraj 1989), while in 1994, Singapore produced more than $US 30 million in cultured fish, 75% of this production being ornamental species (Chua 1996).

The aquarium fish trade often involves a high amount of transshipment, which often masks the country of origin of individual shipments and species. For example, in 1988, 84.3% of Malaysia's total aquarium fish production was exported via Singapore (Siow and Nagaraj 1989). Although Singapore exported a total of $US 57 million worth of ornamental fishes in 1994, the country's domestic production at that time was only about valued at about US$ 22.5 million (i.e., about 40% of the total value exported) (see Chua 1996).

The tropical aquarium fish industry is characterized by a resistance to regulation, and the complexity of the trade often makes guarantees of disease status difficult or impossible. Trends within the industry include an increase in domestic production for some countries (e.g., Australia; see Khan *et al*. 1999); a decreased reliance on wild stocks for freshwater ornamental species (95% of these fish now originate from aquaculture); and a continued reliance on wild stocks for the marine aquarium fish trade (99% are wild-caught) (see Davenport 2001).

The top five exporting countries are Singapore, Hong Kong, the United States, the Netherlands and Germany (Davenport 2001); however, freshwater ornamental fish are raised in many countries around the world, often by relatively small-scale producers.

The top five importing countries are the United States, Japan, Germany, the United Kingdom and France (Davenport 2001), but almost all countries have some importations.

Conclusions

The international trade in live aquatic animals is poorly documented. It appears that freshwater ornamental finfish account for the vast majority of the routine trade. Shipments for aquaculture development may be extremely high for some species/countries/time periods. They are probably responsible for most pathogen introductions, and many of the most serious disease problems faced by aquaculturists are a result of these poorly considered movements.

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Trans-boundary Aquatic Animal Diseases/Pathogens

M.G. Bondad-Reantaso

Sarbanes Cooperative Oxford Laboratory
Maryland Department of Natural Resources
904 S. Morris Street
Oxford, MD, USA 21654

M.G. Bondad-Reantaso. 2004. Trans-boundary aquatic animal diseases/pathogens. p. 9-22. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper presents information on some of the most serious and emerging trans-boundary aquatic animal pathogens/diseases facing the aquaculture sector. Some socio-economic impacts are also reviewed, as well as current regional and international efforts to minimize the international spread of pathogens.

Introduction

Baldock (2002) defined trans-boundary animal diseases (TADs) as epidemic diseases that are highly contagious or transmissible, with the potential for very rapid spread irrespective of national borders and that cause serious socio-economic and possibly public health consequences. Some of the most serious problems currently faced by the aquaculture sector are caused by those pathogens and diseases that are spread through movements of hatchery produced stocks, new species introduced for aquaculture and via the development and enhancement of the ornamental fish trade. Aquaculture is faced with what are known as trans-boundary aquatic animal pathogens/diseases (TAAPs/TAADs), similar to the TADs in the livestock sector. This has been the main subject of technical support and regional/international cooperation since 1999, when the regional aquatic animal health management program of FAO/NACA started (FAO/NACA 2000, FAO/NACA 2001, Bondad-Reantaso *et al.* 2001).

The Office International des □pizooties (OIE, the World Organisation for Animal Health) lists 30 pathogens/diseases of finfish, molluscs and crustaceans that fit the criteria of being of socio-economic and/or public health importance and significant in the international trade of aquatic animals and aquatic animal products (OIE 2002). These pathogens are categorized as either "notifiable" or "significant", and thus reportable to the OIE. These diseases are known, economically significant and affect the most commonly traded species, such as salmonids, catfish, oysters and shrimp. The Network of Aquaculture Centres in Asia-Pacific (NACA)/Food and Agriculture Organization of the United Nations (FAO) and the OIE-Tokyo Quarterly Aquatic Animal Disease Reporting Systems list an additional six diseases deemed important to the Asia-Pacific Region (NACA/FAO 1999, OIE 2000). In addition to the OIE-listed and the NACA/FAO and OIE-Tokyo listed diseases, there are many more diseases of regional and national interest that have impacted Asian aquaculture (Subasinghe *et al.* 2001), and some are newly emerging in the region.

Examples of TAAPs/TAADs Affecting Asian Aquaculture

Viral nervous necrosis (VNN) is a serious disease of larval and juvenile marine fish. It has been reported from at least 22 fish species from 11 families, with greatest impact among sea bass, grouper, parrotfish, puffer and flatfish (OIE 2002). First described in Japanese parrotfish (*Oplegnathus fasciatus*) in Japan (Yoshikoshi and Inoue 1990) and barramundi (*Lates calcarifer*) in Australia (Glazebrook *et al.* 1990), VNN has since been recorded in the Asia-Pacific Region in Indonesia, Korea RO, Philippines, Singapore, Chinese Taipei and Thailand (APEC/AAHRI/FHS-AFS/NACA 2001). Its world-wide distribution also includes the Mediterranean, Scandinavia and North America (Nakai *et al.* 2001).

Epizootic ulcerative syndrome (EUS), defined as "a seasonal epizootic condition of freshwater and estuarine warm water fish of complex infectious aetiology characterized by the presence of invasive *Aphanomyces* infection and necrotising ulcerative lesions typically leading to a granulomatous response" (Roberts *et al.* 1994), remains an international problem. EUS is known by a number of names, such as mycotic granulomatosis (MG) in Japan (Egusa and Masuda 1971, Hatai 1980), red spot disease (RSD) in Australia (McKenzie and Hall 1976, Callinan and Keep 1989, Callinan *et al.* 1989, Fraser *et al.* 1992), and ulcerative mycosis (UM) in the United States (Noga and Dykstra 1986). However, the syndrome is now believed to have a single causative agent - the putative *Aphanomyces* (*Aphanomyces invadans*/*piscicida*) (Callinan *et al.* 1995; Lilley and Roberts 1997; Lilley *et al.* 1997a,b, 1998; Chinabut 1998; Blazer *et al.* 2002). Despite almost three decades of scientific research, much controversy still exists regarding the infectivity of the fungal pathogen, the involvement of various bacterial and viral agents, it's epidemiology and the proper name of the organism. Lilley *et al.* (1998) confirmed histologically that more than 50 species of fish are affected by EUS. A number of important cultured species (e.g., tilapia (*Oreochromis niloticus*), milkfish (*Chanos chanos*), common carp (*Cyprinus carpio*), silver carp (*Hypophthalmichthys molitrix*) and Japanese eel (*Anguila japonica*) appear to be resistant (Kumamaru 1973, Bondad-Reantaso *et al.* 1992, Wada *et al* 1996, Khan *et al.* 1998).

Suspected koi herpes virus (KHV) is a newly emerging finfish disease in the region, causing large-scale mortalities of koi and common carp in Indonesia in 2002 (NACA 2002). At the request of the Government of Indonesia, an International Emergency Task Force was formed by NACA in June 2002. The Task Force recognized the important role that KHV played in the outbreak (based on analogy with other KHV outbreaks elsewhere and positive detection by polymerase chain reaction (PCR) from all case samples); however, due to an absence of typical KHV pathology, failed viral isolation and non-observance by electron microscopy of typical virions, it was not confirmed that the agent responsible was KHV. This suspected introduction of KHV to Indonesia could have a major impact on trade, as it will affect the international and domestic movements of high-value ornamental koi carp and of common carp, which is a regionally important food fish. KHV has been reported in many countries, such as Israel (Ariav *et al*. 1999), the United Kingdom, Germany, the Netherlands, Belgium, Denmark (OATA 2001, Ariel 2002) and the United States (Hedrick *et al.* 2002). The principal mode of transfer is the through the ornamental fish trade.

Shrimp aquaculture has its share of newly emerging diseases. These include the spawner mortality virus (SMV) in Australia reported and described by Fraser and Owens (1996) and Owens *et al.* (1998) and the Mourilyan virus (MoV), a new bunya-related virus affecting penaeid prawns in Australia and possibly elsewhere in the region (Cowley *et al.* 2002). White spot disease (WSD) remains the most serious disease of cultivated shrimp in the world (Flegel 1998), affecting 13 countries in the Asia-Pacific Region and ten countries in the Americas. The major mode of transfer is through the movement of live animals (postlarvae, fry and broodstock). Taura syndrome virus (TSV), an OIE "notifiable disease", was previously known only from the Western Hemisphere, however it now also occurs in Asia, where it was most recently reported from Indonesia in 2002 (NACA/FAO 2003). Importation of *Penaeus vannamei* to Asia for aquaculture, along with several misconceptions among aquaculturists on the utilization of specific pathogen free (SPF) and high health shrimp lead to the introduction of TSV to the region. *Penaeus vannamei* has been illegally imported to several countries in the region.

Hine (2002) reviewed the significant diseases of molluscs in the Asia-Pacific Region and although there have been relatively few reports, he concluded that once molluscan health studies become firmly established in Asia, new diseases of regional importance will become evident. MSX (multinucleate sphere X) caused by *Haplosporidium nelsoni*, previously reported from Korea RO (Kern 1976) (as *Minchinia* sp.) and also recently recorded from Japan, is a classical example of a TAAP. It has now extended its range to Canada, where an outbreak occurred in October 2002 (Stephenson *et al.* 2003)

Newly emerging diseases include mortalities of zhikong scallops (*Chlamys farreri*) in China (Wei 2002, Wang *et al*. 2002) and diseases affecting seabed-cultured scallop (*Patinopecten yessoensis*), abalone (*Nordotis discus discus*) and Akoya pearl oyster (*Pinctada fucata martensii*) in Japan (Kosaka and Yoshimizu 1999, Miyazaki *et al.* 1999, Morizane *et al.* 2001, Nakajima 1999, Nakatsugawa *et al.* 1999, Sorimachi 2000, Muroga 2002). The mass mortality of Akoya pearl oyster in 1994 in southwestern Japan that killed 400 million oysters, with similar mortalities widely observed in other districts of western Japan since 1996 (Muroga 2002), is the most controversial because of uncertainties as to the nature of the causative agent. Muroga *et al.* (1999) reported the results of a workshop on "Emerging Diseases of Cultured Marine Molluscs in Japan" that presented various suspected agents, including the toxic dinoflagellate *Heterocapsa circularisquama*, perkinsosis, a virus or filterable agent and environmental factors. However, the causative agent is still unknown. Although an uncharacterized virus was isolated and grown in a fish cell line (Miyazaki *et al.* 1999), there was no ultrastructural evidence of replication in pearl oyster cells. Pearl oyster is an important resource in the Asia-Pacific Region, with established industries in Australia, China, Japan, India and the Philippines, and health is a serious concern.

Socio-economic Impacts of Trans-boundary Aquatic Animal Diseases

The number of countries providing estimates of losses due to disease is increasing and is particularly evident among major shrimp producing countries that were gravely affected by diseases during the last decade. At the global level, combined estimated losses in production value due to shrimp diseases from 11 countries for the period 1987 to 1994 (i.e., Chinese Taipei-1987, Philippines-1989, Indonesia-1991, China-1992, Ecuador-1992, USA-1993, Bangladesh-1994, India-1994, Mexico-1994, Thailand-1994 and Vietnam-1994) were on the order of US$ 3,019 million (Israngkura and Sae-Hae 2002). Tables 1 and 2 show some socio-economic and other associated impacts of diseases for shrimp aquaculture and for finfish aquaculture, respectively.

Regional and Global Efforts Towards Responsible Health Management

Various global instruments, agreements, codes of practice and guidelines (either voluntary or obligatory) exist that provide certain levels of protection, all aimed at minimizing the risks due to pathogens/diseases associated with aquatic animal movement (FAO/NACA 2000). These are: (a) OIE's *International Aquatic Animal Health Code* (Hastein 1996, OIE 2002), (b) the *Code of Practice on the Introductions and Transfers of Marine Organisms* (ICES 1995) of the International Council for the Exploration of the Sea (ICES) and (c) the *Codes of Practice and Manual of Procedures for Consideration of Introductions and Transfers of Marine and Freshwater Organisms* (Turner 1988) of the European Inland Fisheries Advisory Commission (EIFAC). There are also relevant articles included in the *Code of Conduct for Responsible Fisheries* (CCRF) of the Food and Agriculture Organization of the United Nations (FAO 1995), the Convention on Biological Diversity (CBD) (Bartley 2001) and the Sanitary and Phytosanitary (SPS) Agreement (Chilaud 1996) of the World Trade Organization (WTO). However, the application of these international protocols to the disease concerns of aquatic food production and trade in Asia is not always practical and therefore, the need for effective health management protocols that focus on the species and disease problems of the region was recognized. A regional approach was considered an appropriate

Table 1. Examples of socio-economic and other impacts of diseases in shrimp aquaculture in selected Asian and Latin American countries.

Country	Disease/Pathogen	Losses and Other Impacts	Reference
1992			
Thailand	Yellowhead disease (YHD)	US$ 30.6 million (M)	Nash et al. 1995
1993			
China PR	Shrimp diseases	US$ 420 M	Wei 2002
		60% decline in production from 210,000 to 87,000 metric tonnes (mt)	Jiang 2001
Vietnam	Shrimp diseases (monodon baculovirus (MBV), white spot disease (WSD) & YHD)	US$ 100 M	Khoa et al. 2001
1994-1998			
Australia	Shrimp diseases: mid-crop mortality syndrome (MCMS), gill-associated virus (GAV)	US$ 32.5 M lost value of P. monodon production during the period 1994-1998	Walker 2001
Thailand	YHD and WSD	US$ 650 M in 1994; 12 % production decline from 250,000 mt in 1994 to 220,000 mt in 1995; shrimp losses for 1997 nearly reached 50% of total farm output value. Figures exclude losses in related businesses such as feed production, processing & exporting, feed production, ancillary services & lost income for labourers	Chanratchakool et al. 2001
Honduras	Taura syndrome virus (TSV)	Production decline by 18%, 31% and 25% in 1994, 1995 & 1996, respectively.	Corrales et al. 2001
India	YHD	Production loss of 10,000 to 12,000 mt during 1994-1995 caused by two viral epizootics; US$ 17.6 M economic loss in 1994 alone	Mohan and Basavarajappa 2001
	WSD		
Malaysia	WSD	Annual losses since 1995 estimated at US$ 25 M	Yang et al. 2001
Bangladesh	WSD	US$ 10 M production losses in 1996; export losses; massive unemployment	Rahman 2001
Panama	TSV	1996 outbreak resulted in 30% reduction in production	Morales et al. 2001
Costa Rica	TSV	TSV outbreak in 1996 caused reduction in survival rate from 65% to 15%.	Vargas 2000
Philippines	Shrimp diseases (viral & bacterial infection)	Decline in export from 30,462 mt to 10,000 mt in 1997; great reduction in number of hatcheries	Albaladejo 2001
Sri Lanka	WSD	Production loss of 1 billion Rs in foreign income during 1996 outbreak; 90% of production units closed	Siriwardena 2001
	Mixed infection of WSD & YHD	68% and 70% drop in shrimp exports in terms of quantity & value in 1998	Siriwardena 2001
1999			
Ecuador	WSD	US$ 280.5 in 1999 equivalent to 63,000 mt; closing of hatchery operations; 13% laying off of labor force (26,000 people); 68% reduction in sales & production of feed mills & packing plants	Alday de Graindorge and Griffith 2001
Honduras	WSD	13% reduction in labor force	Corrales et al. 2001
Nicaragua	WSD	5-10% survival rate	Drazba 2001
Panama	WSD	US$ 40 M worth of export loss; closure of major hatcheries; loss of jobs (5000 people directly & indirectly involved in the industry)	Morales et al. 2001

Table 2. Examples of socio-economic and other impacts of diseases in finfish aquaculture in selected Asian countries.

Country	Disease/Pathogen	Losses and Other Impacts	Reference
1989-1993			
Malaysia	Diseases of cage-cultured grouper, snapper & seabass	US$ 1.3 M in potential income - combined loss estimates of private sector & government farms	Wong and Leong 1987, cited in Arthur and Ogawa 1996
Thailand	seabass diseases	US$ 0.8 M in 1989	ADB/NACA 1991
Thailand	grouper diseases	US$ 1.07 M in 1989	ADB/NACA 1991
China	Bacterial diseases of fish (*Aeromonas hydrophila*, *Yersinia ruckeri* and *Vibrio fluvialis*)	> US$ 120 M annual losses between 1990-1992	Wei 2002
Thailand	Jaundice disease in catfish	US$ 4.3-21.3 M in 1992	Chinabut 2002a
Malaysia	Vibriosis	US$ 7.4 M – outbreak in 1990	Shariff 1995, cited in Arthur and Ogawa 1996
Singapore	Grouper diseases	S$360,500 in 1993	Chua *et al.* 1993
1994-1998			
Japan	Marine fish disease	US$ 114.4 M	Arthur and Ogawa 1996
1998-2002			
Thailand	*Alitropus typus*	US$ 234-468/cage culture of tilapia in 1998-1999	Chinabut 2002b
Philippines	Grouper diseases	75% reduction in household income, 19.4% increased debt	Somga *et al.* 2002
Singapore	Grouper iridovirus	>50% mortality among Malabar grouper	Chang 2001
China	Viral nervous necrosis (VNN)	100% mortality among 3 species of grouper	Zhang 2001
Singapore		80 to 100% mortality among fry & fingerlings	Chang 2001
Indonesia		100% mortality among larvae in national hatcheries in 1999-2000	Yuasa and Koersharyani 2001
Indonesia	Suspected koi herpes virus (KHV)	50 Billion Rupiah	NACA 2002

strategy, since many countries in the region share common social, economic, industrial, environmental, biological and geographical characteristics. A regionally adopted health management program will facilitate trade and protect aquatic production and the environment upon which they depend from preventable disease incursions.

The Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy

The lack of cohesive policies and regulatory frameworks in most Asian countries, as well as inadequate technical information to develop guidelines for safe trans-boundary movement of live aquatic animals, were major factors identified as contributing to the spread of trans-boundary aquatic animal diseases.

The *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy* (the "Technical Guidelines") (FAO/NACA 2000), was developed as the first major output of FAO's Technical Cooperation Programme for a project (TCP/RAS 6714 and 9605) "Assistance for the Responsible Movement of Live Aquatic Animals in Asia" (see also Bondad-Reantaso 2003). The Technical Guidelines provide valuable guidance for national and regional efforts in reducing these risks and a strong platform for mutual cooperation at the national, regional and international levels. There is strong technical and political endorsement from regional, inter-governmental and global organizations and a shared commitment from national governments to support its implementation.

Risk Assessment as a Tool to Reduce International Transfer of Pathogens

Risk analysis is an old concept newly applied to aquatic animal health. Application of scientific risk analysis has been prompted by certain rights and obligations of members of the WTO, particularly through the SPS Agreement. The aquaculture sector has become enormously reliant on external inputs through movements of live aquatic animals and animal products (broodstock, eggs, fry/fingerlings, seed and feed). It is now widely recognized that the movement of aquatic animals involves a certain degree of disease risk to the importing country and that the major disease problems faced by the aquaculture sector are the result of unregulated and negligent movement of live aquatic animals. The SPS Agreement encourages WTO members to implement import/export decisions based on international standards or using science-based import risk analysis (IRA), with OIE as the organization responsible for setting the international standard for animal health (including aquatic animal health) and zoonoses. However, there are practical difficulties in interpreting the provisions in the SPS Agreement. Hence, it is important that countries, at the first instance, familiarize, understand and embrace the concept, and not be discouraged by the expected intricacy of the process (FAO/NACA 2001). This is one of the main reasons why the project APEC FWG 01/ 2002 "Capacity and Awareness Building on Import Risk Analysis (IRA)" was proposed and approved by APEC and subsequently received strong support from national governments and regional and international organizations. Countries will be confronted with a range of conditions and scenarios when conducting an IRA, and regulations will vary from country to country. For developing countries, the greatest struggle will be in the areas of information needs (both quantity and quality), capacity of staff, obtaining adequate disease surveillance and epidemiological data to demonstrate country/regional freedom from specific disease agents, developing appropriate legislation and making the decisions necessary for determining what constitutes "acceptable risk".

Health Management is a Shared Responsibility

Aquaculture has suffered enormous losses due to disease, and there are now important lessons to be learned from the past. The sector will continue to intensify and diversify, and this will be heavily based on the movement of live aquatic animals and their products. Countries intending to import live aquatic animals are bound to abide by a number of international agreements and other relevant regional guidelines. Improved compliance is necessary. Trade is important and will continue because it is a necessity for aquaculture development at both the subsistence and commercial levels. As aquaculture intensifies trade in live aquatic organisms and their products, it will face increasing global exposure to disease agents, the impacts of which may be irreversible. On the other hand, strict or excessive controls will also lead to illegal trade. Trade and consumer interest in food safety will continue to give strong pressure towards economically and environmentally sustainable aquaculture. Effective health management protocols will become increasingly important for intra and inter-regional trade in order to protect aquaculture, fisheries resources and the aquatic environment.

A regional approach to aquatic animal health management is considered as an appropriate step, since many countries in the region share common social, economic, industrial, environmental, biological and geographical characteristics. A regionally adopted health management program will facilitate trade and protect aquatic production and the environment upon which it depends from preventable disease incursions.

Strong political will and national commitment from responsible administration; intensified regional and global cooperation; and pro-active involvement, effective cooperation and strategic networking between governments, farmers/industry, researchers, scientists, experts, development and aid agencies, and relevant stakeholders at all levels towards harmonizing aquatic animal health management measures and promoting responsible trans-boundary movement of aquatic animals and products will help reduce the risks. Health management is a shared responsibility and each stakeholder's contribution is essential to the health management process.

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Risks of Species Introduction

R.P. Subasinghe and D. Bartley

Fisheries Department
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00100 Rome, ITALY

R.P. Subasinghe and D. Bartley. 2004. Risks of species introduction. p. 23-31. *In* J.R. Arthur and M.G. Bondad- Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper provides a brief review of the benefits and risks of aquatic species introductions, using data mainly drawn from FAO's Database on Introductions of Aquatic Species (DIAS). If done properly, new species introductions can often have large socio-economic benefits while minimizing the very real potential for unpredicted negative ecological and socio-economic impacts. Before undertaking any introduction, a thorough risk assessment involving all stakeholders should be conducted.

Introduction

The International Council for the Exploration of the Sea (ICES) defines an "introduced species" as "Any species intentionally or accidentally transported and released by humans into an environment outside its present range "(ICES 1995). Such species are also often referred to as "non-indigenous species," "exotic species" or "alien species," while the human-mediated process of moving a species to a new geographical area is termed a "species introduction."

Although aquatic species have been intentionally moved to new geographic areas for many centuries (see Welcomme 1988, Fegan *et al.* 2001), recent advances in transportation and trade have made movements of large numbers of aquatic animals over great distances very easy.

Introduced species have made an important contribution to aquaculture and artisanal fish production (Fig. 1). In 1996 the contribution of introduced species to the total world fishery production by region ranged from a high of 7.7% for Africa, to a low of 0.6% for North America. Introduced fishes are particularly important to aquaculture production in Asia (contribution of 946,220 metric tonnes (mt)), Europe (312,906 mt) and South America (221,710 mt), and to inland capture fisheries in Africa (contribution of 357,377 mt) (Garibaldi 1966).

The importance of introduced species to fish production in Africa is shown in Figures 2 and 3. Figure 2 shows the growth in tilapia production in Africa arising from both capture fisheries and aquaculture from 1970 to 1999, with capture fisheries producing some 372,805 mt in 1999, while aquaculture production reached 114,460 mt in the same year. Figure 3 shows the growth in production due to solely to introduced tilapias from 1979 to 1999. While introduced tilapias still contribute only a small fraction of total tilapia

production, their contribution had grown from an insignificant level in 1989 to around 2000 mt in 1997 (FAO FishStat).

FAO's Database on Introductions of Aquatic Species (DIAS)

Much of the data on introductions of aquatic species presented in this paper was obtained from FAO's Database on Introductions of Aquatic Species (DIAS) (http://www.fao.org/fi/statist/fisoft/dias/index.htm).[1] Information from DIAS' databases has also been incorporated into FishBase, a WorldFish Centre/Food and Agriculture Organization of the United Nations/European Union (ICLARM/FAO/EU) Project (http://www.fishbase.org). FishBase is a relational database available on CD-ROM that contains many types of information on fish and fisheries (e.g., species distributions, photographs, taxonomy, ecology, genetics, aquaculture, etc.).

Benefits and Risks of Species Introductions

Aquatic species have been moved around the world for various purposes. According to DIAS data on the reasons given for introducing marine and brackishwater species, introductions of new species for aquaculture development (701 of 1738 cases, 40.3%) is most frequently cited, followed by capture fisheries development (346 cases, 19.9%). Other reasons cited include accidental releases (6.3%), diffusion (5.2%), biocontrol (5.1%), ornamentals (3.0%), research (2.9%), other reasons (2.7%) and unknown (14.4%) (see Fig. 4).

There are many examples of the positive socio-economic benefits arising from the introduction of aquatic species. These include improved livelihoods, increased production and trade, etc. However, there have also been cases where serious negative impacts have resulted. Data from DIAS (Fig. 5) shows that the vast majority of introductions (88.4%) are perceived as having had positive socio-economic benefits. On the other hand, the ecological impacts of introducing new species are far less certain, only a slight majority of cases (23 vs. 19 cases) are considered beneficial as opposed to harmful. Figure 6 shows that the socio-economic impacts of intentional introductions of aquatic species are generally perceived as being beneficial, particularly so for introductions for aquaculture (95 cases considered beneficial), with intentional introductions for angling (23 beneficial cases), fisheries (17), ornamental (6) and biocontrol (2) purposes also considered to have good socio-economic impacts. On the other hand, there have also been a significant number of cases where intentional introductions for aquaculture, angling, fisheries, etc. have been considered to have negative ecological impacts. The serious negative consequences that often result from unplanned introductions are also shown, 26 cases occurring where accidental introductions were perceived as having detrimental ecological impacts, while only four cases were regarded as having positive socio-economic impact.

An important and often strongly debated question is whether or not the introduction of an exotic species for aquaculture development will lead to the establishment, through escapes, of wild populations of the introduced species. In the case of mariculture (Fig. 7), DIAS information shows that there is about an equal chance that a new species introduction will or will not establish itself in the wild (286 cases indicating yes or probably yes, and 243 cases indicating no or probably no).

When all exotic species introductions in all aquatic environments are considered (see Fig. 8), a slightly different picture emerges. In this case, in both marine/brackish and freshwater environments, the likelihood of establishment is much greater (814 cases of establishment in marine/brackish waters vs. 415 cases where establishment did not occur, and 787 cases of establishment in fresh water vs. 417 cases of non-establishment). This difference is likely due to the inclusion of data from intentional releases in this data set.

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[1] For the purpose of DIAS, an introduced species is defined as a species that has been moved across a national border to a country outside of its natural range.

Information contained in DIAS thus shows that it is important to carefully evaluate the risks and potential benefits before taking a decision on introducing or transferring an aquatic species. It should be noted that genetically modified organisms (GMOs) and living modified organisms (LMOs) pose different risks and should be dealt with separately.

Who is Responsible for Species Introductions?

Figure 9 shows that in the vast majority of cases (3435 of 4468 or 77.6% of all cases), the person or agency responsible for the introduction of an exotic species is unknown. For those cases where the introducer can be identified (total of 1033 cases), the responsible party was most often government (45.3%), followed by industry (25.4%), individuals (16.4%) and international organizations (4.4%) (others accounted for the remaining 8.4%).

The Effects of Introduced Species

Introduced species can have both positive and negative socio-economic and environmental impacts. Prediction of ecological impacts of introduced species is often difficult, due to lack of knowledge of the introduced organism's biology and the impossibility of knowing exactly how it will interact with native populations and the aquatic environment in the new geographic area. These interactions can involve changes in aquatic biodiversity through such mechanisms as inter-species competition, hybridization with native species, predation and herbivory impacts, and the introduction of disease agents highly pathogenic to previously unexposed native fauna and established aquaculture practices. Potential genetic impacts can be either direct (e.g., loss of species integrity, reduced reproductive efficiency, decrease in fitness) or indirect (e.g., loss of genetic diversity and thus the ability to adapt, inbreeding, depression in small populations, loss of disease resistance). Other effects of species introduction can include changes in terrestrial biodiversity, fisheries management, aquatic habitats and socio-economic change, all of which may have biological and/or socio-economic consequences. Table 1 summarizes some of the effects introduced species may have, both positive and negative, on aquatic and terrestrial ecosystems and on the social structure and economy of the receiving country.

Table 1. Effects of introduced species.

Effect	Biological Mechanisms	Social Mechanisms
Change in aquatic biodiversity	Competition, hybridization, predation/herbivory, disease	Change in fishing pressure and land use; treatment measures
Change in terrestrial biodiversity	Change in abundance of waterfowl prey	Fish farms providing more food or shooting birds
Change in fishery management	Change in stock composition	Success breeds interest; failure breeds experimentation
Alteration of habitat	Burrowing, sediment mobilization, removal of vegetation	Change in use, landscape
Socio-economic change	Change in species composition or value	Change in access rights; liability for damages

Minimizing Risks

If done properly, new species introductions can often have large socio-economic benefits while minimizing the very real potential for unpredicted negative ecological and socio-economic impacts. Before undertaking any introduction, a through risk assessment, involving all stakeholders, should be conducted. A

flow chart of the general procedure to be followed is shown in Box 1. Important components of a risk assessment include:

- Developing a proposal or development plan to assess potential risks and benefits
- Establishing reference points and indicators
- Determining protocols for monitoring and evaluation
- Determining how to deal with uncertainty (i.e., what will be done if something goes wrong?)
- Developing lines of communication for policy-makers and other stakeholders

Conclusions

In order to develop public support and establish a "green" image for aquaculture, it is essential that species introductions be conducted in a responsible and transparent way. Following internationally accepted, standardized procedures for risk evaluation will help assure all stakeholders that such introductions have been well thought out and thoroughly evaluated before being undertaken. The most serious impacts of introduced species that have been documented concern freshwater habitats and involve disease organisms that have affected the aquaculture industry. In some cases, these impacts are more theoretical than actual. This may be due to a general lack of pre-introduction baseline studies and/or post-introduction monitoring such that the true impacts, both positive and negative, cannot be accurately determined. There may be differences between coastal and inland environments that make extrapolation of data for one to the other inappropriate. Often, the types of species that cause environmental problems are not those that are used in aquaculture. However, it is important for the health of the aquaculture industry that aquaculturists do not become complacent as to the potential harm to the industry that can result from ill-considered or poorly conducted species introductions.

Assessment of environmental change requires accurate and detailed knowledge of the present situation, and thus thorough scientific description of habitats is important. In this regard, national registries and databases will be increasingly important, as will the continued development of regional and international sources of information such as FishBase, DIAS and AAPQIS (the FAO Aquatic Animal Pathogen and Quarantine Information System).

Increased and better collaboration among aquaculturists, government policy-makers, the scientific community, international and regional agencies and other stakeholders will be essential.

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Figure 1. Contribution of introduced fishes to total fishery production (1996) (numbers in parentheses are regional contributions to total world aquaculture production). (DIAS)

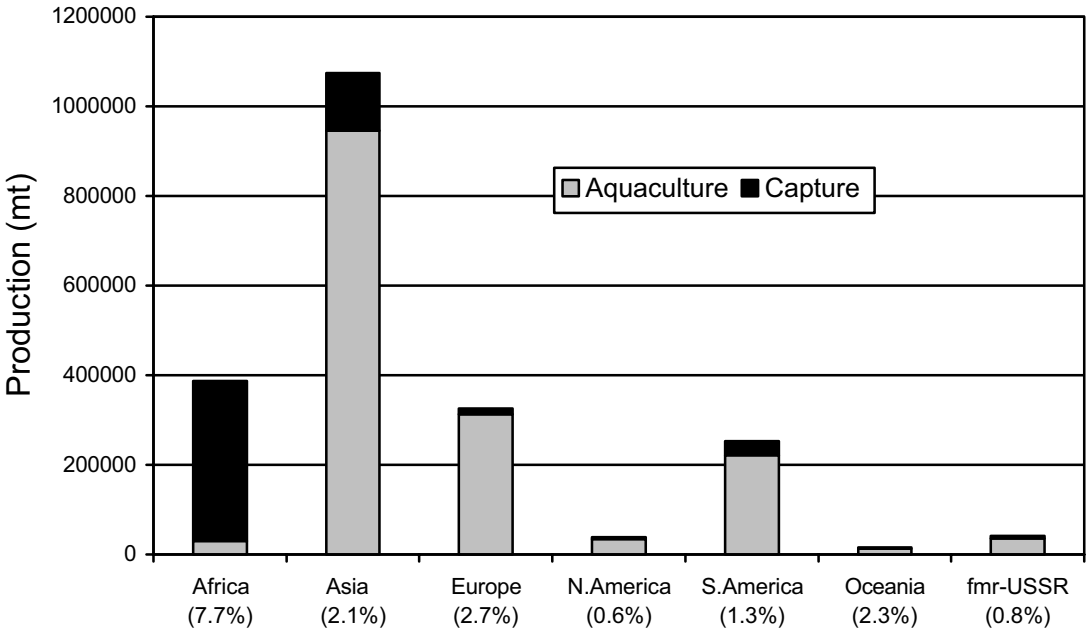


Figure 2. Tilapia production in Africa. (FAO FishStat)

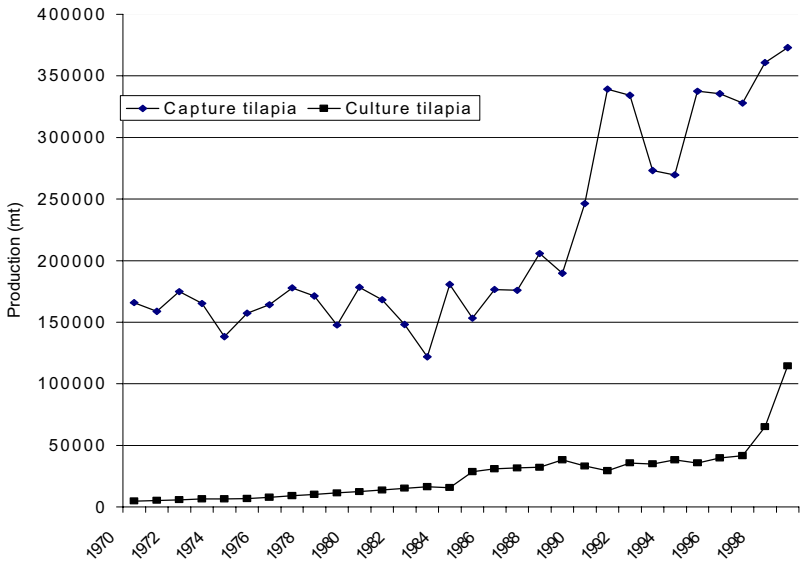


Figure 3. Growth in production derived from introduced tilapia in Africa, 1979-1999. (DIAS and FAO FishStat)

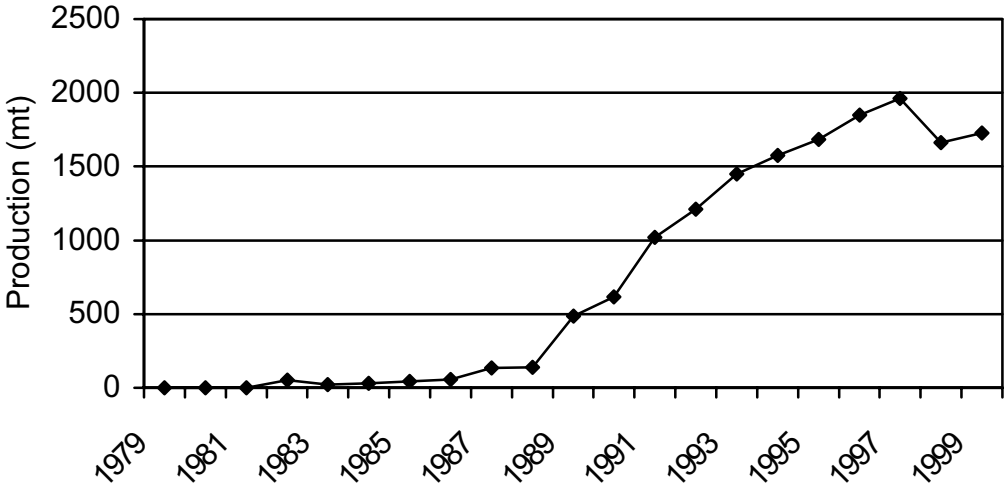


Figure 4. Reasons for introductions of marine and brackishwater species. (DIAS)

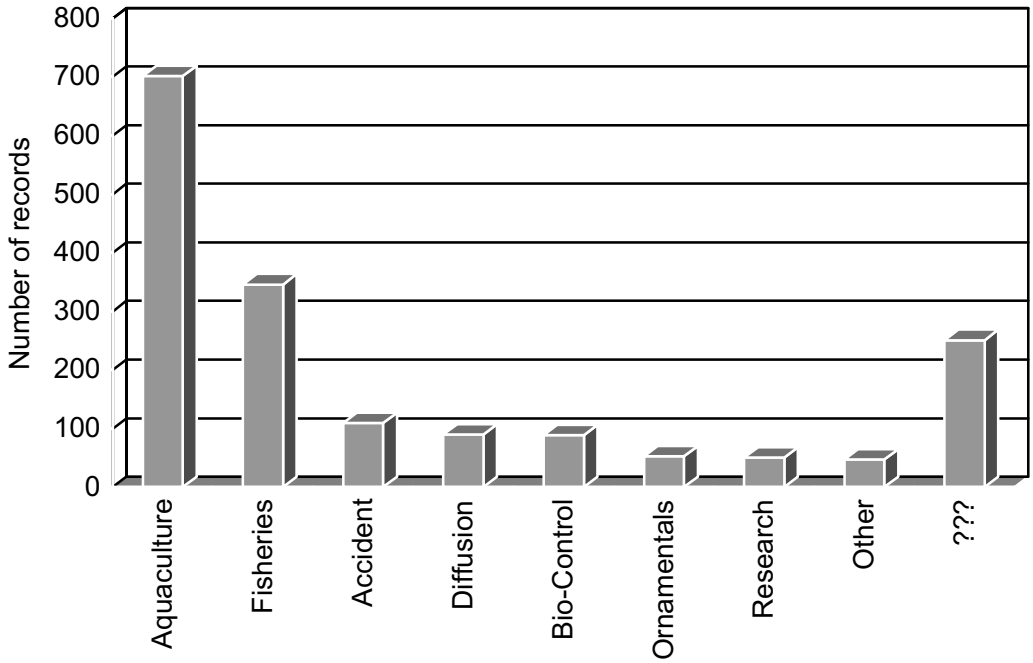


Figure 5. Effects of mariculture introductions. (DIAS)

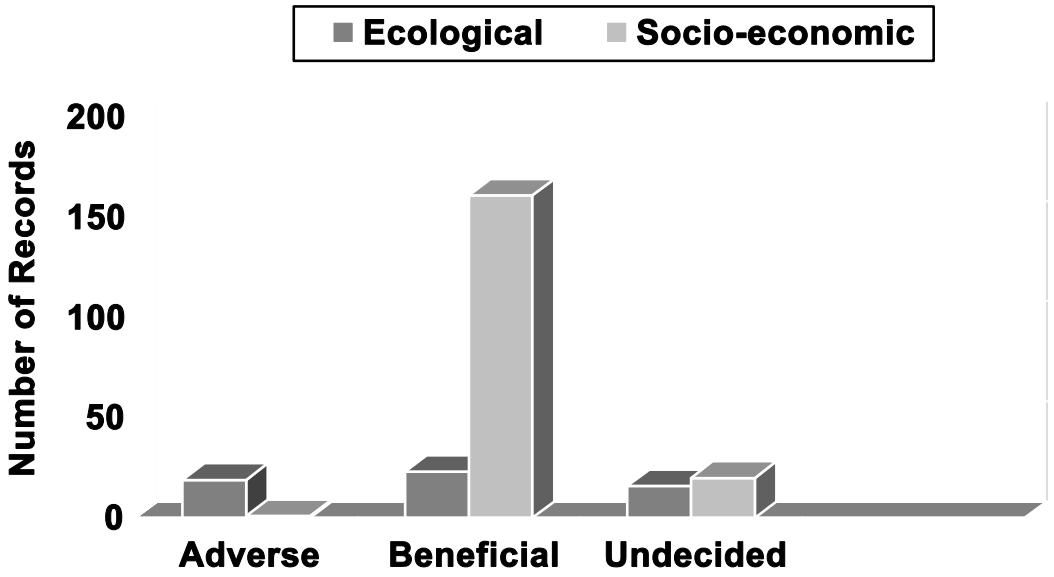


Figure 6. Benefits and risks of introductions. (DIAS)

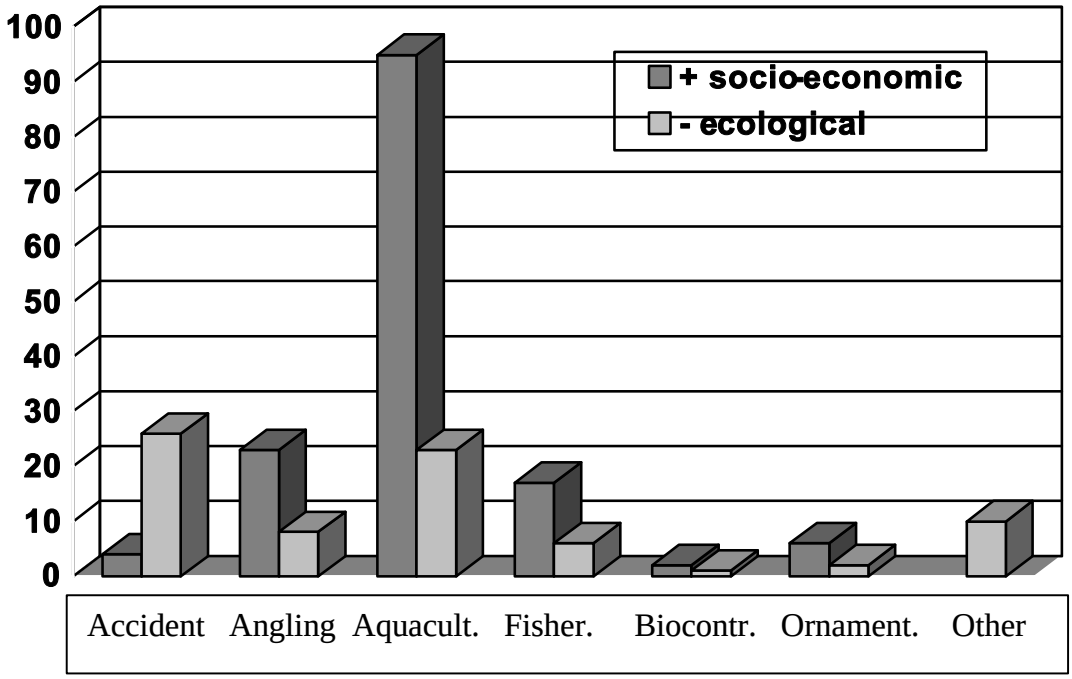


Figure 7. Do introductions in mariculture lead to established wild populations? (DIAS)

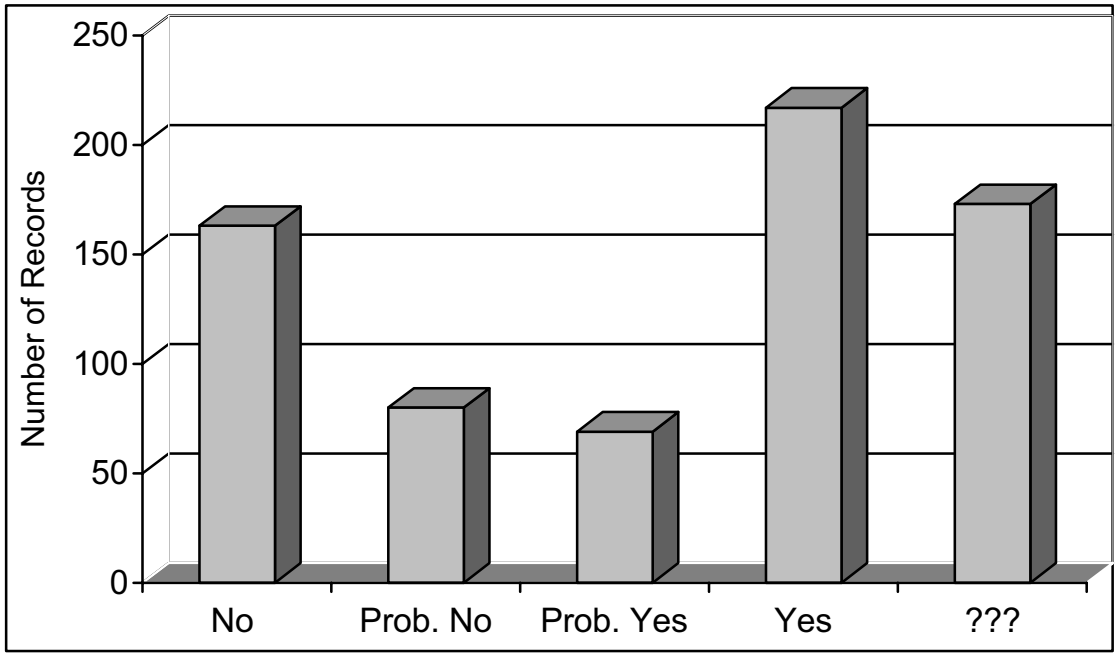


Figure 8. Introduced species established in nature. (DIAS)

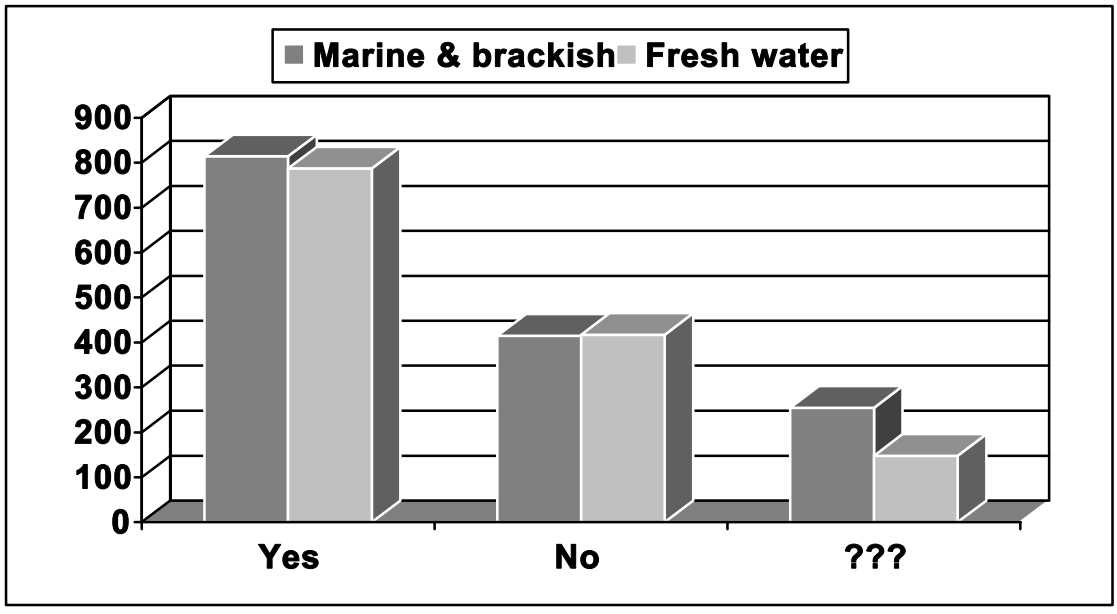
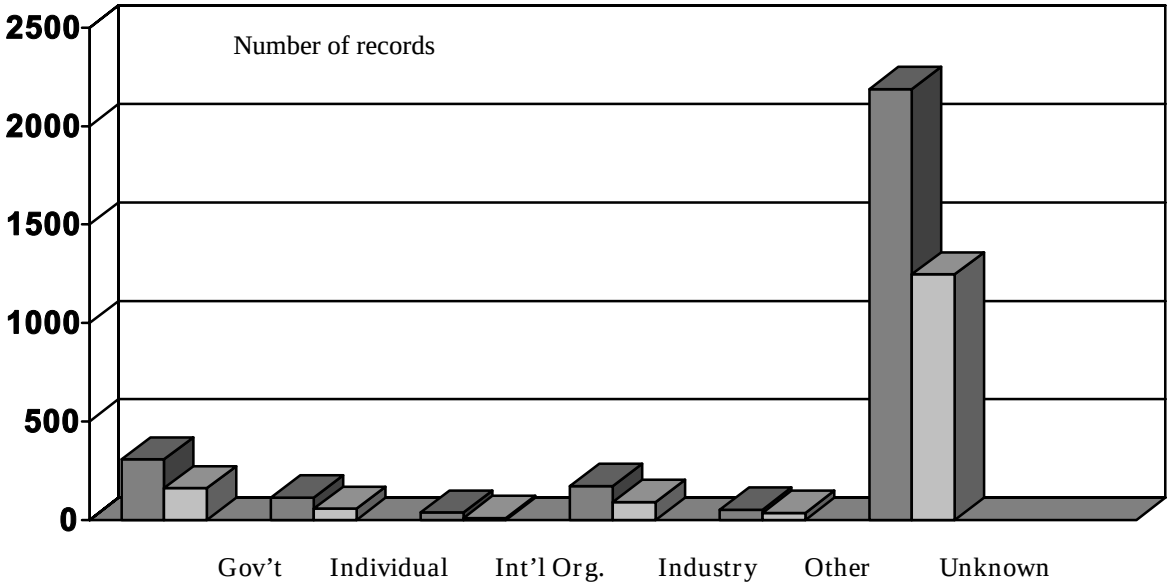


Figure 9. Who is responsible for introductions of new species (Dark bars = inland introductions; light bar = marine introductions). (DIAS)



Box 1. Flow diagram for the responsible movement of aquatic organisms (after ICES, EIFAC, FAO).

- PROPOSAL
  - planned use
  - location
  - passport
  - source

↓ ↺

- INDEPENDENT REVIEW
  - disease
  - ecology
  - genetics
  - socio-economics
  - local species impacted

↓ ↺

- ADVISE/ADVICE

↓

- APPROVAL

↓

- PROTOCOLS IF APPROVED: quarantine & monitor

Risks of Chemical Usage in Aquaculture

R. P. Subasinghe

Fisheries Department
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00100 Rome, ITALY

R.P. Subasinghe. 2004. Risks of chemical usage in aquaculture. p. 33-36. *In* J.R. Arthur and M.G. Bondad- Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper provides a brief overview of the risks associated with the use of chemicals in aquaculture. These include potential impacts on human health, domestic animal production, and the environment, and to access to markets for aquaculture products.

Introduction

World aquaculture production continues to grow tremendously, increasing at an average compounded rate of 9.2% per year since 1970, compared with only 1.4% for capture fisheries and 2.8% for terrestrial farmed meat production systems. According to the most recent statistics available from the Food and Agriculture Organization of the United Nations (FAO 2002), total world aquaculture production in 2000 (including aquatic plants) was on the order of 45.7 million metric tonnes (mmt), valued at $US 56.5 billion, and accounting for more than a quarter (27.3%) of the total world fishery landings.[1] China remains the largest producer, accounting for 71% of total world production.

Low-value inland finfish, such as Indian major carps, Chinese carps, tilapias, etc., produced in extensive or semi-intensive culture systems comprise the bulk of world aquaculture production. Although the culture of high-priced species such as shrimp and marine cage-reared finfish (salmon, seabass, seabream, etc.) often receive the most attention, it is important to note that these species contribute only a relatively small amount to total world aquaculture production, crustaceans, for example, representing only 4.2% of total production by weight and only 18.1% by value. Developing countries contribute more than 86% of total world production, with Low Income Food Deficient Countries (LIFDCs) accounting for more than 75% of the total. The LIFDCs contribute more than 80% of the world finfish production, of which more than 95% is derived from inland freshwater fish culture. Production from the LIFDCs continues to grow at an above average rate of some 13% annually, indicating aquaculture's real and potential contribution to providing low cost protein to those among the world's most impoverished sectors (Subasinghe *et al.* 2000).

In aquaculture, as in all food production sectors, chemicals are one of the external inputs essential for successful crop production. In the most simple, extensive systems, this may be limited to manure or other

[1] World aquatic plant production in 2002 was 10.1 mmt, valued at US $5.6 billion (FAO 2002).

inexpensive and readily available organic fertilizers, while in more complex semi-intensive and intensive systems a wide range of natural and synthetic compounds may be used. It is safe to say that, as in agriculture, chemicals are an essential "ingredient" to successful aquaculture, one that has been used in various forms for centuries.

Chemicals in Aquaculture

Classification of Chemicals

There are many different classifications and working definitions of "chemicals" (see Van Houtte 2000). These include classification of "drug groups" (see Alderman and Michel 1992), the classification provided by the International Council for the Exploration of the Sea (ICES 1994), and a classification developed specifically for prawn culture (see Primavera *et al*. 1993), as well as various working definitions for scientific and legal purposes. In aquaculture, chemicals can be classified by the purpose of use, the type of organisms under culture, the life cycle stage for which they are used, the culture system and intensity of culture, and by the type of people who use them.

Use of Chemicals in Aquaculture

Chemicals have many uses in aquaculture, the types of chemicals used depending of the nature of the culture system and the species being cultured. They are essential components in:

- pond and tank construction,
- soil and water management,
- enhancement of natural aquatic productivity, transportation of live organisms,
- feed formulation,
- manipulation and enhancement of reproduction,
- growth promotion,
- health management, and
- processing and value enhancement of the final product

The benefits of chemical usage are many. Chemicals increase production efficiency and reduce the waste of other resources. They assist in increasing hatchery production and feeding efficiency, and improve survival of fry and fingerlings to marketable size. They are used to reduce transport stress and to control pathogens, among many other applications.

Risks of Chemical Usage

The use of chemicals in aquaculture poses a number of potential risks. These include:

- Risks to the environment, such as the potential effects of aquaculture chemicals on water and sediment quality (nutrient enrichment, loading with organic matter, etc.), natural aquatic communities (toxicity, disturbance of community structure and resultant impacts on biodiversity), and effects on microorganisms (alteration of microbial communities).
- Risks in human health, such as the dangers to aquaculture workers posed by the handling of feed additives, therapeutants, hormones, disinfectants and vaccines; the risk of developing strains of pathogens that are resistant to antibiotics used in human medicine; and the dangers to consumers posed by ingestion of aquaculture products containing unacceptably high levels of chemical residue.
- Risks to production systems for other domesticated species, such as through the development of drug-resistant bacteria that may cause disease in livestock or poultry.

An example of such risks is the recent problem surrounding the presence of residues of the antibiotic chloramphenicol in cultured shellfish (see FAO 2002). Chloramphenicol is a broad-spectrum antibiotic that has wide use in both human and veterinary (pet animal) medicine. This antibiotic is an important weapon against bacterial diseases in humans, such as cholera, and thus its use in aquaculture might, for example, lead to the development of chloramphenicol-resistant strains of *Vibrio cholerae.* It is also reported, on rare occasions, to cause aplastic anemia, a serious human health condition (see FAO 2002).

Reducing Risks

Many countries, including those of the European Union (EU) and the United States, have developed strict controls on the use of veterinary medicines, particularly for their use in food animal species. For example, EU Directive 2001/81 defines a veterinary medical product as "Any substance or combination of substances presented for treating or preventing disease in animals. Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a veterinary medical product."

Before any such medicine is approved for sale, a range of safety and efficacy requirements must be satisfied. Among these is the requirement that residues of any veterinary medicine must be below a predetermined safe level when the animals are slaughtered. This level is the maximum residue level (MRL) in Europe or tolerance in the United States.

Certain compounds, such as chloramphenicol and the nitrofurans are specifically prohibited for use in food animals in Europe and the United States (see FAO 2002). For those chemicals that are approved for use in food animal production, programs of sampling and analysis of the edible tissues of such animals are carried out to ensure that producers do not slaughter animals until the residues of any medicines used have fallen below the predefined safe levels (MRL). These programs also check for the presence of any residues, no matter how small, of drugs that are prohibited for use in food animals. Action is taken if either MRL is exceeded or prohibited residues are found.

Both the European Union and the United States require that countries exporting food animal products into their markets operate a program of checks for residues that will ensure that imported food is safe for their consumers. The presence of residue levels above the MRL or of detectable amounts of prohibited chemicals normally results in the prohibition of imports of the product concerned until the cause of the unsafe residue has been traced and the exporting country has taken appropriate actions to ensure that no further breach will occur. Thus producers wishing to export to the United States or Europe must ensure that sufficient time has elapsed between medication and slaughter so that no residues in excess of the MRL are present in the edible tissues, and must never, under any circumstances, use prohibited medicines. In the case of aquaculture, these include chloramphenicol, nitrofurans and malachite green. The use of such chemicals in any part of the production cycle or during processing and handling involves the risk of transfer of residues to export animal tissues and the potential loss of markets.

The regulatory authorities in exporting countries can assist producers by developing tighter regulation of the supply of veterinary medicines, strictly enforcing existing regulations and implementing residue monitoring programs. A basic overview of the regulatory procedures for the authorization of veterinary medicines, with emphasis on residues in food animals can be found in Alderman and Subasinghe (2003).

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Disease Surveillance

Chris Baldock

AusVet Animal Health Services Pty Ltd.
PO Box 3180, South Brisbane
Queensland, AUSTRALIA QLD 4101

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Abstract

This paper gives an overview of aspects of disease surveillance relevant to reducing the risk of international spread of aquatic animal diseases, as well as control of important epidemic diseases. These issues have always been the focus of international aquatic animal health authorities; however, they have become even more important since the formation of the World Trade Organization (WTO) and subsequent implementation of the various multilateral agreements on trade. Consequent increased international trade in aquatic animal commodities has resulted in increasing scrutiny of the risk of international spread of disease. As a result, there has been a growing interest in developing better systems for investigating and reporting animal diseases. Reliable evidence for freedom from particular diseases is also becoming an issue of major interest. For this reason, the emphasis in this paper is on those aspects of disease surveillance that provide reliable information both to support trade and to meet international reporting requirements.

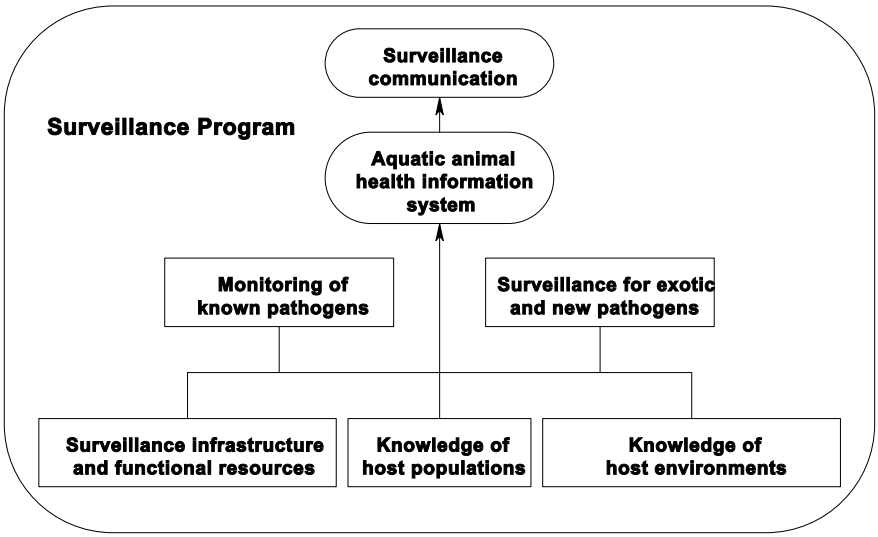
Introduction

Disease surveillance should be an integral and key component of all government aquatic animal health services. This is important for early warning of diseases, planning and monitoring of disease control programs, provision of sound aquatic animal health advice to farmers, certification of exports, international reporting and verification of freedom from diseases. It is particularly vital for animal disease emergency preparedness.

In the Office International des □pizooties' (OIE) *International Aquatic Animal Health Code* (OIE 2001), disease is defined as *clinical or nonclinical infection with one or more of the aetiological agents of the diseases listed in this Code,* while disease surveillance is defined as *a systematic series of investigations of a given population of aquatic animals to detect the occurrence of disease for control purposes, and which may involve testing samples of a population*. The Code does not include a definition of monitoring; however, monitoring can be defined as *a systematic series of investigations of a given population of aquatic animals to detect changes in the prevalence and geographical distribution of disease, and which may involve testing samples of a population*. Thus, surveillance is concerned with detection of new or exotic diseases, while monitoring is concerned with understanding changes in endemic disease levels and distribution. The term *surveillance program* is often used in a wider sense to incorporate both surveillance and monitoring activities.

Figure 1 provides a conceptual summary of the relationships among the broad components of a surveillance program. This figure incorporates the OIE Code concepts of providing an effective surveillance infrastructure as well as including a description of host population and environmental characteristics. The concepts of passive and active surveillance, aquatic animal health information systems, and national and international disease reporting are discussed below.

Figure 1. Relationships among different components of a surveillance program incorporating OIE Code concepts.



Purpose and Objectives of Surveillance

The primary purpose of aquatic animal disease surveillance is to provide cost-effective information for assessing and managing risks associated with trade in aquatic animals and products, animal production efficiency and public health. This statement of purpose is consistent with the OIE Code and international perceptions of what surveillance is meant to achieve.

The disease focus of a surveillance program should be based on the OIE-listed diseases, any national list of notifiable diseases, and other diseases of special concern to the particular country. The recommended statements to precisely articulate objectives that define the boundaries of surveillance are:

- rapidly detect new and exotic infectious diseases in aquatic animals;
- provide evidence of freedom from diseases relevant to domestic and international movement of aquatic animals and products;
- describe the distribution and occurrence of diseases relevant to disease control and domestic and international movement of aquatic animals and products; and
- assess progress in control or eradication of selected diseases and pathogens.

As written, the above objectives are unambiguous and clearly set boundaries on what surveillance is meant to achieve, whether the activity be undertaking a survey to describe the distribution and prevalence of an important disease, collecting information to ensure that disease zones are maintained etc.

Types of Surveillance

A variety of names have been used to describe different types of surveillance programs. There are many ways that different surveillance activities can be described. Terms such as *passive surveillance* and *active surveillance* are commonly used, but it is not always clear what they mean. A brief explanation is given below, since a comprehensive surveillance program can be seen as comprising both active and passive surveillance components.

Passive surveillance

Passive surveillance is the secondary use of routinely collected data that was generated for some other purpose. This involves the routine gathering of information on disease incidents such as requests for assistance from farmers, reports from field officers, submission of diagnostic specimens to laboratories and results of laboratory investigations.

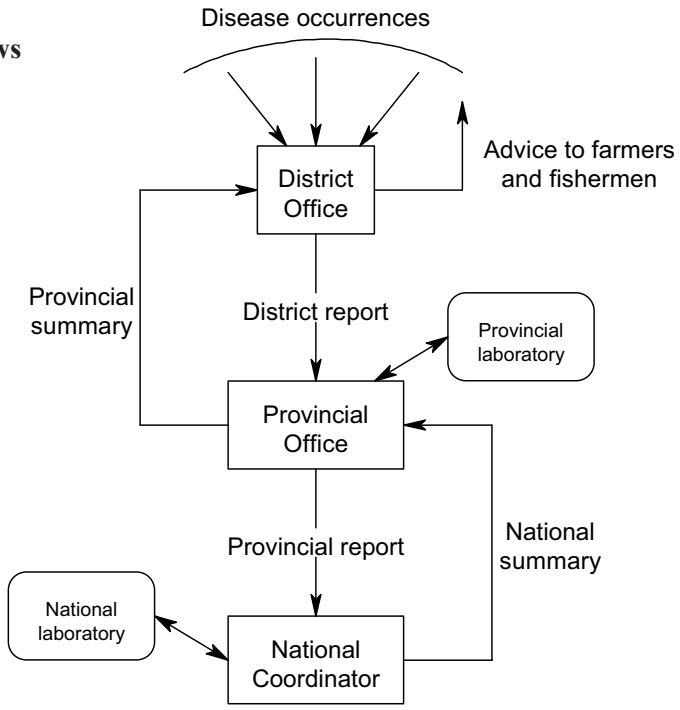
Passive surveillance can be used to create a national disease reporting system based on the day-to-day disease investigation activities of field officers and laboratory network. Such a reporting system should include feedback loops. A theoretical example is shown in Figure 2. At the first stage of investigation, sufficient data are collected to assist the farmer with his/her problem. It is necessary to report only a small portion of this data to the next administrative level. However, an audit trail should be maintained of all records generated at each stage of reporting. Thus, although the national system may contain only a very brief summary of each investigation, the full information can be accessed if required.

It is important that passive surveillance systems are strengthened and that the disease information that they yield be effectively captured and analysed. However, it should be recognised that complete reliance on passive surveillance usually leads to very significant under-reporting of diseases. It is essential that passive surveillance be supplemented by a strong system of active disease surveillance, particularly for emergency diseases.

Active surveillance

In contrast to passive surveillance, active surveillance involves the active collection of accurate and representative field data on the health of the livestock population. Active disease surveillance includes deliberate and comprehensive "searching" for evidence of disease in animal populations and, in some instances, verification that specified populations are free of specific diseases. Active disease surveillance programs may be of a "catch all" nature to detect any significant disease occurrences, or may be purposeful to target specific high-threat diseases or to monitor the progress of individual disease control or eradication campaigns. In order to maximise the value of active surveillance, it should be based on survey techniques that provide representative samples of the population of interest. Bias is avoided by the use of probability sampling techniques, and appropriate analysis provides valid measures of the precision of estimates.

Figure 2. Example of information flows in a national disease reporting system.



The movement of infected animals very frequently spreads epidemic diseases. Emphasis in active disease surveillance for such diseases must be given to situations where animals are on the move, especially where they are then brought together from a number of different sources. This includes markets, trading routes, border areas and floods.

Surveillance in populations of wild aquatic animals should also not be overlooked. Wild animal populations may provide a reservoir of infection for some diseases, but may also act as a sensitive indicator of diseases that are not very clinically apparent in adjacent farmed populations.

Requirements for a Surveillance Program

Diagnosis can be at different levels and in the *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals* (FAO/NACA 2000), three levels are proposed, with Level 1 essentially being the diagnosis made by the investigating field officer. However, at each level, a *case definition* is required for each disease to be reported. Case definitions may be quite general or very specific, depending on the perceived value of the resultant information.

Each investigation that is undertaken as part of the surveillance program will result in a diagnosis at some level of certainty with respect to the specified problems/diseases/pathogens of interest. In some instances, the investigation may not even result in a diagnosis, but merely describe the incident (e.g., in terms of morbidity, mortality, duration of the problem, clinical signs, appearance of gross lesions). The level of diagnostic certainty will be largely determined by the investigating officer's ability to recognise the characteristics of specific diseases, as well as whether or not the report is followed up with a more detailed investigation by people with greater expertise. In most instances, the highest level of diagnostic certainty will be achieved when the investigation includes positive results with an internationally approved laboratory examination. Thus, it will be necessary to include an assessment on the diagnostic certainty with each record of a disease investigation.

Investigations of suspected disease occurrences that eventually result in meaningful surveillance require:

- appropriately trained and motivated personnel;
- standardised field and laboratory methods supported by quality control; and
- access to manuals and training opportunities.

Thus, the basis of all good surveillance programs is observant and skilled people with appropriate resources who understand what is normal, are alert to changes and can describe the abnormalities they see. The design and structure of a surveillance program depend on its purpose. However, all surveillance programs have some basic common features, including:

- a clearly stated and valued purpose;
- a list of problems/diseases/pathogens of interest;
- the capability and capacity to undertake investigations to the required level of diagnostic certainty;
- specifications for the information to be collected; and
- a system to collect, record and collate data, as well as report findings.

Aquatic Animal Health Information Systems

To provide access to surveillance findings, some form of information repository or warehouse is required from which various communications can be produced in a variety of formats. In the case of a repository for information on the health of aquatic animals, this is usually given the name *Aquatic Animal Health Information System* (AAHIS).

An AAHIS is a system for the collection, storage, analysis and reporting of information related to the health of aquatic animals. As such, virtually every organised society that keeps aquatic animals has some

form of aquatic animal health information system. This may range from the system used in a single village in a developing country (in which information is gathered by owners, passed by word of mouth, stored in the memory, analysed mentally, and further reported by word of mouth), to a national system such as that used in developed countries (involving a network of government officers, laboratory diagnostic resources, complex sampling strategies, high-powered computerised data management and analysis systems, and extensive procedures for distributing and acting upon the information gathered).

The word "system" implies a collection of many different components working together for a particular purpose. All too often, the expression "information system" gets mixed up with concepts of information technology, and is understood to refer to a computer system. Computers certainly play a role in most modern aquatic animal health information systems, but they are merely one component, a tool for handling the information. Instead, "system" here refers more to a set of operational and administrative procedures for the collection of data from a range of different sources, the processing of that data to produce useful information, and the application of that information to protect the health of aquatic animals and improve the well-being of their owners.

International Disease Reporting

A comprehensive surveillance program with data and reports collected in a national aquatic animal health information system can provide the basis for international disease reporting. Most countries report disease occurrence in some way. There are various international levels of formal reporting, the most important of which is through the Office International des Épizooties (OIE). However, there may be a number of other levels of reporting in a region. Examples are briefly described below.

Office International des Épizooties (OIE)
OIE has obligatory disease reporting requirements for member countries. This should be factored into the national disease surveillance system. A staff member in the national office of the relevant authority should be allocated the responsibility of preparing draft international disease reports, for OIE and elsewhere, for the approval of the Responsible Officer. The head of the national epidemiological unit would generally be the most appropriate person to carry out this function.

In brief, countries should notify OIE within 24 hours of any of the following events:

- for *diseases notifiable to the OIE*, the first occurrence or re-occurrence of a *disease*, if the country or zone of a country was previously considered to be free of that particular disease;
- for *diseases notifiable to the OIE*, important new findings which are of epidemiological significance to other countries;
- for *diseases notifiable to the OIE*, a provisional diagnosis of a *disease* if this represents important new information of epidemiological significance to other countries;
- for *diseases* not notifiable to the OIE, if there are new findings of exceptional significance to other countries.

Thereafter, monthly reports are sent to OIE to provide further information on the evolution of the disease incident until the disease has been eradicated or the situation has stabilised.

Quarterly and annual reports are sent on the absence or presence and evolution of *diseases notifiable to the OIE* and findings of epidemiological importance to other countries with respect to *diseases* that are not listed.

In addition, there are requirements to report on changes to the status of *infected zones*.

Regional Organisations
Regional organisations may be established whose mandate may include the fostering of international cooperation on aquatic animal health issues and facilitation of safe international trade in aquatic animals

and their products. These organisations may also have requirements of their member countries for reporting and sharing of information on diseases.

The Network of Aquaculture Centres in Asia-Pacific/Office International des □pizooties/Food and Agriculture Organization of the United Nations (NACA/OIE/FAO) Quarterly Disease Reporting System is an example of such cooperation in the Asian Region. The NACA/OIE/FAO list includes all diseases listed by OIE, the notifiable ones as well as the other significant diseases. This list, however, more specifically reflects the Asian situation. Additional diseases are listed that occur in parts of the Asia-Pacific Region, and thus are of concern because they may spread further within the region.

Special Arrangements with Neighbouring Countries and Trading Partners

Many epidemic aquatic animal diseases do not respect borders and can spread very rapidly from country to country. Neighbouring countries should therefore cooperate closely in the control of these diseases. Unless this is done, the disease control efforts of individual countries will be continually frustrated. Part of this cooperation should be the rapid sharing of information on new disease occurrences and the spread of existing epidemic diseases to new areas, particularly near shared borders. Arrangements should not only be made for this information to flow between the respective Responsible Officers, but also at a local level between contiguous district, provincial or regional offices along borders.

Likewise, arrangements should be made for the rapid flow of disease information between the Responsible Officers of major trading-partner countries for aquatic animals and their products.

An example in Asia is the group of countries influenced by the Mekong River.

Conclusions

Aquaculture production is expanding throughout the world during a period of rapid change in international trading arrangements. Acquiring, analysing and reporting information on the health of aquatic animals will become increasingly important to aid decision makers in developing sound policy, not only for disease control but also for quarantine and health certification to permit the safe movement of aquatic animal commodities both within countries and internationally.

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Aquatic Animal Disease Zoning

B. J. Hill

**Centre for Environment,
Fisheries and Aquaculture Science (CEFAS)
CEFAS Weymouth Laboratory
Barrack Road, Weymouth, Dorset DT4 8UB,
UNITED KINGDOM**

B.J. Hill. 2004. Aquatic animal disease zoning, p. 43-50. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper describes the different types of zones currently recognised by the Office International des pizooties (OIE) for aquatic animal diseases, details movement principles under a zoning policy, explains general requirements for zoning, lists the OIE zoning requirements for freedom from specific diseases notifiable to the OIE, and highlights issues that countries need to consider for following a zoning approach for aquatic animal diseases. The information is based on the disease zoning guidelines presented in Chapter 1.4.4 of the OIE *International Aquatic Animal Health Code* (2002). As a current example of zoning in practice, a description is given of how the European Union is achieving zoning for two major salmonid diseases, viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN).

Introduction

Traditionally, political boundaries have been used to delineate the animal disease status within a country. Often this has been extended to the country as a whole, even where the diseases of concern have a limited within-country distribution. This has been a common scenario due to administrative ease, rather than a reflection of true disease risks of animals being moved from one area or country to another. Zoning for disease purposes allows the identification of specific geographical areas within a country or neighbouring countries, as having a defined status with respect to a particular disease. This can facilitate the continuation of trade activities, despite a disease incursion into a particular area, through the establishment and identification of specified zones free of the disease so that only the infected zone is placed under movement restrictions. The other advantage is that it allows for part of a nation's territory to be identified as free of a particular disease, rather than having to demonstrate that the entire country is free. This is particularly helpful for diseases where eradication from an affected country is not a feasible option in the foreseeable future, as it permits protection of zones free of the disease by restricting introduction of animals to those originating from other free zones.

When evaluating the aquatic animal health situation in a country with a view to exports of aquatic animals and/or aquatic animal products, it has been past practice of importing countries to judge that exporting country as a whole. If an infectious disease existed somewhere within a country's borders, or if its presence was suspected, the whole country was considered infected. In many cases, a policy of risk avoidance rather than risk assessment was usually implemented by importing countries, and this frequently has resulted in restrictions to international trade, sometimes without sound justification. Climatic and geo-

graphical barriers are more effective in containing diseases of aquatic animals than are frontiers, and factors such as population density, aquatic animal movements and management practices are of paramount importance in determining the distribution of diseases of aquatic animals, both nationally and internationally. Recognition of the biological basis of variations in the presence or extent of disease is a first step in the application of the concept of zoning to aquatic animal health regulations for international trade.

General Requirements for Zoning

In a country wishing to set up a system of zoning for controlling an aquatic animal disease, the disease must be compulsorily notifiable to the Competent Authority. The requirements for different types of zones vary with the disease for which they are established. Size, location and delineation will depend on the disease, its method of spread and its status in the country. Separate conditions will be developed for each disease for which zoning is considered to be appropriate. The extent of zones and their limits should be established by the Competent Authority and enforced by national legislation. They should be clearly delineated by natural, artificial or legal boundaries, which must be effective.

Constant supervision is essential to prevent live aquatic animals from being transported across borders, unless from a zone of equal or better aquatic animal health status. In addition, it may be necessary to control movement of aquatic animal products, aquatic animal genetic material, biological products, pathological material and aquatic animal feedstuffs within and between zones.

Countries wishing to set up a system of zoning must have an effective organisation and infrastructure for disease control in aquatic animals. There must be adequate administrative structures, provided with legal and financial resources to give adequate cover for the development of the different actions required. The Competent Authority must have the necessary resources at its disposal and must be able to supervise the boundaries, maintain clinical and epidemiological surveillance and carry out the necessary diagnostic tests. There must be prompt reporting of outbreaks of disease to the Competent Authority and to OIE. Documented evidence must be provided that an effective system of disease control and surveillance is in operation, at least in the different zones if not in the whole of the country.

Key points:

- Zones are usually clearly delineated geographical areas within a country, but they can also cross national borders.
- The principal aims of zoning are to facilitate trade for free zones in an otherwise infected country, and to protect those free zones against the introduction of pathogens.
- Free zones can be officially recognised within a country, according to a scheme developed by that country or between neighbouring countries sharing one or more river systems by mutual agreement.
- If a country wishes to gain official recognition as being free, or having zones that are free, from one or more diseases it believes to be exotic to its territory, it needs to establish an official health surveillance and monitoring system.
- The Competent Authority of the country needs to specify how zonal boundaries are to be controlled. Effective systems for legal control of aquatic animal movements into and out of zones need to be established.
- The tools for delineation relate to the possible spread or containment of a disease or delineate an area from which a disease is absent.
- As different diseases have different means of spread, the delineation of zones may depend on the particular disease concerned.
- Diseases of concern must be made notifiable in the country or countries wishing to establish one or more free zones.
- For notifiable diseases, export to a country, zone or aquaculture establishment officially approved as free of such a disease, all live aquatic animals should be derived from a country, zone or aquaculture establishment with equal status.

Types of Zones

For inland waters, a zone may be an entire river system or water catchment area, or two or more adjacent water catchment areas. Tributaries or sections of a river system may comprise a "mini-zone" where physical barriers (e.g., dams not passable for migrating fish) or ecological and/or hydrological characteristics restrict or prevent spread of disease into or out of it. Where a river passes through more than one country or forms the border between countries, clarification of jurisdictional issues will be required, as will full co-operation between the national Competent Authorities of the different countries involved.

For coastal waters, a zone is usually a stretch of coastline that is clearly delineated by its hydrographical properties or the geographic range of the aquatic animal host(s).

The terms "infected zone" or "free zone" always imply "infected with a particular disease" and "free of a particular disease", respectively. A zone is never generally "free of all diseases".

Three types of zones are recognised by OIE: i) free zone, ii) surveillance zone and iii) infected zone. Their characteristics and the conditions that apply to them are as follows:

i) Free zone
A disease-free zone can be established within a country or countries where the disease is present. In the free zone, there must be knowledge of the disease status of wild populations of susceptible species. Establishment of a free zone requires that all aquaculture establishments are registered with the Competent Authority and regularly monitored by that Authority to confirm the absence of the disease(s) of concern. All suspected outbreaks of the disease must be investigated immediately by the Competent Authority. Importation of aquatic animals from other parts of the country or from countries where the disease still exists into the free zone must take place under strict controls established by the Competent Authority. The free zone should not be dependent on importation of aquatic animals or aquatic animal products from infected zones or countries that could introduce the disease agent.

ii) Surveillance zone
A surveillance zone must have certain minimum dimensions, with a precise geographical limitation based on hydrological data and the nature of the disease. Aquatic animal movements into and out of the zone must be controlled.

A surveillance zone must have rigorous disease prevention and control measures. Suspected outbreaks of the disease must be investigated immediately and, if confirmed, must be eradicated. A mechanism for immediate reporting to the Competent Authority must be in place. Adequate surveillance activities must follow in order to ascertain the potential spread of such outbreaks, after which it may be necessary to modify the boundaries of the zone.

Importation of susceptible aquatic animals into the surveillance zone from parts of the country or from other countries where the disease exists can only take place under suitable controls established by the Competent Authority. Freedom from infection should be confirmed by appropriate laboratory tests.

iii) Infected zone
An infected zone is a zone where the disease is present, in an otherwise disease free country. A surveillance zone will separate the infected zone from the remainder of the country. Movement of susceptible aquatic animals out of the infected zone into the disease free parts of the country must be strictly controlled. Four options can be considered:

i. No live aquatic animals may leave the zone.
ii. Aquatic animals can be moved by mechanical transport to special fish slaughtering premises/ mollusc and shrimp production facilities located in the surveillance zone for immediate slaughter.
iii. Exceptionally, live aquatic animals can enter the surveillance zone under suitable controls estab-

lished by the Competent Authority. For diseases in which the disease agent constitutes a surface pathogen, appropriately disinfected eggs can enter a surveillance zone. Freedom from infection of these aquatic animals must be confirmed by appropriate tests before they can enter the zone.

iv. Live aquatic animals can leave the infected zone if the epidemiological conditions are such that disease transmission cannot occur.

Movement of Aquatic Animals Between Zones

As a general principle, live aquatic animals may be moved between zones with the same infectious agents present, or from zones with fewer/none of the same infectious agents that are present in the receiving waters. They should not be moved from zones with infectious agents that are absent from the receiving zone. Live aquatic animals may be moved from higher to lower health status, but not from lower to higher health status.

To accurately assess the health risks associated with moving aquatic animals from one zone to another, it is necessary to know if the animals to be moved are susceptible to the disease(s) of concern. This may not always be known. "Susceptibility" can range from manifest disease, to non-clinical "carriage" of the infectious agent. For notifiable diseases, OIE advises that exported aquatic animals are certified as coming from sources free of these diseases, regardless of species susceptibility. Such certification requires OIE-based surveillance to establish "free-zone" status. The European Union regard all live fish species not known to be susceptible to their listed diseases of concern (currently IHN and VHS for finfish) as being potentially capable of transferring these diseases to free countries, zones or farms, from infected waters, unless otherwise proven.

Where there are zones of equal health status, there should be little if any justification, on disease risk grounds, for preventing trade in the aquatic animals between them. This applies equally to trade between zones that have been demonstrated to be free of particular disease(s) and trade between zones that are positive for the same disease(s). This principle is well illustrated in the harmonised rules governing intra-Community trade of aquaculture animals and their products in the European Union under the terms of Council Directive 91/67/EEC.

An Example of Practical Application of Zoning in the European Union

The application of a zoning system for aquatic animal diseases has been operated in the European Union (EU) since 1993. In the late 1980s, EU Member States agreed that a "single market" should be established within the European Community to allow free movement of goods, including live animals, between all Member States. However, it was recognised that animal health controls would be required to prevent disease spread within the EU, since Europe does not have a uniform fish health situation. This led to the introduction of harmonised fish disease control measures (EC Directive 91/67/EEC)[1] that came into force on 1 January 1993. This Directive stipulates the animal health conditions used to govern marketing of aquaculture animals and products within the EU and from outside the EU, i.e., from "third countries". Three categories of disease are listed according to seriousness and economic impact:

- List I covers highly infectious diseases exotic to the European Community and deemed likely to have a major impact should they be imported. Member States of the EU are required to take immediate action to eradicate any outbreaks that occur (currently restricted to infectious salmon anaemia (ISA)).

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[1] Council Directive of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (91/67/EEC). O. J. No L 46/1, 19.2.1991.
Council Directive 95/22/EC of 22 June 1995 amending Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products. O. J. No L 243/1, 11.10.1995.

- List II deals with highly infectious diseases, of major economic impact, present in certain parts of the EU but absent from other parts. Examples of such diseases are viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) of finfish, and bonamiosis and marteiliosis of bivalve molluscs. (Zoning is applied for these diseases)
- List III covers diseases that have a significant economic or ecological impact under certain circumstances and are considered by some Member States to warrant national control measures, particularly when a country, is free of the disease(s) in question.

Approved Zones and Farms

In order to reduce the risk of List II fish diseases spreading within the EU, Member States with zones (or farms) deemed to be free of these diseases may undertake surveillance to maintain this status. The EU uses the term "approved zones" instead if "free zone" (used by OIE). In addition, the EU Directive does not recognise "disease-free country". Instead, emphasis is placed on establishing "approved zones", whether these are within a country, comprise the entire country, or cover parts or the whole of one or more country(ies).

There is provision for "*coastal zones*", covering estuaries or lengths of coastline, or "*continental zones*", consisting of one or more water catchment areas. Such zones are delineated by the Competent Authorities of the country(ies). The Competent Authorities must have legal powers to enforce the rules and conditions that apply to establishment and maintenance of an "approved zone". The EU definitions of continental and coastal zones are:

Continental zones for fish

"A continental zone consists of:

a part of the territory comprising an entire catchment area from the source of the waterways to the estuary, or more than one catchment area, in which fish is reared, kept or caught, **or**

a part of a catchment area from the source of the waterways to a natural or artificial barrier preventing fish from migrating from downstream of that barrier.

The size and the geographical situation of a continental zone must be such that possibilities for recontamination, e.g., by migrating fish, are reduced to a minimum. That may require the establishment of a buffer-zone in which a monitoring programme is carried out without obtaining the status of approved zone."

Coastal zones for fish

"A coastal zone consists of a part of the coast or sea water or an estuary with precise geographical limits which consists of a homogeneous water system or a series of such systems. If necessary, a coastal zone may be deemed to consist of a part of the coast or sea water or an estuary situated between the mouths of two watercourses or of a part of the coast or sea water or an estuary where there are one or more farms, provided that *provision is made for a buffer zone on both sides of the farms."*

Coastal zones for molluscs

"A coastal zone consists of a part of the coast or sea water or an estuary with a precise geographical delimitation which consists of a homogeneous hydrological system."

For a continental territory, a zone usually comprises a minimum of an entire river system, including all tributaries, from their source(s) to the sea. Where a river system originates in one country and then passes through one or more other countries before reaching the sea, management requires co-operation and

harmonisation of rules/services in the countries involved, if conditions for approval of the zone are to be met. As with OIE zoning guidelines, rivers with impassable barriers can have upstream subzonation, and coastal zones are delineated using hydrographical parameters e.g., bay or coast between two peninsulas, or areas separated by tide or currents.

Achievement and Maintenance of "Approved Zone" Status

Where a Member State of the EU considers that its territory, or part of its territory, is free of one or more of the List II diseases, it may submit to the European Commission evidence that the zone(s) concerned meet(s) the conditions laid down in Directive 91/67/EEC and, in particular, the detailed requirements of Annex B. In essence, all farms within the zone must have been under supervision of Official Services (Competent Authority) for at least two years, during which they have been found to be free from any clinical or other sign of List II disease(s) with two health inspections per year at a time when the water temperature favours development of the disease in question. The health inspections require examination of samples at an approved laboratory. The Member State (country) concerned must also provide evidence of its legal powers to enforce movement restrictions on fish (or bivalve molluscs) into the specified zone during the period of inspections, sampling and laboratory tests over this two-year period and thereafter. The European Commission examines the results, together with representatives of all EU Member States, and a decision (EC) for approval is reached based on these results.

Once a zone is approved, movements of aquatic organisms into the zone are restricted to those from other approved zones, where exporter and importer zone status is dependant upon continuing evidence that the disease agents(s) in question is (are) absent. This requires regular inspection of all the farms in the zone with sampling and laboratory tests conducted at a defined maintenance size and frequency.

The EU Directive also provides for suspension, withdrawal and restoration of "approved zone" status if abnormal mortalities or clinical signs constitute grounds to suspect a listed disease. The Competent Authority (Official Services) of the country must be notified immediately and samples of clinically affected aquatic organisms sent to an approved laboratory to be tested for the listed pathogen. If results are positive, the Competent Authority (Official Services) will withdraw approved zone status for the entire zone or part of the zone, as necessary. The latter normally applies where an infected area can be separated from surrounding zones. Restoration of approved status is achieved following evidence of eradication.

Trade in Aquatic Animals Between Zones

The movement of live farmed, or wild, fish and molluscs to waters within an "approved zone" is restricted to animals originating from within the same zone or from another zone with equal designation, i.e., zones which are free of the same disease(s). There are no health-based restrictions to trade in live fish or bivalves, whether farmed or wild, within or between approved zones, or for introduction to any waters in non-approved zones within the EU (irrespective of which country the waters are in) other than for any safeguards agreed to by all Member States for List III diseases. For all movements of live fish and their ova, or of live molluscs, into approved zones, documentation is required certifying that the fish (or molluscs) originate from a zone having the same List II disease status. Such documents are completed by the national Competent Authority for every consignment, within 48 hours of loading, and must accompany the fish throughout their transportation.

Implementing a Disease Zoning System in Developing Countries and Regions

Although it may not be possible in the near future for some countries to meet all the provisions for zoning specified by OIE or as implemented in the EU, the general principles for zoning and movement can be applied. As experience is gained in the compilation of disease surveillance data and national legislation

and infrastructures developed to control disease spread, the accuracy of zone definitions will increase. During any data collection period, however, there are a number of important basic considerations for initial development of zones:

- Selection of diseases for zoning should take into account the benefits *versus* the cost of setting up and maintaining the zoning system. Benefits include reduction of disease spread and enhancing trade to other countries, or zones with the same disease status. Costs include the costs of surveillance, legislation, enforcement, certification, etc. An additional consideration is where establishment of a zone in shared water bodies such as coastal areas or large river systems (e.g., the Mekong River) requires cross-border co-operation between neighbouring countries.
- When a country wishes to gain official recognition as being free from one or more diseases it believes to be exotic to its territory, it will need to establish an official health surveillance and monitoring system. The diseases selected must be notifiable (mandatory reporting) and resources for these activities have to be allocated with responsibility given for long-term maintenance of the zoning system.
- Clarification of jurisdictional issues is essential, especially identification of the Competent Authority for aquatic animal diseases for each country and, in the case of shared water resources, the mechanism for harmonizing each party's activities and administration of the process. Within a country, the Competent Authority may be the veterinary authorities, or some other regulatory agency with responsibility for the health of aquatic resources e.g., government fisheries department. In the case of shared water resources, the Competent Authority may be a mutually agreed existing authority or a newly established bi- or multilateral decision-making body. The Competent Authority must have, or have access to, aquatic animal health expertise used to specify, delineate and control the boundaries of each zone, including aquatic animal movements into and out of each zone.

Although zoning presents logistical challenges, with sufficient political will and co-operation, it is a mechanism with proven efficacy in decreasing the spread of aquatic animal diseases and providing clear benefits in terms of facilitating trade activities.

Databases for Import Risk Analysis

J. Richard Arthur

6798 Hillside Drive
Sparwood, B.C., CANADA V0B 2G3

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Abstract

This paper briefly reviews the characteristics of good databases for use in supporting import risk analysis (IRA).

Introduction

Databases to support import risk analysis (IRA) are found at the national, regional and international levels; however, because each country's disease concerns and appropriate level of protection (ALOP) will differ, individual countries will need to develop and maintain their own national pathogen databases.

Characteristics of a Good Database

Good databases, whether at the national, regional or international level, have many similar characteristics. These include:

- easy and quick retrieval of desired information by users;
- easy to request information at the level of detail required by the user;
- provision of enough information so that the user can assess the reliability of the information provided;
- easy input of information by the database manager;
- easy modification, such that the database structure and contents can evolve with changing needs; and
- good mapping functions.

At the national level, a good database should be:

- comprehensive - preferably listing information for all known and potential pathogens reported from the country; and
- based on highly detailed individual records (i.e., it should retain as much information as possible). This could include information on:
    - host species,
    - host collection data,
    - sample summaries,
    - individual fish data,
    - identifying laboratory/individual,
    - published source (if any),
    - diagnostic techniques used,
    - comments, etc.

National Databases

Because knowledge on what diseases and pathogens are present in a country and their host and geographic distributions within the country are essential to IRA, each country will need to establish its own national database. In the long-term, it will be easier and less expensive to establish a national database than to conduct a new analysis for each case as it arises. A national database will also provide essential evidence that the national disease status is known, which is increasingly a prerequisite for gaining access for live aquatic animals and their products to international markets. Ideally, national databases for countries within a region or sub-region should be linked and harmonized. Global or regional databases cannot be expected to serve this function due to their wider scope, differing priorities and purposes, lack of resources, and the need to for national databases to be linked with national disease surveillance and monitoring programs, disease surveys, and national taxonomic expertise. However, they can provide an important source of support and information to national efforts. Modified and tested, several could serve as a platform for a generic national database.

Types of Data

National databases can contain several types of data. These include historical data, such as that contained in scientific publications (both reviewed and grey literature), data derived from passive surveillance (e.g., reports of disease outbreaks gathered by extension officers, fish farmers etc.), previous surveys of parasites and pathogens, both published and unpublished, and the databases on "notifiable" and "other significant diseases" maintained by the Office International des Épizooties (OIE, www.collabcen.com).

The other type of data is that specifically collected for national purposes, based on specifically designed survey techniques (i.e., data derived from active surveillance). Such data is generated by national and state surveillance and monitoring programs (i.e., for OIE or FAO/NACA listed diseases) and comprehensive national disease surveys (i.e., the United States Fish and Wildlife Service's (USFWS) National Wild Fish Disease Survey (www.esg.montana.edu/nfhdb/).

Issues with Data

In general, some "official" OIE data and much historical data derived from the literature (both peer reviewed and non-peer reviewed sources) or from the unpublished files of fish health workers must be treated with caution. The accuracy of such data must be accessed on a case by case basis, taking into consideration the individual and national expertise of the reporting individuals and/or institutions, as well as the study design (e.g., the survey design, sampling protocols, sample sizes, collection and diagnostic methods used, etc.). Unfortunately, this is particularly true for data generated within developing countries, where there are many confirmed or suspected cases of pathogen misidentifications, inadequately described species, *species inquirendae*, *nomina nuda* etc. to be found in the literature (see, for example, the checklists of Arthur and Lumanlan 1995; Arthur and Ahmed 2002). In some cases, the historical data provides only a rough indication of the types of pathogens occurring in the country in question.

National Pathogen Surveys

Ideally, a national database should be supported by a national pathogen survey. Such surveys should be targeted so as to maximize the use of limited expertise and resources. Countries that are party to the Convention on Biodiversity (CBD) have an obligation under the terms of the convention to undertake national biodiversity surveys; such surveys should, of course, include inventories of the pathogens and parasites of aquatic animals.

Three Examples of Computer-based Databases

Below are three examples of computer-based databases, one an international database, one a regional database, and the other a national disease survey database.

International Database on Aquatic Animal Diseases (OIE)
The International Database on Aquatic Animal Diseases (www.collabcen.net) is maintained by Dr Barry Hill, at the Centre for Environment, Fisheries and Aquatic Science (CEFAS), Weymouth, United Kingdom. It provides a detailed source of information on aquatic animal diseases listed by the Office International des □pizooties (OIE). It contains information on OIE-listed diseases based on official reports submitted to the OIE by member countries and unofficial records.

Aquatic Animal Pathogen and Quarantine Information System (AAPQIS)
AAPQIS was established by the Food and Agriculture Organization of the United Nations (FAO). AAPQIS-Asia is maintained by the Network of Aquaculture Centres in Asia-Pacific (NACA) (www.enaca.org/aapqis/). The primary purpose of AAPQIS is to assist national quarantine and inspection services by providing information necessary for scientifically based disease risk assessments of the dangers posed by proposed importations of aquatic animals. AAPQIS is constructed using four major databases, a records database, a pathogen database, a host database and a references database. AAPQIS provides the user with information on: pathogens (description, distribution, photos, pathology, taxonomy, etc.), hosts, countries, individual records and references. More information on AAPQIS can be found in Subasinghe and Arthur (1997).

The United States Fish and Wildlife Service (USFWS) National Wild Fish Health Survey Database
The USFWS National Wild Fish Health Survey Database (www.esg.montana.edu/nfhdb/) contains detailed information of selected pathogens of national and regional (sub-national) importance to fish health in the United States. An interesting feature of the database is the use of eight digit "hydrologic unit codes" (HUC) developed by the United States Geological Survey (USGS) for progressive identification of geographic/drainage basin locations along with graphical locator maps. The database contains two sub-databases, one for data generated by the National Wild Fish Health Survey, and another containing historical data for the pathogens of concern.

Conclusions

National pathogen databases are essential to IRA and for implementation of national strategies for aquatic animal health (see FAO/NACA 2000). Examples of software that might be adapted or serve as models for use by developing countries exist; however each country will need to develop or adapt software to its particular needs and situation. National pathogen databases should be supported by national disease surveys targeting specific diseases of international or national importance. For some countries, this will require much work and resources; however, the advantages of having this data readily available should far outweigh the initial effort and expenditures required.

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Role of the OIE Fish Diseases Commission in Aquatic Animal Health Management

B. J. Hill

**Centre for Environment,
Fisheries and Aquaculture Science (CEFAS)
CEFAS Weymouth Laboratory
Barrack Road, Weymouth, Dorset DT4 8UB
UNITED KINGDOM**

B.J. Hill. 2004. Role of the Fish Diseases Commission in Aquatic Animal Health Management. p. 55-58. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper describes the role of the Fish Diseases Commission of the Office International des □pizooties (OIE) and presents information on the various activities (past and present) carried out to fulfill its role in providing advice, guidance and information and in the organisation of scientific conferences on special themes in aquatic animal health management. The Commission actively co-operates with a number of regional and international organisations in developing guidelines on health surveillance and disease control policies in aquaculture so that common standards are reached. The Commission will continue to seek ways to strengthen such collaboration in order to reduce the international transfer of diseases that pose a risk to aquaculture production and/or wild populations of aquatic animals.

The Office International des Épizooties (OIE)

The OIE, also known as the World Organisation for Animal Health, is an intergovernmental veterinary organisation established in 1924 in order to promote world animal health. Its Central Bureau is based in Paris. It currently has 164 Member Countries. One of its main activities is to provide guidelines and standards for health regulations applicable to international trade in live animals and their products. The stated mission of OIE is:

- to promote the transparency of animal disease status world-wide;
- to collect, analyse and disseminate veterinary scientific information;
- to provide expertise and promote international solidarity for the control of animal diseases; and
- to guarantee the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products.

Among the main objectives of the OIE is to increase general awareness of disease problems associated with trade in live animals and animal products, including aquatic animals, and to promote means for diagnosis, control or prevention. These objectives generate an approach based upon the following:

- co-ordination of investigations of communicable animal diseases for which international co-operation is essential;

- collection of information on epizootics and control measures applied by the Member Countries; and
- an advisory role in preparing international standards or agreements pertaining to animal health.

The communication of animal health information to Member Countries occurs through their respective Veterinary/Animal Health Services, although in some Member Countries, another Authority, rather than the National Veterinary Services, is responsible for aquatic animal health. Good communication and co-operation between such different national authorities within a country is important.

The OIE has four Specialist Commissions, one of which is the Fish Disease Commission. The role of these Commissions is to use current scientific information to study problems of epidemiology and the prevention and control of animal diseases, to develop and revise OIE's international standards, and to address scientific and technical issues raised by Member Countries.

OIE established the Fish Disease Commission in 1960 to deal specifically with the increase of fish diseases as aquaculture expanded world-wide. From 1988, the scope of the Commission was extended to include diseases and pathogens of molluscs and crustaceans. The five members of the Commission are elected by the OIE International Committee every three years.

The Roles and Activities of the Fish Diseases Commission (FDC)

The FDC compiles information on diseases of fish, molluscs and crustaceans, and on methods used to control these diseases. To fulfil its remit to propose the most appropriate diagnostic and disease prevention and control methods to ensure safe international trade or movement of aquatic animals, the Commission produces *the* International Aquatic Animal Health Code and the Diagnostic Manual for Aquatic Animal Diseases.
The activities of the FDC fall into three main areas:

- provision of advice and guidance,
- provision of information, and
- organisation of scientific conferences on special themes.

Advice and Guidance on Disease Prevention and Control

The FDC approach to animal health control in aquaculture involves making recommendations to Member Countries to apply the following measures:

- Assessment of the health status of aquatic animals in a production site, zone or country, based upon inspections and standardised sampling procedures followed by laboratory examinations conducted in accordance with the instructions given in the OIE *Diagnostic Manual for Aquatic Animal Diseases* (the "Diagnostic Manual").
- Restocking of open waters and aquaculture facilities with products of a health status higher than, or equal to, that of the area concerned.
- Eradication of diseases of socio-economic importance whenever possible.
- Notification by every Member Country of additional requirements, in addition to those provided by the *International Aquatic Animal Health Code* (the "Aquatic Code") for the importation of aquatic animals and aquatic animal products.

If the above procedures are used, it becomes possible to define the health status of aquaculture animals and products for specified pathogens, according to the country, zone or production site of origin. The health status of the product can thus be warranted by the issue of a health certificate by the appropriate official, stating that the aquaculture products in a defined consignment originate from a country, zone or farm/harvesting site free of the specified pathogens listed in the Aquatic Code and possibly of other specified diseases. Aquatic animal diseases included in the OIE system are classified into two lists ("noti-

fiable diseases" and "other significant diseases") on the basis of their socio-economic importance, geographic range and aetiology.

The FDC approach to disease prevention and control is thus based on surveillance for certain diseases, leading to certification of acceptable sources of aquaculture products for national and international trade. The origin may be considered as an entire country, zone or protected aquaculture facility demonstrated to be officially free of these diseases, through the implementation of a national health surveillance scheme that employs sampling and laboratory techniques described in the Manual.

Both the Aquatic Code and the Diagnostic Manual are updated annually by the FDC. The proposed amendments are submitted to Member Countries for comment. Member Countries may independently propose other changes through their Chief Veterinary Officers who communicate directly with the OIE Central Bureau. Such proposed changes are considered by the FDC and a decision taken on their acceptance. Draft recommendations on all the proposed changes are prepared for consideration by Member Countries, who formally vote on these at the annual OIE General Session held in Paris each May.

Disease Occurrence Reporting

New occurrences of diseases in a previously free region must be reported by Member Countries to the OIE in accordance with the reporting requirements of the OIE. The urgency of despatching information varies according to the nature of the disease. The OIE has devised a warning system whereby Member Countries can take action rapidly should the need arise: countries are required to notify the Central Bureau within 24 hours of the occurrence of an outbreak of a notifiable aquatic animal disease, or any other contagious disease likely to have serious repercussions on public health or the economy of animal production (including aquatic animal production). The OIE immediately despatches these data by telex, telegram, fax or electronic mail directly to Member Countries at risk, and in weekly announcements (in *Disease Information*) to other countries. Disease alert messages and the weekly *Disease Information* are also published on line at the main OIE web site (www.oie.int). In addition to the electronic "alert" system, disease occurrence information received from Member Countries is distributed on a periodical basis through the following publications:

- The monthly *Bulletin* provides data on the course of notifiable diseases month by month. The *Bulletin* also contains sections devoted to the epidemiology and control of the principal contagious diseases and to the activities of the OIE.
- The annual *World Animal Health* provides yearly statistics for the OIE notifiable aquatic animal diseases, giving data on the occurrence of diseases in each Member Country, and annual animal health status reports for all Member Countries. These summarise control methods adopted by each country.

Improving Awareness of FDC Information and Advice on Aquatic Animal Diseases

It is the task of the FDC to assist Member Countries to overcome limitations related to implementing the above aspects. First, this is done by increasing general awareness of the role and activities of the OIE in the health control of aquatic animals. The OIE has published a brochure describing the aims and objectives of the FDC, and the FDC web page (www.oie.int/eng/en_fdc.htm) on the main OIE web site provides information on the work of the FDC as well as making the Aquatic Code and Diagnostic Manual freely available on-line and giving news of any recent important developments in the occurrence of OIE-listed aquatic animal diseases world-wide. There are useful links to other web sites dealing with aquatic animal health issues, including the OIE Collaborating Centre for Information on Aquatic Animal Diseases (www.collabcen.net), which provides on-line access to the International Database on Aquatic Animal Diseases to provide data on the occurrence by country and host of all the OIE-listed diseases of fish and shellfish. There is also active FDC participation in educational programmes to facilitate training of specialists in health problems encountered in aquaculture: members of the Commission have been involved in various training programmes on aquatic animal diseases in several countries.

Organising International Scientific Meetings

Another important FDC activity is to organise scientific meetings on specific topics concerning the prevention and control of aquatic animal diseases. Since it was established, the FDC has organised four international conferences and symposia, as follows:

- Symposium on "Fish Vaccination" (1984)
- Symposium on "Problems of Chemotherapy in Aquaculture : from Theory to Reality" (1991)
- International Conference on "Preventing the Spread of Aquatic Animal Diseases through International Trade" (1995)
- International Conference on "Risk Analysis in Aquatic Animal Health" (2000).

Following the success of the meeting on fish vaccination, it was decided to gather scientific information enabling more acceptable methods of aquatic animal disease therapy, which has been increasingly threatened by restrictive regulations, due not least to media campaigns on residues in farmed aquatic animals. This impact was a major theme at the International Symposium on Chemotherapy in Aquaculture in 1991 and the proceedings were published by OIE in 1992. The problem of disease transfer by international trade in aquatic animals was discussed in depth at the International Conference on Preventing the Spread of Aquatic Animal Diseases through International Trade held in Paris in June 1995; the papers presented and discussions held at this Conference were published in the OIE *Scientific and Technical Review* in June 1996.

Since risk analysis has become more and more important in the international trade of live aquatic animals and animal products, the FDC has decided to increase its involvement in this area. The International Conference on Risk Analysis in Aquatic Animal Health held at OIE in February 2000 is one aspect of this endeavour. This conference provided the first opportunity to bring together experts in this important developing discipline. The meeting was held with the objective of provoking international dialogue and providing the latest information to scientists, academics and regulators responsible for developing, evaluating and implementing measures intended to protect aquatic animal health. The proceedings of this conference have also been published (OIE 2002) providing a compilation of the presentations, session discussions and reports of rapporteurs from the Conference (see also Rodgers 2003).

Collaboration with Other Organisations

The FDC actively co-operates with other international organisations in developing guidelines on health surveillance and disease control policies in aquaculture so that common agreements are reached, resulting in a merging of the various approaches. In recent years, the FDC has provided assistance in this area to the Food and Agriculture Organization (FAO) of the United Nations, the Network of Aquaculture Centres in Asia-Pacific (NACA), South East Asia Fisheries Development Center (SEAFDEC) and the Asia-Pacific Economic Co-operation (APEC). Not least of these was involvement with FAO and NACA in development of the *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals* and the *Beijing Consensus and Implementation Strategy.* Currently, the FDC is providing expert assistance in the present initiative of APEC, NACA and FAO in technical training on import risk assessment (IRA) for Asia and Latin America. The FDC also joined forces with FAO and Canada's Department of Fisheries and Oceans (DFO) in a collaborative initiative and co-organised an Expert Consultation on Policies and Regulatory Frameworks for Responsible Movement of Live Aquatic Animals - Towards Reducing the Risk of Trans-boundary Aquatic Animal Disease in October 2002 in Rome.

The FDC welcomes such co-operation and will continue to seek ways to strengthen collaboration in national and regional initiatives aimed at reducing the international transfer of diseases that pose a risk to aquaculture production and/or wild populations of aquatic animals.

4.2 THE RISK ANALYSIS PROCESS

Risk Analysis in Aquaculture and Aquatic Animal Health[1]

C. J. Rodgers

Carrer Ordre de Malta 10
43540 San Carlos de la Ràpita
Tarragona, SPAIN

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Abstract

This paper provides a brief overview of the process of risk analysis in aquaculture and aquatic animal health.

Introduction

Risk analysis, as a formal discipline, has been used as a tool only relatively recently by those working in the animal health field (MacDiarmid 1997) and as a result, very few animal health risk analyses have been published in peer-reviewed literature. There are even fewer in the aquatic animal health field.

As with many innovations, animal health risk analysis may be regarded with suspicion, or even hostility, by some, and the discipline has been referred to as a fad (Anderson 1994). Certainly, when special interest groups feel their interests may be threatened by decisions based on risk analysis, it is the discipline of risk analysis that is often subject to criticism.

However, in order to understand the subject a little better we can ask questions such as: 'What is risk analysis? What is its importance? What can we expect from it?" and "How should it be carried out?"

[1] This article is largely reproduced from the "Proceedings of the OIE International Conference on Risk Analysis in Aquatic Animal Health" (C. Rodgers, ed.), February 2000, Paris.

What is Risk Analysis?

Risk analysis is a tool intended to provide decision-makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action (MacDiarmid 1997). Risk analysis is intended to answer the following questions:

- What can go wrong?
- How likely is it to go wrong?
- What would be the consequences of its going wrong?
- What can be done to reduce either the likelihood or the consequences of its going wrong?

What is the Importance of Risk Analysis?

Risk analysis is important as a tool to aid decision-making for disease surveillance, disease control and international trade.

So, why do risk analysis? Faced with the choice between, say, two surveillance programmes, risk analysis can assist the decision-maker choose between a highly sensitive but expensive test or a less sensitive but cheaper test (MacDiarmid and Hellstr□m 1988). In this case, the 'What can go wrong?' is that the surveillance programme might fail to detect an infected establishment. 'How likely is it to go wrong?' and 'What would be the consequence?' are answered by the risk assessment component of risk analysis.

However, the main reason that workers in the animal health field are adopting risk analysis is because of the incentives provided by the establishment of the World Trade Organization (WTO). Members of the WTO are obliged to adhere to the *Agreement on the Application of Sanitary and Phytosanitary Measures*, the so-called "SPS Agreement" (WTO 1994). This agreement obliges WTO members to remove barriers to trade unless there is a risk to human, animal or plant health. The agreement further specifies that such a risk must be demonstrated though the process of risk analysis.

Historically, significant diseases of humans and livestock have been spread internationally by trade (Blancou and Meslin 1995). Indeed, international trade in animals or animal products cannot be conducted without some element of risk, but in the past this possibility has sometimes been used to shield local industries from competition. Since the establishment of the WTO, risk analysis has become the basis for attempting to assess whether a particular trade poses a significant risk to human or animal health and, if so, what measures could be adopted to reduce that risk to an acceptable level. In other words, in this context, risk analysis is a discipline to facilitate international trade by removing barriers while at the same time protecting human and animal health in the importing country. It also demonstrates the basis for decisions. Effectively, risk analysis is a tool to help determine which aquatic animal products may enter a country, and under what conditions, thereby safeguarding the health of the national aquatic animal stocks.

What Can We Expect from Risk Analysis?

Risk analysis is a complex discipline, and risk assessments often do not stand up well in an adversarial climate, such as may surround a proposal to import a commodity that would compete with one produced locally. Opposition to importation of commodities is often phrased in terms of concern about disease risks, but may really be based more on fear of competition. Risk analysis cannot be expected to solve all problems, but it can improve decision-making in the face of these types of uncertainty.

An import risk analysis is, in effect, a type of map. Having identified a hazard (a biological agent) in the exporting country, the release and exposure assessments (OIE 1999) attempt to model the various pathways by which that hazard could travel from infected animals in one country into susceptible animals in the importing country (Hine and MacDiarmid 1997, Lightner *et al.* 1997, Vose 1997). However, like all maps, such assessments are an attempt to make a useful representation of a complex reality. As human technology progresses and our understanding of the world increases, our ability to draw maps improves.

Nevertheless, even a relatively primitive map may be useful, and should not be discarded merely because it is not an absolutely accurate representation of the world.

Another analogy is to think of a jigsaw puzzle with pieces missing. However, even when many pieces are missing it may still be obvious what the picture is. Unfortunately, opposition to import proposals tends to focus on one or two aspects of the uncertainty surrounding the proposal and ignores the overall conclusions drawn by the risk analysis. For example, in New Zealand, opponents of a proposal to import ocean-caught Pacific salmon from Canada dismissed a comprehensive risk analysis published in 1994 (MacDiarmid 1994) on the grounds that it was unable to rule out the possibility that a picnicker might be eating raw salmon on a river bank and throw (diseased) scraps to a passing trout.

This is similar to claiming that risk analysis is of no value because it is unable to predict every event, no matter how unlikely. The New Zealand salmon risk analysis was also attacked because some of the inputs were based on assumptions. However, all decision-making is based on assumptions, but the existence of uncertainty and subjectivity does not mean that valid conclusions cannot be drawn. Even though many of the inputs of a risk analysis are surrounded by uncertainty, one is able to have confidence that the "true risk" is unlikely to exceed the estimate resulting from a careful and conservative analysis.

Nevertheless, one of the most difficult problems faced by decision-makers is that of deciding what constitutes an "acceptable risk." In situations where the decision is between different disease surveillance strategies or different control programmes, there may be little controversy, as it may be relatively easy to show the benefits as well as the risks associated with the different options. Issues surrounding trade though are seldom straightforward.

When decisions involving importation are in question, it may be difficult to attain agreement on what constitutes an acceptable risk, even in situations where risk can be quantified relatively objectively. As the risks and benefits of any decision are seldom borne equally between all stakeholders, what is acceptable to one group may not be acceptable to another (MacDiarmid 1997).

How Should Risk Analysis Be Carried Out?

As animal health regulators move to adopt formal risk analysis as a basis for decision-making, there is increasing interest in how to implement the process.

Skills and processes are more important than a structural unit, but structure without appropriate skills and processes is sterile and bureaucratic. However, if the skills and processes are adequately defined, then structures are less relevant and the requirements of good risk analysis can be met in a variety of different ways. Animal health services are organized differently in different countries and instead of attempting to define what is a suitable "structure" for a risk analysis "unit", it is more appropriate to examine the skills and processes required for undertaking risk analysis on aquatic animals and their products.

The new chapter in the Office International des Épizooties (OIE) *International Aquatic Animal Health Code* (OIE 2001) describes the four components of import risk analysis as follows:

- hazard identification
- risk assessment
- risk management
- risk communication

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

Hazard identification

In the terminology adopted by the OIE, the first step of 'What can go wrong?' is called hazard identification. As the Code is focused on trade, hazard identification is defined as "the process of identifying any

pathogenic agents which could potentially be introduced in the commodity considered for importation." In other words, a biological agent that may have an adverse effect. To do this though requires a good knowledge of diseases, patterns of disease and the properties of pathogenic agents. The skills required include those of the fish pathologist, epidemiologist, virologist, microbiologist and parasitologist.

Knowledge of the aquatic animal disease status of the exporting country is also required. Information of this kind is available from the OIE, from the competent authority of the exporting country and from other sources, such as the published literature.

However, risk analysis is equally applicable to other areas of decision-making, such as those affecting disease surveillance or control programmes, and so hazard identification is merely the step of identifying what it is that might go wrong in whatever activity being considered. It must be remembered though that if a hazard cannot be identified, it cannot be assessed or managed and as a result, a risk analysis may not be necessary in certain cases.

Risk assessment

The step that answers the question 'How likely is it to go wrong?' is called risk assessment. The Code, with its focus on trade, defines this as "the evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an importing country." However, the same assessment process would apply if the likelihood of, say, a particular disease escaping detection under different surveillance strategies for aquaculture premises were considered.

Risk assessment may be qualitative or quantitative. In qualitative risk assessments, the likelihood of the outcome, or the magnitude of the consequences, is expressed in terms such as "high", "medium" or "low". In quantitative risk assessments, the likelihood is expressed in terms such as "one disease introduction in 100 years of trade" or "failure to correctly identify one diseased establishment out of 100" or "any one salmonid would need to eat 400 kg of salmon scraps to be 50% certain of receiving an infective dose".

Both qualitative and quantitative approaches to risk assessment are valid and, in fact, every risk assessment must first be carried out qualitatively. Only if further insight is required is it necessary to attempt to quantify the risk.

The risk assessment phase of a risk analysis comprises the following:

- release assessment
- exposure assessment
- consequence assessment.

The release and exposure assessments again call for the skills of the fish pathologist and the epidemiologist. The principles of epidemiology relevant to diseases of mammals and birds can, in many respects, be applied to fish, although there are unique features to the spread of pathogens between hosts in the aquatic environment (Hine and MacDiarmid 1997). The consequence assessment will require the skills of the fish pathologist, the epidemiologist, perhaps an ecologist and possibly an economist. These phases answer the question "What would be the consequences of its going wrong?"

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 also likely to be needed.

When considering products, the skills of people with expertise in the processing industries may 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 formulating and implementing measures designed to reduce the likelihood of the unwanted

event occurring, or the magnitude of its consequences, is called risk management. It answers the question "What can be done to reduce either the likelihood or the consequences of its going wrong?"

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

Risk communication

The OIE Code (OIE 1999) defines risk communication as "…the interactive exchange of information on risk among risk assessors, risk managers and other interested parties." As such, communication and consultation are important at each step of the overall process. Risk communication should be a two-way dialogue between stakeholders, and effort should be focused on consultation rather than a one-way flow of information from the decision-maker to those affected by the decisions.

Effective risk communication is important in ensuring that those responsible for managing risk and those with a vested interest understand the basis on which decisions are made. In this context, transparency is essential in risk analysis. This is necessary so that the exporting country may be provided with clear and documented reasons for the imposition of import conditions or refusal to import. Perceptions of risk often vary between the different stakeholder groups and effective communication is necessary to ensure that those managing risk appreciate the concerns of those affected by the decisions being made.

Scientific review

To ensure the technical robustness of a risk analysis, so that the decision-makers can be sure that it will withstand close scrutiny by stakeholders, it should be subject to a process of:

- scientific review by experts selected for their specialized knowledge of aquatic animal diseases
- scientific review by experts selected for their specialized knowledge of risk analysis

At least some of this scientific review will probably have to be sought outside the organization undertaking the risk analysis, since not all the relevant skills are likely to be available "in-house". However, external scientific review can only be conducted properly when the reviewers are given adequate terms of reference. Risk analyses are usually 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.

It is said that risk analysis is an "objective" process. This is debatable, although commendable. The reality is that in aquatic animal health risk analyses there are often so few data available that the analyst begins, unconsciously perhaps, to substitute value judgements for facts. Indeed, since consequence assessment is considered as 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. Risk analyses are seldom truly "objective", and for this reason transparency is essential.

A team approach

An aquatic animal health import risk analysis requires the expertise of the fish pathologist and epidemiologist, with his or her understanding of the patterns of disease. The analysis may also require the specialized skills of aquaculturalists, virologists, microbiologists and parasitologists. In some instances it may be necessary to seek advice from experts as diverse as climatologists, ecologists, environmental scientists, industry technologists, mathematicians, statisticians 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, with the people having the necessary skills being assembled into the team as appropriate. Members of the project team do not need to be located at the same site, but good risk analyses are not conducted in isolation and require adequate time for completion.

Acknowledgements

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Experiences from the Livestock Sector: OIE Risk Analysis Framework and Obligations for WTO Members under the SPS Agreement

N. J. Murray

Swiss Federal Veterinary Office
Schwarzenburgstrasse 161, Berne-Lieberfeld, CH-3003
Berne, SWITZERLAND

Murray, N.J. 2004. Experiences from the livestock sector: Oie risk analysis framework and obligations for WTO members under the SPS Agreement. p. 65-74. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This presentation outlines the Office International des Épizooties' (OIE) risk analysis framework, which is intended to ensure that stakeholders, risk analysts and decision-makers can be confident that the disease risks posed by imported goods are managed effectively.

Introduction

This paper was originally presented at an International Dairy Federation Symposium in Auckland, New Zealand in 2001 under the title of "Principles of import risk analysis – a New Zealand perspective". While its focus is on the livestock sector and specifically uses examples from the dairy industry, it does outline the principles of import risk analysis, which are just as applicable to the aquatic animal sector.

Import risk analysis for dairy commodities is concerned with effectively managing the disease risks associated with their importation, whether they are intended for human consumption, for animal feeding or for pharmaceutical, agricultural or industrial use. In this context, risk is defined as the likelihood of a disease agent entering, establishing or spreading in a country and its likely impact on animal or human health, the environment and the economy. While some form of risk analysis has always been undertaken, it is only in the last decade, particularly following the implementation of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures* (WTO 1994) (the so-called SPS Agreement), that methodologies have been developed and transparent processes have emerged. It is important to appreciate that risk analysis is an evolving discipline. The objective of this presentation is to outline the Office International des □pizooties' (OIE) risk analysis framework, which is intended to ensure that stakeholders, risk analysts and decision-makers can be confident that the disease risks posed by imported goods are managed effectively.

Establishing the Context

The *International Animal Health Code* (OIE 2000) provides the standards, guidelines and recommendations referred to in the SPS Agreement for effectively managing the risks posed by animal diseases and zoonoses. It aims to ensure the sanitary safety of international trade in animals and animal products so as to avoid the transfer of disease agents that are pathogenic for animals or humans. There is a separate chapter for each disease, detailing sanitary measures applicable to each commodity that the OIE considers capable of transmitting the disease through international trade. Where a particular commodity is not listed, it means that the OIE has not yet been able to develop a recommendation or that the commodity poses no risk. This inconsistency creates a challenge for those managing the risks posed by trade. In situations where the OIE has not formulated recommendations and in those where stricter sanitary conditions may be warranted, a risk analysis needs to be carried out to determine the need for, and type of, sanitary measures that are appropriate. If OIE measures are applied there may be no need to conduct a risk analysis, at least as far as international obligations are concerned.

The International Animal Health Code

General considerations

According to the *International Animal Health Code* (OIE 2000) (hereafter referred to as the Code) 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 and animal products. The analysis must be transparent. This is necessary to ensure fairness and rationality, consistency in decision making, ease of understanding by all the interested parties, that assumptions are documented, uncertainties are dealt with appropriately, the reasons for conclusions and recommendations are obvious and stakeholders are provided with clear reasons for the imposition of sanitary measures or refusal to import.

The risk analysis must be well documented and supported with references to the scientific literature and other sources, including expert opinion. It must provide a reasoned and logical discussion that supports the conclusions and recommendations. There must be comprehensive documentation of all data, information, assumptions, methods, results and uncertainties.

All risk analyses inevitably include a degree of subjectivity. The personal opinions and perceptions of analysts, experts and decision-makers are inescapable. To ensure that a risk analysis achieves a reasonable level of objectivity it should be subjected to peer review. This involves scientific critique and ensures the analysis is based on the most up to date and credible information available. Ideally, each analysis should be submitted to a review process involving experts chosen on the basis of their status as acknowledged authorities in their fields. To facilitate the process, each expert should be given specific terms of reference and asked to provide a detailed critique. Peer review may involve a significant time commitment to ensure a risk analysis, particularly one that is large and/or complex, is properly reviewed.

Scoping a risk analysis

Before undertaking a risk analysis, it is important to carefully define its scope. It is essential to have a clear understanding of the purpose of the analysis from the outset. If an analysis is poorly scoped, problems arise in interpreting and communicating the results. It is also important to appreciate that risk has units. For example, risk might be expressed as the likelihood of at least one disease outbreak per tonne, per consignment or per year.

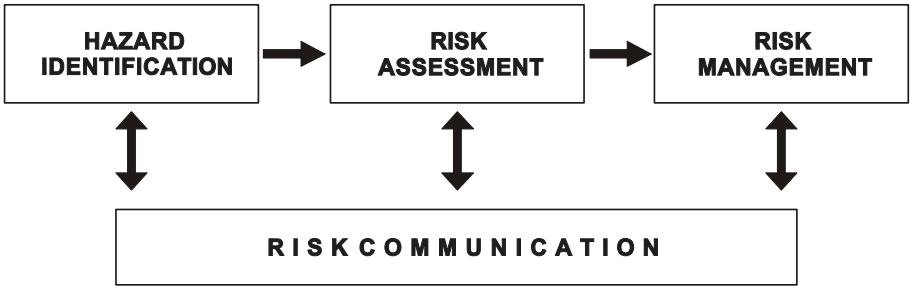
Dairy commodities encompass a broad range of products including milk and cream; condensed and dried milk products; frozen dairy desserts; cheese; butter; milk powders; whey products; extracts such as casein, lactose and fat; and fermented or cultured milk products. For this reason, it is important to adequately describe the particular commodity under consideration and the relevant methods of production and processing, such as pasteurisation and ripening. An estimate of the likely annual volume of trade should also

be provided. While an estimate of the anticipated volume is desirable, it may not be readily available, particularly if the trade is new.

The risk analysis framework

The Code identifies four components of a risk analysis: risk communication, hazard identification, risk assessment and risk management (Figure 1) and provides a list of terms and corresponding definitions. Because the use of different terms and definitions could lead to confusion, it is important to use the Code's terminology in an animal health risk analysis.

Figure 1. The four components of risk analysis (OIE 2000).



Risk communication

Risk communication is the process by which information and opinions regarding hazards and risks are gathered from interested parties during an analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to decision-makers and interested parties in both importing and exporting countries. It is a multidimensional, interactive and iterative process involving a two-way dialogue. Ideally, it should begin at the start of a risk analysis and continue throughout. To ensure that a meaningful dialogue is established, all have an obligation to provide a reasoned and relevant argument and a right to propose a contrary view.

In an increasingly sophisticated society, there are greater expectations from various stakeholder groups, whose interests may be affected by the decisions arising from a risk analysis, that they will be provided with the opportunity for consultation before decisions are made. People today generally have a high level of education and easy access to an enormous variety and quantity of information. They are less reliant on the scientific community or government to evaluate risks and make decisions on their behalf. As a result, it is essential to establish a communication strategy from the start of a risk analysis to ensure that stakeholders are provided with an opportunity to provide comment.

Once a decision is reached not all stakeholders may agree with it. However, by involving them from the outset, taking their concerns seriously and addressing them appropriately, they may have a greater understanding of why a particular decision has been reached.

Hazard identification

Hazard identification must be conducted prior to the risk assessment. It involves identifying pathogenic agents that could potentially produce adverse consequences. To classify an agent as a potential hazard the following criteria need to be fulfilled:

- The agent must be appropriate to the species being imported, or from which the commodity is derived.
- It may be present in the exporting country.
- If present in the importing country, it should be a notifiable disease or subject to control or eradication.[1]

[1] *Notifiable disease* means a disease listed by the Veterinary Authority, and that, as soon as detected or suspected, must be brought to the attention of the Veterinary Authority (OIE 2000).

Each pathogenic agent should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology, including an assessment of its likely presence in the exporting country. This is determined by an evaluation of that country's Veterinary Service, surveillance and control programs and zoning and regionalization systems. A conclusion is then reached as to whether the commodity under consideration is a potential vehicle for the introduction of the agent into an importing country. If it is, it is classified as a potential hazard for further consideration in the risk assessment step. If potential hazards are not identified the risk analysis may be concluded.

Depending on the nature of the commodity or the methods of production, manufacturing or processing, some categories of pathogenic agents may be excluded from consideration. For example, gastro-intestinal parasites need not be considered in a risk analysis that deals with dairy products such as cheese or milk. Obviously it is biologically implausible that these commodities could be a potential vehicle for such agents. Where categories of pathogenic agents are excluded, a description of the category and the rationale for their exclusion should be included.

If an importing country applies the sanitary measures recommended in the Code to the potential hazards, there may be no need to conduct a risk assessment, at least as far international obligations are concerned.

Risk assessment

Risk assessment is the process of evaluating the likelihood and biological and economic consequences of entry, establishment or spread of a potential hazard within an importing country. The commodity under consideration must be evaluated in the form that it is intended to be used, processed or sold when imported. A risk assessment consists of four inter-related steps:

- release assessment
- exposure assessment
- consequence assessment
- risk estimation

No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances. Risks can be evaluated by both qualitative and quantitative methods. A qualitative assessment is essentially a reasoned and logical discussion of the relevant commodity factors and epidemiology of a potential hazard where the likelihood of its release and exposure and the magnitude of its consequences are expressed using non-numerical terms such as "high", "medium", "low" or "negligible". It 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, for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures. Quantification involves developing a mathematical model to link various aspects of the epidemiology of a disease, which are expressed numerically. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication. For example, if a risk is assessed as one disease outbreak per 50,000,000 kg of commodity imported, one might consider this to constitute an extremely small risk. However, if one then learned that this volume was imported over only five years, then the risk of an outbreak per importation year might seem to be rather high.

Regardless of whether a qualitative or quantitative assessment is conducted, it is important to appreciate that a risk assessment inevitably includes a degree of subjectivity. Although a quantitative assessment involves numbers, it is not necessarily more "objective", nor are the results necessarily more "precise" than a qualitative assessment. Choosing an appropriate model structure, which pathways to include or exclude, the level of aggregation or dis-aggregation, the actual values used for each input variable and the type of distribution applied to them all involve a degree of subjectivity. In addition, because data are lacking, some models incorporate expert opinion, which by its very nature is subjective.

Since both types of assessment are inevitably subjective, how can a reasonable level of objectivity be attained? The solution lies not in the method chosen, but in ensuring that the assessment is transparent, based on the best available scientific information and been subject to a rigorous peer review process.

To facilitate risk communication, it is essential that the assessment focuses on information directly relevant to the logic chain of the assessment. Each potential hazard should be discussed only to the extent necessary to enable the reader to gain an appreciation of likelihood of its entry, establishment or spread and of its associated potential consequences. If, for example, it is concluded that the likelihood of a potential hazard being released into the importing country is negligible, there is no need to undertake an exposure and consequence assessment and explore management options. It is not necessary to offer detailed descriptions of clinical syndromes, pathology, treatments etc., unless these have a direct bearing on the likelihood of detecting diseased animals or managing disease risks.

Release assessment

Each potential hazard should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology to:

- describe the biological pathway(s) necessary for the commodity to become infected or contaminated, and
- estimate the likelihood of the commodity being infected or contaminated when imported.

A scenario tree (Fig. 2) provides a useful conceptual framework to assist in identifying and describing biological pathways.

A number of factors to be considered in the release assessment include:

- Biological factors such as the infectivity, virulence and stability of the potential hazard, its route of infection and means of transmission, the susceptibility of animals likely to be exposed, the outcome of infection, predilection sites and the impact of vaccination, testing, treatment and quarantine programs.
- Country factors such as an evaluation of the exporting country's Veterinary Service, surveillance, eradication and control programs, zoning systems including the existence of disease free areas and areas of low disease prevalence, the incidence and/or prevalence of disease, animal demographics, farming and husbandry practices and geographical and environmental characteristics such as rainfall and temperature.
- Commodity factors such as the ease of contamination, relevant processes and production methods, the effect of processing, storage and transport on the survival of the potential hazard and the likely quantity of commodity to be imported.

The analysis may be concluded at this point if the likelihood of the potential hazard being released into the importing country is negligible.

Exposure assessment

Each potential hazard should be dealt with separately:

- Describe the biological pathway(s) necessary for exposure of animals and humans in the importing country to the potential hazard.
- Estimate the likelihood of these exposure(s) occurring.

A scenario tree (Figs. 3 and 4) provides a useful conceptual framework to assist in identifying and describing exposure pathways.

Figure 2. A scenario tree for a release assessment outlining the biological pathways necessary for a dairy commodity to become contaminated with a potential hazard.

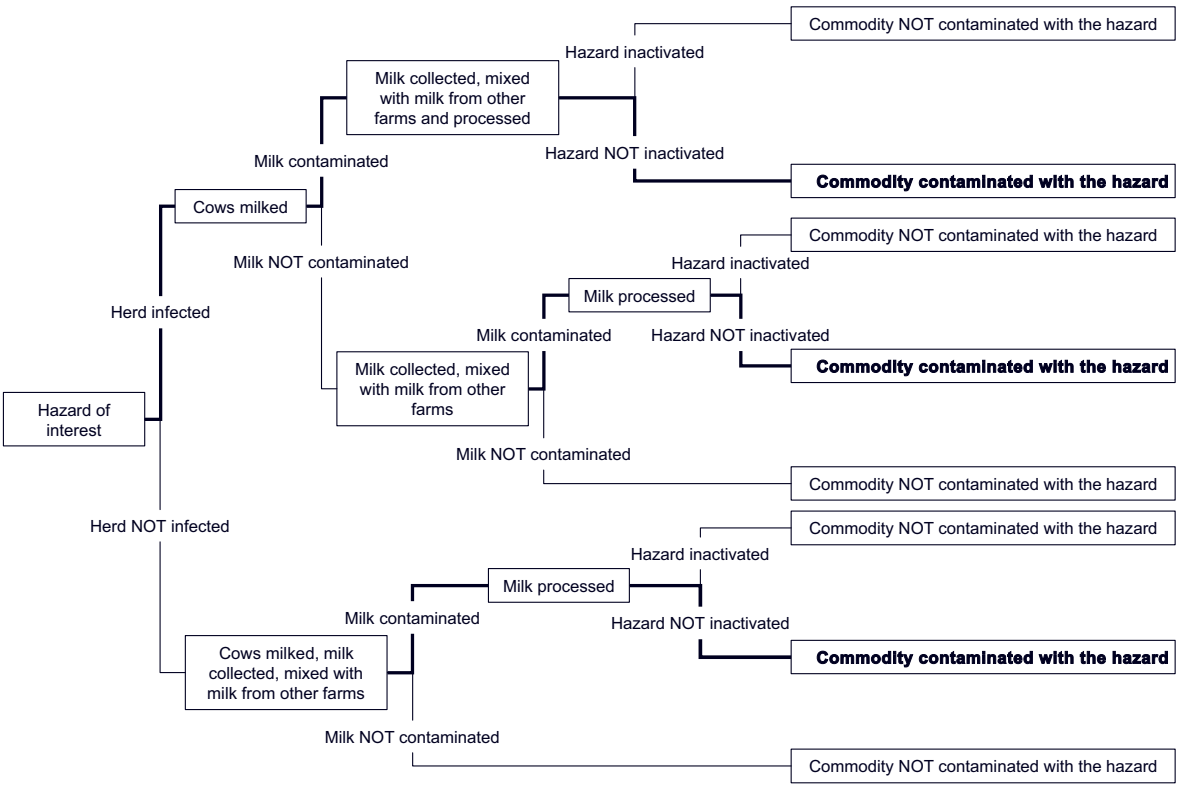


Figure 3. A scenario tree for an exposure assessment outlining the biological pathways leading to scraps being discarded as a result of importing a dairy commodity for human consumption.

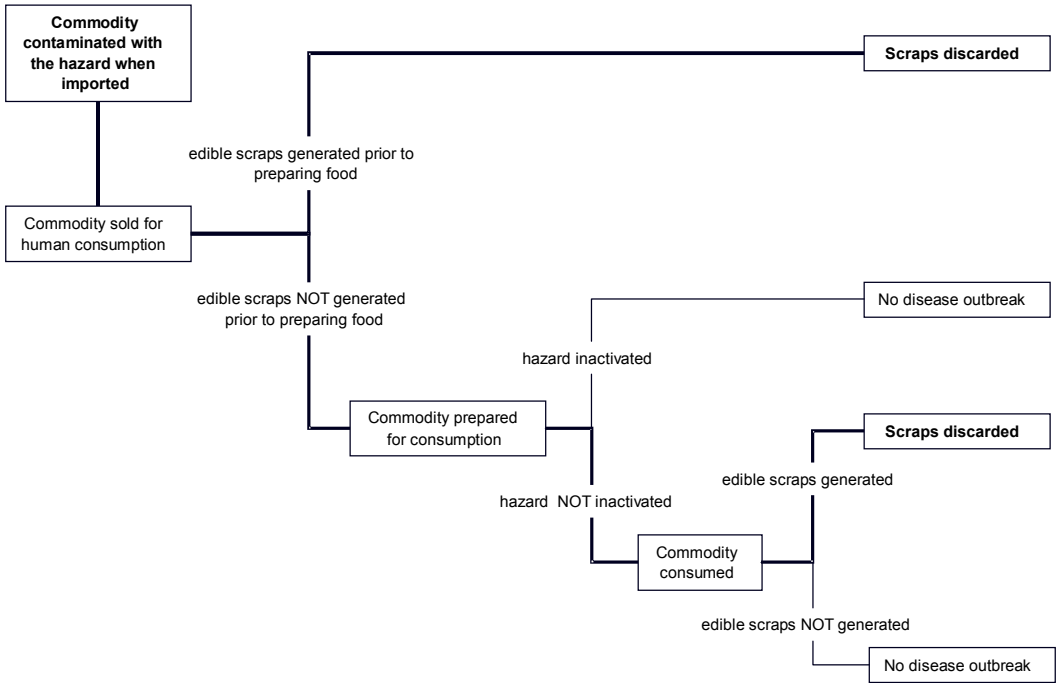
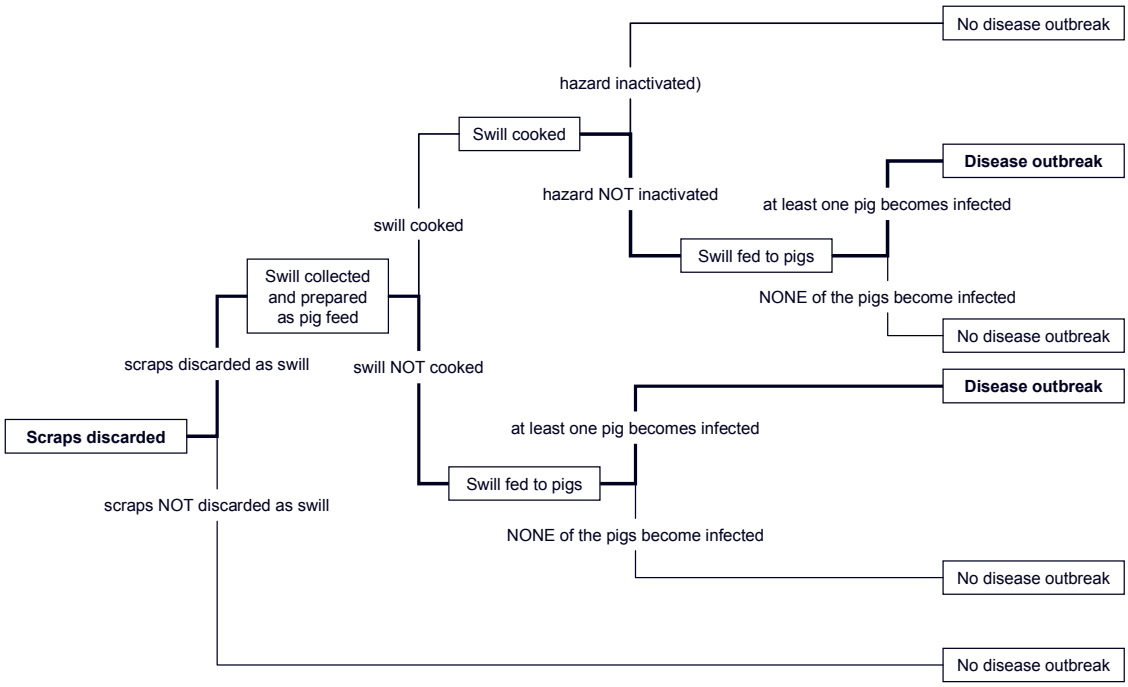


Figure 4. A scenario tree for an exposure assessment outlining the biological pathways necessary for susceptible animals to become exposed to a potential hazard in discarded scraps.



There are a number of factors that may be relevant when considering the exposure assessment. These include:

- Biological factors such as the infectivity, virulence and stability of the potential hazard, its route of infection and means of transmission, and the susceptibility of animals likely to be exposed and the outcome of infection.
- Country factors such as the presence of intermediate hosts or vectors, human and animal demographics, farming and husbandry practices, customs and cultural practices and geographical and environmental characteristics including rainfall and temperature.
- Commodity factors such as the intended use of the imported animals or animal products, waste disposal practices and the quantity of commodity likely to be imported.

The risk analysis may be concluded at this point if the likelihood of susceptible animals being exposed to the potential hazard through all the exposure scenarios is negligible.

Consequence assessment

Each potential hazard should be dealt with separately:

- Identify the potential biological, environmental and economic consequences associated with the entry, establishment or spread of the potential hazard. A causal relationship must exist between exposure to a potential hazard and an adverse affect.
- Estimate the likelihood of these potential consequences.

There are a number of factors that may be relevant when considering a consequence assessment. These include:

- Direct consequences such as the outcome of infection in domestic and wild animals and their populations, including morbidity and mortality, production losses and animal welfare and public health consequences.
- Indirect consequences such as economic considerations involving control and eradication costs, surveillance costs, potential trade losses (embargoes, sanctions etc.) and environmental impacts.

The analysis may be concluded at this point if potential consequences are not identified or the likelihood of all the potential consequences is negligible.

Risk estimation

Each potential hazard should be dealt with individually, summarising the results and/or conclusions arising from the release, exposure, and consequence assessments to estimate the likelihood of the potential hazard entering the importing country, becoming established or spreading and resulting in adverse consequences. It is not sufficient to conclude that there is a mere possibility of entry, establishment or spread or that there may be potential consequences. An evaluation of the likelihood of each of these factors must be undertaken. The decision steps outlined in Figure 5 provide a framework for the risk estimate. If the estimated risk is "non-negligible" the potential hazard is classified as an actual hazard.

Figure 5. Risk estimation decision steps.

1. Release assessment (likelihood of entry)

Is there a non-negligible likelihood that the commodity is carrying the potential hazard when imported?

If the answer is:
NO the risk estimate is classified as *negligible*
YES proceed to step 2

2. Exposure assessment (likelihood of susceptible animals and/or humans being exposed)

Is there a non-negligible likelihood that any of the exposure scenarios(s) will result in susceptible animals and/or humans being exposed?

If the answer is:
NO the risk estimate is classified as *negligible*
YES proceed to step 3

3. Consequence assessment (successful exposure results in infection which may spread with or without establishment)

3.1 If there is a non-negligible likelihood of the potential hazard spreading but not becoming established, are there further significant potential consequences?

If the answer is:
NO the risk estimate is classified as *negligible*
YES Is there a non-negligible likelihood of at least one of these potential consequences occurring?

If the answer is:
NO the risk estimate is classified as *negligible*
YES the risk estimate is classified as *non-negligible*

3.2 If there is a non-negligible likelihood of the potential hazard becoming established are there further significant potential consequences?

If the answer is:
NO the risk estimate is classified as *negligible*
YES Is there a non-negligible likelihood of at least one of these potential consequences occurring?

If the answer is:
NO the risk estimate is classified as *negligible*
YES the risk estimate is classified as *non-negligible*

Risk management

Risk management is the process of deciding upon and implementing sanitary measures to effectively manage the risks posed by the hazard(s) associated with the commodity under consideration. As risk is a function of likelihood and consequence, risk management may seek to reduce either the likelihood of the hazard being introduced or the consequences of introduction. It is not acceptable to simply identify a range of measures that might reduce the risks. There must be a reasoned relationship between the measures chosen and the risk assessment, so that the results of the assessment support the measure(s).

Where there is significant uncertainty, a precautionary approach may be adopted. However, the measures selected must still be based on a risk assessment that takes account of the available scientific information. In these circumstances the measures should be reviewed as soon as additional information becomes available. It is not acceptable to simply conclude that, because there is significant uncertainty, measures will be selected on the basis of a precautionary approach. The rationale for selecting measures must be apparent.

Risk management consists of four steps:

- Risk evaluation - If the risk estimate, determined in the risk assessment, is non-negligible, sanitary measures can be justified.
- Option evaluation, where possible options, including the *Code's* sanitary measures, are identified. To assist in identifying appropriate option(s), an objective, which states what these option(s) should aim to achieve in order to effectively manage the risks, should be formulated.
- Implementation - where the option(s) selected are applied.
- Monitoring and review - where measures are audited to ensure that they are achieving the results intended.

When evaluating risk management options, there are a number of obligations, detailed in the SPS Agreement (WTO 1994), that must be fulfilled. An evaluation of the likelihood of the entry, establishment or spread of the hazard according to the option(s) that might be applied must be undertaken. When selecting an appropriate option or combination of options, it is important to ensure that the option(s) are based on scientific principles and that the Code's sanitary measures are considered. Provided there is scientific justification that the Code's measure(s) do not effectively manage the risks, measures that result in a higher level of protection may be applied. The option(s) chosen should only be applied to the extent necessary to protect human or animal life or health. It is important to ensure that negative trade effects are minimised, that the option(s) do not result in a disguised restriction on trade, that they are not applied arbitrarily, that they do not result in discrimination between exporting countries where similar conditions prevail and that they are feasible.

Conclusions

Decisions about managing animal and zoonotic disease risks associated with international trade are inevitably made in the face of varying degrees of uncertainty. Risk analysis provides a structured approach that facilitates the identification, assessment, management and communication of these risks. By ensuring that it is transparent and subjected to peer review, stakeholders and trading partners can be assured that a reasonable level of objectivity is obtained and that the sanitary measures adopted are appropriate.

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Current Limitations in the Use of Risk Analysis on Aquatic Organisms

P. Mike Hine

National Centre for Disease Investigation
MAF Operations, P.O. Box 40-742
Upper Hutt, NEW ZEALAND

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Abstract

Using molluscs as examples, a brief review of the current limitations of the use of import risk analysis (IRA) for aquatic animals is presented.

Introduction

An import risk analysis (IRA) is only as good as the information that is put into it. Lack of information must result in more use of expert opinion, intelligent guesses, or consideration of a similar scenario in which more information is available. When a lot of information is available, it may be possible to carry out a quantitative or semi-quantitative IRA, but in the absence of information, the IRA must be qualitative. Lack of information also necessitates the Precautionary Approach, and this will result in elevation of risk. Of the three major groups that are widely traded internationally (fish, crustaceans, molluscs), least is known about molluscan diseases. They will therefore be the group to be considered in relation to limitations in the use of IRAs.

Risk-related Issues

Movement of any group of aquatic animals, alive or dead, involves risk. The process or pathway involved comprises stages at which the probability that a pathogen may survive or be introduced has to be assessed. Certain questions must always be asked, and certain information is always needed to answer those questions. Typical questions, and the information needed to answer these questions are:

What is the probability that:

- the stock to be exported carries infections (origin - wild or hatchery?);
- the infections will go undetected in the exporting country (competence of diagnostician; reliability, sensitivity and specificity of diagnostic tests; time of year; carrier state);
- the pathogen will survive transport (survival outside the host, temperature and salinity survival parameters, production of resistant stage (eg, spore));
- the pathogen will be disclosed by stress and crowding (defense suppression caused by stress, direct transmission, rapid proliferation);
- the infection will go undetected in the importing country (competence of diagnostician; reliability,

sensitivity and specificity of diagnostic tests);
- the pathogen will escape from the importation quarantine facility (quality and design of facility, likelihood of accident, presence of vectors such as birds);
- aquatic animals in the vicinity will become infected (presence of susceptible hosts in the vicinity, contact with infectious dose of the pathogen (dilution by currents)); and
- the pathogen will become established and spread (density of susceptible hosts, rapid pathogen proliferation, movement from infection site, vectors)

Epidemiological information on the pathogen will be needed to answer these questions:
- Is transmission horizontal and/or vertical, and is it direct?
- What are the temperature/salinity survival limits of the pathogen?
- How long can the pathogen survive outside the host?
- Is the pathogen likely to be disclosed by stressing the host?
- Does the parasite form a resistant stage (spore)?
- What is the infectious dose?

For molluscs, few of these questions can be answered (Table 1), and even diagnostic techniques are often unreliable (Table 2). This lack of information invariably results in an assessment of high risk for live molluscan translocations. Can risk, therefore, be mitigated by risk management? Whatever measures are introduced, they must not kill the mollusc and reduce its export value. It is known that some pathogens

Table 1. Some epidemiological factors that have to be taken into account when doing an IRA, and the information available in molluscs.

Disease/Pathogen	Life-cycle, Transmission	Seasonality	Pre-patent Period	Infective Dose	Survival Outside Host, Disinfection
Bonamiosis					
Bonamia ostreae	Direct, horizontal	Present throughout year	2.5-4.0 mon	8.0×10^5	Moved by shipping
B. exitiosus	Direct, horizontal	Difficult to detect Sept.-Nov.	2.5-4.0 mon	1.12×10^5	50% survival after 48 hr
Haplosporidiosis					
Haplosporidium costale	Intermediate host, probably horizontal	Sporulates May-June	Unknown	Unknown	Unknown
H. nelsoni	Intermediate host, probably horizontal	Present throughout year	Unknown	Unknown	Unknown
Mikrocytosis					
Mikrocytos mackini	Direct, horizontal	Focal lesions, April-June	3.0 mon	Unknown	Unknown
M. roughleyi	Direct, horizontal	Focal lesions July-Sept.	2.5 mon	Unknown	Unknown
Marteiliosis					
Marteilia refringens	Intermediate host, probably horizontal	Present throughout year	Unknown	Unknown	Unknown
M. sydneyi	Intermediate host, probably horizontal	Not active, May-Dec.	Unknown	Unknown	Unknown
Perkinsosis					
Perkinsus marinus	Direct, horizontal	Present throughout year	<2 wk	Known, may not be affected by distance	Some parameters defined
P. olseni	Direct, horizontal	Present throughout year	Unknown	Unknown	Some parameters defined

have temperature and salinity survival limitations that are more limited than those of their hosts (Table 3). Unfortunately, it is difficult to find conditions that do not adversely affect the hosts, and in dual infections, conditions that destroy one pathogen may favour another. For example, in *Crassostrea virginica,* low temperature and high salinity favour *Haplosporidium nelsoni* (Ford 1985, Haskin and Ford 1989, Bower *et al.* 1994), but high temperature and low salinity favour *Perkinsus marinus* (Bobo *et el.* 1988, Chu *et al.* 1993, Ragone and Burreson 1993, Ragone Calvo *et al*. 1994) (Table 3). Similarly, in *Saccostrea glomerata,* high temperature and low salinity favour *Marteilia sydneyi* (Lester 1982), and low temperature and high salinity favour *Mikrocytos roughleyi* (Bower *et al.* 1994, Hand *et al.* 1998) (Table 3). However, implementation of such conditions may kill one pathogen and disclose whether the other pathogen is present.

Table 2. Techniques available for the diagnosis of OIE-listed diseases of molluscs.

Pathogens/ Gross Signs	Culture	Smears/ Imprints	H & E Histology[1]	TEM[2]	Molecular Techniques
Bonamia spp.					
Unreliable	Unavailable	Unreliable, light infections	Unreliable, very light infections	Not reliable for identification or with very light infections	Developed but unavailable
Haplosporidium costale					
Unreliable	Unavailable	Unreliable, light infections	Unreliable, early & light infections	Unreliable, very light infections	Developed, specific, sensitive ISH[3]
H. nelsoni					
Unreliable	Available, time-consuming	Unreliable, light infections	Unreliable, early & light infections	Unreliable, very light infections	Developed, specific, sensitive ISH
Marteilia spp.					
Unreliable	Unavailable	Unreliable, light infections	Reliable except in very light infections	Unreliable, very light infections	Developed but unavailable
Mikrocytos mackini					
Green pustular lesions, unreliable	Unavailable	Unreliable	Unreliable, light to moderate infections	Unreliable, light to moderate infections	Unavailable
M. roughleyi					
Yellow-brown lesions,unreliable	Unavailable	Unreliable, light to moderate infections	Unreliable, very light infections	Appearance by TEM not reported	Unavailable
Perkinsus spp.					
Unreliable	Available, reliable	Unreliable, light infections	Reliable except in very light infections	Unreliable, very light infections	Developed but unavailable

[1] H & E = haematoxlyn and eosin.
[2] TEM = transmission electron microscopy.
[3] ISH = *in situ* hybridization.

Risk Minimisation

Risk can also be minimised and managed in molluscan translocations by implementation of pre-export and post-import measures. Pre-export measures may include:

- identifying disease-free stocks;
- identifying expertise on molluscan diseases within the exporting country's Competent Authority (if none available, consult an overseas expert);
- requiring certification of randomly selected consignments;
- holding under conditions that may kill specific pathogens or disclose others (stressing the animals); and
- scrubbing shells to remove potential pest species.

Table 3. Survival parameters of OIE-listed diseases of molluscs and their hosts.

Mollusc/Pathogen	Upper Temperature	Lower Temperature	Upper Salinity	Lower Salinity
Crassostrea virginica	<36°C	>-2°C	40‰	~5‰
Haplosporidium nelsoni	>20°C		<30‰	<10‰
H. costale				<25‰
Perkinsus marinus	<28°C	>4°C	>22‰	<22‰
Ostrea edulis	28°C	3°C	41 ± 2 ‰	
Bonamia ostreae	>16°C	<4°C		
Marteilia refringens			35-37‰	
Ostrea chilensis	25°C	6°C	35‰	3‰
B. exitiosus.				
Crassostrea gigas	28°C	6°C	41 ± 2‰	4‰
Mikrocytos mackini	>15°C	<8° C		
Saccostrea glomerata	41°C	<11°C	45‰	<15‰
Marteilia sydneyi	>30°C	<20°C	>30‰	<15‰
Mikrocytos roughleyi	14°C	<10°C	>35‰	29‰
Mytilus spp.	30°C		32‰	0‰
Marteilia refringens			>35‰	
Haliotis laevigata	>27.5°C			
Perkinsus olseni		-60°C		> 7‰

Post-import measures may include:

- holding imports under containment conditions, away from regions where similar species are cultured;
- making sure both transport water and water used in containment are disposed of safely;
- examining randomly selected samples for disease, and examining every animal that dies during containment; and
- putting potentially susceptible hosts from the importing country among the imported animals while still held under containment.

If it is intended to release the imported animals into the wild, or for aquaculture:

- spawn the imported animals while still under containment, and separate progeny from broodstock immediately;
- kill the broodstock and examine each animal for disease; and
- hold the progeny until they can be examined for potential pathogens, before permitting release from containment.

There will be many different scenarios in the future, each requiring risk-minimising procedures to fit the circumstances. Should there be a lack of locally available expertise, consult with experts overseas. The IRA process will not only minimise risk, it will also show where information is needed to further minimise risk in the future.

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Recommendations from the OIE Conference on Risk Analysis in Aquatic Animal Health (Paris, February 2000)[1]

C. J. Rodgers

Carrer Ordre de Malta 10
43540 San Carlos de la Ràpita
Tarragona, SPAIN

Rodgers, C.J. 2004. Recommendations from the OIE Conference on Risk Analysis in Aquatic Animal Health (Paris, February 2000). p. 81-84. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

The recommendations arising from the Office International des □pizooties' Conference on Risk Analysis in Aquatic Animal Health (Paris, February 2000) are reviewed.

The Origins

In early 1996, a United Kingdom government project was started following the identification of a need for a database containing information related to the incidence of fish and shellfish diseases throughout the world arranged by species, country and region. This was subsequently completed and represents data from the official Office International des Épizooties (OIE) published returns and all relevant published scientific information. It has been adopted as the *OIE Aquatic Animal Diseases Database* and is currently available on the internet (www.collabcen.net). The database was regarded as an essential precursor to any study on risk analysis which would attempt to use the data already collated, in conjunction with known risk factors, in a predictive way. As a result of this project, and largely due to the recognition of the development of various problems among groups working with risk analysis for aquatic animals, a workshop entitled *Risk Assessment in Aquaculture* was held at the eighth international European Association of Fish Pathologists (EAFP) conference in 1997. One of the conclusions of this workshop was that these developing problems at that time could be best addressed by a conference, which would be a good short-term method for joint discussion. Subsequently, a full international conference was adopted by the OIE as a means to further progress in the field of risk analysis for aquatic animal health, and this was duly held in Paris in February 2000.

Office International des Épizooties (OIE) International Conference on Risk Analysis in Aquatic Animal Health

During the preparations for the OIE International Conference on Risk Analysis in Aquatic Animal Health and the subsequent presentations, it was apparent that the material could be broadly divided into three

[1] This article is largely reproduced from *the Proceedings of the OIE International Conference on Risk Analysis in Aquatic Animal Health* (C. Rodgers, ed.), February 2000, Paris

main areas of concern. These were summarised as: application problems, data problems and international guidelines. During the conference suggested corrective action points for these problems were considered as potential solutions.

Application problems

The point was made that risk analysis is relatively new for aquatic animal health and there have been few adequately documented examples. Those models that are available have been derived from problems involving non-aquatic species, which means that the methodologies require careful validation. In addition, risk analysis is recognised as a complex discipline, requiring careful evaluation of information. Agreement on what constitutes an acceptable level of risk is difficult to reach since all risk assessments involve scientific uncertainty and care must be taken to avoid false underlying assumptions. There is still limited knowledge of the aquatic environment, which presents the analyst with problems not encountered when dealing with terrestrial animal problems. As a result, scientific peer review should be undertaken by experts in both diseases and risk analysis, as this is the best means of reducing or even avoiding subjectivity and ensuring transparency.

Suggested action for application problems:

- Document risk analysis examples.
- Adapt or develop modelling techniques.
- Validate and standardise methodologies.
- Urgently accumulate a body of peer-reviewed literature on the application of risk analysis to aquatic animal health problems.
- Improve risk communication.
- Improve expertise with a team approach.
- Target epidemiology projects.
- Allocate resources.

Data problems

It was recognised that there are deficiencies and gaps in the knowledge base and it can be difficult to obtain accurately defined input parameters. In some cases, there are no quantifiable data or the available data may be unreliable. There are sources of uncertainty in areas such as the accuracy of fish diagnostic tests (e.g., test sensitivity and specificity), sampling error and misrepresentation of input parameters. Some of the parameters in aquatic animal health are poorly understood and the interpretation of results can be difficult, with no cross comparison between studies.

Suggested action for data problems:

- Develop reliable quantifiable data.
- The information required for all relevant pathogens concerns their modes of transmission, life cycles, the ease and reliability of their detection, and their survival parameters within the host species, both before and after processing as well as in the environment.
- To "develop reliable quantifiable data" means to verify the dependability and authenticity of all data.
- "Research" should be conducted into the quality of aquatic animal health services and in data-deficient areas.
- Default assumptions should be made, or science policies developed.
- Standard methods should be urgently produced.
- Expert opinion should be used where necessary.
- Allocate resources.

International guidelines

International agreements provide for specific provisions and obligations, with the OIE being one of the standard-setting organisations. However, it was felt that there is little guidance on good quantitative risk analysis and more detailed information is required on actually conducting a risk analysis.

Suggested action for international guidelines:

- The OIE should continue to review and update guidelines.
- The OIE Working Group on Informatics and Epidemiology and the compilers of a handbook

should seek contributions from the Fish Diseases Commission (FDC).
- The availability and publication of actual risk assessments should be improved continually (e.g., through the OIE website and associated links).

Discussion of the way forward

The conference discussion concerning these potential and real problems endorsed the suggested action points as a means to promote and continue the development of risk analysis in aquatic animal health. In general, the main current and future needs were divided into:

- the establishment of an aquatic working group on risk analysis,
- the proposal of a workshop, and
- other proposals.

The establishment of an aquatic working group on risk analysis

This working group would consist of a multi-disciplinary team of experts in the areas of risk analysis and aquatic animal health. The group would meet to discuss applying risk assessment techniques to one particular species and one particular disease, and attempt to build a risk assessment model that could be used to determine important data gaps in the chosen problem area.

The idea of establishing such a working group generated positive feedback from conference participants. However, concern was expressed at the idea of using hypothetical problems to demonstrate the use of risk analysis techniques. In particular, it was felt that the use of hypothetical examples would not illustrate the problems faced in real life. Nevertheless, a working group with a carefully defined remit should be urgently considered. The idea of a session using expert opinion was also proposed as a possibility that should receive careful attention.

The proposal of a workshop

The focus of a workshop on risk analysis in aquatic animal health would be to present fish health risk analyses which have already been undertaken. For example, the New Zealand Ministry of Agriculture and Forestry (MAF), the Australian Quarantine and Inspection Service (AQIS) and the Norwegian National Veterinary Institute (NNVI) have already undertaken such analyses. Presentations would be made by the institutes involved in the development of the models and would cover the various stages needed for the analyses. In particular, the data used in these models would be discussed with respect to different sources of data and any particular areas of data deficiency. Real problems with data collection would also be discussed, with one aim being to highlight additional sources of information for future analyses. In addition, the modelling techniques employed would be outlined, and this would serve as a tutorial on risk assessment methodology.

The workshop would involve participants with expertise in both risk analysis and fish health. Presentations by risk assessors would enable fish health experts to acquire a more detailed understanding of the requirements of risk assessments and, in particular, of the data requirements. It was felt that such an understanding would lead to better data collection in the future, as well as increasing the transparency of the risk analysis process.

In addition, a workshop might also serve as a forum for peer review and critiques of the analyses that had previously been undertaken. Furthermore, it would provide the opportunity for risk analyses to become more widely available. At present there is no journal for the publication of animal or fish health risk analyses and thus access to such documents is limited. By establishing a workshop of this nature, various interest groups would come together to enable an open exchange of information in the future. It was generally agreed that such an information exchange would provide a starting point for the advancement of risk assessment in the area of aquatic animal health. The delegates at the conference generally felt that they wanted to know more about specific analyses to enable them to identify particular problem areas, as well as clarify the way in which risk analysis could fit into their future research strategies.

Other proposals

Apart from the working group and workshop proposals, other important discussions focused on the need for standardisation of tests, the use of expert opinion within risk assessments and confirmation of opinion by targeted research.

It was agreed that standardisation was something that will have to be considered in the future by the OIE Fish Diseases Commission (FDC). However, it was pointed out that it might take time for individual countries or research teams to validate and standardise existing techniques or develop new ones.

With regard to expert opinion, the discussions centred on consideration of how useful expert opinion would actually be in the short term to fill recognised data gaps. It was pointed out that expert opinion is often used in risk assessments, and in many cases this is a necessary approach. Various key points regarding the use of expert opinion were raised; for example, which experts to use, how to elicit expert opinion, how to avoid biases and how to combine results from different experts. It was also noted that, after the use of expert opinion within any model, sensitivity analyses should be undertaken to determine the magnitude of the effect that such data have on the final estimates of risk. If the model showed this to be a crucial area of data deficiency, future experimental targeted research could be planned to confirm or refute the opinion. However, in general, it was felt that expert opinion could be used effectively in the short term. Nevertheless, it was stressed that established methods for using expert opinion should be followed and all information and methods should be documented in the most transparent way. This concept could also be considered for inclusion on a trial basis within the suggested workshop.

Conclusions

The conference was considered a success and a possible way forward had materialised. Nevertheless, only two of the conclusions reached at the EAFP Workshop in 1997 (Rodgers 1997) had been addressed in the intervening period. These related to the inadequacy of the then OIE guidelines on risk analysis (now reviewed and redrafted) and the need for a specific symposium or conference (hosted by the OIE, Paris, February 2000) to highlight and document current problems.

The importance of the other conclusions from the 1997 workshop was reinforced by the OIE Conference in 2000. These were, namely:

- The lack of data in support of meaningful quantitative risk assessment for many areas related to the diseases of fish and shellfish. This is particularly evident for species susceptibility, diagnostic techniques, survival parameters for pathogens and pathogen inactivation.
- The need to provide basic risk assessment information to regulatory authorities, trade organisations and the industry in support of aquatic animal movements and the continued use of pharmaceutical preparations.
- There is a real need for risk analysis in aquaculture, but this has already led to a parallel need to conduct basic epidemiological studies, and the provision of expert opinion as a potential short-term aid in the absence of data for many key areas should be considered.
- Risk analysis is proving difficult, since there is a lack of expertise and the current guidelines need to be more specific and reviewed regularly.

Despite any deficiencies in the current methodology and available examples, the conference concluded that formal science-based risk analysis remains the best tool available for addressing transparency and objectivity.

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4.3 RISK ANALYSIS AND THE WORLD TRADE ORGANIZATION: COUNTRY EXPERIENCES

Lessons from WTO Disputes: Salmon, an Importing Country Perspective

Peter Beers

Biosecurity Australia
Department of Agriculture, Fisheries and Forestry - Australia
GPO Box 858, Canberra ACT 2601, AUSTRALIA

Beers, P. 2004. Lessons from WTO disputes: salmon, an importing country perspective. p. 86-89. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper presents information about the WTO disputes on salmon between Australia and Canada, with emphasis on lessons learned from the perspective of a risk analyst from the importing country.

Introduction

This presentation is made from a risk analyst's point of view. It presents personal perspectives and observations and is not intended as a technical or legal analysis. As such it does not represent the views of the Australian Government.

Legal Framework

As a risk analyst, the most striking feature of a World Trade Organization (WTO) dispute is that it is primarily a legal exercise. The issues at the heart of the dispute are looked at in terms of the legal texts of the WTO Agreements and the rights and obligations that these provide to WTO Members. The important agreements in terms of the dispute between Canada and Australia over Australia's restrictions on the importation of salmon product were the Dispute Settlement Understanding (DSU), the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), and the *General Agreement on Tariffs and Trade* (GATT 1994).

Lawyers run the dispute and the case is prepared from a legal perspective. The Dispute Settlement Panel (the Panel) which is set up to hear particular disputes and the Appellate Body that hears legal appeals against the rulings of the Panel have trade and legal experts as their members. The dispute process can be "foreign" to scientists and risk analysts. The case is argued in terms of legal concepts, the meaning and interpretation of which are usually not immediately apparent, and often legal terms in Latin are used.

Scientists provide supporting evidence for the legal case being made by the disputants. It can be difficult at times to ensure that the technical detail and its interpretation, which can be important to scientists, is not lost in the translation to a legal argument. Experts in disciplines that are critical to the dispute are also engaged to provide expert advice to the Panel.

Background to the Dispute

Australia banned the importation of raw salmonid products in 1975 because of concerns about the potential introduction of exotic fish diseases. Since that time, Canada had been negotiating with Australia to have the restrictions removed. In 1994, Canada commenced dispute proceedings in the GATT; this was prior to the formation of the WTO. Canada recommenced the dispute in 1995 under the new WTO rules, which had become operative on 1 January 1995. At this time, the new rules had not been fully tested and in the case of the SPS Agreement, no disputes had been finalised, although the European Union (EU) Hormones dispute was in progress. The Australian salmon dispute was the first SPS dispute dealing with animal health issues.

It is common practice in international treaty drafting to use terms the meaning of which are apparent but that still lack a degree of precision. This enables countries with divergent views to assent to the treaty. As a consequence, many of the concepts that were involved in the dispute, such as risk assessment and appropriate level of protection (ALOP), were untested. However, there was a large amount of existing jurisprudence from the old GATT that did provide guidance in interpreting some of the new provisions.

Defined Dispute Process

The DSU provides an outline for the conduct of disputes including the steps to be followed and indicative timetables. There were a number of distinct steps in the salmon dispute that commenced with the consultations between the disputing parties, in this case the governments of Australia and Canada. The consultations provide an opportunity for the parties to discuss the issues at dispute and reach a mutual resolution; there is no Panel at this stage of the dispute.

If the dispute cannot be resolved at the consultations, the complaining party (the Canadian Government) can ask for the establishment of a Dispute Settlement Panel. The Panel procedures follow a set process, which can be varied as required to ensure high-quality outcomes, but not if the process is unduly delayed. In the salmon dispute, Australia and Canada made submissions to the Panel setting out their legal arguments and interpretations of the relevant parts of the WTO agreements and presenting their supporting evidence. Each party also made submissions rebutting the legal arguments of the other. The Panel also put questions to the parties seeking their comments and answers to a number of legal and technical questions. A number of hearings were also held where these issues were further explored through oral statements and questions and answer sessions.

Other WTO Members with an interest in a dispute can participate as third parties. Third parties may make a written submission and oral statement to the Panel based on the first submissions of the main parties to the dispute. Issues raised by third parties may be responded to by the parties to the dispute or followed-up by the Panel. In the salmon dispute, the European Union, Norway, the United States of America and India participated as third parties.

The Panel also engaged a number of experts to provide advice on issues such as risk assessment, fish health and international standards. The experts were provided several series of questions to answer in writing and were posed some additional questions in a hearing. The parties to the dispute could comment on the questions to the experts and their answers, and were provided an opportunity to question the experts in an oral session.

The Panel produces a descriptive report (containing factual and argumentative material) which is made available to the parties for comment. A further draft including the Panel's findings and recommendations is released to the main parties for review. In the salmon dispute, comments were provided on both these draft reports and a further hearing was held to clarify some of the issues. The Panel's report, with any corrections, is released to all WTO members following this review stage.

If a party to the dispute disagrees with the legal interpretation of the Panel or other issues of law, it may lodge an appeal, which is heard by the WTO's Appellate Body. In the salmon dispute, appeals were lodged by both Australia and Canada. Appeals have a shorter course than panel processes and comprise of written argument and rebuttals, and a hearing where the Appellate Body members question the parties. Third parties may make submissions to the Appellate Body both in writing and orally. Although appeals deal with issues of law, considerable scientific issues were discussed to clarify their legal interpretation.

Australia was found not to be meeting a number of its WTO obligations as a result of the findings of the Panel, as modified by the Appellate Body. The findings included that Australia's measures (i.e., Australia's biosecurity restrictions) were not supported by a risk assessment and that Australia had acted inconsistently with Article 5.5 of the SPS Agreement. Australia was asked by the WTO to bring its measures into compliance with its WTO obligations.

The next stage of the dispute was the arbitration on a reasonable period of time that Australia should have to bring its measures on the importation of raw salmon into compliance. This arbitration involved written arguments and a hearing to determine what procedures Australia would have to undertake to bring its measure into compliance. This involved discussion about the legal processes that would be necessary for Australia to amend the biosecurity restrictions that had been found to be inconsistent with its WTO obligations.

The arbitrator gave Australia eight months, backdated four months, to bring its measures into compliance. This time period was provided to implement the necessary changes, and it was specifically noted that conducting risk assessments is not pertinent to the determination of the reasonable period of time.

Australia undertook accelerated import risk analyses on the importation of raw salmonid product, raw marine finfish product and live ornamental finfish. The latter two IRAs were undertaken as the biosecurity policies for these commodities had been found to be inconsistent with those in place for raw salmon product in the earlier dispute. Following the completion of these IRAs, new measures were put in place for all of the relevant commodities. The Australian State Government of Tasmania did not agree with the new biosecurity restrictions for salmon and put its own additional measures in place for product moving into Tasmania.

Canada disputed that the amended requirements for raw salmon were inconsistent with Australia's WTO obligations and sought to have the WTO sanction retaliatory action against Australia. To address these issues the original Dispute Settlement Panel was reconstituted under DSU article 21.5 to determine if Australia was meeting its obligations. Canada and Australia agreed to suspend processes to sanction retaliatory action pending finalisation of the Article 21.5 Panel.

The 21.5 Panel received written submissions and rebuttals from the parties and held a hearing with them. The Panel engaged scientific experts to provide advice, including via written and oral questions. An Article 21.5 dispute has an accelerated timetable and fewer opportunities for written submissions and hearings compared to the original dispute process. The 21.5 Panel found that 10 of Australia's 11 measures on raw salmon were justified and that the new measures put in place by the Tasmanian State Government did not meet WTO obligations.

Neither party lodged an appeal to the findings of the 21.5 Panel. Canada and Australia then held bilateral negotiations and came to a mutually satisfactory agreement, including noting that the Tasmanian State Government measures were still inconsistent with international obligations.

For all stages of the dispute there are recommended time periods. These were modified as required by the Panel to ensure matters were dealt with appropriately. As the salmon case was the first WTO dispute involving animal health SPS measures, many procedural issues and legal interpretations were being dealt with for the first time. This helped to slow the process down. However, the tight deadlines still placed considerable demands on the technical and legal staff involved in the dispute. Large volumes of published scientific matter were submitted as evidence, which took much time to consider and analyse. Technical and legal arguments were subject to much scrutiny, so considerable time and effort had to be expended in ensuring that facts were correct and appropriately presented.

Issues Considered

The complaining party, by virtue of the allegations that it makes, determines the issues considered in the dispute. The issues considered may shift depending on the nature of the response to the allegations and the information provided by experts. The initial burden of proof falls to the complaining party, but if sufficient evidence is presented in support of the allegations, the burden then falls to the other party to rebut. The burden may continue to switch between the parties during the dispute process.
The facts of the case are important as it is used as evidence to support the legal case put by both parties. Evidence, either documentary or the expert opinion provided by the scientific experts advising the Panel, is crucial to support the legal claims of the parties.

The dispute is considered at two levels. Firstly, whether the legal requirements are met. This is carried out much like a "tick the box" exercise; for example, is the risk assessment a proper risk assessment that meets the legal definition of a risk assessment?

At the second level, the scientific basis of the dispute is considered. Is the science reasonable? Is the analysis based on scientific principles? At this level, the facts of the case are important, as is its scientific interpretation. The scientific experts advising the Panel have a very important role to play in this part of the dispute. The individual views of the scientific experts are important, as the WTO recognises that there may not be universal agreement on the interpretation of evidence and that governments need to take a prudent approach to managing risk. However, the interpretation of science must be reasonable.

Resources

Important considerations in any WTO dispute are the level of resources that are necessary to fully participate and the level of commitment that is required to follow the dispute to its conclusion. A dispute such as the salmon dispute is a very resource intensive process in a number of ways. It can be expensive - Australia spent more than $2 million in preparing and putting its case. There were direct expenses such as travel, commissioning advice from experts and staff time in preparing and running the case. There were also indirect expenses such as the diversion of resources from other projects, which then fell behind schedule.

A wide range of expertise was required to mount a defence, including experts in law (trade, international and Australian law), science (fish health), risk analysis, international standards, biosecurity, economics etc. In the original dispute, Canada argued that Australia's management of biosecurity risks was not consistent for different commodities (i.e., salmon product, marine finfish products and live ornamental finfish). Expert resources were needed to deal with all the issues raised by these arguments and when the WTO agreed with Canada on these matters, Australia had to perform IRAs for these products, in addition to that for salmon, to ensure that it could justify its new measures for salmon.

At hearings both parties often had teams of 10 or more to ensure that all of the relevant expertise was available to answer questions that may be put to them. Several Australian Government departments were involved in the dispute and coordination between the agencies required considerable effort and time.

As mentioned above, disputes have a tight timetable to meet, though there may be lulls and peaks in activity. There were many deadlines imposed during which material had to be prepared for the Panel or Appellate Body. Such material had to be checked by several experts to ensure that all aspects were correct and so went through several redrafts. In Australia's case, the time spent travelling to and from Geneva (where all of the hearings were held) presented an additional difficulty in meeting deadlines. Consulting with domestic industries and State Governments that were directly affected by the outcomes also complicated the process of meeting deadlines.

The protracted nature of the dispute also presented its own difficulties. The dispute ran from 1994, when Canada requested consultations under the old GATT rules, till the mutually agreed outcome was reached in 2000. Staff turnover added some complexity to managing the dispute. The externally imposed demands resulted in high workloads over a protracted period for the staff involved in the case, with the consequential flow-through effect on their personal life.

Conclusions

Import risk analyses (IRAs) should be undertaken consistent with WTO rights and obligations. A properly written and argued IRA should demonstrate that your measures are reasonable and meet international obligations. Trading partners will be less likely to challenge your measures formally and if there are differences, rational discussions can be held that focus on the relevant issues.

An IRA should be well structured so that it is easy to understand and has a story to tell. WTO Panellists and Appellate Body members are generally not scientifically trained and may have difficulty in understanding the reason for your SPS measures. Information should be presented in a way that will facilitate their understanding of the issues. If the reasons are easy to understand, they are more likely to accept your arguments.

Avoid formal WTO disputes if practicable/possible, as considerable resources will be required irrespective of whether you are complaining or the defending party. For a number of reasons it may not be possible or practicable to avoid formal dispute. Discussions with your trading partner and presentation of a well argued case that meets your WTO rights and obligations is the best disincentive to formal disputes arising.

If dispute is likely, ensure that you are ready and that your claims are well prepared or your defences are in place. The dispute may not be restricted to the commodity at its heart; in the salmon case, the national biosecurity policies for marine finfish products and live ornamental finfish, as well as aquatic animal product movement controls imposed at the State Government level became central issues in the dispute. Be prepared to examine old policies developed before contemporary risk assessment procedures were elaborated and expect that the scientific bases of these policies would not stand up to present-day scrutiny.

Finally, remember that a WTO dispute is a legal issue and that you should approach it from this perspective.

Salmon Exports from the United States to Australia, Canada and Chile - Case Histories in Import Risk Analysis

Kevin H. Amos

National Aquatic Animal Health Coordinator
National Marine Fisheries Service
U.S. Department of Commerce
Olympia, Washington, USA

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Abstract

Three case histories of import risk analysis (IRA) between the United States of America (USA) and trading partners Australia, Canada, and Chile are examined. The first case history involved the export of fresh and frozen wild salmon from the USA (and Canada) to Australia. While Australia conducted and published a comprehensive IRA in a scientific and transparent manner, Australia's findings were contrary to those of the USA, Canada, and the World Trade Organization (WTO) - eviscerated, headed salmon were determined not to pose a significant risk to the resources of Australia.. Subsequent to the IRA, imports of salmon were made into Australia. The second case involved a request to export live salmon smolts from the USA (Washington State) into Canada (British Columbia). Though the smolts were certified to be pathogen-free and met other Office International des Épizooties (OIE) criteria, they were not allowed into Canada. This was contrary to the practices of the USA (and some provinces in Canada) that allow like imports to occur. While Canada conducted an informal IRA to identify the risk of imports, there was no science-based data provided to demonstrate that the risk was significant. This matter has yet to be resolved.

A third case history demonstrates how restrictions placed by a country on the trade of eggs can restrict or prevent safe commerce. Chile imposed limitations on the import of salmon eggs from the USA without conducting a comprehensive IRA. In many cases, the restrictions should not have been applicable considering the health history of the eggs to be exported. The situation was resolved by bi-lateral discussions and thus avoided the costly and time-consuming process of taking the dispute to WTO for resolution.

Introduction

Aquatic animal products have been transported across international boundaries for hundreds of years. Only recently has the concept of import risk analysis (IRA) been incorporated into the process for determining the health risks associated with such transfers. Even then, most of these analyses were simple and subjective and quite likely, not science-based.

While import risk analysis is not a new concept for terrestrial animals, this approach has had limited application in aquatic animals for many reasons. First, the cost of conducting a comprehensive, science-based analysis is significant in terms of human and financial resources. For example, the case of the Australian Salmon IRA (which will be examined in detail below), was estimated to cost several million US dollars and several staff years for scientists, lawyers, and politicians in Australia, Canada, and the United States.

Another factor that limits the ability to conduct meaningful IRA is the lack of a reliable and sufficient database. When trying to assess the potential impact of the transport of fish pathogens from one territory to another, it is necessary to know the prevalence of infection not only in the product to be imported, but also the pathogen status in aquatic animals in the importing country. This information must reflect pathogen status in both cultured and wild populations. As many countries lack a comprehensive pathogen surveillance program in their cultured stocks, there is little or no knowledge of the prevalence of disease in wild stocks. Thus, a situation is created where a quantitative analysis is impossible and the reliability of a qualitative IRA is questionable.

Due to the cost of IRA and the lack of sufficient data, there are few examples of "good" IRAs in aquatic animals. Yet, even though comprehensive studies are not always possible, there is still value in "abbreviated" or informal IRAs that provide some information and enable the competent authority to make some judgement on the potential risks of a given import. This paper examines three examples of IRAs that involved the United States and range from comprehensive to very limited in scope.

Case History #1, Australia

The United States of America (USA) was a third party participant in an action brought by Canada against Australia. Under the rules of the World Trade Organization (WTO), a country may participate and provide testimony, even though the are not the lead country in the action brought before the WTO. The action brought before the WTO involved the import of fresh or frozen salmon captured in the Northeast Pacific Ocean and shipped to Australia for human consumption. Australia was concerned that fish pathogens associated with the imported salmon posed an unacceptable health risk to salmon, trout and other aquatic resources in Australia. Australia was concerned not only about protecting the health of the emerging Atlantic salmon industry in Tasmania, but also protecting the wild stocks of salmon and trout inhabiting their waters. These wild fish stocks form the basis for an important recreational fishery for local residents and tourists, alike.

In 1975, Australia put a ban on the import of uncooked salmon. The basis for this ban was the known occurrence of certain pathogens in wild salmon in regions outside of Australia coupled with the apparent absence of these pathogens in the fish and waters of Australia. Under the *Agreement on the Application of Sanitary and Phytosanitary Measures* (WTO 2002), a country is entitled to establish its own "acceptable level of protection" (ALOP), provided that there is scientific evidence to justify this restriction. Further, upon request, the importing country is required to draft a formal IRA that explains the basis for such restrictions.

The Australian government published their final report, *Salmon Import Risk Analysis,* in December, 1996 (DPIE 1996). The 400+ page document outlined the necessary components of a risk analysis - hazard identification, risk assessment, risk management and risk communication. Under hazard identification, Australia listed a number of fish pathogens that were known to occur in North American salmon stocks but not yet isolated in Australia. In risk assessment, routes of entry and method of exposure to local stocks were considered. Mechanisms to manage the risk were discussed and the method by which information would be shared was illustrated. The Department of Primary Industries and Energy (DPIE) of Australia did an excellent job of producing a comprehensive, science-based IRA.

In spite of the quality of the IRA, Canada (along with other third parties, including the USA) argued before the WTO that many of the scientific issues raised by Australia were without merit. First, the scenarios proposed for exposure and route of infection seemed unlikely. Given the relative health and pathogen status of healthy, wild-caught salmon, it seemed unlikely that consumers (or saboteurs) would be successful in transmitting infectious agents to local fish stocks by feeding or disposing of tainted scraps to Australian wildlife, including fish. The USA also noted that prior to 1975, salmon were imported as frozen products to Australia. Prior to that time, live salmon and trout eggs had also been imported from endemic areas in the USA to Australia. The USA questioned the concern over salmon pathogens as a risk when other baitfish species, known to be carriers of pathogens of concern, were being imported and fed to tuna in open-water systems. Finally, the general standard in the OIE *International Aquatic Animal Health Code* (OIE 2001) for the international commerce of salmon is to allow their transboundary movement provided they are headed and eviscerated, regardless of their pathogen status.

The WTO found for the complainants, stating that the import of headed, eviscerated salmon did not pose an unacceptable risk to Australia. The decision was appealed by Australia, but upheld by the WTO. While the outcome of this suit was not in Australia's favor, the analysis prepared by Australia is an excellent illustration of a comprehensive IRA process, conducted in a scientific and transparent manner.

As an aside to this Australian IRA, while the issue was in dispute, a request was made by a fish farmer in Washington State to import salmon eggs from a fish farm in Tasmania, Australia. Officials from Washington State conducted a risk analysis on the proposed import. Inspections were made by a Washington State official at the brood facilities in Tasmania and the testing and reference laboratories involved, and the health histories of the relevant farms in Australia were inspected by a Washington State fish health official. All data and inspections indicated the import from Australia represented a low-risk to the health of the fish in Washington State, and the importation was allowed to proceed.

Case History #2, Canada

A second example of risk analysis was provided in a disputed issue between the Province of British Columbia, Canada and Washington State. British Columbia (BC) and Washington State share a common border in the northwest region of North America. Both are bordered to the west by the Pacific Ocean. Anadromous stocks of Pacific salmon, as well as other fish species, travel north to Alaska and south to the State of California with BC and Washington in between. Pathogens endemic in salmon stocks in Washington are also endemic in fish stocks in BC. Likewise, there are zones (individual farms with pathogen-free water supplies and fish stocks) established within Washington and BC that are known to be free of pathogens due to an extensive histories of pathogen testing. The Department of Fisheries and Oceans (DFO), the federal competent authority of Canada, has a responsibility to protect wild and cultured stocks alike from the import of exotic diseases. In this light, and after careful consideration, DFO permits the import of salmon and trout eggs from inspected sources, however, DFO/BC refuses to allow the import of any live salmonids, other than eggs, from any source in the USA, regardless of health status and health history. The basis for allowing eggs but refusing fish is that eggs present a lower risk for carrying pathogens than swimming fish, and the surface of eggs may be sanitized while swimming fish cannot. The DFO used a scientific basis of disallowing the entry of salmon smolts from Washington State, however, the sources of smolts in Washington were known to be free of relevant pathogens and to pose no greater risk than smolts that were transferred within the boundaries of British Columbia.

Many requests were made to DFO by Washington farmers and state officials to import smolts in a like manner to how the transfer of smolts was allowed to occur within BC, however, juvenile salmonids continue to be refused entry from Washington into BC, regardless of health status. Under WTO, the USA could bring action against Canada for having unlawful measures in place. One can only speculate whether Canada would be allowed to keep in place an ALOP that seems to be inconsistent with practices conducted in other regions of Canada or within BC itself. The point is that BC conducted an informal IRA and concluded that import of live fish was unacceptable. Regardless, whether the risk is real or perceived, the

USA would not be successful in overcoming this non-tariff trade barrier unless it chose to pursue the expensive and lengthy process of bringing action against Canada in the WTO. It is yet to be seen if this will occur. Meanwhile, the USA is still hopeful that the regional authorities will institute science-based measures that will give equivalent consideration to smolts from certain sources in Washington to those currently shipped within the Province of British Columbia.

Case History #3, Chile

A third example, again involving live salmon products from Washington State, represents how a risk analysis process affects trade. The aquaculture industry in Chile has rapidly expanded in the last 20 years. The basis for this industry has been the import of live salmon and trout eggs from throughout the world. In addition to trout and salmon eggs shipped from private farms with impeccable health histories, wild coho and chinook salmon eggs were shipped from Washington State. The wild salmon eggs are known to be carrying *Renibacterium salmoninarum,* the causative agent of bacterial kidney disease (BKD), and are also known to come from areas enzootic for other pathogens of significance, some of which are reportable to the OIE (OIE 2001). Whether imported with eggs or by fish, the same pathogens in wild salmon in Washington State have also been reported in cultured salmon stocks in Chile. Thus, there are many similarities in the pathogen status of waters of the Pacific Ocean off Chile and North America.

The egg import process into Chile was relatively simple prior to 1990. In 1990, Chile initiated a requirement that imports from the USA must be inspected by a competent federal authority, not by state inspectors, who had conducted health inspections previously. Once salmon and trout brood stocks became established in Chile, the need for eggs from outside the country appeared to decrease. Also, there was apparently a heightened concern to prevent the introduction of new foreign diseases into Chile. Consequently, after 1990, the rules for the import of eggs into Chile changed on almost an annual basis. The rule-making process was not transparent and usually occurred very near or during the time the eggs were being taken by growers in Washington, thus making it difficult to meet the needs of the growers and government regulators in Chile.

A major impediment to trade between the USA and Chile emerged in the year 2000. The emergence of infectious salmon anemia (ISA) in Atlantic salmon in Europe and the east coast of North America resulted in Chile discontinuing the import of salmon eggs from anywhere in the United States, even though at the time there had been no findings in the USA and no findings at all on the west coast of North America.

Chile declared in August 2000, that each salmonid egg import would be treated as a "first" import, requiring lengthy quarantine periods (120 days), environmental impact analyses, and other limnological and water quality studies. Prior to this time, Chile had no quarantine requirements, only routine pathogen screening for egg imports. The consequence of these actions resulted in most growers in Washington being unable to ship eggs to Chile. At the same time, it appeared that no similar restrictions were put in place in Chile. It was the belief of the USA that the Chilean government's measures constituted a barrier to trade and contradicted Chile's responsibilities under the OIE, as clearly there was no connection to the pathogen-free brood farms in Washington and those of the eastern USA, so ISA should not have been an issue.

In 2001, the Animal, Plant, and Health Inspection Service (APHIS) of the United States Department of Agriculture commenced bilateral discussions with Chile on the requirements for egg export. A one-year memorandum of understanding was agreed upon between the two countries. Ultimately, Chile implemented regulations in 2001 and 2002 that were consistent with their obligations under WTO, OIE policies, and were scientifically defensible. Chile, like many other countries, including the United States, has yet to publish a comprehensive science-based risk analysis on the import of salmon eggs into their country.

Lessons Learned from the Three Case Histories

The case histories described in this paper are not unique to, or limited to, the countries mentioned. Similar scenarios are repeated daily with different species in different parts of the world. The purpose of the examples given in this paper was not to represent the USA as being free from fault in the risk analysis and trade arena. Like Australia, Canada and Chile, rules and procedures for dealing with interstate commerce of aquatic animals are often inconsistent from state to state in the United States and would be challenging to an entity inside or outside of the USA wishing to trade in each of the 50 states. The lessons learned from these examples include the following:

- Countries are reluctant to conduct trade risk analysis unless action is brought before the WTO.
- This is understandable, as the IRA process can be time-consuming and require significant investment of resources, and, as in the case of Australia, result in a quality IRA which does not guarantee the WTO will rule in your favor.
- A WTO action is avoidable if an informal risk analysis is science-based and satisfies the needs of the countries involved.
- Not all risk analyses need to be as comprehensive as the Salmon Import Risk Analysis conducted by Australia. If the science is sound and politics kept out of the discussions, an informal IRA will often provide a safe and efficient mechanism to enable commerce.
- The IRA process and associated rule promulgation must be conducted in a transparent process.
- While being unfair and against the rules of WTO, import bans without proper IRA still serve as an effective means to delay or stop trade, as damaged countries do not have resources available to allocate to this area.

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Social Justice Litigation: The CIT and WTO. "Setting the Record Straight on Sea Turtles and Shrimp"[1]

David A. Balton

Director, Office of Marine Conservation
United States Department of State
Washington, USA

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Abstract

This paper attempts to elaborate the 1989 United States law designed to protect endangered sea turtles, including its treatment under the World Trade Organization (WTO) and the Court of International Trade (CIT). Some further thoughts are provided in addressing transboundary environmental problems using the shrimp/turtle case as an example.

Introduction

The *New York Times* recently reported that "the WTO overturned a federal law barring imports of shrimp from countries whose fishing fleets used nets that were unable to release endangered sea turtles." Along the same lines, *The Economist* recently reported that "America's ban on shrimp from countries that use nets which trap sea turtles…was found to be violating world trade law." The *Washington Post* added that the World Trade Organization (WTO) "found against a U.S. requirement that all shrimp imported into the United States must be caught with fishing nets that do not ensnare sea turtles."

These statements are incorrect or, at best, misleading. Perhaps more importantly, they reflect widespread misunderstanding about a 1989 United States (US) law designed to protect endangered sea turtles, and the treatment of that law in the World Trade Organization (WTO) and the Court of International Trade (CIT). This misunderstanding may, in fact, have contributed to the intensity of the protests that disrupted the WTO Ministerial Meeting in Seattle last week, which featured environmental activists wearing sea turtle costumes.

This presentation will attempt to set the record straight. The first part of the presentation describes the US law in question – what it does and what it doesn't do. The second part attempts to summarize the CIT litigation over the implementation of this law. Next, the presentation reviews the 1998 decision of the WTO Appellate Body and the steps being taken by the United States Government to give effect to this

[1] This paper, which formed the basis of a presentation given by Kevin H. Amos, was originally presented at the Eleventh Annual Judicial Conference of the U.S. Court of International Trade.

decision. The presentation closes with some thoughts on the desirability of multilateral solutions to transboundary environmental problems, using the shrimp/turtle cases as an example.

The US Turtle/Shrimp Law

All species of sea turtles but one are endangered, some critically so, throughout all or part of their range. In the United States and many other countries, the accidental drowning of sea turtles in fishing nets pulled by shrimp trawl vessels contributes significantly to the endangerment of sea turtles. Fortunately for the sea turtles, fishing gear experts have developed a relatively simple, inexpensive piece of equipment - the turtle excluder device or TED - that can reduce the drowning of sea turtles in shrimp trawl nets dramatically. A TED is a metal or mesh grid that can be placed in a shrimp net. As the net moves forward in the water, small objects (such as shrimp) pass through the bars of the TED into the closed end of the net. Large objects (such as sea turtles) bump up against the bars of the TED and are directed out of a "trap door" in the net. If TEDs are properly installed and used, they will allow at least 97 percent of sea turtles to escape, with minimal loss of shrimp.

Since 1990, US laws and regulations have required virtually all commercial shrimp trawl vessels operating in the United States in areas where there is a likelihood of intercepting sea turtles to use TEDs.

In 1989, Congress also included a provision in an annual appropriations act - Section 609 of Public Law 101-162 - to prohibit the importation of shrimp and products of shrimp harvested in ways that are harmful to species of sea turtles. To avoid this trade embargo, shrimp harvesting nations may seek to be certified by the Department of State as having a program to protect sea turtles in their shrimp trawl fisheries that is comparable to the US program. Section 609 also permits certification of nations whose shrimp fishing environments do not pose a threat to sea turtles (e.g., because their shrimp fisheries occur exclusively in cold waters where there is no likelihood of intercepting sea turtles, or because their shrimp fishermen use exclusively artisanal gear in which sea turtles cannot be drowned).

The Department of State initially determined that Congress had intended Section 609 to apply only within the Wider Caribbean and Western Atlantic region. Recognizing that the United States had taken approximately 10 years to develop its own TEDs program, the Department also determined that foreign shrimp harvesting nations would have three years to phase in a comparable sea turtle protection program, prior to becoming subject to the import prohibition on shrimp.

First CIT Case

Following a determination by the US Court of Appeals for the Ninth Circuit that the CIT had exclusive jurisdiction over cases involving the import prohibition of Section 609, certain environmental and animal rights groups brought suit in the CIT, primarily to overturn the limitation of Section 609 to the Wider Caribbean and Western Atlantic region. The CIT ruled in December 1995 that Congress intended Section 609 to apply on a worldwide basis, and ordered the Department of State to comply with that ruling by May 1, 1996. At the same time, the CIT upheld a number of other decisions of the Department of State relating to the implementation of Section 609.

The Department of State asked the CIT to delay the effect of this ruling for an additional year in order to allow newly affected foreign nations adequate time to develop sea turtle protection programs, but the CIT denied that request. Accordingly, embargoes on imports of shrimp harvested in ways harmful to sea turtle species went into effect with respect to many nations on May 1, 1996.

Second CIT Case

To give effect to the worldwide application of Section 609 mandated by the first CIT decision, the Department of State made a number of noteworthy changes in the way it implemented the law. Most signifi-

cantly, we imposed the following requirement: every shipment of shrimp imported into the United States must be accompanied by a form, executed and signed by the exporter and importer, indicating that the shrimp was harvested under circumstances that are not harmful to sea turtle species. If the shrimp was harvested in a nation certified by the Department of State under Section 609, the United States will assume that the shrimp meets this standard. If, however, the shrimp was harvested in an uncertified nation, it may still be imported - but only if a government official in the harvesting nation also signs the form and affirms that the shrimp was harvested under certain specific conditions that do not pose a threat to sea turtle species.

Once the Department of State instituted these changes, the plaintiffs in the first CIT case reopened the litigation in an effort to reverse one specific aspect of the changes. The reopened case posed this question: if some but not all shrimp trawl vessels in a foreign nation use TEDs, may shipments of shrimp harvested by such vessels be imported into the United States? The Department of State believes the answer must be yes - the harvesting of such shrimp does not harm sea turtles and is thus not subject to the import prohibition of Section 609. The plaintiffs argue otherwise. In their view, unless a foreign nation has a TEDs program comparable to the US program, none of its shrimp harvested by shrimp trawl vessels may be imported.

The CIT ruled in favor of the plaintiffs' position in late 1996. However, in June 1998, the US Court of Appeals for the Federal Circuit vacated that ruling, finding that the CIT lacked jurisdiction to issue the decision because the plaintiffs had previously withdrawn the case. The Department of State then reinstated its decision to permit the importation of shrimp harvested with TEDs in uncertified nations, subject to a number of safeguards and conditions designed to minimize the possibility of fraud and to maintain the protection of sea turtles. The plaintiffs subsequently refiled the case. A decision is pending.

WTO Case

In September 1996, four nations newly affected by Section 609 as a result of the first CIT decision (India, Malaysia, Pakistan and Thailand) brought a case against the United States in the World Trade Organization (WTO), claiming that the shrimp embargo violated US obligations under the WTO Agreement. The United States defended the case, claiming that Section 609 fell within Article XX(b) and (g) of the WTO Agreement, which permit WTO Members, subject to certain constraints, to take measures to protect human, animal and plant life and health and to conserve exhaustible natural resources, even if such measures conflict with other provisions of the WTO Agreement.

A WTO panel of arbitrators ruled against the United States on most issues. The United States then appealed the panel decision to the WTO Appellate Body. The decision of the Appellate Body, issued October 12, 1998, reversed the panel's findings on many key points. Most importantly, the Appellate Body found that Section 609 itself was not inconsistent with US obligations under the WTO Agreement and was, in fact, covered by Article XX(g) relating to the conservation of exhaustible natural resources. Press accounts of the WTO ruling seem not to have grasped this vital point. In addition, the Appellate Body decision reversed the earlier WTO panel ruling by determining that WTO panels may accept amicus briefs and other information submitted by non-governmental organizations.

At the same time, however, the Appellate Body decision found that certain aspects of the way in which the Department of State was implementing Section 609 were, in their cumulative effect, inconsistent with US obligations under the WTO Agreement. The Appellate Body report recommended that the United States revise its implementation of Section 609 accordingly.

On November 25, 1998, the United States announced its intention to implement the WTO decision in a manner which is consistent not only with US WTO obligations, but also with the firm commitment of the United States to the protection of threatened and endangered species, including sea turtles.

The following paragraphs summarize the findings of the WTO Appellate Body decision and the steps being taken to implement the recommendations and rulings:

(1) WTO finding: While Section 609 requires as a condition of certification that foreign programs for the protection of sea turtles in the course of shrimp trawl fishing be *comparable* to the US program, the practice of the Department of State in making certification decisions was to require foreign programs to be *essentially the same* as the US program. In assessing foreign programs, the Department of State should be more flexible in making such determinations and, in particular, should take into consideration different conditions that may exist in the territories of those other nations.

Implementation: In response to this recommendation, the Department of State will now fully consider any evidence that another nation may present that its program to protect sea turtles in the course of shrimp trawl fishing is comparable to the US program. In reviewing such evidence, the Department will take into account any demonstrated differences in foreign shrimp fishing conditions, to the extent that such differences may affect the capture and drowning of sea turtles in commercial shrimp trawl fisheries. The Department will also take such differences into account in making related determinations under Section 609.

(2) WTO Finding: The certification process under Section 609 is neither transparent nor predictable and denies to exporting nations basic fairness and due process. There is no formal opportunity for an applicant nation to be heard or to respond to arguments against it. There is no formal written, reasoned decision. But for notice in the *Federal Register*, nations are not notified of decisions specifically. There is no procedure for review of, or appeal from, a denial of certification.

Implementation: In response to this finding, the Department of State has instituted a broad range of procedural changes in making certification decisions under Section 609. The intention is to create a more transparent and predictable process for reviewing foreign programs and for making decisions on certifications and other related matters. Governments of harvesting nations will be notified on a timely basis of all pending and final decisions and will be provided a meaningful opportunity to be heard and to present any additional information relevant to the certification decision. The governments of harvesting nations that are not granted a certification shall receive a full explanation of the reasons that the certification was denied. Steps that the government must take to receive a certification in the future shall be clearly identified.

(3) WTO Finding: At the time the WTO complaint arose (i.e., after the decision in the second CIT case but before the Court of Appeals vacated that decision), the United States did not permit imports of shrimp harvested by vessels using TEDs comparable in effectiveness to those used in the United States, unless the harvesting nation was certified pursuant to Section 609. In other words, shrimp caught using methods identical to those employed in the United States had been excluded from the US market solely because they had been caught in waters of uncertified nations.

Implementation: Following the decision of the Court of Appeals to vacate the decision of the CIT on this point, the Department of State, as noted above, once again decided to allow the importation of shrimp harvested by vessels using TEDs in uncertified nations, subject to certain safeguards and conditions designed to minimize fraud and to maintain sea turtle protection. That decision remains in effect, pending the outcome of the litigation in the second CIT case.

(4) WTO Finding: Although the United States successfully negotiated a treaty to protect sea turtles with other nations in the Western Hemisphere, the United States failed to engage the nations that brought the complaint, as well as other WTO Members outside the Western Hemisphere that export shrimp to the United States, in serious across-the-board negotiations for the purpose of concluding other agreements to conserve sea turtles before enforcing the import prohibition on those other Members.

Implementation: As early as 1996, the United States proposed to governments in the Indian Ocean region the negotiation of an agreement to protect sea turtles in that region, but received no positive response. In 1998, even before the WTO Appellate Body issued its report, the United States reiterated its desire to enter into such negotiations with affected governments, including those that had brought the WTO complaint. During the summer of 1998, the United States informally approached several governments in the Indian Ocean region, as well as numerous non-governmental organizations, in an effort to get such negotiations underway. In October 1998, the Department of State formally renewed this proposal to high-level representatives of the embassies of the four complainants in Washington, D.C., and delivered the same message to a wide range of nations in the Indian Ocean region through our embassies abroad. In each case, the United States presented a list of "elements" that we believed could form the basis of such an agreement. The Department also made clear the willingness of the United States to support the negotiating process in a number of ways and is continuing to pursue this initiative.

The Department of State is gratified that there seems to be an emerging willingness on the part of governments in the Indian Ocean region to negotiate such an agreement. In the past few months, we have participated in meetings in Malaysia and Australia that brought together government officials, sea turtle experts and fishing industry representatives to explore ways to protect sea turtles in that region. We believe that the next concrete step should be for one or more of those governments to convene an actual negotiating conference to begin the hard work of elaborating an agreement.

(5) WTO Finding: As compared to the nations of the Wider Caribbean and Western Atlantic that were initially affected by Section 609, the United States provided less technical assistance in the use of TEDs to those nations that first became affected by the law at the end of 1995 as a result of the first CIT decision.

Implementation: The United States has renewed its offer of technical training in the design, construction, installation and operation of TEDs to any government that requests it. Training programs will be scheduled on a first come, first served basis, although special efforts will be made to accommodate nations whose governments are making good faith efforts to adopt and maintain nation-wide TEDs programs and who have not previously received such training. In this way, the United States hopes to create an additional incentive in favor of such programs.

In summary, the WTO decision did not require the United States to repeal or even to amend Section 609. Instead, the WTO decision called upon the United States to implement Section 609 in a more transparent, flexible and even-handed manner, to seek to negotiate relevant multilateral agreements with the affected nations and to provide technical assistance to those nations when asked. The WTO did not undermine the goal of sea turtle protection in this case. Indeed, many aspects of the WTO decision have strengthened efforts to achieve this goal.

Conclusions

Section 609 represents an attempt by the United States to promote the protection of sea turtles by ensuring that all shrimp sold in the US market - roughly 80 percent of which is imported - have been harvested in ways that are safe for sea turtle species.

On one level, Section 609 has been effective. A number of foreign nations have adopted TEDs programs following its enactment. It is reasonable to assume that at least some of them would not have done so otherwise. It is also reasonable to assume that these TEDs programs have prevented the needless drowning of many sea turtles in shrimp trawl nets.

However, Section 609 has entailed certain costs as well. It has prompted hard-fought - and continuing - litigation in the CIT by environmental and animal rights groups who believe that the United States Government is not implementing the statute strictly enough. Section 609 has also sparked an equally hard-fought case in the WTO, in which foreign governments have expressed their deep-felt antipathy toward

what they perceive as a unilateral imposition of environmental standards. They also point out, justifiably, that sea turtles are endangered for a wide variety of reasons, not just due to drowning in shrimp trawl nets.

The Department of State has tried in good faith - and with some success, we think - to balance these competing views. We believe that we are implementing Section 609 in a way that respects the letter of the law and congressional intent, while also honoring US obligations under the WTO Agreement.

We nevertheless believe that we can achieve greater protection for sea turtles - and also resolve much of the conflict and controversy that Section 609 has sparked - through multilateral approaches. If sea turtles or other endangered migratory creatures are to be protected effectively, nations within their migratory ranges must act cooperatively. Unilateral actions are not a complete solution, and may undermine cooperative efforts. That is why the United States welcomed the decision of the WTO in calling for the negotiation of a comprehensive sea turtle protection agreement involving the United States, the complaining nations and other interested parties. One such agreement already exists - the 1996 Inter-American Convention for the Protection and Conservation of Sea Turtles. Another is needed for the Indian Ocean.

4.4 NATIONAL STRATEGIES ON AQUATIC ANIMAL HEALTH

Development of National Strategy on Aquatic Animal Health Management in Asia

M.G. Bondad-Reantaso

Sarbanes Cooperative Oxford Laboratory
Maryland Department of Natural Resources
904 S. Morris Street
Oxford, MD, USA 21654

M.G. Bondad-Reantaso. 2004. Development of national strategy on aquatic animal health management in Asia. p. 103-108. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.). Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

National strategy on aquatic animal health management in Asia was a major output of the FAO/NACA Regional Technical Cooperation Programme (TCP/RAS 6714 and 9605) on "Assistance for the Responsible Movement of Live Aquatic Animals in Asia". It served as the framework containing the government's action plans at the short, medium and long-term for the national-level implementation of the *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy*. The processes involved in developing national strategies and a few examples are presented in this paper.

Introduction

Between 1998-2002, the Food and Agriculture Organization of the United Nations (FAO) and the Network of Aquaculture Centres in Asia-Pacific (NACA), together with participating Asian governments (through their designated National Coordinators) and with the support of regional and international institutional partners such as the Office International des Épizooties (OIE), as well as individual experts, developed and implemented a regional program on aquatic animal health management. This program, which was undertaken through FAO's Technical Cooperation Programme (TCP/RAS 6714 and 9605) for a project "Assistance for the Responsible Movement of Live Aquatic Animals in Asia", had the following objectives:

(a) assist countries in the Asia-Pacific to move aquatic animals in a way that minimizes the disease risks associated with pathogen transfer and disease spread, both within and across boundaries;
(b) enhance protection of the aquatic environment and biodiversity, as well as the interests of aquaculture and capture fisheries;
(c) provide a mechanism to facilitate trade in live aquatic species and avoid unjustifiable trade barriers based on aquatic animal health issues; and

(d) implement relevant provisions of FAO's Code of Conduct for Responsible Fisheries (CCRF) (FAO 1995) and other international treaties and agreements (e.g., the World Trade Organization's (WTO) Sanitary and Phytosanitary (SPS) Agreement, the Convention on Biodiversity (CBD)) applicable to the Asian Region.

The *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy* or "Technical Guidelines" (FAO/NACA 2000), was the first major output of the regional program. The Technical Guidelines, supported by a *Manual of Procedures* (FAO/NACA 2001) and an *Asia Diagnostic Guide to Aquatic Animal Diseases* (Bondad-Reantaso *et al.* 2001), were based on a set of 15 guiding principles developed through a consultative process. The Technical Guidelines provide valuable guidance for national and regional efforts in reducing the risks of disease due to aquatic animal transfers by undertaking appropriate health management processes/measures[1] for the safe and responsible movement of live aquatic animals.

Development of National Strategy on Aquatic Animal Health

The National Strategy on aquatic animal health management, representing a third major output of the regional program, provides a framework for the national-level implementation of the Technical Guidelines. It contains the action plans of government at the short, medium and long term to implement the provisions in the Technical Guidelines using the concept of *"phased implementation based on national needs"*.

The development and contents of the National Strategy were thoroughly discussed during two regional workshops held in 1998 and 1999 (Anon. 1998). At the national level, the process commenced as early as 1999, and the draft versions were presented by participating governments during the final workshop of the regional program in Beijing in 2000. For some countries, national-level consultation with governments and related institutions and stakeholders through a series of meetings/workshops/consultations was made in order to assess the needs, determine the objectives, set priorities, finalize the elements of the National Strategy, and develop project proposals to seek funding (internal and external) for its implementation. The National Strategies are expected to be incorporated into National Aquaculture Development Plans. The various elements contained in the National Strategy framework include:

- national coordination,
- legislation and policy,
- list of pathogens,
- institutional resources,
- diagnostics,
- disease zoning,
- surveillance and reporting,
- contingency planning,
- import risk analysis,
- capacity building,
- awareness building and communication,
- farmer/private sector involvement,
- financial resources,
- monitoring and evaluation, and
- regional cooperation.

[1] The health management process is defined as aquatic animal health management in its broadest sense, encompassing pre-border (exporter), border and post-border (importer) activities, as well as relevant national and regional capacity-building requirements (infrastructure and specialized expertise) for addressing health management activities, and implementation of effective national and regional policies and regulatory frameworks required to reduce the risk of disease spread through movement (intra- and international) of live aquatic animals (FAO/NACA 2001).

These elements are elaborated in the *Manual of Procedures*, which provides technical protocols to guide countries. It is up to the governments to limit or expand the scope of the National Strategy based on a comprehensive assessment of their needs and the setting of priorities according to available resources.

The development of the National Strategy is an on-going process and builds on the resources available for its implementation. The countries participating in the regional program have already been prepared with technical skills and documents that will guide them in National Strategy development. There are costs involved, and although there are opportunities to seek funding and technical assistance from donor agencies, the primary responsibility of finalizing the National Strategy and identifying and allocating resources rests within the responsible authorities. Political will is essential. Because of the diverse economic, social and ecological conditions surrounding aquaculture development in the region and the varied access to technical, financial and institutional resources, priority setting based on a comprehensive assessment of the needs for aquatic animal health management is the essential first step. Mechanisms for monitoring and evaluating the development and implementation of the National Strategy are also being put in place jointly by NACA and FAO.

The Technical Guidelines was adopted in principle by the 21 participating governments/territories during the final workshop in Beijing, China PR in June 2000, has received strong support from the Association of South East Asian Nations (ASEAN), which endorsed the Technical Guidelines as an ASEAN policy document during the 9th Meeting of the ASEAN Working Group on Fisheries held in September 2001 in Bali, Indonesia.

The ASEAN-SEAFDEC (South East Asean Fisheries Development Center) Fisheries Consultative Group (FCG), during the development of the "Regional Guidelines for Responsible Fisheries in Southeast Asia – Responsible Aquaculture" in Iloilo, Philippines in July 2001 endorsed the provision of support for the implementation of the Technical Guidelines and the National Strategies. The major references are:

(a) Article 9.3.2 "States should cooperate in the elaboration, adoption, and implementation of international codes of practice and procedures for introductions and transfers of aquatic organisms".
The two relevant statements are:

4) *"States should support the implementation of the 'Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy' with emphasis on phased implementation based on national needs",*

and

5) *"The National Strategies on Aquatic Animal Health Management in the 'Technical Guidelines' should be integrated into the national aquaculture development plans of States in the region. States should provide funds for its implementation".*

Support for the implementation of the Technical Guidelines was again re-emphasized during the ASEAN-SEAFDEC Millenium Conference "Fish for People" held in Bangkok, Thailand on 19-24 November 2001, and was included as one of the major recommendations and action plans under Session 3.4 – Healthy and Wholesome Aquaculture (see Anon. 2002).

The above developments are important indicators of the on-going mutual cooperation and support to regional policies and the increasing attention that health management is getting. It is also a manifestation of the strong political support for agreements reached at the regional level. Such political support can serve not only as a significant influence on governments in carrying out aquatic animal health programs at the national level, but also as a mechanism to influence standard-setting organizations at the regional and international levels.

Examples of National Strategies

Countries that have participated in the regional program are at different stages of development of the National Strategy. Australia's five-year national strategic plan for aquatic animal health, "AQUAPLAN", was already in place prior to the implementation of the regional program (AFFA 1999); other countries such as Hong Kong SAR China and Singapore also have existing national strategies in place. These countries were provided the opportunity to further develop their national strategies and/or enhance its implementation (e.g., in the case of Australia, enhance its international linkages) according to the various regional activities and new aquatic animal health concepts introduced under the regional program. Other countries such as Indonesia, India, Philippines, Thailand and Vietnam, on the other hand, conducted national-level consultations with relevant government agencies and stakeholders involved in aquatic animal health management, as a first step in the process.

Some examples of National Strategies (e.g., China PR, Japan and Thailand) can be found elsewhere in this report; some others are highlighted below:

Australia: Australia has a National Strategic Plan for Aquatic Animal Health 1998-2003 – AQUAPLAN – in place since April 1999. The Fish Health Management Committee (FHMC), which is ministerially appointed, is the body that oversees the development and implementation of AQUAPLAN. AQUAPLAN is a broad, comprehensive strategy that outlines objectives and projects to develop a national approach to emergency preparedness and response and to the overall management of aquatic animal health in Australia. It is comprised of eight key programs under which Australia's government and private sectors have identified priority projects to achieve the program objectives (AFFA 1999). These are: (a) international linkages, (b) quarantine, (c) surveillance, monitoring and reporting, (d) preparedness and response, (e) awareness, (f) research and development, (g) legislation, policies and jurisdiction and (h) resources and funding. Under the program, the following documents have been released: (a) *Australian Aquatic Animal Disease Identification Field Guide* (March 2000); (b) *AQUAPLAN Zoning Policy Guidelines* (August 2000, January 2001)); (c) *AQUAVETPLAN Enterprise Manual* (December 2000); and (d) *AQUAVETPLAN Furunculosis Disease Strategy Manual* (June 2001).

India: India completed two consultative meetings (May and November 2001) to develop its National Strategic Plan for Aquatic Exotics and Quarantine. The consultation was coordinated by the National Bureau of Fish Genetics and Resources (NBFGR) and participated in by all National Directors of the Indian Council of Agricultural Research (ICAR), fish health experts, policy-makers, and other relevant organizations and institutes. The strategic plan is composed of three documents: (a) a strategic plan, (b) quarantine guidelines and (c) a handbook on exotics and quarantine. The strategic plan is ready for submission to the Ministry of Agriculture for implementation at the national level.

Myanmar: A national workshop was convened in April 2002 to further develop the National Strategy. The objective of Myanmar's National Strategy is to undertake responsible aquatic animal health management in accordance with Myanmar's Aquaculture Law (1989) and in support of the national-level implementation of the Technical Guidelines, as well as other international agreements. The four key priority elements identified were: (a) legal framework, national coordination and cooperative mechanisms among stakeholders; (b) diagnostics, research and education and extension services; (c) disease surveillance, reporting and information systems; and (d) training and capacity building. The following activities were also prioritized in order to speed up the development of the National Strategy: (a) formation of Myanmar's Committee on Aquatic Animal Health (CAAH); (b) review of the Aquaculture Law 1989 with a view to update, revise or formulate provisions on aquatic animal health management through orders/directives to be issued by the Director General of the Department of Fisheries; (c) development of a human resources development program that will upgrade capabilities and facilities for disease diagnostics, research and education and extension; (d) development of mechanisms for aquatic animal disease surveillance and reporting; and (e) communication and awareness-raising among all relevant stakeholders. Further work includes proposal development to seek out funding for its implementation.

Nepal: A national workshop was convened in December 2001 to update the National Strategy and develop a proposal to seek out funding for its implementation. The objective of Nepal's National Strategy on Health is to undertake responsible aquatic animal health management in accordance with the Fisheries Perspective Plan and the 10th Five Year Plan for Fisheries Development, and in support of the national-level implementation of the Technical Guidelines. The Directorate of Fisheries Development (DoFD), through the National Coordinator (NC), is the focal point for implementation through effective coordination with all relevant agencies and stakeholders. An appropriate person was designated as the Focal Person for Aquatic Animal Disease Reporting. An Aquatic Animal Health Committee (AAHC) will also be formed with a clearly defined Terms of Reference. The priority areas of the National Strategy are the following: (a) establishment of a national information system for aquatic animal health management; (b) development of an institutional network and a mechanism for an aquatic animal disease surveillance and reporting system; (c) identification of institutional responsibilities for intersectoral coordination and co-operation (i.e., national, regional and international co-operation); (d) development of capabilities and facilities for disease diagnostics and research; (e) establishment of cooperative and functional linkages between farmers, fisheries extension workers, fisheries resource centers, diagnosticians and researchers (diagnostic, research and teaching laboratories); (f) review of all existing acts and regulations relevant to aquatic animal health with a view to update, revise or formulate them as required; (g) development of national standards/procedures for health certification, quarantine and quality control based on the Technical Guidelines, the supporting Manual of Procedures, the Asia Diagnostic Guide and other relevant documents; and (h) capacity building on import risk analysis (IRA) for live aquatic animal importation.

Philippines: A national workshop was convened in February 2002 involving key personnel of the Philippine Bureau of Fisheries and Aquatic Resources (BFAR) to further develop the National Strategy. In this workshop, the different elements were prioritized and follow-up action plans with clear time frame (short, medium and long term) as well as responsible staff were identified. The National Strategy will be subject to further consultation with all relevant stakeholders before approval by the highest authority. The workshop prioritized the following elements of the National Strategy: (a) legislation and policy; (b) list of pathogens (for issuance of health certificates; (c) capacity building; (d) surveillance and reporting; (e) contingency planning; (f) import risk analysis; (g) disease zoning; (g) private sector consultation; (h) institutional resources; (i) national coordination and formation of a National Aquatic Animal Health Management Committee; (j) regional and international cooperation; (k) diagnostics; (l) fish kill investigation and prevention; and (m) responsible use of feeds/biochemicals in aquaculture. The BFAR will be the focal point for the development and implementation of the National Strategy.

Singapore: Singapore administers an Accredited Ornamental Fish Exporter's Scheme where members must observe and comply with the terms and conditions of the program, as well as a Code of Practice for Accredited Ornamental Fish Exporters. Almost all major exporters are members of this scheme, which emphasizes good management, hygiene practices and general lay-out of the premise, especially with reference to quarantine facilities (Cheong 1996). Singapore's National Strategy is currently looking at (a) import risk assessment and (b) consideration of a plan to monitor disease occurrence in newly introduced species for a period of three months. The Agri-food and Veterinary Authority of Singapore (AVA) continues to review and update the national list of diseases in order to prioritize health management actions for important marine foodfish pathogens. AVA continues to hold dialogues with stakeholders and to bring awareness of the Technical Guidelines and other health related issues.

Conclusions

The development and implementation of National Strategy on Aquatic Animal Health Management in Asia is an important step and an on-going process, and Asian governments have agreed to implement the Technical Guidelines at the national level. There is good support from various regional and international organizations and strong commitment from national governments for its implementation. The various processes involved and the importance of regional and international cooperation and commitment from responsible authorities provide valuable experiences that can be used when establishing health manage-

ment measures in many countries of other aquaculture regions of the world, particularly Latin America. Health management is a shared responsibility and the contribution of all relevant stakeholders is essential in the process.

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The Import Risk Analysis Process in Australia

Ramesh Perera

Biosecurity Australia
Department of Agriculture, Fisheries and Forestry - Australia
GPO Box 858, Canberra ACT 2601, AUSTRALIA

Perera, R. 2004. The import risk analysis process in Australia. p. 109-113. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

The process for developing Australian national policies on importation of animal and plant-based commodities, including aquatic animal commodities, has undergone a considerable change over the last few years. These changes have occurred at both the level of overall administrative processes and with respect to methodologies used in import risk analyses (IRA) that underpin Australia's biosecurity policies and associated import controls. Because aquatic animal biosecurity in Australia has, in the past, lagged behind its terrestrial counterpart, Biosecurity Australia is fast working toward ensuring consistent and science-based policies across all plant and animal-based commodities.

Introduction

Biosecurity Australia (formerly the policy wing of the Australian Quarantine and Inspection Service, AQIS) is a group within the Commonwealth Government responsible for providing policy and technical advice to the AQIS on importation of plants and animals (including aquatic animals) and their products.

Most aquatic animal biosecurity policies on importation of aquatic animal commodities to Australia were established in the mid-1930s. Since that time, there has been a significant growth in the aquaculture sector around the world, particularly in the Asian region, including Australia. As a result, the region has experienced increased impact of aquatic animal disease, leading to a greater awareness of the biosecurity risks to wild fishery stocks, aquaculture and the environment associated with international trade in aquatic animal commodities.

Recognising this increased risk, over the last decade Australia has committed resources to combat the threat, resulting in a general increase in aquatic animal health infrastructure at both provincial and federal levels. The federal level initiatives have been incorporated into a national aquatic animal health strategy, which includes Biosecurity Australia's role in developing biosecurity policies with respect to importation of aquatic animals and their products.

Biosecurity Australia, like many other agencies with similar responsibilities, is improving its IRA processes, both at an overarching administrative level as well as in terms of specific methodologies used to assess risk. We have learned a great deal from the World Trade Organization (WTO) trade dispute with Canada on biosecurity restrictions applied to salmonid products and have introduced a uniform and structured process aimed at achieving a consistent approach to IRA across all plant and animal-based com-

modities, including those based on aquatic animals. These processes were designed to be consistent with our international obligations (such as those associated with WTO membership) and where appropriate, consistent with international standards.

This paper outlines Biosecurity Australia's processes with respect to IRA in aquatic animal commodities, including the current IRA work program.

IRA - The Administrative Process

The IRA administrative process followed by Biosecurity Australia in undertaking IRAs is set out in the AQIS IRA Process Handbook (AQIS 1998). The Australian Quarantine Review Committee, as commissioned by the Commonwealth Government, recommended in 1996 that IRAs should be consultative, scientifically based and politically independent, transparent, harmonised and subject to appeal on process. The government endorsed these principles in 1997.

The IRA Process Handbook was published in 1998 and provided the detailed implementation of those principles. The handbook noted that the IRA process would be kept under review and improvements made in the light of experience and, in November 2000, Biosecurity Australia began a process of evaluating the IRA administrative process. A revised draft process is now being finalised, prior to approval and implementation (see Fig. 1).

Some key elements of the process include:

- extensive consultation with stakeholders throughout the process, including release for public comment of a hazard identification paper and a draft risk assessment report,
- an IRA Team to conduct each IRA - membership of the team is governed by whether the required technical expertise is available in Biosecurity Australia and to what extent expertise outside Biosecurity Australia may be required,
- provision for appeal against decisions, and
- independent scientific peer review.

IRA - Risk Assessment Methodology

Within the above overarching administrative process, we have developed guidelines for our officers working on IRA, i.e., for internal departmental use. While this is a draft document under development, it has been adopted as the methodology for the IRAs that Biosecurity Australia is currently conducting. As the guidelines are general, individual IRAs may depart from the guidelines to suit the individual circumstances of an analysis so as to ensure the resulting IRA is appropriate to the circumstances. These guidelines may be accessed from our website at:
http://www.affa.gov.au/content/publications.cfm?ObjectID=85B98CC3-86DE-48AE-8A76D4A40F33245A

If you experience difficulties in accessing the files from the above website, a copy can be obtained from:

Biosecurity Development and Evaluation
Biosecurity Australia
GPO Box 858, CANBERRA ACT 2601
Phone: +61 2 6272 4914, Facsimile: +61 2 6272 4568
E-mail: bde@affa.gov.au

The guidelines provide guidance on the different types of import risk analysis methods used by Biosecurity Australia. They describe a structured approach to import risk analysis that is consistent with Australian government policy, the *Quarantine Act (1908)* and subordinate legislation, the requirements of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agree-

ment) and with the international standards for import risk analysis developed by the Office International des □pizooties (OIE) and under the International Plant Protection Convention (IPPC).

IRAs are normally conducted using qualitative methodologies, i.e., disease risks (comprising likelihood of occurrence and magnitude of consequences) are calculated using descriptive terms such as "negligible", "low", "moderate" etc. However, we are beginning to introduce quantitative elements into our risk analyses where likelihoods are described using numerical probabilities. Since Australia's appropriate level of protection (ALOP) is defined qualitatively, the guidelines have been developed in a way that accommodates an interchangeable range of qualitative and quantitative approaches.

Work Program

Historically, less attention has been paid to aquatic animal biosecurity compared to terrestrial counterparts. In 1996, the National Taskforce on Imported Fish and Fish Products (NTIFFP) identified priority areas for review of existing policies by IRA, including import polices on ornamental finfish, baitfish, non-viable bivalve molluscs and freshwater crayfish (Higgins 1996).

Over 90% of aquatic animal work at Biosecurity Australia is on developing import policies. IRAs on non-viable salmonids/marine finfish and ornamental finfish, all of which were associated with the WTO salmon case, have been completed to date. Import risk analyses on non-viable animals/products of prawns, bivalves, freshwater crayfish and freshwater finfish are currently under way.

Following the discovery of viral haemorrhagic septicaemia virus (VHSV) in pilchards and mackerel in Californian fish and subsequent introduction of interim import restrictions in May 2002, we are conducting a detailed policy review of VHSV risks associated with product intended for direct introduction into natural waters.

A major auxiliary project is a consultancy on recreational fishing bait and berley use that will provide much needed information on bait-use patterns, particularly with respect to imported product. This project is expected to be completed by the end of the year and will feed into current and future IRAs. Also related to end-use of aquatic animal products is an educational campaign, the main focus of which is to increase public awareness of proper handling and disposal of aquatic animals and their products, aimed at reducing the risk of spreading aquatic animal diseases and pests.

As a major component of our work program, we have on-going input into operational implementation of previous IRAs, including assessment of equivalence measures, and providing advice to the AQIS on the operational aspects of quarantine.

To cope with this growing IRA workload, Biosecurity Australia's aquatic animal import policy group has increased from one part-time position in 1996 to a current total of seven staff.

Conclusions

As Australian aquaculture continues to grow, there will be increasing demands for protection against pests and diseases that may affect or threaten productivity. For our part, i.e., managing risks associated with aquatic animal imports, we expect there will be greater emphasis on defensible, science-based import policies and a continued improvement in risk analysis methodologies

Driven mostly by volume of trade issues, we expect that the current trend toward better quantification of quarantine risks will continue. We also expect to be involved in targeted research, mainly in the areas of pathogen inactivation and domestic fish/shellfish health status.

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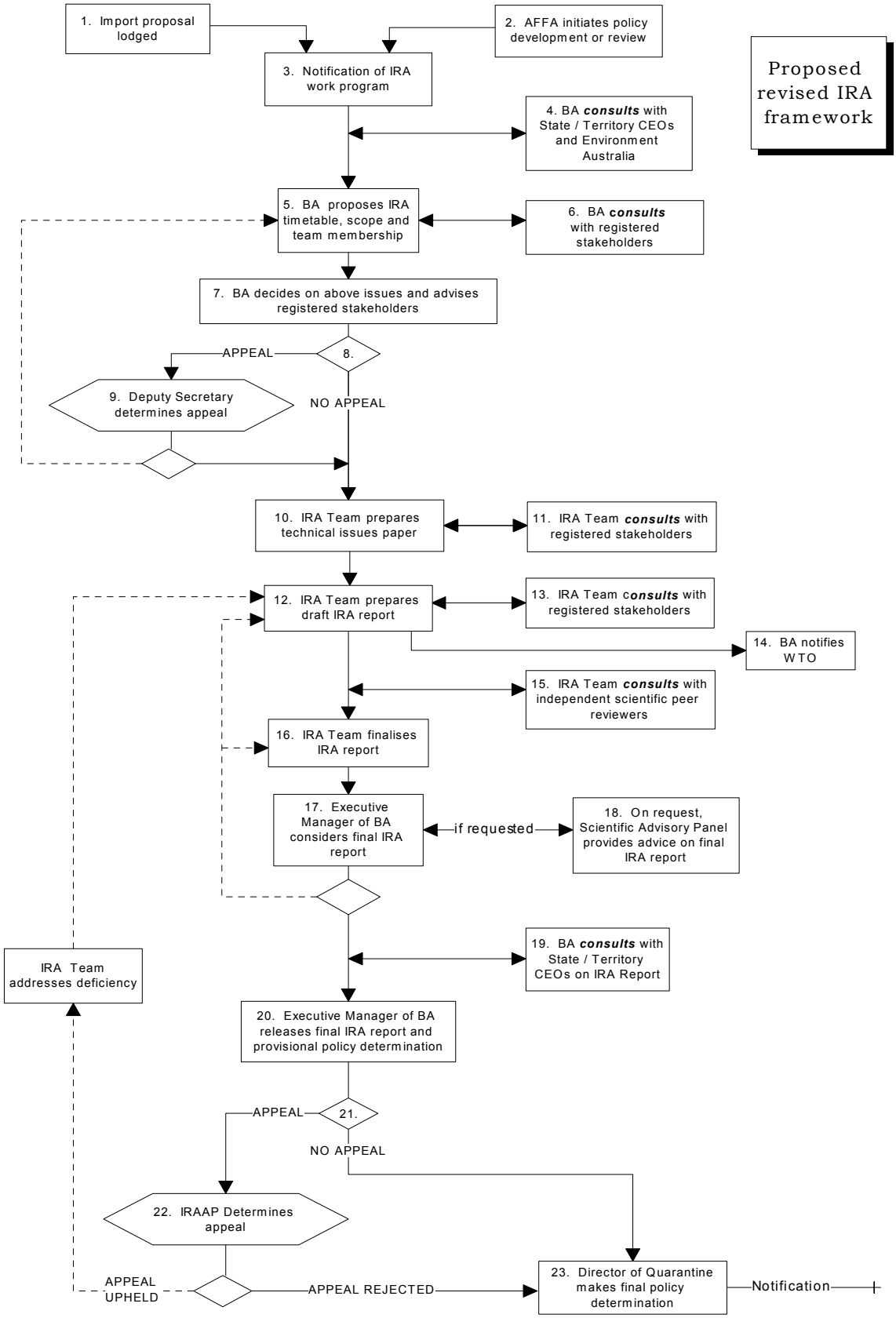

Figure 1. Biosecurity Australia's draft risk analysis framework.

Canada's National Aquatic Animal Health Program

Gilles Olivier

Fisheries and Oceans Canada
Aquaculture Sciences Division, Science Branch
343 University Avenue, Moncton NB
CANADA E1C 9B6

Olivier, G. 2004. Canada's National Aquatic Animal Health Program. p. 115-117. *In* J.R. Arthur and M.G. Bondad- Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper provides a brief overview of Canada's Fish Health Protection Regulations. In the last 10 years, the field of aquatic animal health has evolved rapidly and international standards are now available. Canada started to revise its national fish health legislation beginning in the early 1990s; these changes are captured in the proposed National Aquatic Animal Health Program.

The Fish Health Protection Regulations

The primary purpose of federal Fish health legislation is to control the importation of live aquatic animals into Canada and their transfer between provinces in order to minimize the risk of introduction and spread of economically and ecologically significant aquatic animal diseases (Carey and Pritchard 1995, Carey 1996).

In Canada, the Fish Health Protection Regulations (FHPR) are a discrete set of regulations under the Fisheries Act that are administered by the Department of Fisheries and Oceans Canada (Anon. 1977). The FHPR currently apply solely to salmonid movements into Canada and between provinces/territories.

The FHPR were promulgated in 1977, with minor amendments to the regulations being implemented in:

- 1986 – transfer of bacterial kidney disease (BKD) from the list of "certifiable" diseases to the list of "notifiable" diseases
- 1992 – removal of the requirement for certification of sources of dead eviscerated salmonids
- 1998 – allowing "like to like" transfers and requiring health certification for viruses only for sources of disinfected eggs

Shellfish Health Protection Regulations have been drafted and parallel the FHPR, but with a separate "Manual of Compliance." They cover all shellfish groups (crustaceans, molluscs and echinoderms).

In addition to the above regulations:

- the Fisheries Act, Section 4 covers the movement of research animals of any species (quarantine control is generally required in these instances) and the transfer of salmonid eggs from uncertified

sources. In the latter case, 100% lethal sampling of broodstock at origin is required. Furthermore, quarantine/isolation of eggs/hatchlings is required until broodstock and F_1 health status is established.

- Fishery (General) Regulations apply for most Canadian Provinces and require a review of available fish health information for each proposed shellfish or finfish transfer on a case by case basis (specifically Part VIII Section 56b).

The National Aquatic Animal Health Program

The government of Canada, the provinces and the aquaculture industry are working together to ensure that our fisheries and aquaculture industries remain healthy. Fisheries and Oceans Canada (DFO) is leading the effort to develop a new program called the National Aquatic Animal Health Program (NAAHP). This effort is being assisted by the Canadian Food Inspection Agency, which is providing assistance to ensure that the NAAHP is consistent, where possible and/or practical, with disease control principles and procedures used for Canada's terrestrial animal stocks.

The NAAHP takes into account the need to meet increasingly stringent aquatic animal health requirements for international trade. The creation of the World Trade Organization (WTO) and the signing of the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) strongly support the current efforts to establish a Canadian NAAHP. Canadian regulations must be standardized with the aquatic animal health standards for international trade established by the Office International des pizooties (OIE), as specified in the OIE's *International Aquatic Animal Health Code*. Several countries are revising or implementing aquatic animal health programs to meet national and international standards and increased consumer awareness and demand for sustainable and quality products.

The NAAHP is designed to be a collaborative effort between the federal government, the provincial governments and all sectors of the aquaculture industry. Private and university fish health expertise, as well as provincial, private and university veterinarians also provide additional input.

The guiding principles of the NAAHP are that the program should:

- be science-based;
- be national and regional in scope;
- be credible;
- be flexible;
- be efficient, effective and economical;
- involve stakeholders; and
- be fully enabling

The proposed NAAHP contains the following elements:

Appropriate Legislation – For the NAAHP to be effective, an appropriate federal regulatory environment must be developed. Several avenues are being proposed, ranging from the amendment of existing regulations to the development of new ones.

Surveillance and Zoning – This element proposed the creation of a national standard for disease surveillance of wild and cultured aquatic animals. It includes the establishment and maintenance of disease-free "zones", as per internationally recognized zoning and surveillance standards.

Disease Detection Methods – Disease detection methods are a key element of a national aquatic animal disease surveillance program. National standards for aquatic animal disease diagnosis will be developed to ensure that diagnostic methods provide reliable, accurate and consistent results.

Quality Assurance/Quality Control (QA/QC) - QA/QC standards for health certification and disease surveillance diagnostic laboratories will be established through scientific validation processes. International standards will be used where appropriate. A comprehensive QA/QC program will be required to ensure accurate and reliable results performed by multisectorial (government, academic and private sector) laboratories.

Aquatic Animal Health Studies – Aquatic animal health research is necessary to ensure that adequate scientific data are available for risk assessment and the design of effective contingency plans and disease control options. In the present context of the NAAHP, for diseases of national concern, this is considered a federal responsibility.

Response to Diseases of Concern – This includes coordinated disease response procedures, emergency disease control and endemic disease management. Preparedness requires pre-planning for diseases of known concern or of unknown etiology. The NAAHP includes disease response planning, an on-going process, to cover all types of disease. It is federally coordinated for national diseases of concern and is shared for provincial/regional diseases of concern.

Best Management Practices – Best management practices (BMPs) for aquatic animal health will be consistent with international, federal and provincial aquatic animal health regulations, policies and standards; provide a common standard for different industry sectors; and provide transparency for measures undertaken to protect stock health.

The roles and responsibilities of the different sectors are currently under discussion, as is the potential for funding to support all elements of this initiative as a comprehensive program.

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Canada's National Code on Introductions and Transfers of Aquatic Organisms

Gilles Olivier

Fisheries and Oceans Canada
Aquaculture Sciences Division, Science Branch
343 University Avenue, Moncton NB
CANADA E1C 9B6

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Abstract

This paper provides a brief review of Canada's National Code on Introductions and Transfers of Aquatic Organisms. The National I&T Code aims at standardizing regional processes in Canada. The Code includes a risk analysis component to facilitate decision-making.

Introduction

The National Code on Introductions and Transfers of Aquatic Animal Organisms (National I&T Code) sets in place a mechanism (Introductions and Transfers Committees) for assessing proposals to move aquatic organisms from one water body to another. It also provides all jurisdictions with a consistent process (the Risk Analysis Procedure) for assessing the potential impacts of intentional introductions and transfers of aquatic organisms. The Code applies to all aquatic organisms (called fish hereafter) in freshwater or marine habitats and to all activities by which live aquatic organisms are introduced or transferred into fish-bearing waters or fish-rearing facilities, such as aquaculture farms.

The National I&T Code aims at standardizing regional processes in Canada. The Code includes a risk analysis component to facilitate decision-making. It is undergoing experimental trial for 18 months. Historically, each Canadian province has its own I&T Committee, and committee members are drawn from both levels of government, provincial and federal.

The Code is intended to protect aquatic ecosystems while encouraging responsible use of aquatic resources for the benefit of Canadians. Federal, provincial and territorial governments have agreed to work cooperatively in applying this Code to national and regional regulations and policies that govern intentional introductions and transfers. Provinces and territories and the federal government will work to ensure that affected jurisdictions are given a voice when aquatic organisms are introduced or transferred to shared watersheds.

The Contents of the Code

The National I&T Code covers all fish and shellfish transfers, and it is based on avoidance of:

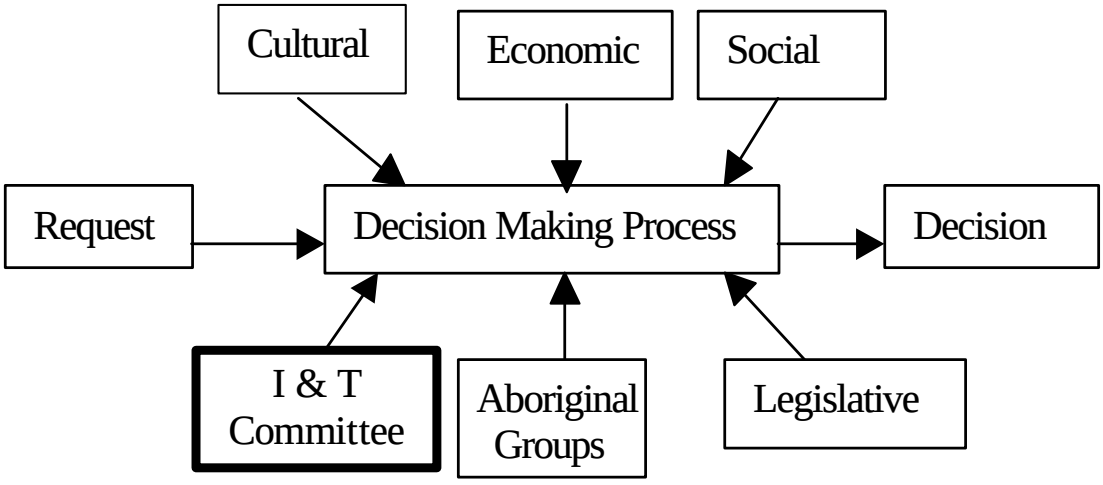
- risks of harmful alterations to natural aquatic ecosystems,
- risks of deleterious genetic changes in indigenous fish populations, and
- risks to aquatic animal health from the potential introduction and spread of pathogens and parasites that might accompany aquatic organisms being moved.

The Code has two parts. Part I includes general background information, while Part 2, which is the main body of the Code, briefly describes the legal framework and the Guiding Principles. Various appendices follow:

- Appendix I contains information on the regional, provincial, national and international policies and guidelines that apply to introductions and transfers of aquatic organisms in Canada.
- Appendix II outlines the roles and responsibilities of all concerned.
- Appendix III outlines the nature and scope of information that the proponent of an introduction or transfer should provide in support of a proposal.
- Appendix IV, the Risk Analysis, is perhaps the most important part of the document. The object of the risk analysis is to identify whether the proposed introduction or transfer presents a low, medium or high risk for the receiving environment. The risk analysis is an adaptation of internationally acknowledged models and processes and takes into consideration the level of uncertainty associated with the available scientific knowledge.
- Appendix V is a summary of the whole risk assessment and is used as the permanent record of the proposal and the review process. It finishes with the Introductions and Transfers Committee's advice to the decision-making authority.

The Introductions and Transfers Process

The process involved for an Introductions and Transfers request is illustrated below:



The process starts with a submission to the I & T Committee. For routine requests, the Chair usually makes the decision. However, in "nonroutine" cases a risk analysis is required.

If risks are identified, then mitigation measures are considered. In the risk analysis process:

- A HIGH rating means that the risk is likely or very likely to occur.
- A MEDIUM rating means that there is a probability of negative impact.
- A LOW rating means that the risk is considered to be insignificant.

It is important to note that for the HIGH and MEDIUM risk categories there is a requirement to apply appropriate mitigation measures to lessen the risk to a LOW rating. However, it is recognized that this may not be possible for all proposals.

A proposal or request will only be approved if the Organism Risk Potential is LOW or can be reduced to LOW through mitigation procedures.

In the process described above, the strength of the review process is not in the ratings, but in the detailed biological and other relevant information statements that motivate them.

The risk analysis process described in the National I&T Code contains two parts. Part 1, the aquatic organism ecological and genetic risk assessment process, containing the following steps:

- Step 1: Determining the probability of establishment
- Step 2: Determining the consequences of establishment of an aquatic organism.
- Step 3: Estimating aquatic organism risk potential where the final risk estimate is established
- Step 4: Completing the risk assessment documentation

Once the above process is completed, there is a possibility that mitigation measures would be needed to reduce risks to a LOW rating. For example, in a case where the aim is to reduce the risk of genetic impact on local stock, the risk mitigation measures that could be employed include, but are not necessarily limited to:

- holding in containment facilities to prevent escape
- using stocks genetically similar to stocks in receiving waters
- sterilizing organisms to prevent interbreeding with local populations

If the aim is to reduce the risk of ecological impacts on local ecosystems, the following measures might be employed:

- using local stock only
- sterilizing organisms to prevent natural reproduction and increase in population size
- using species that cannot reproduce naturally in receiving waters
- holding in containment facilities to prevent escapes

Part 2 of the risk analysis relates to the pathogen, parasite or fellow traveler risk assessment process; the general process identified above is repeated:

- Step 1: Determining the probability of establishment
- Step 2: Determining the consequence of establishment of a pathogen, parasite or
- fellow traveler
- Step 3: Estimating pathogen, parasite or fellow traveler risk potential
- Step 4: Completing the risk assessment documentation

Completion of the risk analysis will help answer whether or not the organism is likely to become established in the receiving environment and if the answer is yes, to state what the consequences of that establishment will be in terms of ecological, genetic or disease impact. The risk analysis should be supported with references. The final steps in the risk analysis are to place all the answers given in a summary table and, using pre-established format, come up with a judgement of whether the introduction or transfer will have a LOW, MEDIUM or HIGH risk of negative environmental impacts. As described above, once the process is completed, there is a possibility that mitigation measures would be needed to reduce risks to a LOW rating.

Additional information on the National Code on Introductions and Transfers of Aquatic Organisms is available at the following website:

http://www.dfo-mpo.gc.ca/science/aquaculture_e.htm

Safe Control of Aquatic Products in China

Fan Xiangguo

Division of Aquaculture
Bureau of Fishery
Ministry of Agriculture
Beijing, People's Republic of CHINA

Fan Xiangguo. 2004. Safe control of aquatic products in China. p. 123-125. *In* J.R. Arthur and M.G. Bondad- Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper briefly reviews recent legislation adopted to implement procedures for aquatic animal quarantine and the control of genetically modified organisms (GMOs) in the People's Republic of China.

The Status of Quarantine Work

Legislation to support the quarantine of aquatic animals

The Chinese government has always paid attention to the importance of aquatic animal quarantine and has made great progress in the past few years. In October 1991, China passed the *Animal and Plant Import/Export Law of the People's Republic of China*, which was implemented on 1 April 1992. In January 1997, the *Implementing Regulations of the Animal and Plant Import/Export Law of the People's Republic of China* was put into force. In addition to these two legislative acts, related laws and regulations include the *Law of Fisheries of the People's Republic of China* and the *Administrative Rule of Aquatic Seeds*.

The latter was issued by the Ministry of Agriculture to ensure that aquatic seed are included within the quarantine system. It requires that people go to a fishery administrative office to pass through a quarantine procedure before they move aquatic seed from one place to another. At the same, quarantine staff must give proper documentation to individuals whose aquatic seed have passed through the quarantine procedure A Sub-committee for Standardization on Aquatic Animal Disease Control, under the National Standardization Committee on Animal Disease Control, has been set up. The Sub-committee is mainly responsible for the following areas of work: putting forward principles, policies and technical measures regarding the standardization of aquatic animal disease control; drafting, examining and modifying national and sectoral standards for aquatic animal disease control; assuming responsibility for the publicity, definition and technical consultation for the standardization of aquatic animal disease control; and conducting international exchanges and collaboration on the techniques of standardization on aquatic animal disease control.

Organizational management and other relevant activities

Since the promulgation of the *Law of Quarantine for Entry-Exit Animals and Plants of the People's Republic of China*, China has strengthened its efforts and improved the work on quarantine for the entry and exit of animals and plants. A complete network for the quarantine of animals and plants has been

established across the country, with more than 300 institutions located at various major ports. All these institutions have made remarkable contributions in the areas of strengthening the management of animals and plants for entry and exit, ensuring the healthy development of aquaculture production and preventing diseases from entering the country.

At the same time, efforts have been made to advance aquatic animal quarantine efforts in various places of the country. The Superintendence for Fishing Harbors and Fishing Administration of the People's Republic of China in 2000 and 2001, respectively, published and distributed *Views on Implementation of Aquatic Animal Disease Control*, *The Administrative Measures for Examining and Appointing Quarantine Staff on Aquatic Animal Disease Control (Proposed Measures)* and *The Administrative Measures for Examining and Appointing Supervision Staff on Aquatic Animal Disease Control (proposed measures)*. Thus, great efforts have been made to actively promote work on disease control and quarantine for aquatic animals in China.

Jiangsu Province has formulated and drafted quarantine standards such as the *Administrative Measures for Quarantine of Freshwater Aquatic Seed* and the *Technical Rules of Operation for Quarantine of Five Species of Freshwater Aquatic Seed*, with which a successful pilot implementation has been carried out in the priority areas. The Ministry of Agriculture has carried out pilot implementation in four provinces and cities, such as Tianjing City, Hunan Province and Chongqing City. Based on the good experiences from pilot areas, the legislation has been further strengthened and disease control work for aquatic animals has been carried out across the country. Significant progress has been made in formulating the rules of operation for quarantine and for training the staff for aquatic animal quarantine. By the end of January of this year, more than 790 people have received professional training in aquatic animal quarantine and 96 people have been trained for the supervision of aquatic animal disease control. After the qualification examination, the results were published and qualification certificates issued by the Superintendence for Fishing Harbors and Fishing Administration of the People' Republic of China.

Since the year 2000, China has carried out disease surveillance of fish farms and monthly reporting activities in some provinces and cities. In 2000, there were 11 provinces (regions and cities) that took part in the pilot reporting work. In 2001, reporting was extended to 17 provinces. Eighty-nine diseases affecting 21 farmed species have been monitored. Ten issues of the *Monthly Magazine for Disease Situation on Aquatic Animals and Plants*" and two issues of *Annual Magazine* have been distributed free of charge to various relevant departments. The work of disease monitoring and reporting has had an increasingly important impact and received positive comments from the experts concerned. At the conference held in Bangkok in 2001, which was jointly organized by the Network of Aquaculture Centres in Asia-Pacific (NACA), the Office International des □pizooties (OIE) and the Food and Agriculture Organization of the United Nations (FAO), the participants spoke highly of China's newly established monitoring and reporting network. It is our plan that the monitoring and monthly reporting of aquatic animal diseases in aquaculture farms will be extended to the entire country in 2002.

Recommendations for future development

The following recommendations are made to assist the development of aquatic animal quarantine in China:

- To further improve and perfect the relevant laws and regulations so as to form a complete legal system for aquatic animal quarantine that is adaptable to the production requirements.
- To strengthen collaboration between all parties concerned with establishing a coordinated, efficient and quickly responding quarantine mechanism.
- To organize scientific research in order to closely follow the international disease situation, so that the quarantine work in China can be positively carried out accordingly.
- To increase inputs, so that a comprehensive system for disease monitoring, reporting, prevention and control can be established across the country.
- To intensify training activities in order to enhance awareness of the work of quarantine by people in all walks of life and to increase the active participation of fishermen in this work.

- To strengthen international exchanges and cooperation, and to formulate and perfect the relevant standards more quickly, so as to make quarantine more standardized and systemized.

The Management of Genetically Modified Organisms (GMOs) in China

On 23 May 2001, China promulgated the *Regulation on Safe Administration of Agro-GMOs*. In order to guarantee implementation of this legislation, the Ministry of Agriculture on 5 January 2002 published three supporting measures, *Administrative Measures on Safety Evaluation of Agro-GMOs*, *Administrative Measures on Safe Importation of Agro-GMOs* and *Measures on Administration Labeling of Agro-GMOs*. These three supporting measures have been implemented since 20 March 2002. The first of these measures requires that a safety evaluation must be conducted if activities undertaken in China involve Agro-GMO research (including aquatic seed), experiments, production and importation. Labeling for Agro-GMOs must be done if the 17 species for five types of Agro-GMOs that have been listed in the labeling category are to be sold in China. China has implemented comprehensive management of Agro-GMO research, pilot production, processing and import and export activities. The administrative measures on labeling stipulate such requirements as labeling targets, methods, examining and supervising institutions, the formulation of labeling categories and readjustment, as well as release procedures.

Framework for the Control of Aquatic Animal Disease in Japanese Aquaculture

Mahito Masuda

Fish Ranching and Aquaculture Division
Fisheries Agency of Japan
1-2-1 Kasumigaseki, Chiyoda-ku
Tokyo, JAPAN

and

Norihisa Oseko

Pathology Division
National Research Institute of Aquaculture
224-1 Hiruta, Tamaki, Watarai-gun
Mie 519-0423, JAPAN

Masuda, M., and N. Oseko. 2004. Framework for the control of aquatic animal disease in Japanese aquaculture. p.127-131. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper gives a brief overview of the framework for the control of aquatic animal diseases in Japanese aquaculture, including the enabling legislation and the organizational structure. It also provides some background information on aquaculture, pathogens and disease outbreaks, and the use of drugs in aquaculture in the country.

Introduction

Before explaining the framework for the control of aquatic animal diseases in Japanese aquaculture, we will first provide (1) an outline of aquaculture in Japan, (2) a review of disease outbreaks in Japan, and (3) a review of the use of drugs in cultured aquatic animals in Japan.

Aquaculture in Japan

In Japan, many species of aquatic organisms, ranging from finfish to seaweeds are raised through aquaculture (Table 1). In the year 2000, the total weight of the production derived from aquaculture was about 1.2 million metric tonnes (mt), while the total production obtained from Japanese coastal capture fisheries was about 1.6 million mt. So based on these total weights, the production from aquaculture and coastal fisheries were almost the same.

Yellowtail, amberjack, and red seabream are the major finfish species cultured, while scallops and oysters are the principle molluscs. Prawns (*Penaeus* spp.) are not major cultured species in Japan.

Table 1. The major aquatic species cultured in Japan.[1]

Commodity
• **Finfish**
Yellowtail
Amberjack
Red seabream
Ocellate puffer
Salmonidae
Eel
Carp, etc.
• **Molluscs**
Scallop
Oyster
Abalone, etc.
• **Crustaceans**
Penaeus spp. (prawns)
• **Seaweeds**
Kombu (*Laminaria*)
Wakame (*Undaria*)
Nori (*Porphyra*)

[1] Total aquaculture production = 1,230,783 mt (Year 2000).

Disease Outbreaks in Japan

Aquaculture is very important to the Japanese, because it provides a stable supply of aquatic foods that are reasonably priced. However, great losses caused by many diseases have occurred in intensive aquaculture.

Streptcoccosis, pseudotuberculosis, iridoviral infection, edwardsiellosis, and vibriosis are problems affecting marine fishes, while infectious haematopoietic necrosis (IHN), bacterial gill disease, furunculosis, paracolo disease, and bacterial cold water disease are major problems in Japanese freshwater fishes. Penaeid acute viremia (PAV), vibriosis and *Fusarium* are common diseases of *Penaeus*. Unfortunately, outbreaks of IHN, oncorhynchus masou virus disease (OMVD) and PAV are still recognized in Japan.

Recently, outbreaks of viral haemorrhagic septicemia (VHS) were seen in flatfish and black rockfish, but not in salmonids. Although there have been no outbreaks haplosporidiosis in Japan, these pathogens were detected from Japanese oyster.

Drugs for Use in Japanese Aquaculture

For the diseases mentioned above, aquaculturists use drugs such as antibiotics for treatment and vaccines for prevention. Therefore, Japan has some regulations dealing with the manufacture, sale and use of drugs in aquaculture.

Drugs for use in aquatic animals belong to the category "Veterinary Drugs". The *Pharmaceutical Affairs Law* and relevant regulations are directly concerned with these drugs. Only drugs approved by the Minister can be used. For approval, an extensive data set is required. This includes information in such areas as stability, toxicity, safety, effectiveness, residues etc. Presently, 54 drugs (322 products) are approved. These include 26 antibacterial drugs and five vaccines for use in aquaculture. The use of drugs for which there exists a "residue problem" must follow proscribed criteria, the methods of administration and dosage, and the withdrawal period being defined by regulation.

Administrative Framework for Aquatic Animal Disease Control in Japanese Aquaculture

Four organizations are interrelated within this framework, the Fishery Agency of the Government of Japan, the National Research Center, the local governments and the fish disease centers of private organizations.

The Fishery Agency is in charge of issuance of import permits, and provides guidance, assistance and funds to local governments and the fish disease centers. Local government is in charge of measures related to the domestic culture of aquatic animals. This includes measures for specific diseases, on-site inspections based on the law, guidance to associations and farmers, patrol and consultation, training to farmers, residue testing, inspection of live fish and eggs, and reporting to the Fishery Agency. The Fish Disease Center is in charge of advanced training, providing information of fish diseases, voluntary pathogen inspection for imported live fish and eggs, research and development of techniques, and reporting to the Fishery Agency (see Fig. 1).

Legislation

In relation to this framework, Japan has two laws, one is the law on *Disease Prevention System for Imports* and the other is the law on *Disease Prevention Systems for Domestic Aquacultured Animals*.

The law on *Disease Prevention System for Imports* is a fishery resources conservation law that was established in 1996 to protect domestic aquatic animals from exotic diseases. Three categories of cultured aquatic organisms (carp, Salmonidae and *Penaeus*), and 10 diseases that are among the Office International des □pizooties' (OIE) notifiable diseases are of concern. However, so far there have been no outbreaks and thus no control measures have been implemented in Japan (see Table 2). Anyone wishing to bring carp fry; eyed eggs or fry of Salmonidae; or larvae, postlarvae or juveniles of *Penaeus* into Japan requires the permission of the Minister of Agriculture, Forestry and Fisheries, and a certificate issued by a competent authority of the exporting country.

Table 2. Listed diseases for the Aquatic Animal Import Permission System.

Species	Infectious Disease
Carp fry	Spring viremia of carp (SVC)
Salmonidae - eyed eggs	Viral haemorrhagic septicemia (VHS)
Salmonidae - fry	Epizootic haemorrhagic necrosis (EHN) Piscirickettsiosis Enteric redmouth disease (ERM)
Penaeus - Larvae, postlarvae & juveniles	Infectious disease caused by Baculovirus penaei (BP) Infectious disease caused by Penaeus monodon-type Baculovirus (MBV) Yellowhead disease (YHV) Infectious hypodermal hematopoietic necrosis (IHHN) Penaeid acute viremia (PAV) White spot disease (WSD)

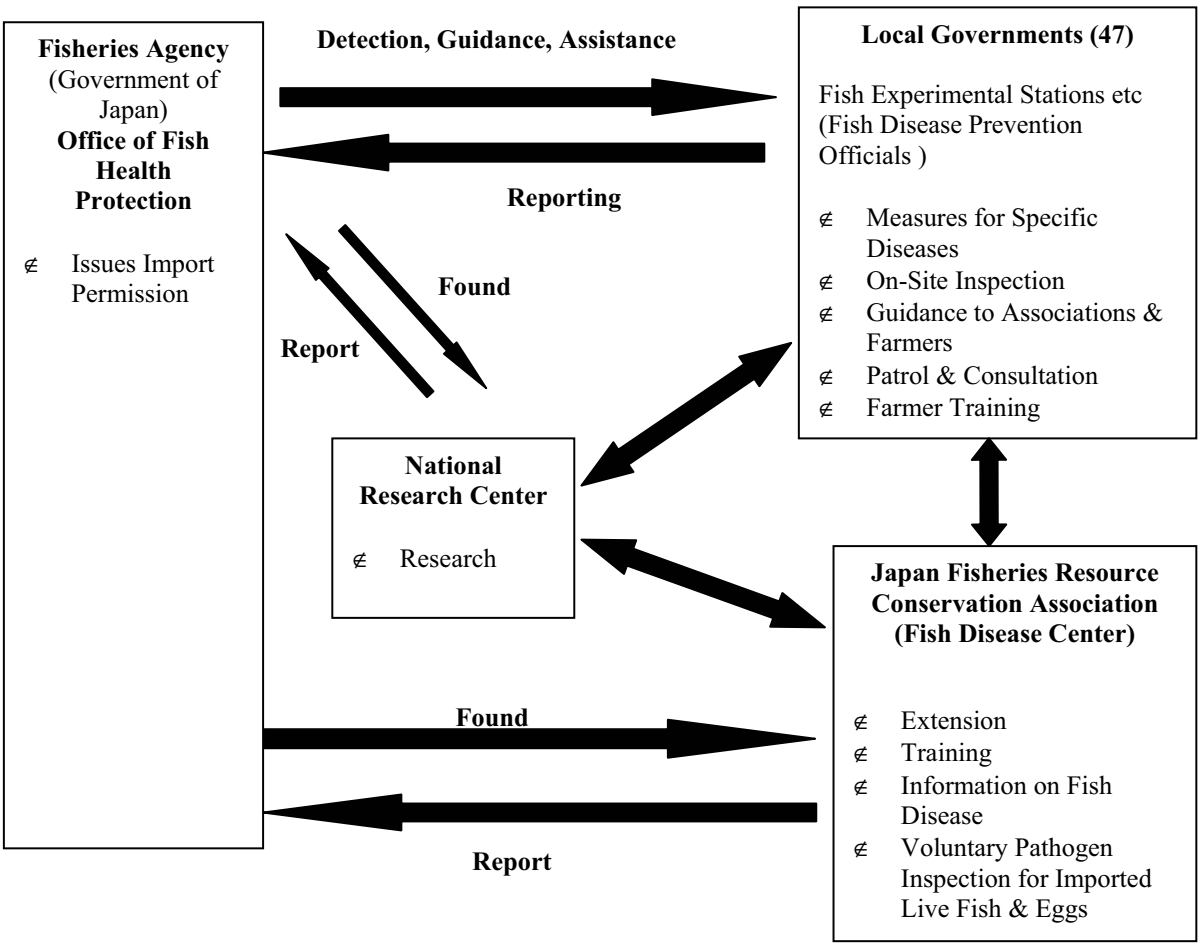
The law on *Disease Prevention Systems for Domestic Aquacultured Animals* was implemented to ensure sustainable aquaculture production. Under this law, the local governor can make orders prohibiting or restricting movement, requiring incineration or burying, and requiring the sterilization of contaminated materials to prevent diffusion of specific diseases that are among the OIE notifiable diseases or for which there has been no outbreaks in Japan (see Table 3).

Table 3. Specific diseases covered under the law on Disease Prevention Systems for Domestic Aquacultured Animals.

Species	Infectious Disease
Carp	Spring viremia of carp (SVC)
Salmonidae	Viral haemorrhagic septicemia (VHS) Epizootic haemorrhagic necrosis (EHN) Piscirickettsiosis Enteric redmouth disease (ERM)
Penaeus	Infectious disease caused by Baculovirus penaei (BP) Infectious disease caused by Penaeus monodon-type Baculovirus (MBV) Yellowhead disease (YHD) Infectious hypodermal hematopoietic necrosis (IHHN)

On-site inspection of aquaculture facilities by Fish Disease Prevention Officials is also prescribed for all diseases. The Fish Disease Prevention Officials, who are local government officials, provide guidance to associations and farmers on proper feeding management and proper utilization of drugs according to the law, undertake patrol and consultation activities for the diagnosis of aquatic animal disease, supervise proper feeding management and the use of drugs, and take samples for diagnosis and residue testing.

Figure 1. The fish disease control system in Japan.



The Development of Import Risk Analysis (IRA) In Relation to the History of New Zealand

P. Mike Hine

National Centre for Disease Investigation
MAF Operations, P.O. Box 40-742
Upper Hutt, NEW ZEALAND

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Abstract

This paper presents a brief history of the introduction of exotic aquatic animals into New Zealand and the development of the country's import risk analysis (IRA) process.

Introduction

New Zealand split off from Gondwanaland, the Southern Continent, about 80 million years ago, before the evolution of modern mammals and snakes. The islands took with them plants and animals that continued to evolve in isolation, forming a unique biota. When the Polynesian (Maori) people arrived about 1,000 years ago, they found a fauna lacking top predators, in which birds had become large (>3 m high) and flightless. By the time European settlers arrived 200 years ago, the largest flightless birds had been driven to extinction. To make a living, the new settlers burnt down 60% of the forest that covered the country, to create pasture for a farming industry. They brought with them domestic animals, many birds and mammals from Europe, and also from Australia. Three animals soon became pests - rats, rabbits and brush-tailed possums. To control these, the settlers introduced two carnivorous mammals - stoats and weasels, but they found it easier to prey on flightless birds, rather than chase fast-running prey. Thus the unique and vulnerable fauna of the country was threatened, and several bird species became extinct, or are on the verge of extinction.

Introductions of Aquatic Animals

The settlers also introduced fishes that were either desirable as food and as game animals (trout, salmon) or that reminded them of Europe (cyprinids). The sequence of introductions is shown in Table 1. Fortunately the early imports of salmonids (*Salmo* spp., *Salvelinus* spp., *Oncorhynchus* spp.) were as fertilised eggs, unwittingly reducing the risk of importing parasites and pathogens. Many consignments of eggs and juveniles died in transit, possibly of disease, but more likely because of environmental conditions onboard ship. In the Nineteenth Century, New Zealand had a rich and diverse freshwater fish fauna. After the introduction of salmonids, many species declined, and one large dominant species, the New Zealand grayling (*Prototroctes oxyrhynchus*) became extinct.

Table 1. List if exotic aquatic animals introduced into New Zealand (from McDowall 1990).

Species Introduced	Date Introduced	Source of Introduction	Life Stage Introduced	No. Parasites Introduced (Acquired)[1]
Fishes				
Salmo trutta	1867 onwards	United Kingdom, (UK); Tasmania	Ova, fingerlings	1 (13)
S. salar	1868 onwards	England, Germany	Ova, fingerlings	1
Salvelinus fontinalis	1877 onwards	Eastern USA	Ova	0 (1)
S. namaycush	1906	Michigan, USA	Ova	NE[2]
Oncorhynchus mykiss	1883 onwards	California, USA	Ova	0 (5)
O. tshawytscha	1875 onwards	California, USA	Ova	0 (10)
O. nerka	1902 onwards	Western Canada	Ova	0 (2)
Ictalurus nebulosus	1877	California, USA	Juveniles	NE
Tinca tinca	1864	UK	Juveniles	0 (1)
Carassius auratus	1864 onwards	Unknown	Juveniles	2 (2)
Cyprinus carpio	1960s	Unknown	Juveniles	NE
Scardinius erythrophthalmus	1967	Essex, UK	Juveniles	NE
Leuciscus idus	After 1970	UK; California, USA	Juveniles	NE
Ctenopharyngodon idellus	1972	Hong Kong	Juveniles	6[3]
Hypophthalmichthys molitrix	1970	Hong Kong	Juveniles	NE
Perca fluviatilis	1868 onwards	Tasmania, Australia	Juveniles	0 (2)
Gambusia affinis	1930	Hawaii, USA	Juveniles	NE
Poecilia latipinna	Before 1967	Unknown	Juveniles	NE
P. reticulata	About 1970	Unknown	Juveniles	NE
Xiphophorus helleri	About 1985	Unknown	Juveniles	NE
Crustaceans				
Macrobrachium rosenbergii	1980s	Southeast Asia; Hawaii, USA	Adults	0
Metapenaeus japonicus	1980s	Southeast Asia	Adults	0
Cherax tenuimanus	1980s	Australia	Adults	0

As can be seen in Table 1, some of these species introduced parasites. It is impossible to know whether ciliated protozoans such as *Ichthyophthirius multifiliis* and *Chilodonella* spp. occurred in New Zealand before the introduction of fish by Europeans, but given that these are freshwater parasites and that New Zealand is some 2,000 km from its nearest neighbour, Australia, this seems unlikely. Other likely introductions with exotic freshwater fish are the agent of whirling disease, *Myxobolus cerebralis,* in brown

[1] Acquired = number of parasite species acquired since arrival in New Zealand.
[2]NE = never examined.
[3]All six species were eradicated in quarantine.

trout (*Salmo trutta*) and Atlantic salmon (*S. salar*) from Europe, and the parasitic crustaceans *Lernaea cyprinacea* and *Argulus japonicus* in cyprinids. When grass carp (*Ctenopharyngodon idellus*) were introduced in the early 1970s, they were parasitised by *I. multifiliis, Tripartiella* sp. (Ciliata), *Dactylogyrus ctenopharyngodonis* and *Gyrodactylus ctenopharyngodontis* (Monogenea), *Bothriocephalus acheilognathi* (Cestoda), and *L. cyprinacea* (Copepoda). All were eradicated under quarantine (Edwards and Hine 1974).

Development of the Import Risk Analysis Process

Up until the late 1960s, exotic species were cultured and introduced into the wild by Acclimatisation Societies, and the state Wildlife Service had a policy of spreading salmonids throughout the country. After the 1970s, imported live species had to be obtained from a disease-free source, but no government department took responsibility for managing introductions. Later, the Fisheries Research Division took responsibility, and in the 1980s it became part of the Ministry of Agriculture and Fisheries (MAF). The Ministry for the Environment (MfE) demanded that environmental impact should also be assessed.

However, the legislation was still inadequate, and unauthorised importations succeeded because of inadequacies in the law. In the late 1980s and early 1990s, the Animals Act (1967) was redrafted into the Biosecurity Act (1993). This blocked loopholes in the law and specified that MAF must assess disease risk, and MfE environmental risk. A new agency, the Environmental Risk Management Authority (ERMA) was established to assess importation of live exotic animals for release into the wild, and importation of genetically modified organisms (GMOs).

By this time, it was becoming apparent that introductions of exotics had to be justified in detail and had to show some benefit to the country that offset risk. In 1994, the ground-breaking import risk analysis (IRA) on the risk of introducing furunculosis (*Aeromonas salmonicida*) into New Zealand with importation of Canadian salmon showed the risk to be acceptable. Following demands by other salmon-producing countries, a generic IRA on the risks of importing disease with salmonid products was released in 1997, which showed the risks to be acceptable and therefore, the borders were opened.

Now IRAs are developed at two levels. For a government to government request involving trade, a team of experts is put together by MAF Biosecurity Authority (BA). When the first draft of the IRA is completed, it is circulated for comment by experts within the country and overseas, to stakeholders and, if necessary, to the general public. The draft is refined and the process repeated until a final draft is presented. At a lower level, a request to import live animals of a species already in the country is considered by MAF BA, and if uncomplicated, an IRA may be undertaken by an outside group for submission to MAF BA for consideration. This IRA is then circulated to experts for comment, before being accepted or declined by MAF BA. Acceptance may come after modification by the submitter.

There have been no applications to import live exotic aquatic animals since the development of the Biosecurity Act. This has been partly because the import process would be costly to an importer, and partly because consumers no longer want to eat the same few cultured products all over the world. Native species are being cultured more and more, to give consumers variety. Biodiversity is being valued again.

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Import Risk Analysis: the Philippine Experience

Jose O. Paclibare, Joselito R. Somga and Mario G. Trio

Bureau of Fisheries and Aquatic Resources
Arcadia Building, 860 Quezon Avenue
Quezon City, The PHILIPPINES

Paclibare, J.O., J.R. Somga and M.G. Trio. 2004. Import risk analysis: the Philippine experience. p. 135-138. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

The development of the import risk analysis process in the Philippines is reviewed and the results of a number of recent IRA analyses are discussed.

Brief History

A more scientifically based import risk analysis (IRA) process in the Bureau of Fisheries and Aquatic Resources (BFAR) started way back in 1992. Prior to that period, the Foreign Trade Section of the Fisheries Regulatory and Quarantine Division of BFAR would solicit the comments of the Fish Health Section, Inland Fisheries and Aquaculture Division, and other units regarding proposed importations. However, clear-cut guidelines on decision-making were believed to be needed.

In 1992, the Department of Agriculture (DA), through the recommendation of BFAR (a staff bureau), created a national "Committee on the Introduction of Exotic Aquatic Organisms" by virtue of Special Order No. 642. The committee was composed of members from BFAR, the Philippine Council for Aquatic and Marine Research and Development (PCAMRD), the Southeast Asian Fisheries Development Center-Aquaculture Department (SEAFDEC-AQD), and the University of the Philippines Marine Science Institute (UPMSI). The committee was established to serve as an advisory body to the Secretary of the Department of Agriculture on matters concerning aquatic introductions. The creation of that committee planted the "seed" for IRA in BFAR.

In 1993, with the increasing awareness of the local shrimp aquaculture industry and BFAR on the importance of regulating transboundary movements of shrimp, the DA, through the recommendation of BFAR, issued Fisheries Administrative Order No. 189, Series of 1993 "Prohibiting the importation of live shrimp and prawn of all stages". This rule has been strictly enforced since then (although there have been unconfirmed reports of cases of smuggling).

The new Philippine Fisheries Code, which strengthened the Fisheries Inspection and Quarantine Service, among other things, was signed into law on 25 February 1998. Shortly thereafter, a draft Fisheries Administrative Order regulating the importation of fish and fishery products, microorganisms and biomolecules was prepared by fish health specialists of BFAR.

Through the request of BFAR, the Food and Agriculture Organization of the United Nations (FAO) and the Canadian Executive Service Organization (CESO) commissioned Dr J. Richard Arthur in 1999 and 2001 to the Philippines to provide expert advice on an aquatic animal quarantine service. As part of his invaluable help, Dr Arthur has been instrumental in improving the previously mentioned draft rules on live fish importation.

In 1999, the FAO, the Network of Aquaculture Centres in Asia-Pacific (NACA), BFAR, the Australian Agency for International Aid (AusAID), and Agriculture, Fisheries and Forestry of Australia (AFFA) organized and co-sponsored the Philippine National Training Workshops on Aquatic Animal Health Management. The workshops focused on (i) import risk analysis and (ii) aquatic animal disease surveillance, reporting and contingency planning. The workshops gathered together for the first time key BFAR officials involved in quarantine and educated them on IRA. Because of these workshops, BFAR officials are now more aware of IRA.

In 2000, the Import Risk Analysis Panel in BFAR was formally created by the Director. One of its immediate tasks is to ensure the expeditious approval of the rules on importation of live fish by the Secretary of Agriculture.

Salient Features of the Draft Rules on Importation of Fish and Fishery Products, Microorganisms and Biomolecules

The draft Order covers not only live fish, but also fishery products, microorganisms and biomolecules. Fish and fishery products include finfish, mollusks, crustaceans, echinoderms, marine mammals and all other products of aquatic resources in any form.

As proposed in the draft Order, the IRA process focuses not only on fish health concerns, but also on public health and ecological concerns as well.

As proposed in the Order, fish species for importation will be categorized based on risk: 1) low-risk species, 2) medium-risk species, 3) high-risk species and 4) prohibited or banned species.

- Low-risk species include certain aquarium fishes perceived to present no or low ecological, genetic and disease threats to native Philippine species and to aquaculture.
- Medium-risk species are those used in aquaculture or the ornamental fish trade and considered by BFAR to pose some risk of environmental impact. This may include both native or transferred species and previously introduced species in natural bodies of water.
- High-risk species include exotic species that may pose risk adverse environmental impact. Genetically modified organisms (GMOs) may also be included in this category.
- Prohibited or banned species include exotic species with known adverse effects on local fauna, human health and/or environment.

Upon categorization of the fishes proposed for importation, the corresponding inspection and quarantine requirements will be imposed. For instance, for high-risk species the quarantine protocol recommended by the International Council for the Exploration of the Sea (ICES) Code of Practice will be followed i.e., only healthy F_1 offspring shall be allowed to be cultured and released.

Recent Cases Handled by the BFAR Import Risk Analysis Panel

Since the creation of the IRA Panel in April 2000, it has encountered several requests for importation. We describe below a few special cases that we think define the nature and extent of the IRA process that is evolving in BFAR right now.

Proposed Importation of* Penaeus vannamei *from Chinese Taipei

In April 2000, a businessman from Chinese Taipei wanted BFAR to issue him a permit to import *Penaeus vannamei* for immediate commercial culture in the Philippines. He successfully sought the intercession of the Office of the Secretary of Agriculture. But since this species is exotic to the Philippines, the IRA panel, which was very much aware of its potential impact on the local shrimp (*Penaeus monodon*) industry, held firm to its position to impose the necessary health certification and quarantine requirements as recommended by the ICES Code of Practice. The political pressure went on for many months. The BFAR did not hear from the proponent again, but later found out that he illegally imported the species.

The IRA Panel investigated the case and upon its recommendation, the BFAR Director instructed the Panel to "file appropriate administrative charge". With the cooperation of local police, an application for a search warrant was sought at the local court, but because of the inadequate appreciation of the case on the part of the judge (and the witness's inexperience in court procedures) the application was denied. Although the case was no longer pursued in court, it apparently served its deterrent purpose, because there have been no more reports of grow-out culture of *P. vannamei* in the subject area.

Proposed Importation of Specific Disease Resistant (SDR) -* Litopenaeus stylirostris *from the United States of America (USA)

Sometime in November 2000, a local feed company with foreign partnership proposed to import SDR-*L. stylirostris* from the USA. The proponents were asked to present their proposal in a meeting attended by key players from the industry and research community. Some members of the industry were inclined to welcome the said species, which, for them, seemed to offer a better alternative than the already problematic *P. monodon*. The BFAR imposed the necessary health certification and quarantine requirements. Fortunately, because of some internal problem on the part of the proponents, they did not push through with their proposal.

Proposed Importation of Specific Pathogen Free (SPF) –* Penaeus vannamei *from Hawaii

In June 2001, a private farm with foreign partnership proposed to import SPF – *P vannamei* from Hawaii, initially for research and development (R&D), but with the hope of successful commercial production in the future. The farm had already built a quarantine facility that the IRA Panel inspected. A scientist from the USA with whom the IRA Panel consulted commented that the source of the shrimp in his opinion "ranks near the very top of the safest source in the United States of SPF for *Penaeus vannamei*". Scientists from the SEAFDEC-AQD were also consulted, but they expressed their reservations with regard to both disease and ecological risks. A scientist from Thailand gave the IRA Panel a new insight on the potential risk of importing supposedly SPF-shrimp. Hence, BFAR decided to impose stricter health certification and quarantine requirements. Since then, the BFAR has not heard from the proponent, who apparently has been discouraged to proceed with his proposal.

Proposed Importation of* Cherax *spp. from Australia

Australian freshwater crayfish belonging to the genus *Cherax* have caught the interest of a German farmer in the Philippines. Hence, he proposed to import for experimental purpose *Cherax albidus* and *C. rotundus*.

The IRA Panel took note of the fact that Australia is free from *Aphanomyces astaci*. The Panel studied the different aspects of the biology and culture of the species and upon its evaluation, recommended the approval of a permit to import for experimental purpose. The experimental animals will be confined until an ecological study (e.g., on the effect on rice plants) has been completed.

The proponent, upon seeing many promising aquaculture species in Australia during his visit there, became excited about introducing more exotic species into the Philippines. Hence, for now, he is proposing the introduction of *C. quadricarinatus* (red claw). However, BFAR's IRA Panel has decided to act circumspectly on this recent request because of the increasing opposition from certain quarters, especially now that we have learned of the species' potential as a carrier of whitespot syndrome virus (WSSV) and other previously unknown viruses.

Proposed Importation of* Ictalurus punctatus *from the USA
In February 2002, an American businessman applied for a permit to import channel catfish, *Ictalurus punctatus,* from the USA. He sees the prospect of channel catfish farming in the Philippines. His proposal is still being evaluated as we continue to solicit comments from scientists from the Philippines and abroad.

Prohibition on Importation and Breeding of* Cichla *spp.
In June 2001, BFAR learned of the successful breeding of peacock bass (*Cichla* spp.) by a local hobbyist. (Peacock bass is a carnivorous fish species native to South America and is considered by many as the world's greatest freshwater game fish.) The news caused alarm among environmentalists, who feared that the species might decimate local fish species. Hence, BFAR confiscated the said fish from the breeder, who was promised compensation, an additional administrative assignment given to the IRA Panel. The IRA Panel is right now re-thinking what should be the policy of BFAR on the importation and breeding of peacock bass, taking into consideration the potential benefits and releasing the fish into bodies of water.

Prohibition on Importation and Breeding of Piranhas
Since 1979, by virtue of Fisheries Administrative Order No. 126, the importation and possession of live piranhas have been prohibited because they are perceived to be dangerous as they "take big bites out of the flesh of its victime". However, unscrupulous importers and breeders have been successfully breeding and selling the fish illegally. The said Order is one among many rules that the government finds difficult to enforce. Hence, the IRA Panel is currently re-thinking what should be the policy of BFAR on the importation and breeding of piranhas.

As described above, the IRA Panel of BFAR not only attends to the "analysis" part of the work, it also takes the liberty of attending to enforcement of the rules. At the moment, the existing law enforcers have yet to receive training on the technical intricacies of IRA so that they can properly perform their functions. As previously mentioned, the IRA Panel also performs administrative functions, such as providing compensation for confiscated fish.

Lessons Learned

Political pressures brought to bear on the decision-making process for IRAs for live fish importation are very real in a government bureaucracy like BFAR. Hence, it is a challenge to the IRA Panel to maintain objectivity.

Introducing new ideas and practices, such as the IRA process, into a bureaucracy takes much time and effort. However, external forces (e.g., globalization) will force bureaucracies to adapt to change.

Although there is still much to be done to further develop IRA capabilities within BFAR, with good staff commitment and continuing external support from NACA, FAO, APEC and other organizations and institutions, we believe it is possible.

Strategies for Aquatic Animal Health Management in Thailand

Somkiat Kanchanakhan and Supranee Chinabut

Aquatic Animal Health Research Institute
Department of Fisheries
Bangkok, THAILAND

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Abstract

The nine components of Thailand's National Strategy for Aquatic Animal Health are discussed.

Introduction

Awareness of the spread of aquatic animal disease through international trade has been increasing since the first edition of the Office International des □pizooties' (OIE) *International Aquatic Animal Health Code* in 1995. How to control diseases that are spread through international trade and the development national strategies for aquatic animal health have been discussed in great detail by representatives from 21 Asian governments during a three-year (1998-2000) regional program funded by the Food and Agriculture Organization of the United Nations (FAO) and the Network of Aquaculture Centres in Asia-Pacific (NACA). Among the results of this program were the "*Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals"* (FAO/NACA 2000) and a supporting manual of procedures for the implementation of the guidelines (FAO/NACA 2001). All of the 21 participating Asian countries accepted the guidelines and agreed to its implementation.

In Thailand, the strategic plans for aquatic animal health management were discussed during a seminar and workshop held in Bangkok in May 2001 that was attended by staff from the Department of Fisheries (DOF), the Department of Livestock Development (DLD), the universities and the farmers. Nine strategic plans developed from this seminar have been accepted by the DOF. These plans are summarized and discussed in this presentation.

Background

In the Asia Region, aquaculture is becoming increasingly important in the production of food for the world's population. Hundreds of millions of people are involved in aquaculture activities and thus securing and strengthening the aquaculture sectors are highly important to all governments. Thailand's aquaculture industries are growing rapidly, and aquaculture's production value is among the top incomes of the country within the agricultural products. Aquatic animal health problems have been increasing as a consequence of intensive aquaculture farming. In Thailand, the DOF has full responsibility for aquaculture, including aquatic animal health. A scientific review has indicated that the international trade in aquatic animals and their products has spread diseases to many countries for years (H□stein 2000). Thus,

there is a need to prevent the spread of epizootic diseases, and it is, therefore, necessary that the Department of Fisheries, Thailand's competent authority, take a lead role in formulating a National Strategic Plan for Aquatic Animal Health.

National Strategies for Aquatic Animal Health: Strategic Plans (2001-2005)

DOF has many disease diagnostic service units in its various institutions and divisions. In order to link all of these units, the Network of Aquatic Animal Health (NAAH) was established on 30 March 2001. NAAH is now based at the Aquatic Animal Health Research Institute (AAHRI). On 1 May 2001, the NAAH held a seminar and workshop in Bangkok on *Strategic Plans for Aquatic Animal Health*. Participants, who included staff from DOF, DLD and the universities, as well as farmers, held discussions during the workshop. The nine strategic plans developed from this workshop and accepted by the DOF are as follows:

1. Laws and legislation

Legislation granting the competent authority and other authorized official personal the legal powers for disease control and prevention is necessary. In Thailand, aquaculture and fisheries are under the DOF, but the existing Fisheries Act (1956) and Wildlife Conservation Act (1992) do not address control of aquatic animal diseases. Both Acts do have small sections dealing with regulations controlling the movement of imported and exported aquatic animals. Thailand also has a law to control terrestrial animal diseases, the Animal Epidemic Act (1947), which is used by the Department of Livestock Development (DLD). However, as this Act does not include aquatic animals, additional legislation is needed to control aquatic animal diseases.

The strategic plan for the development of legislation for controlling aquatic animal disease aims to use the existing Animal Epidemic Act, and in this regard, an agreement was reached at the Lawyer Consultation of the Parliament in September 2002 that diseases of aquatic animals will be controlled through use of the Act. A joint DOF-DLD working group will be appointed to work on the details needed to apply the law to control aquatic animal diseases.

2. Import/export regulation

Thailand has over 19 import/export regulations announced through Emergency Decree, Royal Decree, Ministerial Regulation, Notification or Rule to control the movement of certain aquatic animals, both via importation and exportation.

Currently, for importation of live aquatic animals we do request a health certificate from the country of origin. However, there is no standard format of health certificate. In this plan, DOF will develop standard forms for health certificates for live aquatic animals that will be based mainly on risk assessment.

DOF has set up a Rule for regulating the exportation of live aquatic animals. The exporting farms must register with the DOF, and the Health Inspector will inspect the farms every three months to ensure good sanitary conditions and freedom from those diseases listed by the OIE. The Inspector takes fish samples from the farms and sends them to the laboratory for comprehensive diagnosis of all fish pathogens. We use viral isolation in tissue culture system or polymerase chain reaction (PCR) amplification for viral detection.

3. Disease surveillance, monitoring and control systems

Disease surveillance, monitoring and control systems are very important to understanding the disease situation of the country. To make the systems work, we need legal power, training in epizootiology for Fishery Biologists and the setting up of a disease information center to keep all disease records. Once the systems are developed, it will be easy to define specific disease-free zones or disease-free aquaculture establishments. The systems also assist import risk analysis (IRA).

4. Aquatic animal diseases – research and development

Collaborative research among scientists in the DOF, the universities and the private sector needs to be developed. National research plans for different aquatic animal diseases must have a clear direction and must avoid duplication of research effort. Research results have to be transferred to other scientists, extension fishery officers and to the fish farmers. A central aquatic animal disease research information system has been discussed in the NAAH and needs to be established in the near future.

5. Diagnostic units - capability building

The DOF has three main institutions for the issuance of health certificates, the Aquatic Animal Health Research Institute (AAHRI) in Bangkok, the National Institute of Coastal Aquaculture (NICA) in Songkhla Province and the Shrimp Research and Development Center (SRDC) in Phuket Province. DOF also has three other disease diagnostic units and 11 PCR service units in the Coastal Aquaculture Division. Providing training in disease diagnostic techniques to staff of satellite laboratories is necessary. There is a plan to standardize all disease diagnostic techniques among the units of the DOF. The plan also aims to set up a Rule for the standardization of private diagnostic laboratories. The Rule will be developed through close consultation with the private sector.

6. Technology/knowledge transfer

As Thailand has many disease diagnostic laboratories or units, there is a need to support research on the production of disease diagnostic kits. Training workshops for farmers and extension fishery officers on the treatment, prevention and control of disease are also necessary. There is a need to develop a disease information technology network that can be easily accessed by extension fishery officers and farmers.

7. Public awareness

The plan is to increase public awareness of aquatic animal diseases through the use of different media. Clear and accurate messages about disease outbreaks must be released as soon as possible to avoid panic among the pubic. An information center for each disease outbreak needs to be assigned to facilitate the exchange of aquatic animal health information between the government and the farmers.

8. Contingency plan to control disease outbreaks

Contingency plans to control and eradicate disease outbreaks have to be developed. The plans will involve many departments and the private sector in order to minimize the consequences of the outbreak. The activities assigned to each department or sector must be clear and well planned in advance. The contingency plan will cover activities during the pre-outbreak, outbreak and post-outbreak periods.

9. Funding support

The development of Thailand's National Strategy needs funding support from both internal and external sources.

Discussion and Summary

Thailand has developed National Strategies for Aquatic Animal Health Management, and their implementation is underway. Major activities during the first year of the strategic development will be the development of laws and other supporting legislation and the establishment of a disease surveillance system. An aquatic animal information center needs to be established. Systematic work on disease surveillance and reporting will be assigned to 75 Fishery Province Offices. The import and export regulations will be based mainly on a disease control plan, the disease situation of the country and the results of import risk analysis.

Recently, the DOF has implemented some additional measures to prevent new diseases from entering the country through the importation of live aquatic animals, such as through an importation of white shrimp (*Peneaus vannamei*). Also, during the developmental period of the strategy, DOF can certify that the

registered exporting farms are free of certain pathogens. Thirty-six exporting farms have registered since 1999, most of them being ornamental fish farms or marine finfish hatcheries.

The nine strategic plans discussed in this presentation were an output from brainstorming among the various governmental agencies and concerned stakeholders, and the DOF has accepted the plans. The full details of the plans are being developed, and their implementation has begun. Suggestions drawn from the *Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals,* the *Manual of Procedures for the Implementation of the Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals* (FAO/NACA 2000, 2001) and the *International Aquatic Animal Health Code* (OIE 2001) will be integrated into Thailand's National Strategy. As part of the National Strategic Development, an Aquatic Animal Health Commission (AAHC) was established in November 2001. Its members are scientists from the DOF and the universities who will assist the DOF with aquatic animal health research and development.

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The Role of the Private Sector in Import Risk Analysis and its Implementation

Daniel F. Fegan

Shrimp Biotechnology Programme
National Center for Genetic Engineering and Biotechnology
18th Fl. Gypsum Building, Sri Ayuthya Road
Bangkok, THAILAND

Fegan, D.F. 2004. The role of the private sector in import risk analysis and its implementation. p. 143-145. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

This paper briefly summarises the role of the private sector in import risk analysis (IRA) and its implementation. The private sector's key role in hazard identification, risk management, and risk communication, and as a source of information essential to the IRA process is discussed.

Introduction

The private sector is often overlooked in the development of import risk analysis (IRA) plans despite the fact that it is often a private sector entity that generates an import or request for the import of exotic species or non-native strains. Many IRA attempts focus on regulation of the activities of the private sector to prevent or control imports, especially of exotic species, rather than involving the private sector in discussions of the issues that need to be addressed and actions taken to reduce the level of risk involved. Private sector compliance is generally crucial if import risks are to be controlled, as individuals or organizations in this sector may be the supplier of imported animals, the importer or both.

Introductions and imports are made for several reasons:

- Trade in aquatic animals and animal products
- To explore new or existing market niches
- Exotic species or strains may be more suited to local conditions
- Exotic species or strains may command a higher value or rate of return than local species
- Non-native species or strains may be required for a breeding programme
- Exotic species may have specific advantages over local species
- Research

The Role of the Private Sector

Where the request for import is made by the private sector, it may be based on limited knowledge of the stocks/species to be imported. The purported benefits of the species or its suitability for local conditions may be exaggerated or poorly understood by the prospective importer, and an open discussion of this would help to clarify such issues from both sides.

In many cases, especially in developing countries, there are either no, or few, regulations, or the existing regulations are poorly publicised and understood by the private sector. In such cases, it may be assumed that there is no requirement, and imports may take place without following an appropriate risk management strategy. On the other hand, if it is widely publicised that import is not permitted, or if the system of approval is too onerous, there is a possibility that the system will be circumvented.

It is also important to realise that the objectives, priorities and definition of risk may differ between the public and private sectors. Attitudes to risk also vary widely between and within both sectors. Business risk evaluation, whether formal or informal, is a routine part of normal business operations. This may be as simple as a farmer deciding when to stock fry, or as complex as an importer hedging foreign exchange movements against future purchases of seafood. However, business risks and the priorities given to identified risks are not the same as the risks evaluated for imports by national and international authorities. There are also distinct differences in the level of acceptable risk, not only between the private sector and the public sector, but within the private sector, either between individuals or organizations at the same level or between different levels of the supply chain. Key business risks revolve around finance, market issues such as competition, and the need to continually develop better, more efficient (or profitable) means of production. It is these latter two that frequently drive the desire to import exotic species or strains where it is felt that these confer a distinct advantage or benefit over local ones. "Technical" risks related to disease transfer and environmental considerations may be acceptable from a business point of view, especially where there are strategies (use of specific pathogen free (SPF) animals, for example) that may be used to manage such risks.

It is clear that an open and frank discussion of the pros and cons of a given import from both sides is likely to lead to a more reasoned basis for regulation and promote better understanding and cooperation on the part of the private sector. Some of the key benefits the private sector can provide at all stages of the process are:

Hazard identification
Private sector entities often have a wealth of information on possible hazards. In the exporting country, they may have specific knowledge of potential hazards associated with the stocks, whereas importers may have specific knowledge of potential hazards that may affect imported stocks. This is particularly useful when importing from a country with limited capability or capacity in government organisations

Information
The private sector can also be a valuable source of information on important risk assessment criteria such as trade patterns and volumes, logistics, historical production and trade data, and existing animal health risks.

Risk management
The involvement of the private sector is fundamental to effective risk management. Where imports are made to the private sector, the authorities require a substantial level of cooperation if risks are to be contained and managed effectively. Such cooperation may include:

- Maintenance of introduced stocks in secure conditions
- Following agreed procedures in importation and handling of stocks
- Reporting of animal health to the appropriate authorities
- Cooperation in dealing with animal health emergencies

It has been said that compliance is better achieved through self-regulation, and it is true that self-regulation can be effective. However, effective self-regulation requires agreement on the risks and benefits of a given course of action or strategy, and compliance with identified obligations. This will require that the private sector is aware of, and accepts, the importance of non-business risks and agrees with the need for management of these risks. Finally, it is important that the authorities provide regulatory support when self-regulation is not possible.

However, it is sometimes the case that the regulatory process, whether voluntary or enforced, is ignored, and imports are made without regard to the appropriate procedures or risk management. The temptation to "sidestep" import regulations increases when:

- Regulatory mechanisms are too cumbersome, onerous or time-consuming
- Procedures for approval are not available
- Official requirements for approval are unrealistic
- Official mechanisms are weak or ineffective
- Political pressure can be exerted to gain exemption or special privileges

It is important that each of these is addressed if illicit import is to be minimised. Although such problems may indicate a lack of concern or cooperation from the private sector, it is often the actions of a few individuals, at least initially. Lack of enforcement of existing legislation may result in the situation getting out of control. Many private sector groups may share the authorities' concerns but wait for the authorities to take a lead in confronting the issue. The support of such groups can be used effectively in import risk management, especially where one or more sectors of the industry share the government's concerns. Exporters, for example, tend to be quite conservative with regards to new species introductions, especially where these may affect their capacity to obtain raw materials for their business. They can be effective allies in risk management because of their position as key customers of producers.

Risk communication

The communication of risks and awareness of the importance of the IRA is more effective when the private sector is involved as a part of the process. Farmers associations, feed companies and other suppliers, exporters and processors and trade journals/magazines can all be used to effectively communicate risks. Many of these companies routinely have regular access to farmers in a way that would be prohibitively expensive for national authorities, and through effective collaboration, can be used to communicate risks widely. During the yellowhead and whitespot viral epidemics in Thailand, for example, a series of informative brochures produced by the Department of Fisheries (DOF) was partly paid for and distributed by feed companies to their customers.

Communication from farmers to the authorities is an essential component of risk communication. Simple mechanisms to allow easy reporting to the national authorities should be available. Once again, the private sector can be enlisted to assist in such endeavours. Feed companies and suppliers can cooperate with the collection of relevant data and information and pass this on to the authorities. Although there are issues of confidentiality, there are mechanisms through which this can be managed.

Ultimately, effective risk management will require an effective partnership between the public and private sectors. This partnership should be based on an understanding of the objectives and priorities of both sides that can be gained by entering into a dialogue early in the risk assessment process.

National Aquatic Animal Health Plan for the United States of America

Kevin H. Amos

National Aquatic Animal Health Coordinator
National Marine Fisheries Service
U.S. Department of Commerce
Olympia, Washington, USA

Amos, K.H. 2004. National Aquatic Animal Health Plan for the United States of America. p. 147-150. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Abstract

The United States is in the process of developing a national aquatic animal health plan. The purpose of the plan is to facilitate safe and effective commerce, protect cultured and wild resources from exotic diseases, ensure the availability of diagnostic and certification services, define the roles and responsibilities of Federal agencies, ensure the development and implementation of the plan in a cooperative and collaborative process, and identify the resources needed for implementation. The mission, outputs, and outcomes are described in detail. This effort is being conducted by the National Aquatic Animal Task Force, under the auspices of the Sub-committee on Aquaculture, Committee on Science and Technology, Executive Office of the United States.

This paper review progress towards development and implementation of a National Aquatic Animal Health Plan for the United States of America.

Introduction

The National Aquaculture Act of 1980 authorized the establishment of the Joint Subcommittee on Aquaculture (JSA) under the auspices of the President's Office of Science and Technology Policy. The JSA is composed of the Secretaries of many United States federal agencies, including Agriculture (who sits as permanent chair), Interior and Commerce. The primary purpose of this coordinating group is to increase the overall effectiveness and productivity of federal aquaculture, research, technology transfer and assistance programs.

Early on in the deliberations of the JSA, it was identified that fish diseases were a primary cause in a decrease in productivity and effectiveness of aquaculture. To address this problem, in 1992, the JSA established a National Aquatic Animal Health Strategy Steering Committee and tasked that committee to develop a national strategy. While some progress was made by this group, its efforts did not result in a finalized plan, and for a variety of reasons, it subsequently disbanded in 1995. Clearly, the fish health issues did not go away, and a need still existed for a national fish health plan for the United States.

The National Aquatic Animal Task Force ("Task Force") was reconstituted in 2001 with a new cast of players and a defined objective of developing and implementing a National Aquatic Animal Health Plan

(NAAHP), not just a strategy. Members of the new Task Force represent the departments of Interior, (United States Fish and Wildlife Service, USFWS), Agriculture (Animal and Plant Health Inspection Service, APHIS) and Commerce (National Marine Fisheries Service, NMFS). This paper will review the current authorities of federal agencies in aquatic animal health and the challenges to operate in the current environment. The paper will then examine the mission, purpose and the expected outcomes of the Task Force, including the appropriate role for risk analysis. Progress made to date by the Task Force on this initiative will be reported.

Status of Federal Authorities

Until recently, there was limited authority by United States federal agencies to regulate the import and export of live aquatic animals. This authority was expressed primarily in Code of Federal Regulation, Title 50, Part 16, which gives the U.S. Fish and Wildlife Service the ability to prevent the introduction of live salmonids or their gametes into the United States without first having health inspections and appropriate health histories as prescribed in Title 50. The Department of Commerce/NMFS maintains authority for aquatic animals in the exclusive economic zone (EEZ) - the coastal zone between three and 200 miles off the shores of the United States. This authority is defined in the Magnuson-Stevens Act (16 USC 1801 et seq.). Until recently, the Department of Agriculture apparently only had authority to issue export certificates under 7 CFR 353 and to declare emergencies when foreign animal diseases were found in the United States. Each of the 50 U.S. states also has the authority to regulate imports into its respective borders, contingent on specific rules passed by local and state governments.

This playing field changed substantially in May 2002, when H.R. 2646, also known as the "Agriculture, Conservation, and Rural Enhancement Act of 2002 " (also known as the "Farm Bill"), was signed into law by President George W. Bush. This new law gives the Secretary of Agriculture, through APHIS, the authority to protect and control the health of all livestock in the United States to include imports, exports and interstate commerce of aquatic animals. At the writing of this paper, many details need to be worked out as to how APHIS will develop and administer regulations to implement this new authority, however, H.R. 2646 also requires that the new rules will be developed in consultation with other federal agencies.

Even with the new authority identified for the Department of Agriculture for managing the health of farmed aquatic livestock, there are many issues to be resolved. Some of these issues include:

- the potential for overlapping jurisdictions,
- the roles and responsibilities of various federal and state agencies,
- the absence of formal risk analysis for diseases of concern,
- the interactions of wild stock and cultured fish stocks, and
- the absence of a comprehensive national aquatic animal health plan.

The consequence of not having a plan in place and roles defined is that safe and effective commerce is impeded.

Mission and Purpose

To respond to the need for a national plan, the Task Force assembled with interested stakeholders in December 2001, to start crafting a mission statement, purpose and planned outputs of a national plan. The main concerns of the participants at the meeting were to:

- facilitate safe intrastate, interstate and international commerce;
- protect the health and productivity of cultured aquatic animals;
- minimize the spread of pathogens; and
- protect wild fish stocks.

The product of the first stakeholders meeting is as follows:

National Aquatic Animal Health Task Force on Aquaculture

Mission:
Develop and implement a National Aquatic Animal Health Plan for Aquaculture (NAAHP) in partnership and cooperation with industry, regional organizations, state, local, and tribal governments and other stakeholders.

Purpose:
The purpose of the NAAHP is to:

- Facilitate the legal movement of aquatic animals and their products in interstate and international commerce.
- Enhance the protection of aquaculture in the United States from the importation of foreign aquatic pests, diseases and their causative agents.
- Ensure the availability of diagnostic and certification services equivalent to those provided to other sectors of agriculture.
- Define the roles and responsibilities of federal agencies in order to implement the NAAHP, recognizing that the Chief Veterinary Officer of USDA/APHIS is the official representative for the United States to the Office International des Épizooties (OIE). The process by which roles and responsibilities are identified will enhance and encourage interaction, collaboration and cooperation in a transparent manner between federal agencies.
- Ensure that the NAAHP is developed through shared leadership of the relevant federal agencies because of their perspectives, history, resources, expertise and authorities each brings to bear on implementing the plan.
- Provide to the Secretaries of appropriate federal agencies resolutions concerning roles and responsibilities of federal agencies, the infrastructures to carry out their responsibilities, and resources needed to implement the NAAHP. Identify new resources needed if current programs are insufficient..

Expected Outcomes:
The expected outcomes are:

- Cultured aquatic animals and aquatic animal products continue to be healthy, productive and of high quality.
- Cultured aquatic animals are protected from introductions of exotic pathogens and other pathogens of concern.
- Cultured and wild aquatic animals are protected from the impact of diseases as a result of interactions with each other.
- Adequate surveillance and reporting systems implemented to support protection.
- Readily available diagnostic, inspection, and certification services as needed for the aquaculture industry.
- Legal movement of aquatic animals and their products facilitated in interstate and international commerce.
- Stable and predictable trading environment.
- Consistent and seamless regulatory environment.
- Improved research and technology development for aquatic animal health management.
- Recognition of the United States by the OIE and other foreign trading partners as being a leader in the field of aquatic animal health management, policy and regulations.

Development of the National Plan
The Task Force held a meeting on 24 May 2002 and formally adopted the mission, purpose and the outputs as stated above. The next step for the Task Force is to complete in detail the various elements of the plan. The framework identified to date includes the following elements:

- Mission statement (already written - see above)
- Guiding principles (science-based, transparent, collaborative process)

- Definitions
- Disease prevention (biosecurity, import controls, protocols, biologics, risk analysis)
- Disease surveillance, monitoring, and reporting (diseases of concern, surveillance strategies)
- Disease control (isolations, quarantine, eradication, indemnification, GMPs)
- Emergency management (preparedness, response plans)
- International movements (negotiations with foreign governments, health certificates, transfer permits risk analysis)
- Interstate movement (harmonization at regional level, health certificates, risk analysis)
- Laboratory approvals (accreditation, quality control and quality assurance, reference labs)
- Professional certification (qualifications, authorities, procedures)
- Inspection and testing methodologies
- Roles and responsibilities (federal, state, tribal, private industry, others)
- Budget
- Implementation strategy and time line

It is the goal of the Task Force to have a significant portion of the plan implemented within two years. Note that risk analysis plays an important role in the chapters that deal with disease prevention and international/interstate movement of aquatic animal products. The ability of the Task Force in completing the development of the NAAHP will rely heavily on resources made available to conduct this work. The Task Force is optimistic the United States will make the necessary commitments that allow aquaculture to be successful and at the same time protect our wild resources and cultured aquatic animal products from losses due to the introduction or spread of unwanted diseases.

ANNEXES

ANNEX I

WORKSHOP PROGRAMS

Annex I (A)

APEC FWG[1] 01/2002
"Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals"
First Training/Workshop, NACA Headquarters, Bangkok, Thailand
31 March to 7 April 2002

Programme[2]

Date	Activities
29-31 March	Arrival of Delegates
1 April (Monday)	**Opening Ceremonies** ***(0830-1000 hrs)*** Opening Remarks from Dr Maitree Duwangsawasdi, Deputy Director General (Thailand's Department of Fisheries), APEC FWG Member (Thailand), and Project Overseer (APEC FWG 01/2002) Welcome Remarks from Mr Pedro B. Bueno, Director General of NACA Introduction of Participants
	APEC FWG 01/2002, Objectives and Expected Outcomes (M.B. Reantaso, NACA)
	Part 1: Training Course ***(from 1030 hrs)***
	Session 1*:* Regional and International Agreements/Treaties/Codes/Guidelines ***Session 2:*** Introduction to the Import Risk Analysis (IRA) Process
2 April (Tuesday)	***Session 2:*** Introduction to the Import Risk Analysis (IRA) Process ***Session 3:*** Application of IRA on Aquatic Animals: Examples and Case Histories ***Session 4:*** Group Exercise on IRA
3 April (Wednesday)	***Session 4:*** Group Exercise on IRA ***Session 5:*** Group Presentations ***Session 6:*** General Discussions, Conclusions and Recommendations
	Part 2: Workshop
4 April (Thursday)	Opening Remarks from Dr Y. Ozawa on behalf of OIE Regional Representation for Asia-Pacific
	Session 1: Technical Presentations
	Dinner Hosted by NACA at 1900 hrs
5 April (Friday)	***Session 2:*** Country Presentations
	Session 3: Working Group Discussions
6 April (Saturday)	***Session 3:*** Working Group Discussions ***Session 4:*** Working Group Presentations and General Discussions ***Session 5:*** Evaluation of the Training/Workshop ***Session 6:*** The Way Forward: Presentation of Workshop Recommendations and Conclusions
	Closing Ceremonies Remarks from Representative/s of Workshop Participants Closing Remarks from Project Overseer and NACA Director General
7-10 April	Departure of Delegates

[1] Fisheries Working Group of the Asia-Pacific Economic Cooperation
[2] Morning sessions start at 0830 hrs; afternoon sessions start at 1330 hrs and finish at 1800-1700 hrs
Morning and afternoon coffee will be served at 1000-1030 hrs and 1500-1530 hrs; lunch will be served at 1230-1330 hrs

Part I: Training Course (1-3 April)

April 1: MONDAY

Moderator: C.J. Rodger

Session 1: Regional and International Agreements/Treaties/Codes/Guidelines	
The objective of this session is to familiarize participants on a number of regional and international agreements/treaties/codes/guidelines containing provisions with respect to aquatic animal health management. Some of these are obligatory where countries are bound to abide with their implementation, while others are voluntary. The session consists of brief presentations as follows:	
1030-1050	Recent Asian Initiatives under the NACA Regional Programme on Aquatic Animal Health Management and the FAO[3]/NACA[4] "Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy" (M.B. Reantaso)
1050-1110	WTO[5]'s Agreement on the Application of Sanitary and Phytosanitary Measures (The SPS Agreement) (P. Beers)
1110-1130	OIE[6]'s International Aquatic Animal Health Code (C.J. Rodgers)
1130-1200	Other Relevant International Agreements: ICES[7]/EIFAC[8]/Codex Alimentarius/CBD[9] (J.R. Arthur)
1200-1230	**ession 2: Introduction to the Import Risk Analysis (IRA) Process**
1230-1330	Lunch Break
1330-1500	**ession 2: Introduction to the Import Risk Analysis (IRA) Process**
1500-1530	Coffee Break
1530-1730	**ession 2: Introduction to the Import Risk Analysis (IRA) Process**

1200-1730 of April 1 continued until 0830-1500 of April 2

Session 2: Introduction to the Import Risk Analysis (IRA) Process

The session is an introduction to the Import Risk Analysis (IRA) process which includes a background or overview, the process of initiating an IRA, beginning from the request for importation followed by the four important steps: (a) hazard identification, (b) risk assessment, (c) risk communication, and (d) risk management, an introduction to IRA methodologies and finally policy application and implementation.

Main Lecturers: C. Baldock, R. Perrera and P. Beers

- Background/Overview
- Initiation of an IRA
- Hazard Identification
- Risk Assessment
- Release Assessment
- Exposure Assessment
- Consequence Assessment
- Risk Estimation
- Risk Communication
- Risk Management
- Introduction to Methods used in IRA: qualitative and quantitative methods, modeling
- Policy Application

[3] Food and Agriculture Organization of the United Naions
[4] Network of Aquaculture Centres in Asia-Pacific
[5] World Trade Organization
[6] Office International des Epizooties or World Organisation for Animal Health
[7] International Council for the Exploration of the Seas
[8] European Inland Fishery Advisory Commission
[9] Convention on Biological Diversity

April 2: TUESDAY

0830-1000	**Session 2: Introduction to the Import Risk Analysis (IRA) Process**
1000-1030	Coffee Break
1030-1230	**Session 2: Introduction to the Import Risk Analysis (IRA) Process**
1230-1330	Lunch Break
1330-1500	**Session 2: Introduction to the Import Risk Analysis (IRA) Process**
1500-1530	Coffee Break

Moderator: C.J. Rodgerss

Session 3: Application of IRA on Aquatic Animals: Examples and Case Histories	
This session includes presentations by a panel of experts on examples of the application of the IRA process to different aquatic animal host groups. The objective of this session is to familiarize participants with the different scenarios that will be faced when conducting an IRA through providing specific experiences, examples and case histories.	
1530-1550	Risks of Spreading Shrimp Pathogens through Live Aquatic Animal Movement (T. Flegel)
1550-1610	Progress on IRA on shrimp (non-viable products) (P. Beers)
1610-1630	IRA on finfish (G. Olivier)
1630-1650	IRA on ornamental fish (R. Perrera)
1650-1710	The development of molluscan IRAs in Asia-Pacific Region (M. Hine)
1710-1730	Experiences on US product(s) acceptance/rejection based on Canada, Australia and Chile IRAs (K. Amos)
1730-1800	Discussion

April 3: WEDNESDAY

Moderator: C. Baldock

Session 4: Group Exercise on IRA	
During this session, participants will be divided into 4 groups to work on the case examples as indicated below. The membership for each group will be determined during the first day of the training course. Guidelines and background information/material needed for each case study will be provided. Experts and resource speakers will be available to facilitate discussions.	
0830-0840	General Guidelines to Group Exercise (C. Baldock)
0840-1000	Group Exercise
Group 1: IRA on shrimp (P. Beers, T. Flegel, D. Fegan) Group 2: IRA on ornamental fish (R. Perrera) Group 3: IRA on non-indigenous and exotic species (K. Amos, G. Olivier, M. Hine) Group 4: Country case study (J.R. Arthur)	
1000-1030	Coffee Break
1030-1230	Group Exercise
1230-1330	Lunch Break
1330-1430	Preparation of Group Exercise Presentation
Moderator: P. Beers	
Session 5: Group Presentations	
1430-1500	Group 1 Presentation
1500-1530	Coffee Break
1530-1600	Group 2 Presentation
1600-1630	Group 3 Presentation
1630-1700	Group 4 Presentation
Moderator: C. Baldock	
Session 6: General Discussion, Conclusion and Recommendations	
1700-1800	General Discussion, Conclusion and Recommendations

Part 2 : Workshop Programme (4-6 April)

April 4: THURSDAY

0830-0840 Opening Remarks from Dr Y. Ozawa on behalf of OIE

Moderator: J.R. Arthur

Session 1: Technical Presentations	
This is the first part of the workshop proper and consists of 30 min presentations on various subjects to set the scene and to provide important technical background that will be useful for the working group discussions in Session 3.	
0840-0900	International trade on aquatic animals (J.R. Arthur)
0900-0930	Trans-boundary Aquatic Animal Diseases/Pathogens (M.B. Reantaso)
0930-1000	Risk Analysis in Aquaculture (C.J. Rodgers)
1000-1030	Coffee Break
	Examples and experiences/lessons from WTO international trade negotiations
1030-1100	Importing Country Perspective (Australia – P. Beers)
1100-1130	Exporting Country Perspective (Canada – G. Olivier)
1130-1200	Shrimp and Turtle Exclusion Device (TED) (K. Amos)
1200-1230	Surveillance/reporting/zoning, information (epidemiological data and disease databases) and research requirements necessary to support IRAs (C. Baldock and J.R. Arthur)
1230-1330	Lunch Break
1330-1400	Surveillance/reporting/zoning, information (epidemiological data and disease databases) and research requirements necessary to support IRAs (C. Baldock and J.R. Arthur)
1400-1430	Limitations of applying risk analysis to aquatic organisms (M. Hine)
1430-1500	Recommendations from the OIE Conference on IRA for Aquatic Animals) (C.J. Rodgers)
1500-1530	Coffee Break
1530-1700	OIE Risk Analysis Framework and Obligations for WTO Members under the SPS Agreement, and experiences from the livestock sector (N. Murray)
	Import Risk Analysis: A Case Study from the Livestock Sector (A New Zealand example) (N. Murray)
1700-1730	General Discussions
1900-	Dinner hosted by NACA

April 5: FRIDAY

Moderator: C.J. Rodgers

Session 2: Country Presentations	
This session consists of 20 min presentations by some countries which have relatively good experience in conducting IRAs for aquatic animal, countries that are initiating the application of IRA, or countries establishing policies on aquatic animal health; and private sector perspective. The presentation may include information on national policies and/or policy development, implementation strategies, and other relevant information. The presentations will provide valuable information that can be used as a reference during the Working Group Discussions in Session 3.	
0830-0850	IRA Process in Australia, Technical Guidelines on IRA, Current Work Program and Future Perspective of Biosecurity Australia (R. Perrera)
0850-0910	Canada (G. Olivier)
0910-0930	China PR (F. Xiangguo/X. Zhen)
0930-0950	Framework of Aquatic Animal Disease Control in Japan (M. Masuda/N. Oseko)
0950-1010	IRAs in New Zealand (M. Hine)
1010-1030	Coffee Break
1030-1050	Initiation of the IRA Process in the Philippines (J.O. Paclibare/J.R. Somga/M. Trio)
1050-1110	Strategies on Aquatic Animal Health Management in Thailand (S. Chinabut/S. Kanchanakhan)
1110-1130	Current Strategies on Aquatic Animal Health Management in Chinese Taipei (Shiu Nan Chen)

1130-1150	Use of IRA and Science for Developing US Trade Policies (K. Amos)
1150-1210	Elements of the New Aquatic Animal Health Plan in the US (K. Amos)
1210-1230	Role of Private Sector in Import Risk Assessment and its Implementation – Thailand Experience (D. Fegan)
1230-1330	Lunch Break
1330-1400	General Discussion
	Session 3: Working Group Discussions
1400-1420	Introduction to Working Group Discussions (M.B. Reantaso) Expected Outcomes The Working Group discussions are expected to develop recommendations through a further discussion of the issues and other relevant background and technical information provided during the training course, and supported by the technical and country specific presentations, including available information which participants have been requested to bring to be used as reference materials for the working group discussions; and the broad range of experiences of participants from the government, science, and private sector. *Organization of the Working Groups* *Workshop participants will be split into three Working Groups, a Chair, Vice-Chair, Rapporteur/s and Working Group Presentor will be designated.* ***The Terms of Reference of the Working Groups are:*** **Working Group 1:** Working Group 1 will discuss matters pertaining to policies and regulatory frameworks governing trade (domestic and international), health certification and quarantine procedures, competent authorities on IRA, criteria for establishing an IRA panel (government/experts/private sector), the IRA process in health management and other policy development requirements. Working Group 1 will try to evaluate the problems/limitations (e.g. capacity, policy) in the practical implementation of the IRA process and make suggestions for what can be done to overcome constraints, improving current situation, and identifying mechanisms for private sector (exporter/importer/other stakeholder participation) and expert cooperation and involvement in supporting responsible trade in aquatic animals Facilitators/Resource Experts: P. Beers, N. Murray, K. Amos, D Fegan, S.Kanchanakhan Chair/Vice-Chair/Rapporteurs/Presentor/Members: to be identified **Working Group 2:** Working Group 2 will look at national level requirements for implementing an IRA with respect to research, diagnostics, surveillance/reporting/zoning, epidemiology and other health information needs as well as training needs; and mechanisms for networking both at national and regional levels. Facilitators/Resource Experts: C. Baldock, G. Olivier, T. Flegel, S. Chinabut, Shiu Nan Chen Chair/Vice-Chair/Rapporteurs/Presentor/Members: to be identified **Working Group 3:** Working Group 3 will look at a possible outline/framework for the development of an IRA Manual on Aquatic Animals that will provide guidance to APEC economies. Facilitators/Resource Experts: J.R. Arthur, C.J. Rodgers, R. Perrera, M. Hine, M.B. Reantaso Chair/Vice-Chair/Rapporteurs/Presentor/Members: to be identified
1420-1500	Working Group Discussion
1500-1530	Coffee Break
1530-1800	Working Group Discussion

April 6: SATURDAY

Continue Session 3: Working Group Discussions	
0830-0930	Working Group Discussion and Pepare Group Presentation
Moderator: K. Amos	
	Session 4: Working Group Presentations and General Discussions
0930-1000	Working Group 1 Presentation
1000-1030	Working Group 2 Presentation
1030-1100	Coffee Break
1100-1130	Working Group 3 Presentation
1130-1200	General Discussions
Moderator: C. Baldock	
	Session 5: The Way Forward
1200-1220	Project Output and Inter-sessional Activities (M.B. Reantaso)
1220-1240	General Recommendations
	Closing Ceremonies
1240-1300	Closing Remarks from Representatives of Delegates/Participants/NACA Director General
1300-1400	Lunch Break
1400-	Free Afternoon

April 7: SUNDAY – Departure of Delegates/Participants

ANNEX I (B)

APEC FWG[1] 01/2002
"Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals"
Second Training/Workshop, Mazatlan, Mexico
12-17 August 2002

Programme[2]

Date	Activities
10-11 August	Arrival of Delegates
12 August (Monday)	Opening Ceremonies *(0830-1000 hrs)* Opening Remarks from **Dr Maitree Duwangsawasdi**, Deputy Director General (Thailand's Department of Fisheries), APEC FWG Member (Thailand), and Project Overseer (APEC FWG 01/2002) Welcome Remarks from: **Lic. Gerardo Rossete Ramírez,** Presidente Municipal de Mazatlán Mr Pedro Bueno, **Director General (NACA)** **Dr Miguel Ángel Cisneros Mata,** Director General de Investigaciones en Evaluación y Manejo de Recursos Pesqueros. Instituto Nacional de la Pesca (INP) **Dr Rohana Subasinghe**, FAO **Dr Jerónimo Ramos Sáenz Pardo,** Comisionado Nacional de Acuacultura y Pesca (CONAPESCA) The kind presence **Ing. Rubén Ocaña Soler,** Director de Planeación, Programación y Evaluación (CONAPESCA) **Ocean Alfredo Herrera Mesina,** Director General de Organización y Fomento, CONAPESCA **Ing. Alfredo Fernández Gallegos,** Delegado Federal de SAGARPA en el Edo. de Sinaloa.
	APEC FWG 01/2002, Objectives and Expected Outcomes **(M.B. Reantaso)**
	Coffee Break
	Part 1: Training Course *(from 1030 hrs)*
	Session 1*:* Regional and International Agreements/Treaties/Codes/Guidelines ***Session 2:*** Introduction to the Import Risk Analysis (IRA) Process
	Welcome Cocktail
13 August (Tuesday)	***Session 2:*** Introduction to the Import Risk Analysis (IRA) Process ***Session 3:*** Application of IRA on Aquatic Animals: Examples and Case Histories ***Session 4:*** Group Exercise on IRA
14 August (Wednesday)	***Session 4****:* Group Exercise on IRA ***Session 5:*** Group Presentations ***Session 6:*** General Discussions, Conclusions and Recommendations
15 August (Thursday)	**Field/Cultural Trip**
	Part 2: Workshop

[1] Fisheries Working Group of the Asia-Pacific Economic Cooperation
[2] Morning sessions start at 0830 hrs; afternoon sessions start at 1330 hrs and finish at 1800-1700 hrs
Morning and afternoon coffee will be served at 1000-1030 hrs and 1500-1530 hrs; lunch will be served at 1230-1330 hrs

16 August (Friday)	Opening Remarks from **Lic. Ricardo Belmontes Acosta,** Director de Asuntos Pesqueros Internacionales, CONAPESCA
	***Session 1*:** Technical Presentations
	Dinner
17 August (Saturday)	***Session 2:*** Working Group Discussions
	Session 3: Working Group Presentations and General Discussions ***Session 4:*** Evaluation of the Training/Workshop ***Session 5:*** The Way Forward: Presentation of Workshop Recommendations and Conclusions
	Closing Ceremonies Remarks from: Representative/s of Workshop Participants **Mr Pedro Bueno**, NACA Director General and Project Implementor **Mr Colin McIff**, on behalf of APEC FWG Lead Shepherd **Dr Jerónimo Ramos Sáenz Pardo,** Comisionado de CONAPESCA **Dr Guillermo Compean Jiménez,** Director en Jefe del INP **Dr Javier Trujillo Arriaga,** Director en Jefe del SENASICA
	Farewell Dinner
18-19 August (Sunday-Monday)	Departure of Delegates

Part I: Training Course (12-14 August)

August 12: MONDAY

Session 1: Regional and International Agreements/Treaties/Codes/Guidelines	
Moderator: C.J. Rodgers	
The objective of this session is to familiarize participants on a number of regional and international agreements/treaties/codes/guidelines containing provisions with respect to aquatic animal health management. Some of these are obligatory where countries are bound to abide with their implementation, while others are voluntary. The session consists of brief presentations as follows:	
1030-1100	Recent Asian Initiatives under the NACA Regional Programme on Aquatic Animal Health Management and the FAO[3]/NACA[4] "Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy" (M.B. Reantaso)
1100-1130	WTO[5]'s Agreement on the Application of Sanitary and Phytosanitary Measures (The SPS Agreement) and OIE's International Aquatic Animal Health Code (B.J. Hill)
1130-1200	Introduction to Other Relevant International Agreements: ICES[6]/EIFAC[7]/Codex Alimentarius/CBD[8] (J.R. Arthur)
1200-1230	Discussion
	Rapporteur (R.P. Subasinghe)
1230-1330	Lunch Break
Moderator: C.J. Rodgers	
1330-1500	**Session 2: Introduction to the Import Risk Analysis (IRA) Process**
1500-1530	Coffee Break
1530-1730	**Session 2: Introduction to the Import Risk Analysis (IRA) Process**

[3] Food and Agriculture Organization of the United Nations
[4] Network of Aquaculture Centres in Asia-Pacific
[5] World Trade Organization
[6] International Council for the Exploration of the Sea
[7] European Inland Fishery Advisory Commission
[8] Convention on Biological Diversity

1330-1800 of August 12 continued until 0830-1500 of August 13

Session 2: Introduction to the Import Risk Analysis (IRA) Process

The session is an introduction to the Import Risk Analysis (IRA) process which includes a background or overview, the process of initiating an IRA, beginning from the request for importation followed by the four important steps: (a) hazard identification, (b) risk assessment, (c) risk communication, and (d) risk management, an introduction to IRA methodologies and finally policy application and implementation.

Main Lecturers: C. Baldock, P. Beers, C. Rodgers

- Background/Overview
- Initiation of an IRA
- Hazard Identification
- Risk Assessment
- Release Assessment
- Exposure Assessment
- Consequence Assessment
- Risk Estimation
- Risk Communication
- Risk Management
- Introduction to Methods used in IRA: qualitative and quantitative methods, modeling
- Policy Application

August 13: TUESDAY

Moderator: C.J. Rodgers	
0830-1000	Session 2: Introduction to the Import Risk Analysis (IRA) Process
1000-1030	Coffee Break
1030-1230	Session 2: Introduction to the Import Risk Analysis (IRA) Process
1230-1330	Lunch Break
1330-1500	Session 2: Introduction to the Import Risk Analysis (IRA) Process
1500-1530	Coffee Break
Session 3: Application of IRA on Aquatic Animals: Examples and Case Histories	
Moderator: M.J. Phillips	
This session includes presentations by a panel of experts on examples of the application of the IRA process to different aquatic animal host groups. The objective of this session is to familiarize participants with the different scenarios that will be faced when conducting an IRA through providing specific experiences, examples and case histories.	
1530-1550	Risk Analysis in Aquaculture and Aquatic Animal Health (C.J. Rodgers)
1550-1610	Risks of Exotic Species Introduction (R.P. Subasinghe)
1610-1630	Risks of Spreading Shrimp Pathogens through Live Aquatic Animal Movement (D. Fegan)
1630-1650	Risks of Chemical Usage in Aquaculture (R.P. Subasinghe)
1650-1710	Risks of Spreading Molluscs Pathogens through Live Aquatic Animal Movements (F. Berthe)
1710-1730	Progress on IRA on Shrimp (Non-viable Products) (P. Beers)
1730-1750	National Code on Introductions and Transfer Policy, a Risk-Based Approach (G. Olivier)
1750-1810	IRA on Ornamental Fish (P. Beers)
1810-1840	Salmon Exports from the US to Australia, Canada and Chile (K. Amos)
1840-1900	Discussion
	Rapporteurs (C. Chavez and A. Montero)

"National Code on Introductions and Transfer Policy, risk-based approach"

August 14: WEDNESDAY

Session 4: Group Exercise on IRA	
Moderator: C. Baldock	
During this session, participants will be divided into 4 groups to work on the case examples as indicated below. The membership for each group will be determined during the first day of the training course. Guidelines and background information/material needed for each case study will be provided. Experts and resource speakers will be available to facilitate discussions.	
0830-0840	General Guidelines to Group Exercise (C. Baldock)
0840-1000	Group Exercise
Group 1: IRA on shrimp (V. Alday, A. Montero, L. Mariduena, M.J. Phillips, D. Fegan) Group 2: IRA on ornamental fish (B. Hill, P. Beers, L. Contreras, S. Chinabut) Group 3: IRA on non-indigenous and exotic species (K. Amos, G. Olivier, P. Bueno, J.R. Arthur, C. Rodgers) Group 4: IRA on molluscs (F. Berthe, C. Chavez, M.B. Reantaso, R.P. Subasinghe)	
1000-1030	Coffee Break
1030-1230	Group Exercise
1230-1330	Lunch Break
1330-1430	Preparation of Group Exercise Presentation
Session 5: Group Presentations	
Moderator: C. Chaves	
1430-1500	Group 1 Presentation
1500-1530	Coffee Break
1530-1600	Group 2 Presentation
1600-1630	Group 3 Presentation
1630-1700	Group 4 Presentation
Session 6: General Discussion, Conclusion and Recommendations	
Moderator: C.J. Rodgers	
1700-1800	General Discussion, Conclusion and Recommendations
	Rapporteurs (P. Beers, M.B. Reantaso)

Cultural Trip/Free Day: 15 August (Thursday)

Part 2: Workshop Programme (16-17 August)

August 16: FRIDAY

0830-0840
Opening Remarks - **Ricardo Belmontes Acosta**, Director de Asuntos Pesqueros Internacionales, CONAPESCA

Moderator: S. Chinabut	
Session 1: Technical Presentations	
This is the first part of the workshop proper and consists of 30 min presentations on various subjects to set the scene and to provide important technical background that will be useful for the working group discussions in Session 3. This session consists of 20 min presentations by some countries which have relatively good experience in conducting IRAs for aquatic animals, countries that are initiating the application of IRA, or countries establishing policies on aquatic animal health; and private sector perspective. The presentation may include information on national policies and/or policy development, implementation strategies, and other relevant information. The presentations will provide valuable information that can be used as a reference during the Working Group Discussions in Session 3.	
0840-0900	Disease Surveillance and Monitoring (C. Baldock)
0900-0920	Aquatic Animal Disease Zoning (B.J. Hill)
0920-0940	Databases for Import Risk Analysis (J.R. Arthur)
0940-1000	Information and Research Requirements Necessary to Support IRAs (B.J. Hill)
1000-1030	Coffee Break

	Examples and Experiences/Lessons from WTO International Trade Negotiations
1030-1100	Salmon IRA: Importing Country Perspective (P. Beers)
1100-1130	Salmon IRA: Exporting Country Perspective (G. Olivier)
1130-1200	Sea Turtles, Shrimp and the WTO: A Case Study (K. Amos)
1200-1230	Discussion
	Rapporteurs (R.P. Subasinghe and M.J. Phillips)
1230-1330	Lunch Break
1330-1350	IRA Process in Australia, Technical Guidelines on IRA, Current Work Program and Future Perspective of Biosecurity Australia (P. Beers)
1350-1410	Canada's National Aquatic Animal Health Program (G. Olivier)
1410-1430	National Aquatic Animal Health Plan for the USA (K. Amos)
1430-1450	Development of National Strategies on Aquatic Animal Health in Asia-Pacific (M.B. Reantaso)
1450-1510	Recommendations from the OIE Conference on IRA for Aquatic Animals) (C. Rodgers)
1510-1530	Coffee Break
1530-1550	Role of Fish Diseases Commission of OIE in Aquatic Animal Health Management (B.J. Hill)
1550-1610	Role of Private Sector in the IRA Process (D. Fegan)
1610-1630	Import Risk Analysis: Experiences from the Livestock Sector (A. Heneidi)
1630-1700	General Discussions
	Rapporteurs (V. Alday and M.B. Reantaso)

Moderator: J.R. Arthur

1700-1800	Session 2: Introduction to Working Group Discussions (A. Montero) <u>Expected Outcomes</u> The Working Group discussions are expected to develop recommendations through a further discussion of the issues and other relevant background and technical information provided during the training course, and supported by the technical and country specific presentations, including available information which participants have been requested to bring to be used as reference materials for the working group discussions; and the broad range of experiences of participants from the government, science, and private sector. Organization of the Working Groups *Workshop participants will be split into three Working Groups, a Chair, Vice-Chair, Rapporteur/s and Working Group Presentor will be designated.* *The Terms of Reference of the Working Groups are:* Working Group 1: Working Group 1 will discuss matters pertaining to policies and regulatory frameworks governing trade (domestic and international), health certification and quarantine procedures, competent authorities on IRA, criteria for establishing an IRA panel (government/experts/private sector), the IRA process in health management and other policy development requirements. Working Group 1 will try to evaluate the problems/limitations (e.g. capacity, policy) in the practical implementation of the IRA process and make suggestions for what can be done to overcome constraints, improving current situation, and identifying mechanisms for private sector (exporter/importer/other stakeholder participation) and expert cooperation and involvement in supporting responsible trade in aquatic animals Working Group 2: Working Group 2 will look at national level requirements for implementing an IRA with respect to research, diagnostics, surveillance/reporting/zoning, epidemiology and other health information needs as well as training needs; and mechanisms for networking both at national and regional levels. Working Group 3: Working Group 3 will look at IRA Manual Draft Outline from the Bangkok Workshop

August 17: SATURDAY

	Session 2: Working Group Discussions
0830-1000	Continue Working Group Discussion
1000-1030	Coffee Break
1030-1230	Finish Working Group Discussion/Preparation of Group Presentation
1230-1330	Lunch Break
Session 3: Working Group Presentations and General Discussions	
Moderator: P. Bueno	
1330-1415	Working Group 1 Presentation and Discussion
	Rapporteur (K. Amos)
1415-1500	Working Group 2 Presentation and Discussion
	Rapporteur (B. Hill)
1500-1530	Coffee Break
1530-1615	Working Group 3 Presentation and Discussion
	Rapporteur (F. Berthe)
1615-1645	Session 4: Evaluation of the Training/Workshop (AB Montero)
	Session 5: The Way Forward (R.P. Subasinghe)
1645-1715	Presentation of Workshop Recommendations and Conclusions (J.R. Arthur)
1715-1745	Discussion
	Rapporteurs (A. Montero and G. Olivier)
1745-	Closing Ceremonies Remarks Representative/s of Participants Mr Pedro Bueno, NACA Director General Mr Colin McIff, on behalf of APEC FWG Lead Shepherd Dr Jerónimo Ramos, Comisionado del CONAPESCA Dr Guillermo Compean Jiménez, Director en Jefe del INP Dr Javier Trujillo Arriaga, Director en Jefe del SENASICA
1930	Farewell Dinner

August 18-19: SUNDAY/MONDAY – Departure of Delegates/Participants

ANNEX II(A)

LISTS OF PARTICIPANTS

APEC FWG[9] 01/2002
"Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals" First Training/Workshop, NACA Headquarters, Bangkok, Thailand
31 March to 7 April 2002

#		Name and Contact Details of Delegates/Resource Speakers/Experts
	APEC Economies	
1	Australia	Dr Ramesh Perrera Principal Scientist, Biosecurity Australia Department of Agriculture, Fisheries and Forestry - Australia GPO Box 858, Canberra ACT 2601 Tel: +61 2 6272 4675; Fax: +61 2 6272 3399 E-mail: Ramesh.Perera@affa.gov.au
2	Australia	Dr Peter Beers Manager, Aquatic Animal Biosecurity, Biosecurity Australia Department of Agriculture, Fisheries and Forestry - Australia GPO Box 858 Canberra, AUSTRALIA ACT 2601 Tel: +61 2 6272 5330; Fax: +61 2 6272 3399 E-mail: Peter.Beers@affa.gov.au
3	Canada	Dr Gilles Olivier A/Manager, Aquaculture Division Department of Fisheries and Oceans 343 University Avenue Moncton, NB, CANADA E1C 9B6 Tel: + 506-851-2054; Fax: + 506-851-2079 E-mail: OlivierG@dfo-mpo.gc.ca
4	China PR	Mr Fan Xiangguo Deputy Director of Division of Aquaculture Bureau of Fishery, Ministry of Agriculture PEOPLE'S REPUBLIC OF CHINA E-mail: aqucfish@agri.gov.cn
5	China PR	Mr Xiong Zhen Deputy Chief of Division of Technology Extension National Fishery Extension Center PEOPLE'S REPUBLIC OF CHINA
6	Hong Kong China	Ms Louise Li Wai-Hung Fisheries Officer Agriculture, Fisheries and Conservation Department 5-8/F, Cheung Sha Wan, Government Offices 303 Cheung Sha Wan Road, Kowloon HONG KONG CHINA Tel: 852 24719204; Fax: 852-23142866 E-mail: louise_wh_li@afcd.gov.hk

[9] Fisheries Working Group of the Asia-Pacific Economic Cooperation

7	Indonesia	Mr Widodo Head of Division of Controlling and Eradicating Pests and Fish Disease Directorate General of Aquaculture Ministry of Marine Affairs and Fisheries INDONESIA
8	Indonesia	Mrs Budi Sugianti Head of Division of Programme and Cooperation of Central Fish Quarantine Ministry of Marine Affairs and Fisheries Jl. MT Haryono Kav. 52-53, Jakarta (12770), INDONESIA E-mail: primaqua@indosat.net.id
9	Japan	Dr Mahito Masuda Director, Fish Ranching and Aquaculture Division Fisheries Agency of Japan 1-2-1 Kasumigaseki, Chiyoda-ku Tokyo, JAPAN Tel: +81-3-3502-0895; Fax: +81-3-3591-1084 E-mail: mahito_masuda@nm.maff.go.jp
10	Japan	Dr Norihisa Oseko Senior Scientist, Histopathology Section National Research Institute of Aquaculture Pathology 224-1 Hiruta, Tamaki, Watarai-gun Mie 519-0423, JAPAN Tel: +81-596-58-6411; Fax: +81-596-58-6413 E-mail: ohseko@fra.affrc.go.jp
11	Korea RO	Dr Sung Hee Jung Fisheries Researcher, Pathology Division National Fisheries Research and Development Institute 408-1, Sirang-ri, Gijang-eup, Gijang-gun Busan 619-902, KOREA Tel: +82 51 720 2482; Fax: +82 51 720 2498 E-mail: Immu@nfrdi.re.kr
12	Malaysia	Mrs Fauzidah bt. Othman Head, Fish Health Management and Quarantine Department of Fisheries Malaysia MALAYSIA Tel: 603-87874095; Fax: 603-87874107 E-mail: Fauzidah_Othman@hotmail.com
13	Malaysia	Ms Badariah bt. Mohd Ali Head, Fish Health Management and Quality Assurance Section (FIQC) Department of Fisheries Malaysia MALAYSIA E-mail: badariah@pd.jaring.my
14	Mexico	Dra. Ana Bertha Montero Rocha Mexican Representative Researcher Instituto Nacional de la Pesca Pitágoras 1320 Sta Maria Atoyac, C.P.03310. MÉXICO D.F. Tel: 0052 55 5422 3053/ 5422 3054; Fax: 0052 55 5688 4014 E-mail anabmont@servidor.unam.mx o anabmont1@yahoo.com
15	New Zealand	Dr Paul Michael Hine Ministry of Agriculture and Fisheries NEW ZEALAND Tel: +64-4-526-5600; Fax: +64-4-526-5601 E-mail: hinem@maf.govt.nz

16	Philippines	Dr Joselito R. Somga, D.V.M. National Coordinator on Aquatic Animal Health Fish Health Section Bureau of Fisheries and Aquatic Resources Arcadia Building, 860 Quezon Avenue Quezon City, PHILIPPINES Tel: (632) 372 5055; Fax: (632) 372 5055 E-mail: somga@edsamail.com.ph
17	Philippines	Mr Mario G. Trio Fisheries Regulation Officer II Assistant Chief, Fisheries Quarantine Service (Designated) Fisheries Inspection and Quarantine Service Ninoy Aquino International Airport NAIA, Paranaque, Metro Manila, PHILIPPINES Tel: + 63 46 5021533; Mobile: 0916-3037972
18	Philippines	Mr Jose O. Paclibare Senior Aquaculturist, Fish Health Section Bureau of Fisheries and Aquatic Resources Arcadia Building, 860 Quezon Avenue Quezon City, PHILIPPINES Tel: (632) 372 5055; Fax: (632) 372 5055 E-mail: jopac@edsamail.com.ph
19	Singapore	Mr Hanif Loo Jang Jing Programme Executive (Good Farm Management) Aquaculture Branch, Food Supply and Technology Division Agri-food and Veterinary Authority 5 Maxwell Road #01-00 Tower Block MND Complex Singapore 069110, REPUBLIC OF SINGAPORE Tel: 65-67519838; Fax: 65-67523242 E-mail: LOO_Jang_Jing@ava.gov.sg
20	Singapore	Dr Chang Siow Foong Head, Epidemiology and Surveillance Branch Agri-food and Veterinary Authority of Singapore 5 Maxwell Road, #02-00 MND Tower Block Singapore 069110, REPUBLIC OF SINGAPORE Tel: 65 - 6325 7674; Fax: 65 - 6220 6068 E-mail: CHANG_Siow_Foong@AVA.gov.sg
21	Singapore	Dr Tay Choon Nghee Head, SPS Risk Monitoring and Planning Branch Agri-food and Veterinary Authority of Singapore 5 Maxwell Road, #02-00 MND Tower Block Singapore 069110, REPUBLIC OF SINGAPORE Tel: 65 - 6325 7674; Fax: 65 - 6220 6068 E-mail: TAY_Choon_Nghee@ava.gov.sg
22	Chinese Taipei	Prof. Chen Shiu Nan Professor, Department of Zoology National Taiwan University CHINESE TAIPEI Tel: 886-2-23642910; Fax: 886-2-23687122 E-mail: snchen@ccms.ntu.edu.tw
23	Thailand	Mr Amornchai Somjetlertcharoen Biologist, Aquatic Animal Health Research Institute Department of Fisheries Jatuchak, Ladyao, Bangkok 10900, THAILAND Tel: 0-2579-4122, 0-25796803; Fax: 0-2561-3993

24	Thailand	Mrs Thitiporn Laoprasert Biologist, Aquatic Animal Health Research Institute (AAHRI), Department of Fisheries Paholyothin Rd, Jatuchak, Bangkok 10900, THAILAND Tel: 66 2 5794122, 66 2 5796803; Fax: 66 2 5613993 Email: thitipop@fisheries.go.th
25	Thailand	Mrs Tanittha Chongpeepien Senior Fisheries Biologist Coastal Aquaculture Division Department of Fisheries Ministry of Agriculture and Cooperatives Jatuchak, Ladyao, Bangkok 10900, THAILAND Tel: 0-2561-4683, 0-2579-4762; Fax: 0-2561-3997
26	Thailand	Mr Somsak Tuntisaowapap Biologist, Freshwater Fisheries Division Department of Fisheries Jatuchak, Ladyao, Bangkok 10900, THAILAND Tel: 0-2565-0540-1; Fax: 0-2579-8560, 0-2562-0541
27	Thailand	Miss Kyssana Soponpong Head, Physical and Sensory Assessment Sub-Division Fish Inspection and Quality Control Division Department of Fisheries Kaset-klang, Chatuchak,Bangkok 10900, THAILAND Tel. 02-5580150-5 or 02-5580143; Fax. 02-5580136 Email: krissans@fisheries.go.th or krissana_s@yahoo.com
28	Thailand	Mrs Rajit Jala Fisheries Biologist, Fishery Resources Conservation Division Department of Fisheries 1st floor, Cherdchai Building Chatuchak, Bangkok 10900, THAILAND Tel: 0-2558-0196; Fax: 0-2558-0197 E-mail: rjala40@yahoo.com
29	USA	Mr Kevin Amos National Aquatic Animal Health Coordinator US Department of Commerce, NOAA National Marine Fisheries Service 8924 Libby RD NE Olympia, Washington 98506 USA Tel/Fax: +360-709-9001 E-mail: Kevin.Amos@noaa.gov
30	Vietnam	Ms Bui Thi Viet Hang Fisheries Resources and Environment Conservation Department Ministry of Fisheries 10 Nguyen Cong Hoan Ba Dinh, Hanoi, VIETNAM Tel: 84-4-8345953; Fax: 84-4-8353363
31	Vietnam	Mr Kim Van Van Researcher Research Institute for Aquaculture No. 1 (RIA 1) Dinh Bang, Tien Son Bac Ninh, Hanoi, VIETNAM Tel: +84-4-8780102; Fax: +84-4-8273070 E-mail: ria1@hn.vnn.vn; kimvanvan@hn.vnn.vn
32	Vietnam DANIDA (SUMA)	Ms Phan Thi Van Research Institute for Aquaculture No. 1 (RIA 1) Dinh Bang, Tien Son Bac Ninh, Hanoi, VIETNAM Tel: +84-4-8780102; Fax: +84-4-8273070 E-mail: phanvan@hn.vnn.vn

33	Vietnam DANIDA (SUMA)	Mr Le Hong Phuoc Research Institute for Aquaculture No. 2 (RIA 2) Ho Chi Minh City, VIETNAM Fax: + 08 8226807 E-mail: lehongphuoc@yahoo.com
	NACA Member Governments	
34	Bangladesh	Mr Bhuiyan Rafiuddin Ahmed Joint Secretary Ministry of Fisheries and Livestock Bangladesh Secretariat Dhaka, BANGLADESH Fax: 880-2-8611117; 880-2-8618182
35	Bangladesh	Mr Romesh Chandra Mondol Deputy Director, Shrimp Department of Fisheries Matchya Bhaban, Ramna Dhaka 1000, BANGLADESH Tel: +880-2-9561715; Fax: +880-2-9568393 E-mail: coates.business@usa.net
36	Cambodia	Mr Ouk Vibol Chief of Research Section, Aquaculture Division Department of Fisheries 186 Norodom Blvd, PO Box 582 Phnom Penh, CAMBODIA Tel No: (855-23) 210 565; 219 685 Fax No: (855-23) 210565; 219685 E-mail: smallfish@bigpond.com.kh; aims1@bigpond.com.kh
37	India	Dr Rehana Abidi Senior Scientist, National Bureau of Fish Genetic Resources Canal Ring Road, Tolibagh P.O. Dilkusha, Lucknow – 226 002 (U.P.), INDIA Tel: + 0522 442440 442441; Fax: + 0522 442403
38	Myanmar	Daw Hla Hla Kyu Chief Inspector (Physical Assessment) Staff Officer (Export Quality Control Section) Department of Fisheries Ministry of Livestock and Fisheries Ahlone Township, Sinmin Road Yangon, MYANMAR Fax: 095-01-228, 289711 E-mail: DOF@mptmail.net.mmat
39	Nepal	Mr Shankar Prasad Dahal Kathmandu Central Fish Hatchery Balaju, Kathmandu, NEPAL Tel: 977-01-350833, 350662, 360609 E-mail: dofd@mail.com.np
40	Pakistan	Dr Muhammad Hayat Assistant Fisheries Development Commissioner Ministry of Food, Agriculture and Livestock Government of Pakistan Block, Pak. Secretariat Islamabad, PAKISTAN Tel: +051 920 8267; Fax; +051 9221246

41	Sri Lanka	Mr H.A. Mahinda Kulathilaka Research Officer National Aquatic Resources Research and Development Agency, Ministry of Fisheries and Ocean Resources Crow Island, Mattakkuliya, Colombo -15, SRI LANKA Tel: 94-1-521000, 94-1-521006, Residence: 94-8-476634 Fax: 94-1-521932, 94- 1-524430, 94-1-521699 E-mail: hamkulathilaka@yahoo.com
	Consultants, Resource Speakers, Representative/s of Organizations	
42	Consultant (Canada)	Dr James Richard Arthur Professional Consultant 6798 Hillside Drive Sparwood, B.C. CANADA V0B 2G3 Tel: (250) 425 2287 E-mail: rarthur@titanlink.com
43	Consultant (Australia)	Dr Francis Christian Baldock Director, AusVet Animal Health Services PO Box 3180, South Brisbane, Queensland AUSTRALIA, QLD 4101 Tel: +61 7 3255 1712; Fax: +61 7 3511 6032 E-mail: chris@ausvet.com.au
44	Consultant (Spain)	Dr Christopher John Rodgers Professional Consultant Carrer Orde de Malta 10, 43540 San Carlos de la Rapita Tarragona, SPAIN Tel/Fax: +34 977 744660 E-mail: crodgers@terra.es
45	OIE Regional Representation for Asia and the Pacific	Dr Y. Ozawa Special Adviser OIE Regional Representation for Asia and the Pacific East 311, Shin Aoyama Building 1-1-1 Minami Aoyama, Minato-ku Tokyo 107-0062, JAPAN Tel: +81-3-5411-0520; Fax: +81-3-5411-0526 E-mail: oietokyo@tky.3web.ne.jp Home page: http://www.oie-jp.org
46	OIE Resource Speaker	Dr Noel J. Murray Veterinary Epidemiologist Swiss Federal Veterinary Office Schwarzenburgstrasse 161 Berne-Lieberfeld CH-3003 Berne, SWITZERLAND Tel: +41 31 3233042; Fax: +41 31 3239543 E-mail: noel.murray@bvet.admin.ch
47	Resource Speaker (Thailand)	Prof. Tim W. Flegel Centex Shrimp, Chalerm Prakiat Building Faculty of Science, Mahidol University Rama 6 Road Bangkok 10400, THAILAND Tel: (66-2) 201-5870 or 201-5871 or 201-5872 Fax: (66-2) 201-5873 E-mail: sctwf@mahidol.ac.th

48	Resource Speaker (Thailand)	Mr Dan Fegan National Center for Genetic Engineering and Biotechnology (BIOTEC), Shrimp Biotechnology Programme 18th Fl. Gypsum BuiLding Sri Ayuthya Road, Bangkok, THAILAND Tel: 662-261-7225; Fax:662-261-7225 E-mail: dfegan@usa.net
49	InterVet Norbio (Singapore)	Dr Zilong Tan Manager, Aquatic Veterinary Services Intervet Norbio Singapore Pte Ltd. 1 Perahu Road Singapore 718847, REPUBLIC OF SINGSPORE Tel: +65 6397 1121; Fax: +65 6397 1131 E-mail: Zilong.Tan@Intervet.com
50	Mekong River Commission (MRC)	Dr Nguyen Quoc An Programme Officer, Fisheries Programme Mekong River Commission Secretariat P.O. Box 1112 Phnom Penh City, KINGDOM OF CAMBODIA Tel: (855-23) 720 979 Ext. 4018; Fax: (855-23) 720 972 E-mail: an@mrcmekong.org
51	Secretariat of the Pacific Community (SPC)	Dr Stephen D. Angus Veterinary Epidemiologist Secretariat of the Pacific Community SPC, Private Bag, Suva, FIJI ISLANDS Tel: (679) 370733; Fax: (679) 370021 E-mail: SteveA@spc.int
52	AAHRI (Resource Speaker)	Dr Supranee Chinabut Director, Aquatic Animal Health Research Institute Department of Fisheries Kasetsart University Campus Jatujak, Ladyao, Bangkok 10900, THAILAND Tel: 662-5796803; Fax: 662-5613993 E-mail: supranee@fisheries.go.th
53	AAHRI (Resource Speaker)	Dr Somkiat Kanchanakhan Fish Virologist, Aquatic Animal Health Research Institute Department of Fisheries, Kasetsart University Campus Jatujak, Ladyao, Bangkok 10900, THAILAND Tel: 662-5796803; Fax: 662-5613993 E-mail: somkiatkc@fisheries.go.th
54	DoF Thailand Project Overseer	Dr Maitree Duwangsawasdi Deputy Director General Thai Department of Fisheries Department of Fisheries Compound Kasetsart University Campus Ladyao, Jatujak, Bangkok, THAILAND Fax: 662 562 0554 E-mail: maitreed@fisheries.go.th
55	NACA	Mr Pedro Bueno Director General Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Fax: (662) 561-1727; Tel: (662) 561-1728 to 9 ext. 114 E-mail: Pedro.Bueno@enaca.org

56	NACA	Dr Michael Phillips Environment Specialist Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Fax: (662) 561-1727; Tel: (662) 561-1728 to 9 ext. 115 E-mail: Michael.Phillips@enaca.org
57	NACA	Mr Yoothana Suansook Information and Communication Technology Specialist Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Fax: (662) 561-1727; Tel: (662) 561-1728 to 9 ext. 107 E-mail: ict@enaca.org
58	NACA (on secondment)	Dr Khamchai Lawonyawut Senior Fishery Biologist National Inland Fisheries Institute Department of Fisheries Kasetsart University Campus Jatujak, Bangkok 10900 THAILAND Tel and Fax 662-5794121 E-mail: khamchal@fisheries.go.th
59	Project Coordinator (NACA)	Dr Melba B. Reantaso Aquatic Animal Health Specialist Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Fax: (662) 561-1727; Tel: (662) 561-1728 to 9 ext. 113 E-mail: melba.reantaso@enaca.org; http://www.enaca.org

ANNEX II (B)

LISTS OF PARTICIPANTS

APEC 01/2002 "Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals" (Second Training Course/Workshop) 12-17 August, Fiesta Inn Hotel Mazatlán, Sinaloa, México

#		Name and Contact Details of Delegates/ Resource Speakers/Experts
APEC Economies/FAO Members		
1	Australia	Dr Peter Beers Manager, Aquatic Animal Biosecurity, Biosecurity Australia Department of Agriculture, Fisheries and Forestry – Australia (AFFA) GPO Box 858 Canberra, AUSTRALIA ACT 2601 Tel: +61 2 6272 5330 ; Fax: +61 2 6272 3399 E-mail: Peter.Beers@affa.gov.au
2	Belize	Andrea Reneau Fish Health Officer Belize Agricultural Health Authority Central Investigation Laboratory, Food Safety Department P.O. Box 181, St. Joseph Street Belize City, BELIZE Tel.: 501-224-4794; Tele/fax: 501-224-5230 E-mail: a_reneau@hotmail.com
3	Brasil	Leonardo Galli Technical Manager Tecnarao – Natal – RN Fazenda de Lord, Arez, BRASIL Tel: 084-242-2341; 084-982-3061; Fax: 0055-84-242-2341 E-mail: gallimat@hotmail.com
4	Brasil	Cleber Tailor Melo Cameiro Coordenador da CIA Departamento de Defesa Animal Secretaria de Defesa Agropecuaria de Ministerio de Agricultura, Pecuaria y Abastecimento Ministerio de Agricultura, Pecuaria y Abastecimento Esplanada dos Ministerios Bloco D Anexo/Ala A sala 432 Brasilia – Distrito Federal, BRASIL CEP : 70.043.900 Tel : 61 223 3316 ; 61 218 2259 ; Fax : 61 226 3515 E-mail : clebertm@agricultura.gov.br
5	Canada	Dr Gilles Olivier A/Manager, Aquaculture Division Department of Fisheries and Oceans 343 University Avenue Moncton, NB, CANADA E1C 9B6 Tel.: + 506-851-2054; Fax: + 506-851-2079 E-mail: OlivierG@dfo-mpo.gc.ca

6	Chile	Félix Inostroza Cortes Jefe de Departamento de Administración Pesquera (Head of Fisheries Administration Department) Servicio Nacional de Pesca (SERNAPESCA) Victoria N° 2832, Valparaíso, CHILE Tel: 56-32-819262; Fax: 56-32-819260 E-mail: finostroza@sernapesca.cl
7	Chile	José Miguel Burgos González Jefe del Departamento de Salud de Pesqueras (Head of Fishing Health Department) Servicio Nacional de Pesca (SERNAPESCA) Victoria N° 2832 Valparaíso, CHILE Tel: 56-32-819202; Fax: 56-32-819200 E-mail: jburgos@sernapesca.cl
8	Costa Rica	Dr Alvaro Otárola Fallas Jefe del Departamento de Acuicultura Instituto Costarricense de Pesca y Acuacultura (INCOPESCA) Guapiles, Estación los Diamantes Guapiles, COSTA RICA Tel: 763-3293; Fax: (506)296-2662 E-mail: otarosan@racsa.co.cr
9	Costa Rica	Felix Carranza Cubero Coordinador Nacional del Programa Sanitario de Acuicultura Ministerio de Agricultura y Ganadería Dirección de Salud Animal C.P. 3-3006 Cenaida Heredia, COSTA RICA Tel : 2608 300 ext. 2195-2038 ; Fax : 2620 221 E-mail : fcarranza@protecnet.go.cr
10	Colombia	Consuelo Vásquez Diaz Instituto Nacional de Pesca y Acuicultura (INPA) Diagonal 27 N° 15-09, Bogota D.C., COLOMBIA Tel: 340-2331; Fax: 340-2331 E-mail: consuvasquez@hotmail.com
11	Cuba	Raquel Siviera Coffigny Director of Division Aquatic Health Centro de Investigaciones Pesqueras 5ta Ave. y 246 Barlovento. Santa Fe. Playa. Ciudad Habana, CUBA Tel: 537-297875; Fax: 537 2049827 E-mail: raquel@cip.fishnavy.inf.cu
12	Ecuador	Leonardo Maridueña Camara Nacional de Acuacultura Av. Francisco de Orellana Centro Empresarial las Camaras, 3° Piso Guayaguil, ECUADOR Tel: 593-4-683017 ; Fax: 593-4-683019 E-mail: lmariduena@can-ecuador.com
13	El Salvador	Zobeyda Valencia de Toledo Centro de Desarrollo de la Pesca y la Agricultura (CENDEPESCA) Final 5ta. Av. Nte.y Av. Manuel Gallardo Nueva San Salvador, EL SALVADOR Tel: 503-228-1066; Fax: 503 228 0074 E-mail: zobeydavt@hotmail.com

14	Guatemala	Luis Arturo López Paredes Especialista en Acuacultura y Pesquerías Unidad de Manejo de la Pesca y Acuicultura (UNIPESCA) Km 22 Carretera. Pacífico Barcenas Villa Nueva Villanueva, GUATEMALA Tel: 6358230; 6367740 E-mail: unipesca@c.net.gt
15	Honduras	Francis Carolina Cardona Romero Dirección General de Pesca y Acuicultura Cd. Humuya Segunda Calle Norte Calzada Victoria Casa 1102, Tegucigalpa, HONDURAS Tel: 232-8600; Fax: 239 1994 E-mail: cardonaromero@yahoo.com
16	México-INP Mexican Project Coordinator	Dra. Ana Bertha Montero Rocha Coordinadora del Proyecto en México Investigadora del Instituto Nacional de la Pesca (INP) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Pitágoras 1320, Sta Cruz Atoyac, C.P.03310. MÉXICO D.F. Tel: 0052 55 5422 3053/ 5422 3054; Fax: 0052 55 5688 4014 E-mail anabmont@servidor.unam.mx o anabmont1@yahoo.com.mx
17	México – INP	Esteban Cabrera Mancilla Tecnología de Alimentos Instituto Nacional de la Pesca (INP) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Pitágoras 1320 Sta Cruz Atoyac, C.P.03310. MÉXICO D.F. Tel: 0052 55 5422 3053/ 5422 3054; Fax: 0052 55 5688 4014
18	México-SENASICA	Octavio Carranza De Mendoza Secretario Técnico de la Dirección en Jefe de SENASICA Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Amores No. 321 Piso 1 Col. Del Valle Delegación Benito Juárez C.P. 03100 MÉXICO D.F. Tel: 5543 2211 Fax: 5687 7938 E-mail:stec@conasag.sagar.gob.mx; octavio.carranza@sagarpa.gob.mx
19	México-CIESA	Dr Valente Velazquez Ordóñez Jefe de Vinculación y Desarrollo del CIESA Centro de Investigaciones y Estudios Avanzados en Salud Animal (CIESA) Universidad del Estado de México Km. 15.5 Carretera Toluca-Atlacomulco San Cayetano de Morelos, CP 50200 Toluca Edo. de México, MÉXICO Tel/Fax: 01 722 296 5555 E-mail: valentevelazquez@hotmail.com

20	México-SENASICA	Assad Heneidi Zekua Asesor del Dispositivo Nacional de Emergencia en Salud Animal Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Km. 15.5 Carretera México – Toluca Col. Palo Alto, Deleg. Cuajimalpa, C.P: 05110, MÉXICO D.F. Tel: 5543 2211, 5259 3035, 5259 1441, 5259 5048; Fax: 5687 7938 E-mail: sive.dgsa@sagarpa.gob.mx
21	México-SENASICA	Leticia Vivas Enríquez Departamento de Análisis de Riesgos Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Guillermo Pérez Valenzuela No. 127, Col Del Carmen Coyoacán, Delg. Coyoacán, C.P. 04100, MÉXICO D.F. Tel/Fax. 5554 0341, 5554 0349 ext 273 Fax 5658 5402 E-mail: bpa@senasica.sagarpa.gob.mx o letyvivas@yahoo.com.mx
22	México-SENASICA	Mayren Cristina Zamora Nava Responsable de Inocuidad Acuícola y Pesquera Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Guillermo Pérez Valenzuela No. 127, Col Del Carmen Coyoacán, Deleg. Coyoacán, C.P. 04100, MÉXICO D.F. Tel/Fax. 5554 0341, 5554 0349 ext 273 Fax 5658 5402 E-mail mayrenz@yahoo.com.mx o bpa@senasica.sagarpa.gob.mx
23	México – CRIP, Mazatlán	Ing. Teodosio Pacheco Jefe del Programa de Aseguramiento de Calidad Centro Regional de Investigaciones Pesqueras Unidad Mazatlán (CRIP) Calzada Sábalo-Cerritos S/N Colonia estero El Yugo Mazatlán, Sinaloa, C.P: 82010 MÉXICO Tel:01 669 988 002; Fax: 01 669 988 0049 E-mail: tpachecq@red2000.com.mx
24	México – CRIP, Mazatlán	Flor Delia Estrada Investigador Centro Regional de Investigaciones Pesqueras Unidad Mazatlán (CRIP) Calzada Sábalo-Cerritos S/N Colonia estero El Yugo Mazatlán, Sinaloa, C.P: 82010 MÉXICO Tel: 01 669 988 002; Fax: 01 669 988 0049 E-mail: flor@ola.icmyl.unam.mx
25	México – CRIP, Mazatlán	Vicente Hernández Covarrubias Investigador (Técnico Asociado) Centro Regional de Investigaciones Pesqueras Unidad Mazatlán (CRIP) Calzada Sábalo-Cerritos S/N Colonia estero El Yugo Mazatlán, Sinaloa, C.P: 82010 MÉXICO Tel:01 669 988 0002; Fax: 01 669 988 0049 E-mail: videz44@hotmail.com; videz@hotmail.com

26	México – CRIP/INP Mazatlán	Víctor González Gallardo Director del Centro Regional de Investigación Pesquera en Mazatlán Centro Regional de Investigaciones Pesqueras Unidad Mazatlán (CRIP) Calzada Sábalo Cerritos S/N Col. Estero el Yugo Mazatlán, Sinaloa, C.P: 82010 MÉXICO Tel: 988 0002; Fax: 988 0049 E-mail: vglezga@yahoo.com , cripmaz@red2000.com.mx
27	México– CONAPESCA, Mazatlán	Luis Contreras Flores Subdirector de Sanidad Acuícola Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinaloa, C.P. 82100 MÉXICO Tel: 01 669 913 0891; Fax: 01 669 913 0890 E-mail: lcontreras47@terra.com.mx
28	México– CONAPESCA, Mazatlán	Lucia Rosas Ortiz Área de Normatividad Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinaloa, C.P. 82100 MÉXICO Tel: 01-669 913 0926; Fax: 01 669 913 0921 E-mail: lrosas55@hotmail.com
29	México SAGARPA	Yahaira Blanquel Rojo Jefe del Departamento de Fomento Pesquero Delegación Federal de SAGARPA en Morelos Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Universidad No. 5 1er piso. Col. Santa María Ahuacatitlan Cuernavaca Morelos C.P. 62100, MÉXICO Tel/Fax: 777 313 6189 Mor_subg@sagarpa.gob.mx o y_blanquel@yahoo.com.mx
30	México - CINVESTAV	Dra. Rossana Rodríguez Investigador del Departamento de Recursos del Mar Centro de Investigaciones y Estudios Avanzados del Instituto Politécnico Nacional (CINVESTAV) Km 6 Carretera Antigua a Progreso C.P. 97310 Mérida Yucatán, MÉXICO Tel: + (999) 981 – 2973, Fax: 01 999 981- 2334
31	México – CIAD, Mazatlán	Dr Cristina Chávez Sánchez Investigador (Researcher) Centro de Investigación Alimentación y Desarrollo (CIAD) Unidad Mazatlán en Acuicultura y Manejo Ambiental del CIAD, A.C Av. Sábalo-Cerritos s/n. Apdo postal 711. CP. 82010, Mazatlán, Sinaloa, MÉXICO Tel: + (669) 988 01 57; 988 01 58; Fax: + (669) 988 01 59 E-mail: marcris@victoria.ciad.mx
32	México – CIAD, Mazatlán	María Eugenia Ménez Robles Centro de Investigación Alimentación y Desarrollo (CIAD) Unidad Mazatlán en Acuicultura y Manejo Ambiental del CIAD, A.C Av. Sábalo-Cerritos s/n. Apdo postal 711. CP. 82010, Mazatlán, Sinaloa, MÉXICO Tel: + (669) 988 01 57; 988 01 58; Fax: + (669) 988 01 59

33	México – Sector Privado	Anabel Leyva Rojo Jefe de Área Super Shrimp S.A. de C.V. Av. Camarón Sábalo No. 310 Loc. 25 y 26 C.P. 82110 Zona Dorada, Mazatlán, Sinaloa, MÉXICO Tel: + (669) 912 4640; Fax: +669 914 00
34	México	Eliézer Gallardo Valenzuela Oficial de Sanidad del Comité Estatal de Sanidad Ciudad Obregón Sonora, MÉXICO Tel: 01 (6444) 1508-05; Fax: 01 (6444) 1508-06
35	México	José Luis Martínez Grijalva Oficial de Sanidad del Comité Estatal de Sanidad Ciudad Obregón Sonora, MÉXICO Tel: 01 (6444) 1508-05; Fax: 01 (6444) 1508-06
36	México	Jesús Miguel Urrea Salazar Oficial de Sanidad del Comité Estatal de Sanidad Ciudad Obregón Sonora, MÉXICO Tel: 01 (6444) 1508-05;Fax: 01 (6444) 1508-06
37	México	Hugo Iván Reyes Castro Oficial de Sanidad Acuícola del Comité Estatal de Sinaloa MÉXICO Tel: 01 6699 982 8721;Fax: 01 6699 982 0891
38	Nicaragua	Lucia Saavedra Cuadra ADPESCA/MIFIC Contiguo Hotel Camino Real Metrocentro, NICARAGUA Tel: 2700956/2650592 E-mail: liscni26@yahoo.com
39	Panamá	Milton Moreno Tuñón Director nacional de Acuicultura Ministerio de Desarrollo Agropecuario Apdo. Postal 5390 Zona 5 REPÚBLICA DE PANAMÁ Tel: (507) 9984 700; Fax: (507) 2293 332 E-mail: kristin@cerco.net
40	Perú	Enrique Mateo Salas Asesor Científico Instituto del Mar del Perú (IMARPE) Esquina de Gamarra y Gral. Valle – Chucuito Callao, PERÚ Tel: 51 1 4297630 E-mail: ecmateo@millicom.com.pe, emateo@imarpe.gob.pe
41	Perú	Jorge Alberto Llanos Urbina Director Nacional de Acuacultura (National Aquaculture Director) Ministry of Fisheries Av. Aviación 3486-402 San Borja, Lima, PERÚ Tel: 51-1 224-3247; Fax: 51-1 224-3247 E-mail: dna@minpes.gob.pe; jllanos@minpes.gob.pe
42	Thailand	Dr Supranee Chinabut Director, Aquatic Animal Health Research Institute (AAHRI) Department of Fisheries Kasetsart University Campus Jatujak, Ladyao, Bangkok 10900, THAILAND Tel: 662-5796803; Fax: 662-5613993 E-mail: supranee@fisheries.go.th

43	Venezuela	Melida Boada Instituto Nacional de Investigaciones Agrícolas de los Estados Suere y Nueva Esparta (INIA-S/NE) Av. Carupano sector Caiguire, Cumana 6101, VENEZUELA 58 2934317557 Tel: 58-293-43117557; Fax: 58-293-4317427 E-mail: melidaboada@yahoo.es
44	USA	Kevin Amos National Aquatic Animal Health Coordinator US Department of Commerce, NOAA National Marine Fisheries Service 8924 Libby Road NE Olympia, Washington 98506 USA Tel/Fax: +360-709-9001 E-mail: Kevin.Amos@noaa.gov
45	USA	Allan Heres PhD candidate University of Arizona, Tucson 4900 E. 5th Street, # 1112 Tucson, Arizona 85711, USA Tel: 520-621-4438 E-mail: aaheres@aol.com
46	USA	Colin McIff Senior Global Fisheries Officer U.S. Department of State Room 5806 2201 C Street NW Washington, DC, 20520, USA Tel : + 202-647-4824 ; Fax : + 202-736-7350 E-mail : dcmciff@home.com; McIffCL@state.gov; Mciffcl@state.gov
Consultants, Resource Speakers, Representative/s of Organizations		
47	Consultant (Canada)	Dr James Richard Arthur Professional Consultant 6798 Hillside Drive Sparwood, B.C. CANADA V0B 2G3 Tel: (250) 425 2287 E-mail: rarthur@titanlink.com
48	Consultant (Australia)	Dr Francis Christian Baldock Director, AusVet Animal Health Services PO Box 3180, South Brisbane Queensland, AUSTRALIA QLD 4101 Tel: +61 7 3255 1712; Fax: +61 7 3511 6032 E-mail: chris@ausvet.com.au
49	Consultant (Spain)	Dr Christopher John Rodgers Professional Consultant Carrer Orde de Malta 10, 43540 San Carlos de la Rapita Tarragona, SPAIN Tel/Fax: +34 977 744660 E-mail: crodgers@terra.es
50	FAO	Dr Rohana P. Subasinghe Senior Fishery Resources Officer (Aquaculture) Inland Water Resources and Aquaculture Service Fishery Resources Division, Fisheries Department Food and Agriculture Organization of the UN Viale delle Terme di Caracalla 00100 Rome, ITALY Tel: + 39 06 570 56473; Fax: + 39 06 570 53020 E-mail: Rohana.Subasinghe@FAO.Org

51	FAO	Dr Victoria Alday de Graindorge Regional Coordinator TCP/RLA/0071 "Asistencia para el manejo sanitario del cultivo de camarón en América" Avenue de l'Aurore 8 1330 Rixensart, BELGIUM Tel: + 32 2 6539409; Fax: 32 2 6539409 E-mail: Victoria_alday@yahoo.com
52	OIE (Resource Speaker)	Prof. Barry J Hill Chief Advisor for Fish and Shellfish Health Centre for Environment, Fisheries and Aquaculture Science (CEFAS) CEFAS Weymouth Laboratory Barrack Road, Weymouth, Dorset DT4 8UB UNITED KINGDOM Tel: +44 1305 206625; Fax: +44 1305 206627 E-mail: b.j.hill@cefas.co.uk
53	OIE (Resource Speaker)	Dr Francke C.J. Berthe Scientist Institut Francais de Recherche Pour l'Exploitation de la Mer (IFREMER) In Charge of EU and OIE Reference Laboratory for Mollusc Diseases Laboratorie de Genetique et Pathologie BP 133, 17 390 La Tremblade, FRANCE Tel: + 33 5 46 99 0197; Fax:33 5 46 36 3751 E-mail: fberthe@ifremer.fr
54	Resource Speaker (Thailand)	Dan Fegan National Center for Genetic Engineering and Biotechnology (BIOTEC), Shrimp Biotechnology Programme 18th Fl. Gypsum Buidling Sri Ayuthya Road Bangkok, THAILAND Tel/Fax: + 662-261-7225 E-mail: dfegan@usa.net
55	OIRSA (Organismo Internacional Regional de Sanidad Agropecuaria)	Dr Ronald Antonio Bernal Guardado Oficial Agrosanitario Representación OIRSA en El Salvador Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA) Final 1ª. Av. Nte. Y 13 C. Ote., Av. Manuel Gallardo Nueva San Salvador, EL SALVADOR, C.A. Tel: 503-2287899, 2287841; Fax: 503-2287823 E-mail: rbernal@telemovil.com
56	DOF Thailand Project Overseer	Dr Maitree Duangsawasdi Deputy Director General Thai Department of Fisheries Department of Fisheries Compound Kasetsart University Campus Ladyao, Jatujak, Bangkok, THAILAND Fax: 662 562 0554; Tel: 662 562 0524 E-mail: maitreed@fisheries.go.th
57	NACA (Project Contractor)	Mr Pedro Bueno Director General Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Tel: (662) 561-1728 to 9 ext. 114; Fax: (662) 561-1727 E-mail: Pedro.Bueno@enaca.org

58	NACA (Resource Speaker)	Dr Michael Phillips Environment Specialist Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Tel: (662) 561-1728 to 9 ext. 115; Fax: (662) 561-1727 E-mail: Michael.Phillips@enaca.org
59	Project Coordinator (NACA)	Dr Melba B. Reantaso Aquatic Animal Health Specialist Network of Aquaculture Centres in Asia-Pacific (NACA) Suraswadi Bldg., DOF Complex Kasetsart University Campus Ladyao, Jatujak, Bangkok 10900 THAILAND Tel: (662) 561-1728 to 9 ext. 113; Fax: (662) 561-1727 E-mail: melba.reantaso@enaca.org; http://www.enaca.org
Local Mexican Organising Team (SAGARPA/CONAPESCA/INP) and Guests of Honor		
60	Dr Jerónimo Ramos Sáenz Pardo	Comisionado Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sin. C.P. 82100 MÉXICO Tel: 6699 130909; Fax: 6699 130907 E-mail: Jramos.cnap@sagarpa.gob.mx
61	Dr Guillermo Compeán Jiménez	Director en Jefe del Instituto Nacional de la Pesca (INP) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Pitágoras 1320. Col. Santa Cruz Atoyac. Deleg. Benito Juárez, C.P. 03310 México D.F, México Tel: 55 5688 1469; Fax: 55 5688 8418 E-mail: compean@inp.semarnap.gob.mx
62	Dr Javier Trujillo Arriaga	Director en Jefe del Servicio Nacional de Sanidad, Inocuidad y Calidad Agro-Alimentaria (SENASICA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Amores No. 321 Piso 1 Col. Del Valle, Delegación Benito Juárez C.P. 03100 MÉXICO D.F. Tel.: 5687 1081, 5687 7954; Fax: 5687 7938 E-mail: stec@senasica.sagarpa.gob.mx
63	Lic. Gerardo Rossete Ramírez	Presidente Municipal de Mazatlán Ángel Flores y Guillermo Nelson s/n Col. Centro. C.P. 82000 Mazatlán, Sinaloa, MÉXICO Tel: +669 9 82 21 11 ext. 2110, +669 985 35 77 Fax: + 669 982 50 71 ext. 2115
64	Ing. Rubén Ocaña Soler	Director General de Planeación, Programación y Evaluación Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinaloa, C.P. 82100 MÉXICO Tel: 6699 130931; Fax: 6699 130930 E-mail: rocana@conapesca.sagarpa.gob.mx

65	Ocean. Alfredo Herrera Mesina	Director General de Organización y Fomento Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sin. C.P. 82100 MÉXICO Tel: 6699 130891; Fax: 6699 130890 E-mail: aherrera@sagarpa.gob.mx
66	Dr Carlos Rangel Dávalos	Director General de Investigación en Acuacultura Instituto Nacional de la Pesca (INP) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Pitágoras 1320, Col. Santa Cruz Atoyac, Deleg. Benito Juárez, CP 03310, Ciudad de México, MÉXICO Tel.: 55 5422 3014, 5422 3053, 5422 – 3054; Fax: 55 5688 4014 E-mail: crangel@uabcs.mx
67	Ricardo Belmontes Acosta	Director de Asuntos Pesqueros Internacionales Representante de México ante el FWG APEC Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinaloa, C.P. 82100 MÉXICO Tel : 669 913 – 09229 ; Fax : 669 913 - 0937 E-mail: rbelmontes@hotmail.com
68	Verónica Esquivel Medina	Departamento de Acuerdos Comerciales Internacionales Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinaloa, C.P. 82100 MÉXICO Tel : + 669 913 – 09229 ; Fax : 669 913 - 0937 E-mail : faie2000mx@yahoo.com.mx
69	Nelly Avendaño Ortiz	Departamento de Acuerdos Europa, Canadá y Estados Unidos Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinaloa, C.P. 82100 MÉXICO Tel : + 6699 130929 ; Fax : 6699 130903 E-mail: jordynell@yahoo.com
70	Biol. José Antonio Portilla Livingstone	Subdirector de Fomento Pesquero y Capacitación Comisión Nacional de Acuacultura y Pesca (CONAPESCA) Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) Av. Camarón Sábalo S/N Esquina Tiburón. Col. Sábalo Country Mazatlán, Sinalao, C.P. 82100 MÉXICO Tel : 6699 130892 ; Fax : 6699 130891 E-mail: jporliv2002@yahoo.com.mx jportillal@conapesca.sagarpa.gob.mx
71	Translator	María Grimmer Cedros No. 108 y V.E. Estrada Tel: 238 37 28

Annex III

Working Group Recommendations

Annex III(A)(i)

Group 1: Policies/Regulatory Frameworks Governing Trade, Health Certification, Quarantine, Competent Authority, as part of Aquatic Animal Health Management

Terms of Reference: Working Group 1 will discuss matters pertaining to policies and regulatory frameworks governing trade (domestic and international), health certification and quarantine procedures, competent authorities on IRA, the IRA process in health management and other policy development requirements. Working Group 1 will try to evaluate the problems/limitations (e.g. capacity, policy) in the practical implementation of the IRA process and make suggestions for what can be done to overcome constraints, improving current situation, and identifying mechanisms for private sector (exporter/importer/ other stakeholder participation) and expert cooperation and involvement in supporting responsible trade in aquatic animals.

Working Group Members: Peter Beers, Noel Murray, Kevin Amos, Dan Fegan, Somkiat Kanchanakhan, Xiong Chen, Kyssana Soponpong, Daw Hla Hla Kyu, Stephen Angus, Muhammad Hayat, Budi Sugianti, Mario Trio, Tay Choon Nghee, Badariah bt Mohd Ali, Rajit Jala, Nguyen Quoc An, Bhuiyan Rafiuddin Ahmed, Kamchai Lawonyawut, Bui Thie Viet Hang

WHY?

- Encourage safe trade
- Improve national/regional aquatic animal health status
- Increased productivity, food security, resource/ environment protection, promotion of social wealth/welfare
- Recognise commonality of economies' concerns
- Importance of aquaculture in economies
- WTO/SPS issues
- Science-based decisions

THE VISION – WHAT?

- Regulatory/legal framework
  - Ability to implement
  - Transparency
- Education/Awareness of producers
  - Farmer networks, processors, regulatory officers
- Infrastructure
  - Laboratories
  - Information systems
- Harmonisation of international codes/guidelines
- Stakeholder consultation in decision making, upward/downward exchange of information and encourage organization of farmer groups/networks
- Networking and capacity building among regional experts/regulatory officers, etc.

HOW?

- Legal Framework
  - Import/Export
  - Competent Authority (Capability/Capacity)
  - Resource Documents
  - Certification Procedures
  - Regional harmonisation
- Capacity Building and Strengthening all levels, promoting teamwork not duplication
  - Upgrade and improve diagnostic capabilities and facilities

- Alternate sources
  - Budget constraints
  - FAO, JICA, UNDP, AusAID, DFID, DANIDA, USAID, etc.
  - Own sources
  - Private sector
- Regional networking/feedback and cooperation
  - Regional information databases
  - Resource materials
  - Improve computer access
- Workshop in practical use
- Surveillance, monitoring, zoning, competent authority evaluation, survey design, quality assurance, import risk analysis, certification procedures, guidelines
- Review of implementation

CONSTRAINTS

- Absence of legal framework in some countries and overly complex in some
- Lack of enforcement
- Lack of awareness
- Lack of adequate resources
- Lack of political motivation/willingness
- Lack of trained staff
- Lack of transparency or infrastructure to be transparent
- Need for improving cooperation between agencies
- Need for improved communication between government and private sector

RECOMMENDATIONS

- An appropriate legal framework should be eveloped and/or implemented to ensure protection and sustainability of aquatic resources and to support trade in aquatic animals and their products through NACA/APEC/OIE. Regional economies will work together to assist each other in achieving this objective;
- APEC/NACA should recognize the need for capacity building and strengthening of regional economies. Members will cooperate and advise each other in achieving this need.
- APEC/NACA economies and member governments should harmonise their SPS measures on international standards, or if international standards are not appropriate to their circumstance, than IRA should be used to develop alternative measures.
- Economies, as appropriate, should develop and implement policies that facilitate transparency and awareness of their measures to protect the aquatic environment and facilitate trade.
- As appropriate, lead administrators and scientists should meet regularly to facilitate regional harmonization, regional coordination and information exchange, so as to facilitate safe trade, the improvement of aquatic animal health status, capacity building and strengthening.
- Urgent convening of fora to harmonise certification, diagnostic methods, methods for the safe trade in aquatic animals and their products; and develop regional plans to control pests and diseases of aquatic animals to the mutual benefit of member economies to facilitate regional trade.

Annex III(A)(ii)

Group 2: National Level Requirements for implementing IRA for aquatic animal: research, diagnostics, surveillance/reporting, zoning, information, epidemiology, networking

Term of Reference: Working Group 2 will look at requirements for implementing an IRA with respect to research, diagnostics, surveillance/reporting/zoning, epidemiology and other health information needs as well as training needs' and mechanisms for networking both at national and regional levels.

Working Group Members: Chris Baldock, Gilles Olivier, Tim Flegel, Supranee Chinabut, Widodo, Ana Montero, Joselito Somga, Le Hong Phuoc, Romesh Chandra Mondol, Fauzidah bt. Othman, Thitiporn Laoprasert, Kam Van Van, Mahinda Kulathilaka, Fan Xiangguo, Hanif Loo Jang Jing, Tanittha Chongpeepien, Rehana Abidi, Norihisa Oseko, Sung Hee Jung

METHODS

The group began by beginning with the statement:

"Within ? years, all countries in the region should be able to provide disease status information to a specified standard to include ? diseases"

This statement was used as a point for discussion to come up with the following recommendations:

RECOMMENDATIONS

A. Surveillance

- An improved capability should be in place within 2-3 years – this refers to human resources, expertise and facilities
- This should be based on the OIE disease list plus those of concern to the particular country
- Standard methods should be developed for surveillance:
  - Design of data sheets
  - Survey methods
  - Data analysis
  - Reporting standards for OIE, NACA; national websites, etc.
- Expectations of surveillance – more reliable information about the distribution of specified diseases and temporal patterns.

B. Diagnostics

- Based on OIE, NACA and specific country surveillance requirements, each country should produce a list of specified diseases which are important to that country with regard to exports and imports.
- Methods used need to follow the three levels of diagnosis specified in previous NACA recommendations (i.e., Level I, II and III) with a focus on rapid diagnostic methods.
- Countries should specify their present position with respect to their specified list of diseases.
- All countries should be moving to improve diagnostic capabilities to be able to provide the level of diagnosis necessary to support exports and provide more reliable information about imports. The goal should be that all countries in the region should be able to make diagnoses at Level II standard within 3-5 years.
- Diagnostic methods should be standardised within the region, to follow international standards where these are available.
- This will require support from OIE, NACA, national governments and other organisations to provide improvements to laboratory facilities, training and exchange of scientists.
- This will then lead to improvements in the reliability of international reporting.

C. Research

- An increased capacity for research is required in the region.
- This should be directed to improving methods of surveillance and diagnosis to improve the quality of disease reporting with an emphasis on rapid diagnostic techniques.
- Again, support and standards will be required from OIE, NACA, national governments and aid agencies.
- Each country will need to prioritise (list in order of importance) its needs in this area with respect to diagnostic methods applicable to the country needs.
- Interchange of ideas among researchers within the region should be encouraged.

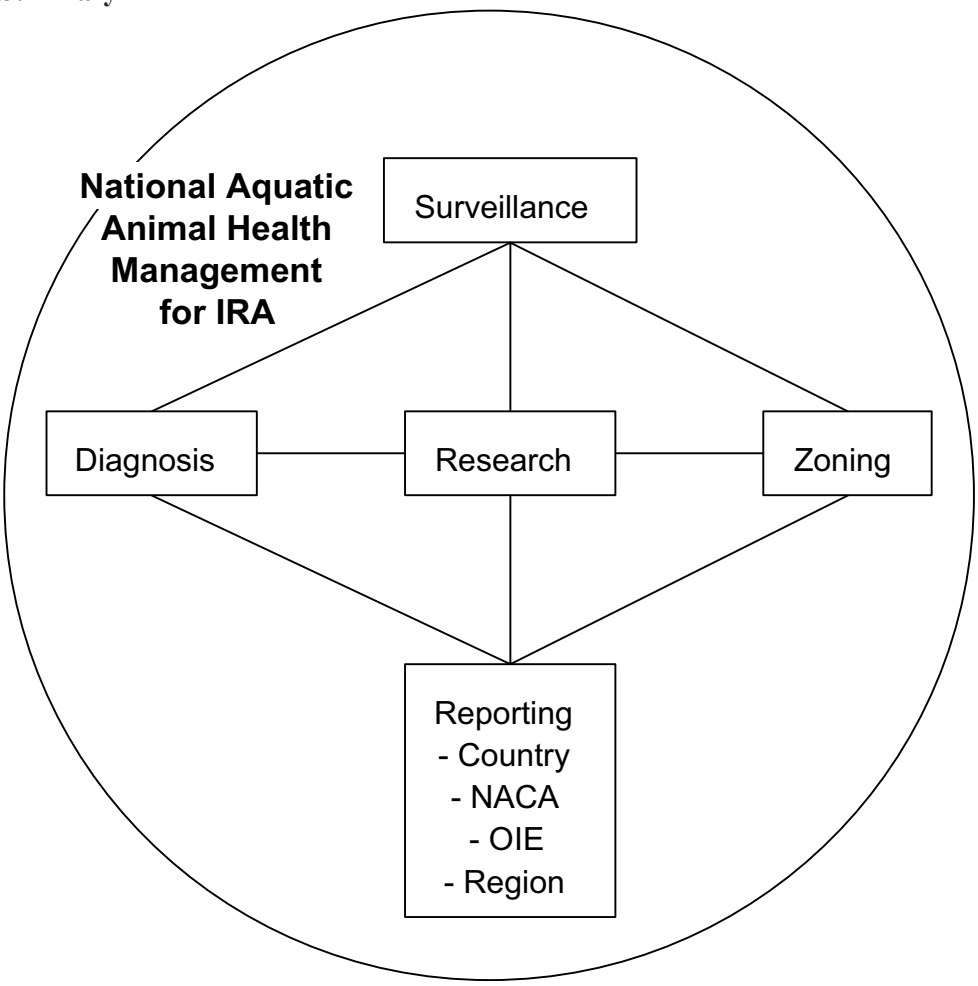
D. Networking

- This should be focussed through NACA within the region.
- Within the country, networking among different organisations such as universities, departments of fisheries etc should be encouraged.

E. Zoning

- This should always be supported by evidence of diagnostic capabilities and surveillance information.

Summary



Annex III(A)(iii)

Group 3: Outline/Framework for an IRA Manual for Aquatic Animals

Terms of Reference: Working Group 3 will look at a possible outline/framework for the development of an IRA Manual on Aquatic Animals that will provide guidance to APEC economies

Working Group Members: J. Richard Arthur, Chris J. Rodgers, Ramesh Perrera, Mike Hine, Melba B. Reantaso, Jose O. Paclibare, Siow Foong Chiang, Zilong Tan, Phan Thi Van, Amornchai Somjetlertcharoen, Pradit Sripatrprasite, Louise Li Wai-Hung, Ouk Vibol, Shankar Prasad Dahal

RECOMMENDATIONS

A. Time-Frame

- Draft Outline to Participants by mid-May
- Another interim draft
- Final outline by July (in time for the Mexico workshop)
- Finalisation by July 2003
- Final Publication by September 2003 (print, CD-Rom, web-uploadable version)
- Draft to all participants: get wider audience to proof-read

B. Responsibilities

- Consultants with input from member governments; working group composed of Richard Arthur, Mike Hine, Jose Paclibare and Melba Reantaso to further develop the outline via e-mail; all participants required essential information/feedback
- Presentation of outline during the Mexico workshop in August and as an attachment of the Draft Report to APEC FWG 13 in Lima, Peru

C. Further notes regarding the content

- Fictitious hosts
- Not to identify specific countries
- Outline key differences between terrestrial and aquatic IRAs
- Include definitions
- Need for some examples/go-buys at every stage – particularly pathways – range of representative scenarios including new spp. introduction, volume of trade, disease agents

ANNEX 3(A)(iii) – Attachment 1

DRAFT OUTLINE:
Practical Handbook on Risk Analysis[1] for Aquatic Animals

Copyright/Citation
Preparation of Document
Preface/Foreword
Abstract
List of Acronyms
Acknowledgements
Table of Contents
Glossary
Introduction
- Purpose
- Scope
- Guide for Users
- The Broad Picture – Benefits and Costs of Risk Analysis
- Protecting National Biological Resources
  - International Standards and Trade Agreements and Responsibilities
  - Legislative and Policy Issues
  - Economics of Risk Analysis

Overview of the Risk Analysis Process
- What is Risk Analysis
- Components of a Risk Analysis
- How to Start
- Scoping a Risk Analysis
  - Routine Vs Non-Routine Risk Analysis
  - Qualitative and Quantitative Approaches to Risk Analysis
  - The Precautionary Approach
  - The Risk Analysis Project Team
- Risk Communication

Transparency
Identification of Stakeholders
Means of Risk Communication
- Hazard Identification
  - Hazard Identification Criteria
  - Guide Questions
- Risk Assessment
  - Release Assessment
  - Exposure Assessment
  - Consequence Assessment
  - Risk Evaluation
    - Appropriate Level of Protection
- Competent Authority
  - Zoning and Regionalization
  - Surveillance and Monitoring

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[1]The Bangkok Workshop (April 2002) participants are in general agreement to use the term International Trade Risk Analysis (ITRA), however the term Risk Analysis is being used in this DRAFT OUTLINE for the time being subject to further consultation during the Mexico workshop (August 2002). This DRAFT OUTLINE will undergo several iterations.

Annex III(B)(i)

Working Group 1: Policies/Regulatory Frameworks Governing Trade, Health Certification, Quarantine, Competent Authority, as part of Aquatic Animal Health Management

Terms of Reference: Working Group 1 will discuss matters pertaining to policies and regulatory frameworks governing trade (domestic and international), health certification and quarantine procedures, competent authorities on IRA, the IRA process in health management and other policy development requirements. Working Group 1 will try to evaluate the problems/limitations (e.g. capacity, policy) in the practical implementation of the IRA process and make suggestions for what can be done to overcome constraints, improving current situation, and identifying mechanisms for private sector (exporter/importer/ other stakeholder participation) and expert cooperation and involvement in supporting responsible trade in aquatic animals.

Working Group Members: Octavio Carranza, Luis Contreras, Vicente Hernández, Leticia Vivas Enriquez, Consuelo Vasquez, Zobeyda Valencia, Lucía Saavedra, Francis C. Cardona, Félix Carranza, Cléber Taylor, Felix Inostroza, Jorge Urbina, Ronald A. Bernal, Chris Baldock, Peter Beers, O. Guilles, Barry Hill

RECOMMENDATIONS:

- Adopt regional guidelines for the enforcement of an IRA, in accordance with OIE regulations.
- Review the Guidelines set out by OIRSA in a regional context.
- Harmonize certification procedures.
- Promote the implementation of a national network of diagnostic laboratories.
- Establish a specific authority for aquacultural health.
- Harmonize quarantine procedures.
- Urge the private sector and research institutions to participate.
- Establish mechanisms for regional coordination.
- Organize technical and financial support by international, regional and sub-regional organizations for the implementation of these mechanisms for coordination.

Annex III(B)(ii)

Group 2: National Level Requirements for implementing IRA for aquatic animal: research, diagnostics, surveillance/reporting, zoning, information, epidemiology, networking

Term of Reference: Working Group 2 will look at requirements for implementing an IRA with respect to research, diagnostics, surveillance/reporting/zoning, epidemiology and other health information needs as well as training needs' and mechanisms for networking both at national and regional levels.

Working Group Members: María Eugenia Menez, Esteban Cabrera, Rossana Rodríguez, Assad Heneidi, Flor Estrada, Valente Velázquez, Anabel Leyva, Leobardo Montoya, Ana Montero, Álvaro Otárola, Leonardo Galli, Enrique Mateo, Milton Moreno, Raquel Silveira, Andrea Reneau, Leonardo Maridueña, José Miguel Burgos, Chris Rodgers

RECOMMENDATIONS:

A. General framework

- Facilitate the creation of risk analysis units by national authorities.
- Improve the links between animal health authorities and aquatic animal health authorities.
- Promote and strengthen the implementation of IRAs at national and local level.
- Create a workgroup concerned with the health of aquatic animals within the regional framework of the OIE.
- Promote the application of the SPS principles of the WTO
- Develop standards in those countries that do not have legislation regarding the health of aquatic animals which will favour the implementation of surveillance and control.

B. Research

- Direct and promote research according to the needs of the regulatory authorities.
- Increase the research capacity in these countries, in order to be able to have sufficient information to develop health programs.
- Implement a system of links between research centres.
- Promote research into alternative diagnostic techniques.
- Estimated time for implemetation: three years.

C. Surveillance systems

- Develop official programs of epidemiological surveillance, oriented towards the detection of diseases and pathogens, which will enable a deeper knowledge of the health situation in these countries.

D. Diagnostics

- Improve diagnostic capacity in the countries of the region.
- Strengthen work systems in accredited laboratories and recognized techniques (OIE).
- Improve the technical capacity of professionals in this field.
- Improve collaboration and exchange of information between these countries.

E. Zonification

- Promote collaboration between the state, the private sector, and research and development centers.
- Financial support in order to establish zonification (development of databases, and geographical, research etc. systems).

F. Networks and operating systems

- Promote the creation of a regional aquaculture network that will allow the exchange of information on health, environment and production.
- Promotethe exchange of experience and specialists between the different countries.
- Create groups of experts (health, environment, laboratories, and feed quality).
- The network must consider creating a system based on health, epidemiological and production data.

G. Education and training

- Education and training of human resources in the area of:
  - IRA
  - Epidemiology
  - Diagnostics
  - Health management

Annex III(B)(iii)

Group 3: Outline/Framework for an IRA Manual for Aquatic Animals

Terms of Reference: Working Group 3 will look at IRA Manual Draft Outline from the Bangkok Workshop.

Working Group Members: Teodosio Pacheco, Luis A. López, Cristina Chavéz, Mélida Boada, Kevin Amos, Dan Fegan, Richard Arthur, Allan Heras, Franck Berthe, Michael Phillips

RECOMMENDATIONS

- The handbook should be translated into Spanish and other languages as required.
- Suggested title - "Practical Handbook on Risk Analysis for Trade in Aquatic Animals".
- Explain IRA etc in preface so that it is clear that the issue is relevant to both exporting and importing countries.
- The title should reflect products as well as animals – could be explained in glossary – OIE Code has definitions for aquatic animals and aquatic animal products. OIE definition does not include amphibians, reptiles, birds or marine mammals. Need discussion on variations in terms and mention amphibians, reptiles and marine mammals.
- "Guide for users" – change name to "Who should read this manual". Add industry stakeholders to list.
- Add reference to relevant websites in annexes.
- Add "risk estimation" to risk assessment steps.
- Add sections on populations at risk (exporting and importing country) and nature of proposed trade including use of product.
- For each hazard identified, use headings from AAPQIS to summarize before proceeding with release assessment. This list may need modification.
- Include pathways (provide examples) in release and exposure assessments.
- Include examples of qualitative measures of likelihood and consequences each on a 6-point scale.
- Include example of risk estimation matrix to combine qualitative measures of likelihoods and consequences.
- Provide a guide and examples for combining qualitative likelihood measures.

ANNEX IV

List of Acronyms and Abbreviations

AAHIS	Aquatic Animal Health Information System
AAHC	An Aquatic Animal Health Committee (Nepal)
AAHRI	Aquatic Animal Health Research Institute (DOF, Thailand)
AAPQIS	Aquatic Animal Pathogen and Quarantine Information System
AFFA	Agriculture, Fisheries and Forestry of Australia
ALOP	Appropriate level of protection/acceptable level of protection
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
AQIS	Australian Quarantine Inspection Service
ASEAN	Association of South East Asian Nations
AusAID	Australian Agency for International Development
AVA	Agri-food and Veterinary Authority of Singapore
BA	Biosecurity Authority (New Zealand)
BFAR	Bureau of Fisheries and Aquatic Resources (Philippines)
BIOTEC	Thai National Center for Genetic Engineering and Biotechnology
BKD	Bacterial kidney disease
BMPs	best management practices
BP	*Baculovirus penaei*
CAAH	Committee on Aquatic Animal Health (Myanmar)
CBD	Convention on Biological Diversity
CEFAS	The Center for Environment, Fisheries and Aquaculture Science (United Kingdom)
CESO	Canadian Executive Service Organization
CIT	Court of International Trade
CONAPESCA	Comisionado Nacional de Acuacultura y Pesca (Mexico)
DA	Department of Agriculture
DANIDA	Danish International Development Agency
DIAS	FAO's Database of Introduced Aquatic Species
DFID	Department for International Development (United Kingdom)
DFO	Department of Fisheries and Oceans Canada
DLD	Department of Livestock Development (Thailand)
DOF	Department of Fisheries (Thailand)
DoFD	Directorate of Fisheries Development (Nepal)
DPIE	Department of Primary Industries and Energy (Australia)
DSU	Dispute Settlement Panel
EAFP	European Association of Fish Pathologists
ECOTECH	APEC's Economic and Technical Cooperation
ECU	Euro Currency Unit
EEZ	Exclusive Economic Zone
EHN	Epizootic haematopoietic necrosis
EIFAC	European Inland Fisheries Advisory Commission
ERM	Enteric redmouth disease
ERMA	Enivronmental Risk Management Authority (New Zealand)
EU	European Union
EUS	Epizootic ulcerative syndrome
FAO	Food and Agriculture Organization of the United Nations
FDC	Fish Diseases Commission (of the OIE)
FHPR	Fish Health Protection Regulations (Canada)
FHMC	Fish Health Management Committee (Australia)
FWG	Fisheries Working Group of APEC
GATT	General Agreement on Tariffs and Trade
GAV	Gill-associated Virus
GEF	Global Environment Facility

GMOs	Genetically modified organisms
GMPs	Good management practices
HUC	Hydrologic unit codes
ICAR	Indian Council of Agricultural Research
ICES	International Council for Exploration of the Sea
IHHN	Infectious hypodermal and haematopoeitic necrosis
IHN	Infectious haematopoietic necrosis
INP	Instituto Nacional de la Pesca (Mexico)
IPPC	International Plant Protection Convention
IRA	Import Risk Analysis
ISA	Infectious salmon anaemia
JICA	Japan International Cooperation Agency
JSA	Joint Subcommittee on Aquaculture (USA)
KHV	Koi herpes virus
MAF	Ministry of Agriculture and Forestry, New Zealand
MBV	*Penaeus monodon*-type baculovirus
MfE	Ministry for the Environment (New Zealand)
MoV	Mourilyan virus
MG	Mycotic granulomatosis
NAAH	Network of Aquatic Animal Health (Thailand)
NAAHP	National Aquatic Animal Health Plan (USA) National Aquatic Animal Health Program (Canada)
NACA	Network of Aquaculture Centres in Asia-Pacific
NBFGR	National Bureau of Fish Genetics and Resources
NC	National Cooordinator on Aquatic Animal Health
NICA	National Institute of Coastal Aquaculture (DOF, Thailand)
NMFS	National Marine Fisheries Service (USA)
NNVI	Norwegian National Veterinary Institute
NTIFFP	National Taskforce on Imported Fish and Fish Products (Australia)
OATA	Ornamental Aquatic Trade Association
OIE	Office International des Epizooties
OIE-Tokyo	OIE Regional Representation for the Asia-Pacific
OIRSA	Organismo Internacional Regional de Sanidad Agropecuaria
OMV	*Oncorhynchus masou* virus
OMVD	*Oncorhynchus masou* virus disease
PAV	Penaeid acute viremia
PCAMRD	Philippine Council for Aquatic and Marine Research and Development
PCR	Polymerase chain reaction
QA/QC	Quality assurance/quality control
RSD	Red spot disease
SAGARPA	Secretaria de Agricultura, Ganadería, Dessarrollo Rural, Pesca y Alimentación (Mexico)
SDF	Specific disease free
SDR	Specific disease resistant
SEAFDEC-AQD	Southeast Asian Fisheries Development Center – Aquaculture Department
SENASICA	Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (Mexico)
SMV	Spawner mortality virus
SPC	Secretariat of the Pacific Community
SPF	Specific Pathogen Free
"SPS Agreement"	Agreement on the Application of Sanitary and Phytosanitary Measures
SRDC	Shrimp Research and Development Center (DOF, Thailand)
SVC	Spring viremia of carp
TADs	Trans-boundary animal pathogens
TAADs	Trans-boundary aquatic animal diseases
TAAPs	Trans-boundary aquatic animal pathogen/s
TED	turtle excluder device
TSV	Taura syndrome virus

VHS	Viral haemorrhagic septicemia
VNN	Viral nervous necrosis
UM	Ulcerative mycosis
UNDP	United Nations Development Programme
UPMSI	University of the Philipppines Marine Science Institute
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
VHS	Viral haemorrhagic septicaemia
VHSV	Viral haemorrhagic septicaemia virus
WSD	White Spot Disease
WSSV	White Spot Syndrome Virus
WTO	World Trade Organization
YHV	Yellowhead Virus