

AQUAPLAN

ZONING POLICY GUIDELINES

prepared by the AQUAPLAN Disease Zoning Policy Project Team
August 2000

The AQUAPLAN Zoning Policy Guidelines explain the generic principles of zoning based on pathogen distribution, the movement principles between zones, and international relevance of national zoning. They were jointly developed by the private sector and Commonwealth and State/Territory Governments.

Standing Committee on Fisheries and Aquaculture and Standing Committee on Agriculture and Resource Management endorsed the AQUAPLAN Zoning Policy Guidelines in April and August 2000, respectively.

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For further information regarding the AQUAPLAN Zoning Policy Guidelines please contact:

Aquatic Animal Health
Officer of the Chief Veterinary Officer
Product Integrity, Animal and Plant Health
Agriculture, Fisheries, Forestry - Australia
GPO Box 858
Canberra, ACT 2601
Phone: 02 6272 4328

FOREWORD

Australia's fisheries and aquaculture industries are a rapidly growing sector of our primary industries. Their capacity to contribute through export earnings and job creation especially in regional Australia is a vital part of our future prosperity.

Australia is fortunate to have our aquatic animal sector free from many diseases that occur elsewhere in the world, and this provides us with a comparative advantage in both production and trade. Australia's capacity to produce "clean green" seafood of superior quality may be attributed to our geographical isolation and strict quarantine.

In the future, however, we will need to be able to substantiate our claim of freedom from many of the significant diseases in order to support our export certification and quarantine import policies. I am pleased therefore to introduce the AQUAPLAN Zoning Policy Guidelines as part of AQUAPLAN, Australia's national five-year strategy for managing aquatic animal health.

These Zoning Policy Guidelines are based on those developed by the OIE and provide principles that may be used to develop zoning policies that are beneficial to both export and import from both the international and domestic trade perspectives. Effective zoning policies can also help minimise the spread of disease throughout the country and enable trade to continue in disease free areas.

I am pleased to see that industry and government, in working together on the development of the AQUAPLAN Zoning Policy Guidelines, have recognised the importance of an integrated and planned approach on aquatic animal health.

GARDNER MURRAY

Executive Manager

Product Integrity, Animal and Plant Health

Agriculture, Fisheries, Forestry - Australia

EXECUTIVE SUMMARY

On April 30th, 1999, Australia's Ministerial Council on Forestry, Fisheries, and Aquaculture endorsed **AQUAPLAN - Australia's National Strategic Plan for Aquatic Animal Health 1998-2003**. Between December 1998 and April 1999, AQUAPLAN was endorsed by fisheries and aquaculture peak bodies in Australia, including the recreational fishing sector. It was formally launched by the Hon Warren Truss MP on December 17 1999.

AQUAPLAN is a broad, comprehensive strategy that outlines objectives and projects to develop a national approach to the overall management of aquatic animal health in Australia, including emergency preparedness and response arrangements. It has been jointly developed by Commonwealth and State/Territory governments and industry in a manner consistent with existing arrangements in the terrestrial animal sector and, wherever possible, links into existing State/Territory Government and industry health management arrangements.

The development of a policy paper on disease zoning was identified as a priority project under AQUAPLAN for 1999. Such a paper should

'explain the generic principles of zoning based on pathogen distribution, the movement principles between zones, and international relevance of national zoning.'

Increasingly, Australia will be called upon (eg. by trading partners through World Trade Organization (WTO) processes) to substantiate its claims of freedom from major diseases, in order to support export certification and quarantine import policies. Identifying disease-free areas in a country, and clearly separating them from infected areas, can be beneficial to both export and import. In the case of disease outbreaks in an infected area, exports could still continue from free areas; for imports into free areas, special protective measures can legitimately be applied, for example allowing import only from other free areas. The procedure of delineating such free and infected areas is called 'zoning'.

The same principles that make zoning a useful tool in international trade provide benefits also in the domestic scene; for diseases with an uneven distribution throughout the country, zoning can help to minimise spread into, so far, uninfected areas.

The Zoning Policy Guidelines have been prepared by the 'AQUAPLAN Disease Zoning Policy Project Team'. In writing the Zoning Policy Guidelines the Project Team considered comments by stakeholders such as the Commonwealth and State/Territory governments as well as the private sector.

The Guidelines discuss the concept of disease zoning and its possible benefits, and explains the background and principles relevant to a future zoning policy highlighting the issues that need to be considered. The Guidelines have been endorsed by the Standing Committee on Fisheries and Aquaculture, Veterinary Committee and the Standing Committee on Agriculture and Resource Management. This means that all of the States and Territories have agreed to follow the Zoning Policy Guidelines as a basis for developing their zoning policies for aquatic animal diseases. Individual zoning cases will need to be discussed and decided on a case-by-case basis by relevant State/Territory and Commonwealth authorities and with the industries affected.

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I. Introduction

Disease zoning is the process of delineating free and infected areas within a country or group of countries. It is a tool that can facilitate domestic and international trade whilst managing the risk of spread of animal diseases. The purpose of this paper is to examine disease zoning and provide the background and principles of zoning, outline the possible benefits of zoning and highlight issues that need to be considered for future zoning policy.

The development of a policy paper on zoning was identified as a priority project under AQUAPLAN for 1999 (see below). The paper should

‘explain the generic principles of zoning based on pathogen distribution, the movement principles between zones, and international relevance of national zoning.’

The Aquatic Animal Health Unit (AAHU) within the National Offices of Animal and Plant Health (now Product Integrity and Animal and Plant Health) was responsible for the development of this paper. AAHU established a project team (see Appendix 1 for membership) with representatives from the Commonwealth and State/Territory governments and industry. The team developed a draft paper which was submitted to stakeholders (government and industry) for comment (see Appendix 2 for a list for stakeholders consulted). All comments received were considered and the draft paper revised. This printed paper has been endorsed by the States and Territories and industry.

This paper discusses the concept of zoning and its possible benefits, explains the background and principles relevant to establishing a future zoning policy, and highlights the issues that need to be considered. Individual zoning cases will need to be discussed and decided on a case-by-case basis by relevant State/Territory and Commonwealth authorities and with the industries affected.

AQUAPLAN - the strategic background for aquatic animal health

On April 30th, 1999, Australia’s Ministerial Council on Forestry, Fisheries, and Aquaculture endorsed **AQUAPLAN - Australia’s National Strategic Plan for Aquatic Animal Health 1998-2003**. Between December 1998 and April 1999, AQUAPLAN was endorsed by fisheries and aquaculture peak bodies in Australia, including the recreational fishing sector.

AQUAPLAN is a broad, comprehensive strategy that outlines objectives and projects to develop a national approach to the overall management of aquatic animal health in Australia, including emergency preparedness and response arrangements. It has been jointly developed by Commonwealth and State/Territory governments and industry in a manner consistent with existing arrangements in the terrestrial animal sector and, wherever possible, links into existing State/Territory government and industry health management arrangements.

AQUAPLAN comprises eight key programs under which governments and private sectors have identified priority projects to achieve the program objectives. The eight key AQUAPLAN programs are:

1. International Linkages
2. Quarantine
3. Surveillance, Monitoring and Reporting
4. Preparedness and Response
5. Awareness
6. Research and Development
7. Legislation, Policies and Jurisdiction
8. Resources and Funding.

AQUAPLAN is a strategic plan. The eight programs provide the necessary framework to develop and implement comprehensive operational plans for aquatic animal health issues. Each program consists of specific projects and project components, which have been identified as the most effective means of meeting the program objectives. Project teams have been established for individual projects and components. The document presented here has been prepared by the 'AQUAPLAN Disease Zoning Policy Project Team'.

AQUAPLAN –Program 3 and ‘Disease Zoning’

The objectives of AQUAPLAN Program 3 (Surveillance, Monitoring and Reporting) are to:

‘consolidate information on and protect Australia’s aquatic animal health status, by facilitating the detection and reporting of, and response to, aquatic animal disease outbreaks; facilitating the enhancement of existing, and development of additional, national and interstate disease control programs and zoning policies; supporting Australia’s international disease reporting obligations to OIE (World Organisation for Animal Health); and supporting regional disease reporting to the Network of Aquaculture Centres in Asia and the Pacific (NACA).’

Increasingly, Australia will be called upon (eg. by trading partners through WTO processes) to substantiate its claims of freedom from major diseases, in order to support export certification and quarantine import policies. Identifying disease-free areas in a country, and clearly separating them from infected areas, can be beneficial to both export and import. In the case of disease outbreaks in an infected area, exports could still continue from free areas; for imports into free areas, special protective measures can legitimately be applied, for example allowing import only from other free areas. The procedure of delineating such free and infected areas is called ‘zoning’.

The same principles that make zoning a useful tool in international trade provide benefits also in the domestic scene; for diseases with an uneven distribution throughout the country, zoning can help to minimise spread into, so far, uninfected areas.

Contents of this paper

This disease zoning policy paper:

- describes the different types of zones as recognised by the World Organisation for Animal Health (*Office International des Épizooties* - 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 OIE¹; and
- highlights issues that Australia needs to consider for following a zoning approach for aquatic animal diseases.

The paper draws on the pertinent chapters in the OIE *International Aquatic Animal Health Code* (Second edition, 1997) and the OIE *International Animal Health Code* (1999), as well as studies on resources required for zoning in a foot-and-mouth disease outbreak (see References). It also takes into account experience gathered in the European Union with zoning programs for two salmonid diseases.

II. What is ‘disease zoning’?

Meaning of ‘disease zoning’:

Disease zoning is the definition of zones (i.e. geographic areas) according to the distribution status of certain diseases/agents within a country.

The concept and purpose of disease zoning

Traditionally, when evaluating the animal (terrestrial and aquatic) disease situation in a country with a view to exports of animals and/or products, the country has been judged as a whole. Thus, if an infectious disease existed somewhere within a country's borders, or if its presence was strongly suspected, the whole country was considered to be infected. Such measures can create significant restrictions to trade and penalise unaffected sectors of an industry.

For diseases of animals, and especially for those of aquatic animals, climatological, geographical and hydrographical barriers as well as a country's political boundaries

¹ For a list of aquatic animal diseases notifiable to the OIE, see Appendix 3.

can be effective in containing diseases (or keeping them out). Such barriers are used to delineate ‘zones’. When a country suffers a disease incursion in a particular farm or water system, an effective zoning scheme can allow the rest of the country or other (‘free’) zones within the country to continue trade whilst the ‘infected’ and clearly described zone is placed under movement restrictions. The OIE encourages member countries to adopt the zoning concept, i.e. the definition of zones according to the distribution status of certain diseases/agents within a country.

The purpose of disease zoning:

Disease zoning is a tool that can be used to facilitate domestic as well as international trade whilst managing the risk of spread of animal diseases.

III. Definition and Description of Zones

What are ‘zones’?

Zones are usually clearly delineated geographical areas within a country; but they can also cross political country borders. Catchment areas and rivers form the basis for continental zones (interbasin water transfers may need to be considered in establishing zones). Coastal zones can also be defined, although delineation becomes more difficult. The tools for delineation must be relevant to the purpose of zoning, i.e. they must 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. Thus, ‘infected zone’ and ‘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’ (see hypothetical example 1).

Hypothetical Example 1 - furunculosis infected but IHN/VHS free zone:

Country ‘Erehwon’ has widely dispersed inland rainbow trout farms. Furunculosis is enzootic in a particular river system of Erehwon, sustained by wild fish populations in the river. There are no attempts at eradication or detailed monitoring, thus the entire river system and its tributaries are considered a ‘furunculosis infected zone.’ All farms in Erehwon are, however, concerned about the introduction of VHS and IHN. Therefore, the Trout Farmers Association of Erehwon runs a surveillance and monitoring program to specifically detect these exotic viruses within the entire country. The program is designed in accordance with OIE guidelines, and the entire country is officially recognised as ‘IHN and VHS free’. Thus, the particular zone in Erehwon is ‘furunculosis infected, IHN/VHS free’.

How are disease zones delineated?

For terrestrial animals, an infected zone on land may simply be defined as an area of a specified radius around an infected property. For aquatic animals, definition of borders

and delineation of zones becomes more difficult. In inland situations, most aquaculture establishments are connected to river systems or other water ways via which the disease agent could easily be transmitted to wild fish in the area (those wild fish may become a vector), or be carried downstream to other farms. Thus, for freshwater aquaculture animals, a minimum size of a 'zone' is usually an entire river system or a water catchment area. Therefore, in a disease outbreak in a pond farm (a pond farm is an enclosed area within which the animals are contained and that has both an inflow and outflow of water), not only the farm but also the entire river system and all dependent farms, plus their effluent waterways, may have to be considered an infected zone, and be placed under movement restrictions. Farms elsewhere in the region which source their incoming water from an unconnected river system, an independent reservoir of surface water, or spring or borehole supply, however, may retain disease-free zone status and thus continue trade (see hypothetical example 2).

Zoning in marine areas is a more complicated process and will depend on oceanographic characteristics and vector/host distribution and characteristics.

Hypothetical Example 2 - IHN virus detection in an IHN/VHS free country:

Country 'Erehwon' is officially recognised as IHN and VHS free. Not only have there never been any recorded outbreaks of these diseases, but the country runs a surveillance and monitoring program to specifically detect these two viruses even in the absence of clinical signs. The program is designed in accordance with OIE guidelines, thus the official recognition as 'IHN and VHS free'. During routine monitoring, a small trout hatchery at the source of a river is found infected with IHN virus. This hatchery, the river system, plus all dependent farms on that river system - i.e. farms that source their inflow water from this river - are now considered an 'IHN-infected, VHS-free zone'. The rest of the country, i.e. all the farms and river systems which are not connected to this zone, are now officially recognised as a 'IHN and VHS free zone.' Note that the country freedom for IHN - but not for VHS - has been lost. The competent authority immediately decides to eradicate the infection to regain their 'IHN-free' country status. To regain this status, movement controls and enhanced monitoring for IHN are put into place.

Types of zones

The OIE recognises three types of zones for diseases of aquatic animals – ‘Free zones’, ‘Surveillance zones’ and ‘Infected zones’.² Criteria given below are as they are listed by OIE.

Note that OIE only provides the principles for zoning, for example, ‘Importation of aquatic animals [...] into the free zone must take place under strict controls’, or ‘The surveillance zone must have an advanced degree of disease control and surveillance.’ OIE does not specify those controls in detail.

Free zone

“A 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 location of all aquaculture establishments and populations of wild aquatic animals containing susceptible species. Suspected outbreaks of the disease must be investigated immediately by the Competent Authority. Outbreaks must be reported to the OIE. If necessary, the free zone is separated from the rest of the country and from the infected neighbouring countries by a surveillance zone. 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 which could introduce the disease agent.”

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 1. Section 1.4. Import Risk Analysis. Chapter 1.4.4. Zoning. Article 1.4.4.3. Types of Zones.

The OIE also defines free ‘aquaculture establishments’ with the intention to enable farms that are located within an infected zone, to have a protected independent water supply, and meet other conditions, to demonstrate freedom of a certain disease and be allowed to supply other free farms within that country or in other countries not officially declared free. Strict conditions do, however, apply.

² The OIE International Animal Health Code - for terrestrial animals - further defines ‘disease free zones with vaccination’ and ‘buffer zones’ with systematic vaccination.

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 must be controlled. The surveillance zone must have an advanced degree of disease control and surveillance.

Suspected outbreaks of the disease must be investigated immediately and, if confirmed, eliminated. 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. Accordingly, 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 tests.”

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 1. Section 1.4. Import Risk Analysis. Chapter 1.4.4. Zoning. Article 1.4.4.3. Types of Zones.

Surveillance zones are sometimes established as ‘buffers’ between an infected zone and a free zone. They serve to protect the free zone and its higher status, and often are used as a step in the expansion of the free zone. In disease outbreak situations, a surveillance zone can be established around an infected zone, to closely monitor spread of the disease from the infected core area (see below).

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 alternatives can be considered:

- i. no live aquatic animals may leave the zone, or
- ii. aquatic animals can be moved by mechanical transport to special aquatic animal slaughtering premises/mollusc and shrimp production facilities located in the surveillance zone for immediate slaughter, or
- iii. exceptionally, live aquatic animals can enter the surveillance zone under suitable controls established 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 entering the zone, or
- iv. live aquatic animals can leave the infected zone if the epidemiological conditions are such that disease transmission cannot occur.”

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 1. Section 1.4. Import Risk Analysis. Chapter 1.4.4. Zoning. Article 1.4.4.3. Types of Zones.

IV. Movement of Animals Between Zones

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 specific pathogens. Free zones can also be geographically expanded. To achieve these aims, restriction of movement of aquatic animals between infected zones, surveillance zones, free zones and zones of unknown status is necessary. The basic principle governing movement of live aquatic animals between different zones is:

The movement principle of disease zoning:

Live aquatic animals may be moved between zones of equal status, or from higher to lower status, but not from lower to higher status.

This is a general principle. In any particular case of movement of live aquatic animals between zones, one will need to establish whether, for example, the animals to be moved are susceptible to the disease of concern. This may not always be known; furthermore, 'susceptibility' can be read in a spectrum ranging from true and proven susceptibility for clinical disease outbreaks, to non-clinical carriage of the disease agent.

For notifiable³ diseases, OIE advises that for export to a country, zone or farm officially approved as free of such a disease, all live aquatic animals - regardless of susceptibility to the disease - should be derived from a country, zone or aquaculture establishment officially approved as free of the particular disease⁴. 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 (see hypothetical example 3).

Hypothetical Example 3 - export of elvers from a VHS-infected zone into a country recognised as VHS free: Country 'Erehwon' is officially recognised as VHS free. A trout farmer wishes to import elvers for grow-out, as a side business. A potential supplier is located in a neighbouring country, in a zone known to be infected with VHS. When applying for an import permit with Erehwon's authorities, the farmer is informed that elvers - although not a species listed as susceptible to VHS - are considered as potential carriers of VHS virus. The farmer is also informed that experiments are being conducted to confirm or rule out this assumption, but - unless proven otherwise, and based on the OIE *Code* - elvers for import into Erehwon - a VHS free country - must be sourced from other countries, zones or aquaculture establishments officially recognised as VHS free.

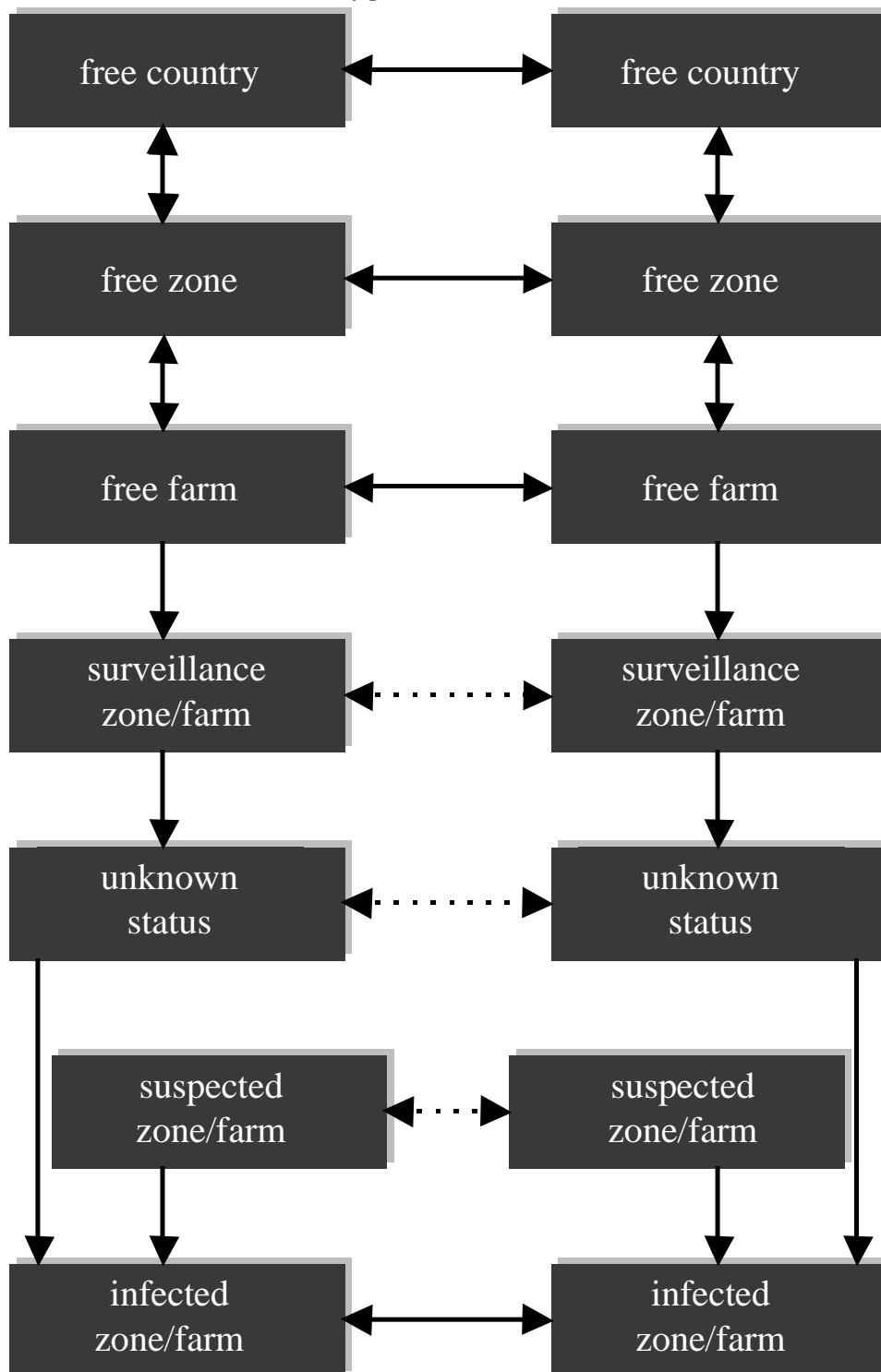
³ For a list of aquatic animal diseases notifiable to the OIE, see Appendix 3.

⁴ OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 1. Section 1.5. Import/Export Procedures. Chapter 1.5.2. Aquatic Animal Health Measures Applicable Before and After Departure. Article 1.5.2.2.; and Chapter 1.5.5. Aquatic Animal Health Measures on Arrival. Article 1.5.5.1., item 3.

The movement principle is best visualised in a picture (Figure 1).

Figure 1: Movement of live aquatic animals between zones.

Lines indicate the direction of permitted movement.



Solid lines with arrows indicate movements that are consistent with the zoning movement principle.

Dotted lines with arrows indicate movements that may need to be regulated.

V. Requirements for Disease-Free Zoning

General requirements for disease-free zones

Free zones can be officially recognised within a country, according to a scheme developed by that country or between neighbouring countries. However, in most cases, it is prudent to follow the OIE requirements closely, as they provide for international recognition of disease free zones and thus international trade advantages. To be recognised as a state, country or zone free from a particular disease requires an ongoing program of surveillance and monitoring for the pathogen rather than an absence of reports of the disease of concern.

The requirements for a country to obtain recognition of a disease free zone are outlined below. These requirements are based on the general requirements specified by the OIE⁵. The OIE does not give details, however, on how these requirements are to be met.

- effective organisation and infrastructure for disease control in aquatic animals, including administrative, legal and financial resources, within a country;
- effective system of disease control and surveillance, including resources to supervise boundaries, maintain clinical and epizootiological surveillance, carry out the necessary diagnostic tests, and to ensure any disease outbreak is promptly reported;
- compulsory notification of the disease to be controlled by zoning;
- establishment and enforcement of zones by legislation;
- clear delineation of zones by effective boundaries;
- prevention of the movement of live animals across borders, unless from a zone of equal or better aquatic animal health.

Hypothetical Example 4 - Spring Viraemia of Carp free zone officially recognised in the state of Utopia within the country of Erehwon: Utopia follows the OIE requirements closely to ensure that they have international recognition as a Spring Viraemia of Carp free zone. They are thus able to export their fish products nationally and internationally. Utopia maintains an effective system of surveillance and monitoring for Spring Viraemia of Carp and the disease has never been reported there. In the nearby state of Collapsitonia there is an outbreak of Spring Viraemia of Carp. Utopia maintains its surveillance and monitoring vigilance and is able to continue exporting to other states within Erehwon and also internationally. The remaining states of Erehwon do not have surveillance and monitoring systems in place to check for Spring Viraemia of Carp and hence are not cleared of the threat of the disease. Zie, an apparently uninfected State within Erehwon, also wishes to trade internationally so it begins a surveillance and monitoring program but is unable to trade as a Spring Viraemia of Carp free area until it has proven clear for a period of two years or more.

⁵ OIE *International Aquatic Animal Health Code* (3rd ed., 1999): Part 1. Section 1.4. Chapter 1.4.4., Zoning. Article 1.4.4.4.

Disease-specific requirements

Different diseases have different characteristics such as status within a country, host range and modes of spread. Thus, different diseases require different zoning boundaries. The OIE *Code* specifies the specific requirements for the aquatic animal diseases notifiable to the OIE⁶, following a generic template.

Diseases of finfish notifiable to the OIE

If a zone is officially recognised as free of one of the finfish diseases notifiable to the OIE, the following requirements regarding the establishment of disease free areas and importation of aquatic animals must be met:

“A disease free zone may be established within the territory of one or more countries if within the zone:

- 1) Aquaculture establishments and wild populations containing susceptible species have been tested in an official fish health surveillance scheme for at least the previous two years using the procedures described in the OIE *Manual*⁷.
- 2) The disease agent⁸ has not been detected during this two-year period.

Such free zones must comprise:

- 1) one or more entire water catchment areas from the sources of the waterways to the sea, or
- 2) part of a catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of fish from lower stretches of the waterway.

Such zones must be clearly delineated on a map of the territory of the country concerned by the Competent Authority and must be observing the conditions referred to in Articles 2.1.1.2., 2.1.1.3. and 2.1.1.4.

[*These latter articles lay down requirements for health certification and specify the import restrictions as shown in Figure 1; the text is given verbatim in Appendix 4*].

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 2. Section 2.1. Diseases of Fish. Chapters 2.1.1 - 2.1.5.

Appendix 4 gives the full OIE text on requirements for the official recognition of a country, zone or aquaculture establishment as ‘free’ of a finfish disease (example: EHN) notifiable to the OIE, and Appendix 5 gives the full text for the importation conditions that must be met for importation into EHN free countries, zones or aquaculture establishments.

⁶ For a list of aquatic animal diseases notifiable to the OIE, see Appendix 3.

⁷ OIE *Diagnostic Manual for Aquatic Animal Diseases* (2nd ed., 1997) 251 pp. Paris, Office International des Épidémiologies.

⁸ Note that it is not sufficient to declare absence of clinical disease outbreaks.

Diseases of molluscs notifiable to the OIE

If a zone is officially recognised as free of one of the molluscan diseases notifiable to the OIE, the following requirements regarding the establishment of disease free areas must be met:

“A zone may be considered free from the disease when:

- 1) no outbreak caused by the listed disease agents has occurred within its territory for at least the previous two years;
- 2) no listed disease agents⁹ have been detected in any mollusc tested during operation of a national mollusc health surveillance scheme for a period of at least two years using the procedures described in the *Manual*¹⁰ (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease surveillance programmes).”

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 2. Section 2.2. Diseases of Molluscs. Chapters 2.2.1 - 2.2.5.

Appendix 6 gives the full OIE text on requirements for the official recognition of a country, zone or aquaculture establishment as ‘free’ of a molluscan disease (example: bonamiosis) notifiable to the OIE, and Appendix 7 gives the full text for the importation conditions that must be met for importation into bonamiosis free countries, zones or aquaculture establishments.

Diseases of crustaceans notifiable to the OIE

There are currently no crustacean diseases listed as notifiable to the OIE¹¹.

Negotiations with trading partners

OIE lays down principles and provides guidelines. Abiding by these principles and following the guidelines when developing a zoning policy is prudent, but does not guarantee that all existing or potential trading partners automatically accept the policy or its implementation protocols. Before developing a zoning policy, a country should therefore negotiate with its relevant trading partners or trade blocks about the particulars.

Within Australia the *Mutual Recognition Act 1992* allows for trade in living animals between Australian States, however this Act also provides exemptions (see Schedule 2) where State quarantine regulations regulate or prohibit the import of specified goods.

Such negotiations will become especially important when a country suddenly experiences an outbreak of a disease so far exotic, then uses its zoning system to declare infected and free zones with the intention to maintain trade with animals

⁹ Note that it is not sufficient to declare absence of clinical disease outbreaks.

¹⁰ OIE *Diagnostic Manual for Aquatic Animal Diseases* (2nd ed., 1997) 251 pp. Paris, Office International des Épidémiologies.

¹¹ Note that this will change – see Appendix 3 for details.

derived from the free zones. In some cases, movement of live animals out of the infected zone into a free zone (for example, for immediate slaughter) may be acceptable for disease control purposes, but may not satisfy the zoning principles (see above) or export certification requirements. Bilateral agreements signed before such an event, explaining the zoning system, and stating that the trading partner accepts animals under these circumstances, will greatly facilitate continuity of trade.

VI. Practical Application of Zoning in the European Union.

After the establishment of a single open market within the European Community it was recognised that there was the potential for the spread of serious fish diseases. This concern led to the introduction of uniform fish disease control measures (EC Directive 91/67/EEC) that have been successfully operated in the European Union (EU) since 1993. Appendix 8 outlines the principles and practices of this working example.

VII. An Australian Disease Zoning Policy: Issues to Consider

Benefits of zoning

The putative benefits of zoning are:

- the continuation of trade from free zones when there is a disease outbreak elsewhere in Australia;
- an ability to restrict imports to the zone on the basis of the movement principle (consistent with domestic movement restrictions, imports into free zones must be derived from other free zones);
- officially demonstrating freedom of disease, based on compulsory notification, surveillance and reporting, in accordance with internationally accepted principles and based on internationally recommended guidelines; and
- being seen as accepting our disease status and be trade 'restrictive' only on disease grounds, in a scientifically sound and transparent manner;
- reinforces translocation policy¹² and reduces interstate risks;
- helps maintain biodiversity and environmental health by, for example, reducing the chances of epizootic diseases escaping into the environment and infecting endemic populations.

It will be possible to allocate dollar figures to some of these benefits. For example, the terrestrial animal sector has done a modelling of the costs incurred by a foot-and-mouth disease outbreak in Australia, considering not only the direct losses due to disease and eradication programs, but more importantly, the loss of export markets for the entire country. Other benefits may appear to be less tangible. They may become relevant only in the future, e.g. for accessing new markets, or in trade disputes.

¹² For Principles for a Translocation Policy refer to the website www.brs.gov.au/fish/translocation.html.

Consequences of not zoning

- Disruption to exports, if a disease agent is introduced or present, as the whole of the country will be considered 'infected'.
- Difficulty in justifying restrictions on imports (not being able to show that an area is free of a certain disease means that imports from other, possibly infected, areas cannot be restricted).

Specific issues that need to be addressed

Selection of a disease as a candidate for zoning

As outlined above, it is not possible to use a zoning system to declare zones in Australia as generally 'disease-free'. Freedom will relate to specified diseases only. As an example, industries exporting live salmonid eggs will need to focus on those diseases where export certification requires proof of absence, for example, VHS. Because of export certification requirements, active surveillance and monitoring is taking place already. Affected authorities and industries will need to explore what other documentation or testing is required to gain OIE approval of zoning plans for a putative VHS outbreak. Obtaining such approval prior to a disease outbreak would greatly facilitate negotiations and continuity in trade in the event of an outbreak.

Candidate diseases are not only the OIE-listed diseases, or diseases exotic to the whole of Australia. As indicated earlier, zoning can also help to minimise spread of disease between or within states. For example, the private sector and relevant State governments may decide to consider goldfish ulcer disease (GUD) a worthwhile candidate, in order to produce, and trade, goldfish derived from GUD-free zones. Another candidate may be EHN. The *National List of Reportable Diseases* (Appendix 10) may be a suitable basis for disease selection.

Surveillance and monitoring

A prerequisite for an Australian zoning system, particularly one expected to achieve international recognition, would be the establishment of relevant surveillance and monitoring systems (these exist in some sectors, but national uniformity and adequate resourcing remain as outstanding issues). It may be possible to create the first zones around existing monitoring systems, and from that starting point develop Australian surveillance and zoning systems in concert. As a backdrop, a national system of monitoring aquatic animal diseases may have to be established.

The costs to set up, 'from scratch', a targeted surveillance system for specific pathogens may appear prohibitively high, however, in many cases, low-cost passive surveillance may already be in place and could usefully be upgraded.

Disease reporting and contingency measures

If zoning is to be initiated in a catchment system, all States and Territories affected will have to conscientiously report presence/absence of those diseases selected for zoning. If, for example, it is decided to initiate a zoning system to approve EHN free

zones in the Murray-Darling catchment, EHN will have to be made compulsorily notifiable in the States affected.

On the issue of contingency planning, AQUAPLAN and AQUAVETPLAN have been developed in consultation with industry and other stakeholders and focus on exotic/emerging diseases.

Outbreaks of enzootic diseases within the States or Territories are the responsibility of the individual State/Territory. Each State and Territory has its own legislative requirements for reporting disease outbreaks in fish and other aquatic animals. In turn the States and Territories have agreed to provide regular reports to the Commonwealth Government on the status of diseases from the *National List of Reportable Diseases*.

Standardising diagnostic techniques

It has to be ensured that all laboratories involved in diagnosis use the same or an equivalent technique, and that the same results are obtained regardless which laboratory performs the testing. This implies the thorough validation and standardisation with a preferred technique. Because of the relative novelty of the field, and because of the wide variety of environments involved, diagnostic techniques for aquatic animal pathology vary considerably across laboratories in Australia.

In order to achieve international recognition, it would be necessary to standardise diagnostic techniques across all participating laboratories, to a level capable of satisfying an agreed auditing system. For some diseases, standardised diagnostic techniques are available and published by OIE (*OIE Diagnostic Manual for Aquatic Animal Diseases*). For other diseases, Australia may need to adopt techniques published elsewhere, or develop new techniques. Acceptance of such new techniques by OIE needs to be obtained for international zoning purposes.

It will also have to be explored to what extent participating laboratories will have to be officially accredited, especially in cases where private laboratories would perform part of the testing.

Delineation of zones

In the terrestrial animal sectors, State/Territory borders are often used as initial boundaries for zone delineation. In such instances, the immediate requirement for clear jurisdiction and administrative control is addressed, but the more complex ecological or environmental considerations may not be. In the aquatic animal sector, this approach needs to be considered very cautiously, as there are cases where catchments cross several State borders (e.g. the Murray-Darling catchment). For aquatic animal diseases, zones will have to be delineated by catchments, the separation of head waters and lower reaches, the limitation of the natural movement of aquatic animals between areas and the recognition of secure water sources. These areas will only become apparent when facilities are mapped, and sources of water determined.

Zoning may best be commenced at the source of a river, or in coastal areas, with a historical absence of a disease or - preferably - historical records of testing with negative results.

In Australia the process for delineation of marine zones will be important, as most of our commercial aquatic activity takes place in marine waters. In the coastal/marine systems (e.g. cage culture or racks/ropes), delineation of zones should take into account currents and water exchange, water temperatures and the nature of the disease such as host specificity and movements, survival outside the host and vector distribution patterns.

Another issue, in relation to marine zones, which may be relevant in case of some diseases/pests is that of the possible changing nature of water bodies due to, for instance, ballast water discharge. Ballast water has the potential to bring novel diseases into the environment. For this reason, zonal planning for some pests/diseases should include areas as a discharge site for ballast water, and the nomination of such areas as being of a higher risk than a zone that does not have the likelihood of ballast water discharge.

Further consideration will be required to help identify the most appropriate way of delineating coastal/marine zones in Australia however each disease should be considered separately.

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.”

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.

Jurisdictional issues and the ‘Competent Authority’

AQIS is the ‘Competent Authority’ for Australia for National import/export matters. However, within Australia, the jurisdictional responsibility lies with the States/Territories. For each State and Territory, the ‘Competent Authority(s)’ will need to be identified.

In concurrence with State/Territory and industry interests, the Competent Authority(s) would need to address zone boundary delineation, jurisdictional limits and responsibilities, and protocols for the establishment or change of zones. This last issue becomes particularly problematical when the alteration of zones brings in additional river/tributary catchments, and/or additional regional Government jurisdictions. They also need to ensure that appropriate 'domestic' legislation exists within the relevant jurisdiction to implement zones and controls over aquatic animal and aquatic animal product movement. Currently all of the States and Territories have movement controls in place that focus on live animals and genetic material, however they vary in the species of aquatic animals covered and the degree of control implemented. In a Memorandum of Understanding on Animal and Plant Quarantine Measures between the Commonwealth, State and Territory Ministers, the States/Territories have agreed not to introduce measures that are inconsistent with Australia's international obligations especially with regard to the Agreement on the Application of Sanitary and Phytosanitary measures. For appropriate and effective zoning policies to be developed may therefore, require complimentary legislation between affected States and Territories.

For terrestrial animal diseases, development of specific disease zoning policies is progressed through the Chief Veterinary Officers via Veterinary Committee and endorsement is sought from the Standing Committee of Agriculture and Resource Management (SCARM). Development of aquatic animal disease zoning policies will follow a similar process but will require approval from Fish Health Management Committee and Standing Committee on Fisheries and Aquaculture as well as Veterinary Committee and SCARM.

Following the implementation of zones for OIE notifiable diseases, the Australian Chief Veterinary Officer conveys the details of the zones proclaimed by the relevant State/Territory government to the OIE.

Resources

Nomination of a disease for zoning purposes should be preceded by a cost-benefit analysis of the gains that can be made from establishing free zones for that disease *versus* the costs incurred for setting up and maintaining the zoning system. Activities to support zoning that need to be considered include the means to achieve zone security, collection of samples, laboratory testing, and - in the case of disease outbreaks - all the operations required for disease control.

To attain and maintain disease free status there will need to be an ongoing program of testing and certification both of farms and laboratories and any necessary movement controls and these activities will attract an ongoing cost. AQUAPLAN addresses the issues of resources and funding under Program 8.

VIII. Acronyms

Acronym	Full spelling
AAHU	Aquatic Animal Health Unit
AQIS	Australian Quarantine and Inspection Service
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EHN	Epizootic haematopoietic necrosis
EU	European Union
FHMC	Fish Health Management Committee
GUD	Goldfish ulcer disease
IHN	Infectious haematopoietic necrosis
NACA	Network of Aquaculture Centres in Asia and the Pacific
NOAPH	National Offices of Animal and Plant Health
OIE	Office International des Épizooties World Organisation for Animal Health
SCARM	Standing Committee on Agriculture and Resource Management
SCFA	Standing Committee on Fisheries and Aquaculture
VHS	Viral haemorrhagic septicaemia
WTO	World Trade Organization

IX. References

- 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.
- 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.
- Garner, MG, Baldock, FC, Gleeson, LJ and Cannon, RM (1997) Surveillance strategies and resources for zoning in a foot-and-mouth disease outbreak. Bureau of Resource Sciences, Canberra.
- OIE *Diagnostic Manual for Aquatic Animal Diseases*. Second edition 1997. 251 pp. Paris, Office International des Épizooties.
- OIE *International Animal Health Code*. 1999. Paris, Office International des Épizooties.
- OIE *International Aquatic Animal Health Code*. Second edition 1997. 192 pp. Paris, Office International des Épizooties.

X. Appendices

Appendix 1: Membership of the AQUAPLAN Disease Zoning Policy Project Team

Name	Title and Organisation	Address	Liaison	Phone	Fax	E-mail
Eva-Maria Bernoth	Manager Aquatic Animal Health Unit Commonwealth Department of Agriculture, Fisheries and Forestry - PIAPH	GPO Box 858 Canberra ACT 2601	project driver	02 6272 4328	02 6272 3150	Eva-Maria.Bernoth@affa.gov.au
Linda Walker	Aquatic Animal Health Unit Commonwealth Department of Agriculture, Fisheries and Forestry - PIAPH	GPO Box 858 Canberra ACT 2601	zoning contact in PIAPH	02 6272 5306	02 6273 5237	linda.walker@affa.gov.au
Pheroze Jungalwalla	Manager - R&D Tassal Ltd	GPO Box 1645 Hobart Tas 7001	Industry contact (salmon), liaison Aquaculture CRC	03 6211 9611	03 6224 0373	Jungalwalla@tassal.com.au
Alex McNee	Commonwealth Department of Agriculture, Fisheries and Forestry - BRS	PO Box E11 Kingston ACT 2604	liaison to FEHC and translocation policy development	02 6272 5861	02 6272 4014	alex.mcnee@brs.gov.au
Colin Price	Sea Ranch Pty	PO Box 97 Mossman Qld 4873	industry contact (prawns)	07 4098 5840	07 4098 5879	searanch@internetnorth.com.au
Rod Andrewartha	CVO Tasmania Department of Primary Industries, Water & Environment	13 St. Johns Avenue, NEWTOWN Tas 7008	liaison to VetComm and terrestrial animal zoning policy development	03 6233 6836	03 6233 3843	Rod.Andrewartha@dpiwe.tas.gov.au

Appendix 2: List of stakeholders consulted on this paper

Aquaculture Committee of Standing Committee on Fisheries and Aquaculture
Fish Environment and Health Committee of the Standing Committee on Fisheries and Aquaculture
Veterinary Committee of the Standing Committee on Agriculture and Resource Management
Aquaculture Council of Western Australia
Oyster Farmers Association of NSW
Southern Aquaculture Corporation
Australian Prawn Farmers Association
Australian Seafood Industry Council
Tuna Boat Owners Association
Tasmanian Oyster Growers
Australian Aquaculture Forum
Tasmanian Salmon Growers Association
Pet Industry Joint Advisory Council
NSW Farmers Association-Oyster Section
SA Oyster Growers
Department of Natural Resources and Environment, Victoria
AQIS Policy and International Division
AQIS Quarantine and Export Operations Division

Appendix 3: Aquatic animal diseases listed by OIE.

(OIE International Aquatic Animal Health Code (2nd Ed., 1997))

Diseases Notifiable to the OIE

Diseases of fish

Epizootic haematopoietic necrosis (EHN)

Infectious haematopoietic necrosis (IHN)

Oncorhynchus masou virus disease

Spring viraemia of carp

Viral haemorrhagic septicaemia

Diseases of molluscs

Bonamiosis (*Bonamia ostreae*, *B. sp.*)

Haplosporidiosis (*Haplosporidium costale*, *H. nelsoni*)

Marteiliosis (*Marteilia refringens*, *M. sydneyi*)

Mikrocytosis (*Mikrocytos mackini*, *M. roughleyi*)

Perkinsosis (*Perkinsus marinus*, *P. olseni*)

Diseases of crustaceans

none listed

Other Significant Diseases

Diseases of fish

Channel catfish virus disease

Viral encephalopathy and retinopathy

Infectious pancreatic necrosis

Infectious salmon anaemia

Epizootic ulcerative syndrome

Bacterial kidney disease (*Renibacterium salmoninarum*)

Enteric septicaemia in catfish (*Edwardsiella ictaluri*)

Piscirickettsiosis (*Piscirickettsia salmonis*)

Gyrodactylosis (*Gyrodactylus salaris*)

Diseases of molluscs

Iridovirosis

Diseases of crustaceans

Baculoviral midgut gland necrosis

Nuclear polyhedrosis baculoviroses

Infectious hypodermal and haematopoietic necrosis

Yellowhead disease

Crayfish plague (*Aphanomyces astaci*)

White spot disease

Note: Changes adopted by the International Committee of the OIE during its 67th General Session, 17 - 21 May 1999, Paris (France)

“THE COMMITTEE DECIDES

1. To include the two agents European catfish virus and European sheatfish virus as causative agents of the notifiable disease Epizootic haematopoietic necrosis.
2. To add to the List of Other Significant Diseases of fish Red sea bream iridovirus disease and White sturgeon iridovirus disease.
3. To add Taura syndrome to the List of Diseases Notifiable to the OIE. To transfer White spot disease and Yellowhead disease from the List of Other Significant Diseases to the List of Diseases Notifiable to the OIE.
4. To add to the List of Other Significant Diseases of crustaceans Spawner-isolated mortality virus disease.
5. To modify the *Code* and *Manual* chapters accordingly.”

Appendix 4: OIE requirements for EHN free countries, zones and aquaculture establishments.

Preamble: For diagnostic tests, refer to Chapter 2.1.1. in the Manual

Susceptible hosts: redbfin perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*), Macquarie perch (*Macquaria australasica*), mosquito fish (*Gambusia affinis*), silver perch (*Bidyanus bidyanus*) and mountain galaxias (*Galaxias olidus*).

For the purposes of this Code:

Epizootic haematopoietic necrosis (EHN): free country

A country may be considered free from EHN when:

- 1) no recorded outbreak of EHN disease has occurred within its territory for at least the previous two years;
- 2) epizootic haematopoietic necrosis virus (EHNV) has not been detected in any fish tested during operation of a national fish health surveillance scheme for a period of at least two years using the procedures described in the Manual;
- 3) it is observing the conditions referred to in Articles 2.1.1.2., 2.1.1.3. and 2.1.1.4.

EHN: free zone

An EHN free zone may be established within the territory of one or more countries if within the zone:

- 1) aquaculture establishments and wild populations containing susceptible species have been tested in an official fish health surveillance scheme for at least the previous two years using the procedures described in the Manual;
- 2) EHNV has not been detected during this two-year period.

Such EHN free zones must comprise:

- 1) one or more entire water catchment areas from the sources of the waterways to the sea, or
- 2) part of a catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of fish from lower stretches of the waterway.

Such zones must be clearly delineated on a map of the territory of the country concerned by the Competent Authority and must be observing the conditions referred to in Articles 2.1.1.2., 2.1.1.3. and 2.1.1.4.

EHN: free aquaculture establishment

An EHN free aquaculture establishment may be located not only within an EHN free country or zone but also within an EHN infected zone provided that:

- 1) it has been tested in an official fish health surveillance scheme for at least the previous two years using the procedures described in the Manual, without detection of EHNV;
- 2) it is supplied by water only from a spring, well or borehole and free of stocks of wild fish;
- 3) there is a natural or artificial barrier that prevents the migration of fish from lower stretches of the waterway into the farm or its water supply;
- 4) it is observing the conditions referred to in Articles 2.1.1.2., 2.1.1.3. and 2.1.1.4.

Appendix 4 cont...

EHN: restoration of free status

A country, a zone or an aquaculture establishment may be restored to EHN free status if it has been subjected to a stamping-out or an effective disease eradication policy and if EHNV has not been detected for the last two years of a surveillance scheme using the procedures described in the Manual.

A newly constructed aquaculture establishment, or one that has undergone a thorough stamping-out policy under supervision of the Competent Authority, may achieve EHN free status in under two years if it otherwise meets all the requirements for an EHN free aquaculture establishment.

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 2. Diseases Notifiable to the OIE; Section 2.1. Diseases of Fish. Chapter 2.1.1. Epizootic haematopoietic necrosis. Article 2.1.1.1.

Appendix 5: OIE requirements for importation of fish and fish products into EHN free countries, zones or aquaculture establishments.

“Article 2.1.1.2.

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

This certificate must certify, on the basis of an official fish health surveillance scheme comprising inspection and laboratory tests on susceptible species conducted according to the Manual, whether or not the consignment originates from a country officially declared EHN free.

If the country of origin is not officially declared to be EHN free, the certificate must state whether the consignment originates:

- 1) from a zone officially declared EHN free, or
- 2) from an aquaculture establishment officially declared EHN free.

The certificate shall be in accordance with Model Certificate No. 1 given in Part 5 of this Code.

Article 2.1.1.3.

Importing countries that are officially declared to be EHN free should only accept for importation live fish or sexual products of fish from exporting countries declared EHN free, or from clearly defined EHN free zones in countries not declared EHN free.

Importing countries not regarded as EHN free, but which have officially recognised EHN free zones, should only import live fish and sexual products of fish into such zones from other countries or zones that are officially declared EHN free.

For aquaculture establishments officially declared EHN free that exist in infected zones, the Competent Authority of the country concerned should allow importation of live fish or sexual products only from officially declared EHN free aquaculture establishments, zones or countries.

Article 2.1.1.4.

For dead fish

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

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

This certificate should declare the health status of the country in respect of EHN and the other fish diseases listed in this Code.”

OIE International Aquatic Animal Health Code (2nd ed., 1997): Part 2. Diseases Notifiable to the OIE; Section 2.1. Diseases of Fish. Chapter 2.1.1. Epizootic haematopoietic necrosis.

Appendix 6: OIE requirements for bonamiosis free countries, zones and aquaculture establishments.

Preamble: The present chapter relates only to bonamiosis when covered by the disease agents listed below in the susceptible host species indicated for each pathogen.

Bonamia ostreae:

Susceptible hosts: *Ostrea edulis*, *O. angasi*, *O. denselammellosa*, *O. puelchana*, *Ostreola conchaphila* (= *O. lurida*) and *Tiostrea chilensis*.

Bonamia sp.:

Susceptible hosts: *Tiostrea chilensis* and *Ostrea angasi*.

These disease agents will be referred to as 'listed disease agents' in the Articles of the present chapter.

For diagnostic tests, refer to Chapter 2.2.1. in the Manual

For the purposes of this Code:

Bonamiosis: free country

A country may be considered free from bonamiosis when:

- 1) no outbreak caused by the listed disease agents has occurred within its territory for at least the previous two years;
- 2) no listed disease agents have been detected in any mollusc tested during operation of a national mollusc health surveillance scheme for a period of at least two years using the procedures described in the Manual.

Bonamiosis: free zone

A zone may be considered free from bonamiosis when:

- 1) no outbreak caused by the listed disease agents has occurred within its territory for at least the previous two years;
- 2) no listed disease agents have been detected in any mollusc tested during operation of a national mollusc health surveillance scheme for a period of at least two years using the procedures described in the Manual (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease surveillance programmes).

Bonamiosis: free aquaculture establishment

A bonamiosis free aquaculture establishment may be located within a bonamiosis free country or zone or within a bonamiosis infected zone provided that:

- 1) it has been tested in an official mollusc health surveillance scheme for at least the previous two years using the procedures described in the Manual, without detection of any listed disease agents, and
- 2) it is supplied with water by a means that ensures removal or destruction of any listed disease agents present.

Appendix 6 cont...

Bonamiosis: restoration of free status

A country, a zone or an aquaculture establishment may be restored to bonamiosis free status if no listed disease agents have been detected for the last two years of a surveillance scheme using the procedures described in the Manual.

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 2. Diseases Notifiable to the OIE; Section 2.2. Diseases of Molluscs. Chapter 2.2.1. Bonamiosis. Article 2.2.1.1.

Appendix 7: OIE requirements for importation of fish and fish products into bonamiosis free countries, zones or aquaculture establishments.

“Article 2.2.1.2.

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

This certificate must certify, on the basis of an official mollusc health surveillance scheme comprising inspection and laboratory tests on susceptible host species conducted according to the Manual, whether or not the consignment originates from a country officially declared bonamiosis free.

If the country of origin is not officially declared to be bonamiosis free, the certificate must state whether the consignment originates:

- 1) from a zone officially declared bonamiosis free, or
- 2) from an aquaculture establishment officially declared bonamiosis free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 5 of this Code.

Article 2.2.1.3.

Importing countries that are officially declared to be bonamiosis free should only accept for importation live molluscs from exporting countries declared bonamiosis free, or from clearly defined bonamiosis free zones in countries not declared bonamiosis free.

Importing countries not regarded as bonamiosis free, but which have officially recognised bonamiosis free zones, should only import molluscs into such zones from other countries or zones that are officially declared bonamiosis free.

For aquaculture establishments officially declared bonamiosis free that exist in infected zones, the Competent Authority of the country concerned should only allow importation of molluscs from officially declared bonamiosis free aquaculture establishments, zones or countries.

Article 2.2.1.4.

Competent Authorities of importing countries should require:

for molluscs of commercial size destined for human consumption

the presentation of an international aquatic animal health certificate attesting that the molluscs listed as bonamiosis susceptible host species come from either a country, a zone or an aquaculture establishment free from bonamiosis.

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

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

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

Appendix 7 cont...

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

Article 2.2.1.5.

Certificates are optional for molluscs not listed as natural or experimental bonamiosis susceptible host species, even if the molluscs come from an infected country, zone or aquaculture establishment.

OIE *International Aquatic Animal Health Code* (2nd ed., 1997): Part 2. Diseases Notifiable to the OIE; Section 2.2.1. Diseases of Molluscs. Chapter 2.2.1. Bonamiosis.

Appendix 8: Practical Application of Zoning in the European Union¹³

The legal framework: Directive 91/67/EEC

The application of a zoning system for aquatic animal diseases has been successfully 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, within such a single open market, animal health controls would be required so that trade in live animals did not lead to disease spread within the EU. Europe does not have a uniform fish health situation so, if existing frontier barriers and restrictions were removed without imposing additional health safeguards, there would obviously be an increase in the risk of importing serious diseases present in one part of the EU into one or more countries, or zones within those countries, enjoying freedom from that disease. Concern about the possible increasing spread of serious fish diseases, yet a need to liberate trade, led to the introduction of uniform fish disease control measures in the form of EC Directive 91/67/EEC¹⁴ which came into force on 1 January 1993. This Directive stipulates the animal health conditions governing the marketing of aquaculture animals and products within the EU to prevent intra-EU spread of disease and introduction of exotic diseases from outside the EU, i.e. from 'third countries'.

The Directive provides safeguards in respect of three categories of disease which are placed in Lists I, II and III according to their seriousness and economic impact:

- List I covers highly infectious diseases exotic to the Community and likely to have a major impact should they be imported. Such diseases are notifiable throughout the EU and individual Member States are required to take immediate action to eradicate it should any outbreaks diseases occur (currently restricted to infectious salmon anaemia [ISA]).
- List II deals with highly infectious diseases of major economic impact already present in some parts of the EU but known to be absent from other parts. Diseases currently on the list 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 which are not as serious as those in List II but which do have a significant economic impact in certain circumstances and are considered by some Member States to warrant national control measures, particularly when the country concerned, or part of its territory, 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, the Directive provides for Member States having zones (or farms) considered free of these diseases to undertake regular disease checking to confirm this. Unlike the OIE Code,

¹³ This section was kindly provided by Dr. Barry J. Hill, Vice President of the OIE Fish Diseases Commission.

¹⁴ 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.

the EU arrangements do not refer to 'free' zones (or farms), but instead use the term 'approved zones', but essentially they are equivalent. However, the Directive does not include any provision for the recognition of 'disease-free country' even though this is a category provided for in the OIE Code. Instead, the emphasis is firmly upon the principle of establishing 'approved (free) zones', whether these be confined within the territory of an individual country, or comprise the entire territory of a country, or cover parts or the whole of territories of one or more countries. There is provision for 'coastal zones', covering complete estuaries or lengths of coastline, or 'continental zones', consisting of one or more water catchment areas. Any such zone is delineated by the Competent Authorities of the country or countries in whose territory it exists, who must also introduce legal powers to enforce the rules and conditions that apply for a zone to be established and maintained as being 'approved' (free) of the specified List II disease(s), i.e. VHS and/or IHN for finfish and bonamiosis and/or marteiliosis for bivalve molluscs. The EU definitions of continental and coastal zones are given below.

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."

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.

Appendix 8 cont...

Thus, for continental territory, a zone usually comprises a minimum of an entire river system, including all the tributaries, from their source(s) to the sea. This need not pose any problems for a country in whose territory the entire river system (or systems) flow. However, where a river system, or part of it, originates in one country and then passes through one or more other countries before reaching the sea, matters become more complicated and require good co-operation and harmonisation of rules and services in the separate countries involved if the conditions for approval of that zone are to be met. The simplest zone for management purposes is most usually an island state or an island which is part of the national territory of the country involved.

An exception to a zone having to comprise an entire river system is allowed in the EU zoning arrangements. If there is part of a catchment area which stretches from the source of the river and its tributaries to a barrier (whether natural or artificial e.g. a man-made dam or high waterfall) which prevents the fish from migrating above it from downriver, this can be accepted as a separate 'mini-zone' which is free of specified disease(s) even though the same disease(s) exists downstream of the impassable barrier. It is not possible to approve 'mini-zones' without such an impassable barrier giving the downstream limit of the zone, nor to approve parts of a river downstream of sections of the river which are non-approved.

Coastal zones can be more difficult to delineate but will usually be a distinct stretch of coastline e.g. a bay or stretch of coast between two peninsulas, or parts of the coast hydrologically separated from adjacent parts by the direction of water current.

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 meets the conditions laid down in Directive 91/67/EEC and, in particular, the detail requirements of Annex B. The requirements are too detailed to be listed here, but essentially all farms in a zone must have been under the supervision of the Official Services for at least 4 years during which they have been inspected at intervals and found free from any clinical or other sign of disease(s) and, as a minimum, have been subjected to 2 health inspections per year for 2 years at a time when the water temperature favours the development of the disease(s) in question. The health inspections require the taking of samples which must be tested for the pathogen(s) in question in an approved laboratory. The Member State 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 2-year period and thereafter. The European Commission scrutinises the information, together with representatives of all EU Member States, and a decision (Commission Decision) is reached on whether the specified zone can be 'approved'.

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Once a zone is approved, it is a requirement that movements of fish (or molluscs) into the zone be restricted to those from other approved zones and that continuing evidence must be provided that the disease(s) in question is (are) still absent. This requires regular inspection of all the farms in the zone but with sampling and laboratory tests being conducted at a lower size and frequency than required for achieving 'approved zone' status.

The Directive also provides for the suspension, withdrawal and restoration of 'approved zone' status. If any abnormal mortalities or clinical signs that might constitute grounds for suspecting an outbreak of the relevant disease, the incident must be notified as quickly as possible to the Official Services of the country and samples of clinically-affected fish sent to an approved laboratory to be tested for the pathogen in question. Where the test results are positive, the Official Services must withdraw the approved status of the entire zone or, where there is justification for this, the part of the zone affected. The latter is normally only possible for large zones comprising several water catchment areas, the affected one of which can be 'excised' from the zone without affecting the rest of the zone. Restoration of approved status for a zone, or the affected part of a zone, can be achieved following satisfactory evidence of eradication of the disease followed by all the conditions for establishing approved status (as above) being met.

Some examples of EU-approved zones

Since Directive 91/67 came into force in January 1993, approved zones have been established (for VHS and/or IHN) in the territories, or parts thereof, of six EU Member States (UK, Ireland, Denmark, France, Italy and Spain). The geographical territory and delineation of the zones in some cases is straightforward, but in others it becomes more complicated.

Although maps showing the delineated zones were submitted in all cases as part of the evidence in support of the application for approved zone status, the maps themselves have not been published and the European Commission instead provides a verbal description.

For example, the first zones to be approved were those of **Great Britain** and **Northern Ireland**, the former being a straightforward distinct entity as an island state without the problem of rivers shared with other countries. Furthermore, the entire territory was well known to be free of the two diseases (VHS and IHN) – no cases ever having been recorded.

A similar situation existed for **Ireland**, again an island state without rivers shared with any other country other than Northern Ireland (which already had been recognised as an approved zone).

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For other countries such as **Denmark**, the situation was less straightforward. In this case, the published Commission Decision states:

- ‘Denmark is recognised as approved continental zone and approved coastal zone for fish with regard to Infectious Haematopoietic Necrosis’;
- ‘the part of Denmark composed of the water catchment areas contained in the Annex and the coastal areas belonging thereto, is recognised as approved ;
- continental zone and approved coastal zone for fish with regard to Viral Haemorrhagic Septicaemia’.

The Annex lists the names of 34 river systems (without a map or any other description of their location or the boundaries of the continental zone!) Other named water catchment systems have since been added by subsequent Commission Decisions to expand the zone.

For **France**, a Commission Decision announced that:

- the catchment areas listed in the Annex hereto are recognised as approved continental zones in respect of IHN and VHS;
- the coastal areas belonging to the catchment areas indicated in paragraph 1 and listed in the Annex are recognised as approved coastal zones in respect of IHN and VHS.

The Annex specifies:

Catchment Areas

All the water catchment areas in the region of Brittany with the exception of the following water catchment areas:

- ◆ Vilaine,
- ◆ Aven,
- ◆ Ster-Goz,

Coastal Areas

The entire coast of Brittany with the exception of the following parts:

- ◆ Rade de Brest,
- ◆ Anse de Camaret,
- ◆ The coastal zone between the ‘pointe de Trévignon’ and the mouth of the river Laita,
- ◆ The coastal zone between the mouth of the river Tohon up to the border of the department.

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For **Spain**, Commission Decision 98/361/EC announced approved zones with regard to IHN and VHS for the continental zone comprising 'all water catchment areas in the region of Astureias, excluding the catchment of the Rio Eo' and for coastal zone 'the entire coast of Astureias'.

For **Italy**, the most recent EU Member State to obtain approval for zones within its territory, the situation is somewhat different in that 'mini-zones', i.e. stretches of river upstream from an impassable barrier to the source(s) have been approved. Again, whilst map and photographic evidence were submitted during the application process, they have not been published and therefore reliance is again upon the written description as follows:

List of approved zones with regard to IHN and VHS in Italy

Region: Provincia Autonoma di Trento

Zona Val die Fiemme e Fassa

Water catchment area of the river Avisio, from the source to the artificial barrier of Stramentizzo.

Zona Valle dei Laghi

Water catchment area of the lakes of San Massenza, Toblino and Cavedine to the downstream barrier in the south part of the lake of Cavedine leading to the hydro-electric power station located in the Torbole municipality.

Zona Cal delle Sorne

Water catchment area of the river Sorna from the source to the artificial barrier constituted by the hydro-electric power station located in the Chizzola (Ala) locality, before reaching the Adige river.

Zona Torrente Adanà

Water catchment area of the river Adanà from the source to the artificial series of barriers situated downstream of the farm Armani Cornelio-Lardaro.

Zona Rio Manes

Zone which collects the Rio Manes water down to a waterfall located 200 metres downstream of the farm 'Troticoltura Giovanelli' located in the 'La Zinquantina' locality.

These examples serve to demonstrate that zoning on grounds of freedom from specified disease(s) is achievable and practicable even if the delineation of the zones could be more clearly made public to avoid confusion and misunderstanding. The exact delineation of a zone is important, since all farms within that zone are affected by the rules applying to approved zones.

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Trade in aquatic animals between zones

The movement of live farmed, or wild, fish or molluscs to waters within an 'approved zone' is restricted to animals originating from within the same zone or from other equally approved zones, i.e. zones which are also free of the same disease(s). There is no restriction on disease grounds in the trade in live fish or bivalve molluscs, whether farmed or wild, within or between approved zones, nor for the 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 by all Member States for any of the List III diseases. For all movements of live fish and their ova, or of live molluscs, into approved zones, movement documents are required certifying that the fish (or molluscs) originate from a zone having the same List II disease-free approved 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 to the approved zone or farm.

Appendix 9: Australian National List of Reportable Diseases of Aquatic Animals

A) Criteria for listing diseases on the National List

1. The *National List* is a list of diseases, some exotic to Australia and some occurring in parts of Australia. The *National List* is not an inventory of diseases occurring in Australia. Diseases listed meet at least one of the following criteria:
 - a disease is internationally notifiable to OIE¹⁵; or
 - a disease is reportable to NACA/OIE¹⁶ under a regional reporting scheme (note that there is no legal reporting obligation to NACA/OIE); or
 - a disease is of national and genuine concern to Australia.
2. Whereas the OIE and NACA/OIE lists are internationally agreed upon, it is Australia's decision to add further diseases to the *National List* (i.e. diseases not covered by OIE and NACA, but of national and genuine concern to Australia).
3. For a disease to be listed because it is deemed to be of national and genuine concern to Australia, the following criteria must apply:
 - a disease is exotic to Australia, or a disease does occur in parts of Australia but vigilance is necessary to minimise its spread; and
 - a disease would have significant socio-economic impacts if it occurred; and
 - a disease can be clearly described by its aetiology (causative agent).
 - an additional, but not compulsory criterion is met when control or eradication programs exist in one or several States/Territories, so that other States/Territories may wish to gain information on the status of the disease in the particular State/Territory administering the controls.

B) Diseases/agents currently listed (as of September 1, 1999)

Disease Agent	Notifiable to OIE	Reportable to NACA/OIE	Exotic to Australia
FINFISH			
<i>Aeromonas salmonicida</i> (atypical strains)	No	No	No
<i>Aeromonas salmonicida</i> var. <i>salmonicida</i> (furunculosis)	No	No	Yes
<i>Aphanomyces invaderis</i> (Epizootic ulcerative syndrome)	No	Yes	No
Channel catfish virus	No	No	Yes

¹⁵ [Aquatic animal] Diseases notifiable to the OIE: means the list of transmissible diseases that are considered to be of socio-economic and/or public health importance within countries and that are significant in the international trade of aquatic animals and aquatic animal products. - *OIE International Aquatic Animal Health Code*, 2nd ed. 1997

¹⁶ means the diseases listed on the OIE/NACA Quarterly Aquatic Animal Disease Report forms, as part of the *FAO/NACA/OIE Regional Programme for the Development of Technical Guidelines on Quarantine and Health Certification, and Establishment of Information Systems for the Responsible Movement of Live Aquatic Animals in Asia*

<i>Edwardsiella ictaluri</i> (Enteric septicaemia of catfish)	No	No	Yes
Epizootic haematopoietic necrosis virus	Yes	Yes	No
<i>Gyrodactylus salaris</i>	No	No	Yes
Infectious haematopoietic necrosis virus	Yes	Yes	Yes
Infectious pancreatic necrosis virus	No	Yes	Yes
Infectious salmon anaemia virus	No	No	Yes
<i>Myxobolus cerebralis</i> (Whirling disease)	No	No	Yes
<i>Oncorhynchus masou</i> virus	Yes	Yes	Yes
<i>Piscirickettsia salmonis</i> (Piscirickettsiosis)	No	No	Yes
<i>Renibacterium salmoninarum</i> (Bacterial kidney disease)	No	Yes	Yes
Spring viraemia of carp virus	Yes	Yes	Yes
Viral Encephalopathy and Retinopathy	No	Yes	No
Viral haemorrhagic septicaemia virus	Yes	Yes	Yes
<i>Yersinia ruckeri</i> (Enteric redmouth disease/yersiniosis)	No	No	No (ERM) / yes
CRUSTACEANS			
<i>Aphanomyces astaci</i> (Crayfish plague)	No	No	Yes
Baculoviral midgut gland necrosis virus	No	Yes	Yes
<i>Baculovirus penaei</i>	No	No	Yes
Infectious hypodermal and haematopoietic necrosis virus	No	Yes	Yes
<i>Penaeus monodon</i> -type baculovirus	No	No	No
Taura syndrome virus	No	No	Yes
Whitespot disease virus	No	Yes	Yes
Yellowhead disease virus	No	Yes	Yes
Necrotising Hepatopancreatitis	No	No	Yes
MOLLUSCS			
<i>Bonamia ostreae</i> (Bonamiosis)	Yes	Yes	Yes
<i>Bonamia</i> spp. (Bonamiosis)	Yes	Yes	No
<i>Haplosporidium costale</i> (Haplosporidiosis)	Yes	Yes	Yes
<i>Haplosporidium nelsoni</i> (Haplosporidiosis)	Yes	Yes	Yes
<i>Marteilia refringens</i> (Marteiliosis)	Yes	Yes	Yes
<i>Marteilia sydneyi</i> (Marteiliosis)	Yes	Yes	No
<i>Mikrocytos mackini</i> (Mikrocytosis)	Yes	Yes	Yes
<i>Mikrocytos roughleyi</i> (Mikrocytosis)	Yes	Yes	No
Iridovirus	No	No	Yes
<i>Perkinsus marinus</i> (Perkinsosis)	Yes	Yes	Yes
<i>Perkinsus olseni</i> (Perkinsosis)	Yes	Yes	No

