Development And Establishment of a National System for Minor Uses Of Products for the Protection Of Livestock In Aquaculture.

Dr Peter A Taylor

FISHERIES RESEARCH & DEVELOPMENT CORPORATION

Project No. 2001/256

Development And Establishment of a National System for Minor Uses Of Products for the Protection Of Livestock In Aquaculture.

AUTHOR: **Dr Peter A Taylor, Director, TS Agricultural Consultants Pty Ltd**
Prepared on behalf of CPA Research Pty Ltd (in liquidation)

DATE: **23rd April 2004**

ISBN:

Table of Contents

Non Technical Summary....4
Background....6
Need....6
Objectives....7
Methods....7
Results/Discussion....8
Database of Items requiring permits/registrations....8
Blueprint for the System....8
Pilot Project....8
Issues regarding GLP Standard Residue Studies....8
Full Implementation....9
Benefits....9
Further Development....9
Planned outcomes....9
Conclusion....9
Appendix 1: Intellectual Property....11
Appendix 2: Staff....12
Appendix 3……..Blueprint for the Minor use System....13
Appendix 4 Text on Liability Issues, originally in draft Blueprint....35
2.3 Liability....36
2.4.1 Liability of Manufacturer....36
2.4.2 Liability of the APVMA....37
2.4.3 Liability of funding body.....37
Appendix 5 Permit 6670....39
Appendix 6 Listing of minor use items requested by aquaculture industries 47

2001/256 Development And Establishment of a National System for Minor Uses Of Products for the Protection Of Livestock In Aquaculture.

Principal Investigator: **Dr Peter A Taylor**
Address: **Crop Protection Approvals Ltd**
5 Everage St
Moonee Ponds, Vic 3039
Telephone: +613 83710001 Facsimile: +613 93757552

OBJECTIVES

1. Establish a producer-driven system to meet the requirements of the various sectors of aquaculture for registered products.
2. In consultation with industry bodies, develop a blueprint for the system and establish frameworks for the ownership of data and permits and for the ongoing servicing and renewal of permits.
3. Develop and verify standard operating procedures for the conduct of GLP - compliant residue trials.

NON TECHNICAL SUMMARY

OUTCOMES ACHIEVED TO DATE

Aquaculturists now have legal access to formaldehyde under a consolidated single permit PER6670 for fresh and salt-water finfish, abalone and crustaceans. Consolidated permit applications for Hydrogen Peroxide for treatment of Kingfish and abalone are pending.

All substances that fit the definition of agricultural and veterinary chemicals under the Chemical and Veterinary Chemicals Code Act 1994 must be registered by the Australian Pesticides and Veterinary Medicines Authority before they can be supplied, sold or used in Australia. In addition, any produce derived from livestock that has been treated with such substances must comply with Maximum Residue Limits as specified in Part 14 a of the ANZFA Food Code.

This project was preceded by Project 96/314 "Registration of Aquaculture Chemicals", which was conducted to identify the most appropriate and industry-accepted drugs and chemicals for each sector of the aquaculture industry, to maximize the cost-effectiveness and efficiency of the registration processes, and to establish registration of key drugs. This project was designed to establish a system that will serve the ongoing needs of the aquaculture industries.

The minor use system developed by CPA Research for horticulture was used as a model for an aquaculture-specific system in which industry sectors identify and prioritise their needs for veterinary chemical products and pass them to an appointed consultant co-ordinator. The individual items are analysed by the consultant in terms of the availability of alternatives, environmental considerations etc and, where

possible, combined with similar requests from other industries. The data requirements for a registration/permit are determined in consultation with the APVMA, and the items are costed and passed back through NAC in the form of proposals for funding.

Ongoing maintenance of the system would be contracted by the NAC to a suitable consultant.

Pilot projects included the consolidation of existing and expired permits for formalin into a single permit for aquaculture industries, permits for hydrogen peroxide and for benzalkonium chloride.

The system is not yet fully operational, because issues in regard to ongoing funding through NAC are still being resolved. Questions regarding intellectual property and the legal liability for misuse are being considered by the NAC. The NAC also has yet to resolve issues concerning administration of the chemical registration process in regard to cost recovery.

KEYWORDS: veterinary medicine, registration system, minor use permits, fish protection

Acknowledgments

We wish to acknowledge the help of Dr Kevin Ellard and Mr Simon Bennison, who provided invaluable technical expertise and advice.

Background

This project was preceded by Project 96/314 "Registration of Aquaculture Chemicals", which was conducted to identify the most appropriate and industry-accepted drugs and chemicals for each sector of the aquaculture industry, to maximize the cost-effectiveness and efficiency of the registration processes, and to establish registration of key drugs. This project is designed to establish a system that will serve the ongoing needs of the aquaculture industries.

In July 1999, Ausveg and Horticulture Australia funded the establishment of Crop Protection Approvals Ltd, a grower-owned company, and it's wholly-owned subsidiary, CPA Research Pty Ltd. These companies were formed to implement and maintain a national system for minor uses of pesticides in horticulture. From then until November 2003, CPA Research Pty Ltd managed residue trials and other studies worth more than $2 million. This project was initiated by CPA Research Pty Ltd to develop aquaculture-specific operating procedures, communication links and systems to enable the ongoing needs of the various aquaculture sectors for permitted/registered products to be fulfilled. The author of this report was previously Director of CPA Research and was the leader of this project.

Need

Today's markets for seafood are extremely sensitive to issues relating to quality. In order to meet the demands of these markets it is often necessary to use Veterinary chemicals and other substances to ensure that fresh, high quality produce reaches the marketplace.

All substances that fit the definition of agricultural and veterinary chemicals under the Chemical and Veterinary Chemicals Code Act 1994 must be registered by the Australian Pesticides and Veterinary Medicines Authority before they can be supplied, sold or used in Australia. In addition, any produce derived from livestock that has been treated with such substances must comply with Maximum Residue Limits as specified in Part 14 a of the ANZFA Food Code.

The cost of generating data and assembling submissions for registration of substances is high. It is understood that the ability of companies to bear high costs of research and registration of veterinary products is limited by market size. Under the existing registration system, veterinary companies set product registration and development priorities according to market sizes and anticipated market share. The uses of veterinary products in aquaculture and wild fisheries represent only small markets to these companies and therefore there is inadequate incentive for them to register their products. As a result, aquaculturists frequently suffer from a lack of legal access to livestock protection products. On the other hand, they are facing increasing requirements to comply with quality assurance programs that insist that registered products must be used. There is also increasing pressure to use products that have minimal environmental impact.

Growers affected by the problem are increasingly trapped in a situation where they face severe losses from pests and diseases if they do nothing to protect their fish, or have their produce rejected by the marketplace if they use a product that is not registered. Poor publicity arising from such occurrences would severely damage the "clean and green" image that the industry wishes to project. The lack of access to registered products that employ new technologies is also likely to hamper the competitiveness and sustainability of the industry in the future.

There is a need to establish a system in which the needs of the aquaculture industry sectors are met on a continuing basis, through industry consultation, cost sharing

and efficient project direction and execution. In this context, we define a “project” as a defined body of work to secure a Minor Use Permit for one product for one species (or one group of closely related species).

Objectives

1. Establish a producer-driven system to meet the requirements of the various sectors of aquaculture for registered products.
2. In consultation with industry bodies, develop a blueprint for the system and establish frameworks for the ownership of data and permits and for the ongoing servicing and renewal of permits.
3. Develop and verify standard operating procedures for the conduct of GLP - compliant residue trials.

Methods

Desirable attributes of a minor use system were defined as follows:

a) Producer / Industry – driven

b) Good lines of communication with the various sectors and with APVMA, AFFA, ASIC, NAC.

c) Facilitates communication within sectors

d) Systems established for collecting and analysing requests for Minor Use Permits.

e) Processes for industry prioritisation of request items.

f) Avenues for funding of projects developed.

g) Good network with cooperating farmers; veterinary prescribers, public and private research agencies, analytical labs.

h) Good network and lines of communication with Ag/Vet product manufacturers.

i) Minimal overheads.

j) Infrastructure and systems maintained to promptly deal with sporadic timing of requests and Minor Use Permit renewals.

k) Newsletter/website/feature articles in industry publications.

Prior to the commencement of this project, Crop Protection Approvals Ltd, the sole shareholder of the principal investigator CPA Research Pty Ltd, established a national system for minor uses of pesticides in horticulture. Key elements of that system, including procedures, database software for tracking projects and generating residue study protocols and feedback mechanisms, were used as a basis for the new aquaculture system. The following steps provide an outline of the methodology in the project.

1. Development of communication links with stakeholders by contact with industry peak bodies, leading producers, government departments, R&D organizations and Ag/vet product manufacturers.
2. Determination of industry needs by personal interviews and consultations with the above groups
3. Identify suitable candidate products for a pilot project.
4. Development of draft blueprint for operation of the system incorporating, if appropriate, alternative modes of operation.
5. Adapt project management and protocol generation software.

6. Implement pilot project (s)
7. Circulation of the blueprint to stakeholders for feedback
8. Conduct a workshop on revised system – produce “final” blueprint.
9. Publicise the system, inform industry of pilot project progress and call for new project requests.

Results/Discussion

Database of Items requiring permits/registrations

CPA Research produced, using software originally developed by TS Agricultural Consultants Pty Ltd, a database, of products (Items) requested by various industry sectors of aquaculture and liaised with AVMPA officers in regard to data requirements and suitability of particular requests for pilot projects. Items in the database are currently listed, until a decision is made on whether to attach them to an NAC web site, on the TS Agricultural Consultants Pty Ltd web page at www.tsac.com.au/fish/. The information in the database is the property of the NAC. TS Agricultural Consultants Pty Ltd has granted NAC permission to use the software developed by it for the purposes of entering and editing data and for production of reports on minor use items.

Requests for items to be added can be made by contacting NAC directly, or by filling in an application form on the web page.

Blueprint for the System

A draft blueprint for the new system, including information and discussions on liability issues, project selection, funding and the role of the National Aquaculture Council, was produced. The draft blueprint was presented and discussed at a national workshop that was held on 17th July 2002.

Following the workshop, the draft blueprint was revised (Appendix 3). Sections on liability, structure of organisations and alternative pathways for funding and operation were removed on the recommendation of the workshop and steering committee and a final blueprint was produced and circulated (Appendix 4). There was little feedback, save for a few further submissions on minor use requirements (Queensland fresh water sector and prawns) and a detailed compilation by Kevin Ellard of the responses of various sectors of the Tasmanian industries.

The final blueprint referred frequently to the role of CPA Research Pty Ltd in administering the operation of the system. The demise of CPA Research does not jeopardise the system in any way because the role of CPA Research could be contracted by NAC to any other suitable consultant.

Pilot Project

As a pilot project, submissions were prepared to support a consolidated minor use permit for formaldehyde treatments of fresh and saltwater finfish (including salmonids), salmonid eggs and crustacean. The permit PER6670 (Appendix 5) was granted on 15th September 2003. A further application was made for hydrogen peroxide treatment of Kingfish and for induction of spawning in abalone and this is currently being evaluated by the APVMA. A third application for benzalkonium chloride for salmon and prawns was in preparation.

Issues regarding GLP Standard Residue Studies

Since January 2003, the APVMA has required that residue data generated to support registrations must be to GLP standard. The APVMA has “strongly recommended” that data to support minor uses should also be of GLP standard, but has not made it compulsory. GLP Residue studies cost significantly more than non-

GLP studies because of increased costs of documentation, certification and quality assurance in both the field and analytical phases.

A decision to commission GLP trials would depend on the nature of the compound (the likelihood of residues occurring in harvested fish), whether or not the fish or fish products are exported and to which countries the products are sent.

Full Implementation

Full-scale operation of the system has been delayed by the lack of clear pathways and procedures for funding the work. The NAC intends to provide a coordinating role in this area, but details have yet to be finalised. In July 2003 the proposed system was discussed at a meeting of the National Aquaculture Development Committee, as part of the Aquaculture Action Agenda item "aquaculture development in an ecological sustainable framework". We were informed by Mr Bruce Zippell, a member of the former NADC and Chairman of the NAC, that the Minister, Mr Ian McDonald, expressed reservations about the proposed system in two areas: liability and ownership of existing intellectual property. As a result of these issues being raised, the Director of CPA Research, Dr Peter Taylor, was requested to give a presentation at the next NADC meeting on 11th November in Brisbane.

Soon after the Brisbane meeting, Crop Protection Approvals Ltd and CPA Research Pty Ltd were placed into administration. The reason was refusal of funding by Horticulture Australia and Ausveg, who had decided to abandon the CPA structure and who would undertake administration of the vegetable minor use system themselves.

Benefits

All sectors of the aquaculture industry will benefit from the operation of this system, through its provision of needed legal access to veterinary products. When fully operational, it will promote the clean and sustainable image that the aquaculture industries wish to project to their markets and will help to protect those industries against market failure.

Further Development

Further development hinges on the establishment of an ongoing funding pathway to support the system, and on development of arrangements for project-specific funding. There are presently very few permits that are still current. There is a need to contact the holders of expired permits to determine whether they wish to renew these permits under the new system and to obtain information from them to support the renewals. Unfortunately the details of the holders of expired permits are not available on the APVMA web site.

Planned outcomes

The major planned outcomes are that producers will gain legal access to chemicals and drugs that they need to maintain productivity and meet the demands of their markets in a sustainable manner. This will often be associated with reduction of risks of losses from diseases and losses due to market rejection.

Unfortunately, these outcomes have not yet been realised. It is anticipated however that they will be, once the anticipated developments in the NAC have been put into place.

Conclusion

The objectives of this project, namely to establish a producer-driven system to meet the requirements of the various sectors of aquaculture for registered products,

develop a blueprint for the system and establish it have been partially met. It is anticipated that they will be fully met following further consultation between the NAC, its members and appointed consultants.

Appendix 1: Intellectual Property

No intellectual property has been generated in this work. Should any intellectual property be generated such as residue data, such data shall remain the property of the NAC and its members.

Appendix 2: Staff

Dr. Peter Taylor Ph.D	Director, CPA Research P/L (now in liquidation) Manager, Crop Protection Approvals Ltd (now in liquidation) Director, TS Agricultural Consultants Pty Ltd
Mr. Peter Dal Santo B.Agri.Sci	Executive Officer, CPA Research P/L (now in liquidation)
Ms. Jennifer Hall B. Agri. Sci (Hons)	Marketing & Administration
Ms Christina Sullivan	Administration
Ms Angela Gaw	Technical/Regulatory Affairs

Appendix 3…….Blueprint for the Minor use System

FRDC Project Number: 2001/256

Development and establishment of a national system for minor uses of products for the protection of livestock in aquaculture and fisheries - a blueprint.

Prepared by

Peter A Taylor B.Sc (Hons), Ph.D

Director, CPA Research Pty Ltd

November 2002

TABLE OF CONTENTS

Preface 15
Introduction 16
2. Components of the System and their Functions. 17
2.2 Permit Holders 17
2.3 Expert Panel 18
2.4 Aquaculture Industries 18
2. 5 Agriculture Forestry & Fisheries Australia (AFFA). 19
Funding System Maintenance 19
2. 6 Australian Pesticides and Veterinary Medicines Authority (APVMA) . 19
Evaluation of Permit Applications and Issuing of Permits. 19
2. 7 CPA Research - Fisheries (CPAF) 19
3. Communication 21
4. Costs. 22
APPENDIX 30
A National System for Minor Uses of Chemicals/Veterinary Products in Aquaculture 30

Preface

This project was preceded by Project 96/314 "Registration of Aquaculture Chemicals", which was conducted to identify the most appropriate and industry-accepted drugs and chemicals for each sector of the aquaculture industry, to maximize the cost-effectiveness and efficiency of the registration processes, and to establish registration of key drugs.

The current project is designed to establish a system that will serve the ongoing needs of the aquaculture industries for renewal of Minor Use Permits and establishment of new registrations. The outcomes of the project will be:

- National Minor Use Program for fisheries
- Coordinated development with the Australian Pesticides and Veterinary Medicines Authority (APVMA) and veterinary industry on minor use issues
- Ability for producers to help prioritise minor use approvals
- Wider range of products legally available for the fisheries industries
- Advice to stakeholders on minor use chemicals and the Program
- Program that can be extended to other primary industries
- Strategy for FRDC, RIRDC, and the agrivet industry to better handle R&D associated with minor use livestock protection products.

This document provides details of a structure and mode of operation of the minor use system, to be managed by a division of CPA Research Pty Ltd called CPA Research - Fisheries (CPAF). It was developed from a draft model that was circulated to industry leaders and the project steering committee, then revised according to recommendations and outcomes of discussions at the Workshop held in Melbourne on 17th July: "Setting up a registration system for minor uses of products for protection of fish in aquaculture and fisheries" (Appendix 1). It is very different to the original draft, because much of the discussion of alternatives has been deleted and discussions of issues relating to legal responsibilities and liabilities are focused on the actual components of the system, not on other possible components. It is an "organic" document that will change as the system develops.

Introduction

Today's markets for seafood are extremely sensitive to issues relating to quality. In order to meet the demands of these markets it is often necessary to use Veterinary chemicals and other substances to ensure that fresh, high quality produce reaches the marketplace.

All substances that fit the definition of agricultural and veterinary chemicals under the Chemical and Veterinary Chemicals Code Act 1994 must be registered by the Australian Pesticides and Veterinary Medicines Authority before they can be supplied, sold or used in Australia. In addition, any produce derived from livestock that has been treated with such substances must comply with Maximum Residue Limits as specified in Part 14 a of the ANZFA Food Code.

The cost of generating data and assembling submissions for registration of substances is high. It is understood that the ability of companies to bear high costs of research and registration of veterinary products is limited by market size. Under the existing registration system, veterinary companies set product registration and development priorities according to market sizes and anticipated market share. The uses of veterinary products in aquaculture and wild fisheries represent only small markets to these companies and therefore there is inadequate incentive for them to register their products. As a result, aquaculturists frequently suffer from a lack of legal access to livestock protection products. On the other hand, they are facing increasing requirements to comply with quality assurance programs that insist that registered products must be used. There is also increasing pressure to use products that have minimal environmental impact.

Growers affected by the problem are increasingly trapped in a situation where they face severe losses from pests and diseases if they do nothing to protect their fish, or have their produce rejected by the marketplace if they use a product that is not registered. Poor publicity arising from such occurrences would severely damage the “clean and green” image that the industry wishes to project. The lack of access to registered products that employ new technologies is also likely to hamper the competitiveness and sustainability of the industry in the future.

There is a need to establish a system in which the needs of the aquaculture industry sectors are met on a continuing basis, through industry consultation, cost sharing and efficient project direction and execution. In this context, we define a “project” as a defined body of work to secure a Minor Use Permit for one product for one species (or one group of closely related species). Desirable attributes of a minor use system are as follows:

a) Producer / Industry – driven

b) Good lines of communication with the various sectors and with APVMA, AFFA, ASIC, NAC.

c) Facilitates communication within sectors

d) Systems established for collecting and analysing requests for Minor Use Permits.

e) Processes for industry prioritisation of request items.

f) Avenues for funding of projects developed.

g) Good network with cooperating farmers; veterinary prescribers, public and private research agencies, analytical labs.

h) Good network and lines of communication with Ag/Vet product manufacturers.

i) Minimal overheads.

j) Infrastructure and systems maintained to promptly deal with sporadic timing of requests and Minor Use Permit renewals.

k) Newsletter/website/feature articles in industry publications.

2. Components of the System and their Functions.

2.2 Permit Holders

National Aquaculture Council (NAC) and Member Organisations

We strongly recommend that the peak industry body, the NAC, should be the permit holder on behalf of its member industries (as does Ausveg for diverse vegetable industry groups). This would not however preclude individual industry organisations from assuming the role of permit holder should they wish to do so. Should the NAC decide not to take on the role and responsibilities of permit holder, the individual member organisations would have to.

The permit holder is responsible for:

- Providing accurate and complete details of the permit, including all conditions, or for indicating from where a copy of the permit can be obtained (i.e. from CPA Research - Fisheries).
- Ensuring that any information provided by them to other persons in relation to the permit is accurate, complete and totally in accordance with the permit (delegated to CPA Research - Fisheries).
- To inform the APVMA of any relevant information of which they become aware concerning the uses dealt with by the permit, which if the APVMA had been aware of prior to issuing the permit, they may not have issued the permit or may have issued the permit with different instructions and/or conditions (delegated to CPA Research - Fisheries).

The responsibilities of the permit holder do not extend to: -

- Ensuring the compliance of persons undertaking the proposed users or
- 'Advertising' the existence of a permit to all potential users; or
- Providing a copy of a permit, or equivalent information, to all potential users.

Conduit for project specific funds

The simplest system is one in which individual industry bodies could channel funds for specific minor use projects through NAC. If not, then each industry body would have to make its own arrangements for fund collection to support minor use projects. Funds for projects that would apply to several industries could be consolidated by NAC.

2.3 Expert Panel

The Expert Panel will approve and help to prioritise minor use projects submitted to it by CPA Research Fisheries. The NAC, and the Steering Committee, after consultation with industries, Vets and Aquatic Animal Health Initiative, will advise CPA on the composition of the Expert Panel.

2.4 Aquaculture Industries

Requests for projects

The individual aquaculture industries will review their needs for minor use permits/registrations on a regular basis, preferably in a session dedicated to this purpose at a regular industry meeting or conference. Requests will be sent electronically to CPA Research - Fisheries, who will collate all requests and forward them to the Expert Panel for evaluation and approval. We would expect the Expert Panel to advise on such issues as the availability of alternatives that might be more efficacious, or have softer environmental or other off target effects etc, including non-chemical measures.

Funds

We envisage that CPA Research Fisheries would assist either NAC or member industries to make submissions to the government for funds to match the grower's contributions. The funds will be channelled through NAC, or through their own organisation. With such assistance, the individual industries will bear the costs of obtaining and maintaining minor use permits for their industry.

Users

The members of the industries and, depending on the scheduling of the substance, veterinary surgeons, will be the User's of fish livestock protection products under the conditions of the Minor Use Permits.

The Users are responsible for compliance with all of the conditions and instructions in the permit document and also with State and Federal laws governing the application of the product.

The User is responsible for obtaining a copy of the permit if it hasn't been provided (facilitated by CPA Research - Fisheries).

2. 5 Agriculture Forestry & Fisheries Australia (AFFA).

Funding System Maintenance

AFFA will fund the costs of maintaining the system for the first three years, with options for ongoing funding to be reviewed after two years. This funding will cover CPA Research - Fisheries internal costs only i.e maintenance of information systems, communication and office costs. It will not cover permit applications costs, nor will it cover the costs of extension activities such as industry mail outs that involve additional printing and postage costs.

2. 6 Australian Pesticides and Veterinary Medicines Authority (APVMA)

Evaluation of Permit Applications and Issuing of Permits.

The APVMA will evaluate permit applications submitted by CPA Research - Fisheries on behalf of the NAC. The APVMA has recently re-structured itself and there is now no dedicated Minor Use Section.

In the case of new project requests for permits, CPA Research - Fisheries will seek the APVMA's advice on data requirements before the projects are commissioned. CPA Research and Fisheries will negotiate with the APVMA on numbers and locations of field residue studies, should they be required.

2. 7 CPA Research - Fisheries (CPAF)

CPAF will collate and cost proposals from industries and individuals, consult with the APVMA and the veterinary company to determine what data are required for a minor use approval, put forward funding submissions to support the project then collect the data or arrange for it to be generated. CPAF will submit applications to the APVMA and communicate the results back to growers and other stakeholders. CPAF will hold copies of APVMA Minor Use Permits on behalf of its client industries and make them available on request.

The operations of CPAF in relation to industry, regulatory authorities, and agrochemical companies are summarised in Fig 1. In essence, the minor use approval process will comprise the following steps: -

Call for submissions.

CPAF will encourage each industry sector to include a session on this in its regular industry meeting. CPAF will provide an application kit to potential applicants, including forms and instructions, or with a simple spreadsheet for electronic submission by email.

CPAF analyses applications.

The requests to CPAF will be checked against criteria including the following:

- Is there an effective, legally accessible control measure available? If so, does the proposed use offer significant therapeutic, environmental or user benefits over the existing control measure. The APVMA has a policy that no Minor Use Permit will be issued if adequate alternatives exist.
- Is the proposed use of the product safe to the fish, the user and the environment? These are APVMA requirements.

- Is the product required for resistance management strategies?
- Will the use have beneficial or adverse effects on product quality/market acceptance?
- Does the manufacturer approve of the use, or have technical grounds for objecting to it?

Requests will then be put before members of the Expert Panel for ratification or modification, and prioritisation.

Determine data requirements.

For each proposal, CPAF will access APVMA reference lists of MRLs and previous Minor Use Permits, external databases (eg through IR4 in the USA), scientific databases and Codex to determine whether additional data are required. It will also, through contacts in the agrivet industry and in various research agencies, attempt to determine whether suitable data may have been generated previously in this country and elsewhere. CPAF will then check with the APVMA to ratify data requirements.

Negotiate with relevant veterinary companies on their level of support.

CPAF will seek support in the form of data, finance and in-kind contributions from veterinary companies affected by the proposal.

Draft development schedule and costing for each proposal

CPAF will determine the number of trials (if required), set time frames and estimate the total costs for each proposal, based on experience from previous work (eg Project 96/314).

CPAF submits analysed list to NAC/Member Industry/Government with a funding application.

The funding application and list will contain details of project costs, timelines and milestone payments. On receipt and approval of the funding application, NAC or the controlling funding body will contract CPA Research – Fisheries to carry out the work, collect the required funds from the relevant industries and forward the first milestone payment to CPA Research - Fisheries.

Since it can take time to collect funds from many different sources, the NAC/controlling funding body should collect the funds to cover the full project costs for each year well in advance of the due date for payment to CPA Research - Fisheries.

CPAF implements the proposals

After finalising funding arrangements with applicants/key stakeholders, the CPAF acquires existing data (including data from other countries). If these data are adequate for the APVMA to issue a temporary MRL, an immediate application (referred to as a "Desktop application") is made for a Minor Use Permit.

If residue, environmental or efficacy trials are required, CPAF will produce field trial protocols and commission suitably qualified contractors to implement them. Residue trials and analyses will be conducted according to the OECD

principles of Good Laboratory Practice (GLP), a standard that will become mandatory for full registrations in January 2003.

- CPAF applies for Minor Use Permits.
- CPAF will collate the data into submissions to the APVMA for minor use approvals.
- CPAF advises industry on outcomes.
- CPAF will closely monitor progress of its submissions to the APVMA and will keep its industry stakeholders informed on progress. When Minor Use Permits are received, CPAF will publicise the Minor Use Permit conditions and make Minor Use Permit documents available to growers, veterinary companies, wholesalers, dealers and major buyers.

Use of External expertise.

CPAF will utilise the Expert Panel, or individual expertise, as necessary to provide assistance in areas relating to efficacy, safety to fish, environmental, OH&S and trade implications of proposals.

Data Generation and Reporting.

Wherever possible, existing data will be accessed from a range of sources: prior APVMA Minor Use Permit approvals, from agrochemical companies, from overseas databases, from published literature and from local research agencies. When required, residue trials will be commissioned with approved consultants to generate the necessary data.

CPAF will use it's in-house database applications to track projects, residue studies, to store and access data, and to generate reports and Minor Use Permit applications.

On-going maintenance of Minor Use Permits.

CPAF will maintain a database dedicated to fisheries, that will flag when Minor Use Permits are due to expire, in adequate time for them to be renewed. When this occurs, CPA will bill NAC for the renewal fees, which NAC will recover from the individual industries.

3. Communication

CPAF's communication strategy will have three key components:

1. CPAF will communicate directly with applicants for Minor Use Permits to ensure that they are advised of progress. CPAF will also communicate directly with national and State regulatory bodies, and with major food quality assurance organisations to facilitate smooth and rapid implementation of Minor Use Permits.
2. CPAF will communicate with all stakeholders, via a news sheet that will be sent to industry publications and to an email list.
3. CPAF will communicate with any interested parties via its World Wide Web page at http://www.cpaltd.com.au/Fish/ Initially, the site will reflect the content of this blueprint and the Newsletter. As the program is established, new pages will be added to provide news on new approvals; existing approvals and information on Minor Use Permit conditions.

In addition to the above, CPAF will be directly accessible to growers and other stakeholders by telephone fax and Email.

4. Costs.

It is envisaged that the activities of CPAF to obtain and maintain specific Minor Use Permits will be funded by grower contributions, channelled through NAC. If there is no existing compulsory levy collection system for particular industry sectors that could provide funds, a mechanism for acceptance of contributions needs to be put in place by the NAC or other funding body. If the funding is voluntary and some members of an industry sector opt out of paying for a proposal, a system of ownership of Minor Use Permits that differs from the ASIC/SSA model may have to be established, if the investment of the supporters needs to be protected. In our experience however, too much concern over whether a few individuals might get a fee ride can delay projects to the detriment of the majority of producers.

Initially, an application will be made to AFFA to meet CPAF operating costs for 3 years to maintain the system. Project-specific costs for new Minor Use Permit applications, data generation etc will be met by annual applications to the NAC, except where an emergency requires an "out of session" application.

Estimates of costs to maintain the system and of permit application costs are provided in Table 1. Note that if there is a need for travel (eg to an industry conference or interstate meeting) these costs will be charged *pro rata.*

Table 1. Costs of System Maintenance and of selected operational items in the minor use system.

Item	Cost
System Maintenance (Annual)	
Manpower (Database management, web page maintenance, communication, project funding applications etc)	$ 5,400
Office costs (printer and office supplies, ISP charges, phone, fax, photocopying)	$ 400
TOTAL	**$ 5,800**
Permit Applications	
New Permit (no research reqd)	$ 750
Permit (research reqd)	$ 1,500
Permit Renewal (no research reqd)	$ 500
Research (desktop) per hour	$ 180
Registration Application	

We anticipate that only rarely would there be a need for full registration of a product. Most work will be on permit renewals and new permit applications. As an example, if there were five new permit applications in the first year requiring 1 hours research each to gather pre-existing data from various sources, and which required no generation of new field data, plus five renewals of other existing permits, the costs in the first year would be:

Item	Cost
New permit applications (5 X $750)	$3750
Research (5 h X $180)	$900
Permit renewals (5 X $500)	$2500
Annual management fee	$5800
Total Cost	**$10,450**

Note that the APVMA may issue permits that are valid for periods ranging from a few months to several years, depending on individual circumstances and on the quality of supporting data.

APPENDIX 1 of Blueprint

Minutes of the Workshop on setting up a registration system for minor uses of products for protection of fish in aquaculture and fisheries.

Aquaculture Workshop

"Setting up a registration system for minor uses of products for protection of fish in aquaculture and fisheries"

Eden on the Park, 6 Queens Road, Melbourne
Wednesday 17th July 2002

Attendance: Kathleen Allan, APVMA; Peter Apple ford, Fisheries Vic; Simon Benison, ACWA; Matthew Dads well, AFFA; Peter Dumas Smith, FRDC; Kevin Ellard, DPIWE; Gwen Fenton, DPIWE; Jennifer Hall,CPA Research – Fisheries; Parick Hone, FRDC; Brett Ingram, NRE; Peter Lawson, Fisheries Vic; Edward Meggett,VTA; Cassandra Nelson, NSW Fisheries; Bob Richards, Barramundi, NT; Derek Shields,Aquenal; Peter Taylor,CPA Research – Fisheries; John Volkman,CSIRO; Louise Vorsterman,VAC; Jonathan Webber,AFFA

Minutes

Objectives of The Workshop :

1. Obtain comment and input from members of aquaculture and fisheries industries on all aspects of the proposed system for registration and maintenance of Minor Use Permits for the use of livestock protection products in aquaculture including

Determination and prioritisation of needs by industry

Avenues for funding of work to obtain Minor Use Permits/registrations and renew Minor Use Permits.

Responsibilities of users of chemicals

Communication of registrations and Minor Use Permits to stakeholders

2. Discuss current uses of veterinary and chemical products

3. Discuss a process for identifying disease or other problems for which no registered products are available

4 Identify candidates for pilot project (s).

To begin the workshop Dr Peter Taylor, Director, CPA Research Pty Ltd, delivered a paper "A National System for Minor Uses of Chemicals/Veterinary Products in Aquaculture." (Appendix). He gave an overview of the proposed system, including the background to the problem, framework for the system and associated costs. Factors driving the minor use problem were pointed out and included the current regulatory requirements, ANZFA food code and maximum residue limits and the high costs of registration.

A group discussion on the key process and procedural issues that were identified in the draft "Blue print" followed Dr Taylor's presentation. The following matters were discussed: -

Liability

A number of concerns were raised regarding liability, particularly which parties are responsible for governing adherence to the conditions of Minor Use Permits and who is responsible if damage occurs as a result of using a product under a permit.

It was concluded that the user of a permitted product is responsible for obtaining a copy of the permit and for using that product according to the conditions stated on the permit. In using a product under permit, the user accepts all liability.

For unregistered products approved for use by permit, it was discussed whether there should be controls in place at the supply stage to prevent illegal use of those products. It was concluded that it would be extremely difficult to control illegal supply of unregistered or un-prescribed products and that codes of practice should be developed, which would outline the responsibilities and legalities associated with the use of unregistered products and minor use products.

Permit ownership

The responsibilities of the permit holder were discussed. Under most circumstances the permit holder is not responsible for how the user uses the product and not responsible for ensuring that all users have a copy of the permit document. However the permit holder is responsible, when providing information to others about the permit, for providing information that accurately reflects the conditions of the permit.

Likely candidates to be permit holders were discussed. These included ASIC, SSA, NAC and individual industry associations. It was decided that individual industry associations are generally too small and do not have sufficient resources to be permit holders. It was proposed that NAC become the permit holder on behalf of all individual industries. It was also agreed that this would not preclude any individual organisation from applying for a minor use permit should they wish to do so.

Briefly, the responsibilities of the permit holder are:

- To provide accurate and complete details of the permit, including all conditions, **or** indicates from where a copy of the permit can be obtained.
- To ensure that any information provided by them to other persons in relation to the permit is accurate, complete and totally in accordance with the permit.
- To inform the APVMA of any relevant information which they become aware of concerning the uses dealt with by the permit, which if the APVMA had been aware of prior to issuing the permit, they may have not issued the permit or may have issued the permit with different instructions and/or conditions.

The responsibilities of the permit holder do not extend to:

- ensuring the compliance of persons undertaking the proposed use; or
- ‘advertising’ the existence of a permit to all potential users; or

- providing a copy of a permit, or equivalent information, to all potential users.

Funding avenues

Several options were discussed. The workshop agreed that CPA's annual fee for managing the system is a fixed overhead cost that all industries or government should share. The workshop noted that there is no mechanism currently in place for collecting funds from all industry sectors for an item such as the CPA's annual fee.

It was proposed that:

1. National Aquaculture Committee would take the national lead on chemical registration as a service to its members. but that AFFA would be approached for the ongoing costs of maintaining the system.
2. That the Commonwealth Government fund CPA's annual fee for the initial implementation of the program. Some evidence of why industry is unable (market failure) to collect and fund the annual fee would need to be established. Establishing a mechanism for registering chemicals and promoting methods for reducing industry's reliance was a recommendation of the National Aquaculture Development Committee for the National Aquaculture Industry Action. The Commonwealth Government will be considering its response to the Committee's recommendations later in the year.
3. That individual industries should bear the cost for obtaining and renewing minor use permits specific to their own industries. Project specific funds from particular industries should be channelled through NAC.

Communication

Good communication was identified as a major requirement for success of the minor use system. It was evident during discussions that there are many misunderstandings about off-label chemical use in aquaculture and the permit system and what a permit allows. Permit holders need to be aware of their responsibilities and more importantly, the users need to be aware of theirs. It was decided that CPA should prepare a one-page instruction sheet on chemical use and Minor Use Permits of the minor use process to be forwarded to all aquaculture facilities.

Included in CPA's annual running fees is the service of notifying the industry of available Minor Use Permits and providing users with access to permit documents. Communication is via various methods including the web, email, mail and news bulletins in industry publications. The use of postal services will however incur additional costs.

The Commonwealth, State and Territory Governments could also work together to promote responsible chemical use practices and this should be done through the various state Ag&Vet Chemical registrars.

Industry's needs

Current registered and permitted uses of products were identified. The group was given a request form and asked to identify industry's needs for further

products. This form was to be returned to CPA. Workshop participants requested that CPA forward electronic lists of currently registered products and known uses to facilitate the process.

Expert panel

The formation of an expert panel for approving and prioritizing minor use projects was discussed. Attendees were asked to think about which associations they would like included in the panel and who should be kept informed of the projects. Aquaculture managers, Ag & Vet Chemical Registrars, technical officers, environmental representatives were some suggestions made at the workshop. Concern was voiced by some at the meeting that such a group should be made up of persons with technical knowledge of the use of veterinary chemicals in aquaculture, thus the suggestion of state aquaculture managers making up such a committee was strongly disputed.

Other matters

The duration that Minor Use Permits are issued for was discussed in relation to permit renewal costs. Kathleen Allan (APVMA) explained that Minor Use Permits might be issued for 1 year only for the first 1-2 years after which time they prefer to extend the duration to 3-5 years, if further supporting data became available.

Restricting the use of a permit to particular individuals and members of specific associations was discussed. The APVMA would prefer the industry to take a more open, coordinated approach to involve all stakeholders under Minor Use Permits. It is allowable to have more than one permit holder and use of a permit can be restricted to a number of specific associations.

Actions required as a result of the workshop

(a) Revised version of the blueprint to be produced, including cost estimates

(b) Revised blueprint to be forwarded to NAC who will be ensuring that it is distributed to members of NAC for further comments and support.

(c) Revised blueprint to be forwarded to the Australian Fisheries Management Forum's Aquaculture Committee (Matthew Dadswell responsible), the Veterinary Committee (Kevin Ellard responsible) and aquaculture researchers (Patrick Hone responsible) for comments by September 9.

(d) Formation of expert panel. NAC to provide advice after consultation with AC and Vets on the technical composition of the expert panel. Due regard should be taken for other health related committees including the Aquatic Animal Health Initiative.

(e) Circulation of industry request form to initiate a project wish list, to facilitate selection of pilot projects and provide a base for future projects.

(f) Circulation of minutes of the workshop.

Timelines for Actions:

August 21	Circulation of minutes of the workshop.
August 24	Revised blueprint to be forwarded to NAC, Dadswell, Ellard and Hone as in b) & c) above for Comments by September 9.
	Circulate industry request form as in d) above
September 9	Comments received on revised blueprint.
	Members of Expert Panel nominated.
September 12	"Final" blueprint sent to workshop participants (it is an organic document that will change).

APPENDIX

Outline of Dr Peter A Taylor's presentation:

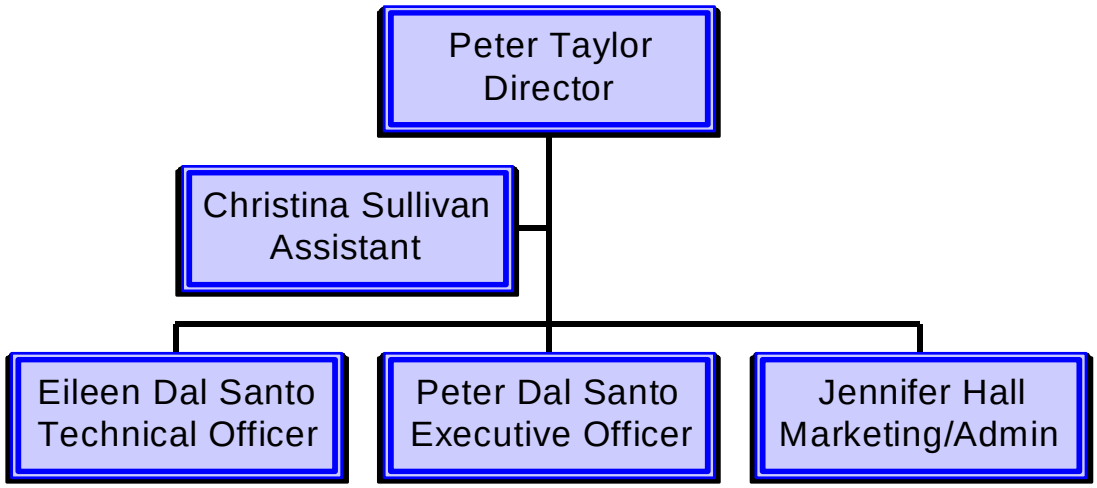
A National System for Minor Uses of Chemicals/Veterinary Products in Aquaculture

---

Background

- ***FRDC Project 96/314 - Steve Percival***
- **Achieved minor use permits for 12 items**
- **4 since expired**
- **No ongoing maintenance of permits except by individual companies or larger industry groups**
- ***FRDC Project 2001/256***
- **Started February 2002**
- **Due for completion September 2002**
- **Provides for ongoing service to industry registration needs**

CPA Research P/L Organisation



CPA Research P/L activities

Current Projects - 159

- ***Number of crops / species*** ***75***
- ***Range:*** ***Artichokes to chooks***
- ***Minor Use permits to full registration***

The Minor Use Problem: DRIVERS

- ***Regulatory environment***
- ***ANZFA food code***
- ***Costs of registration***

– Administration

– Data generation

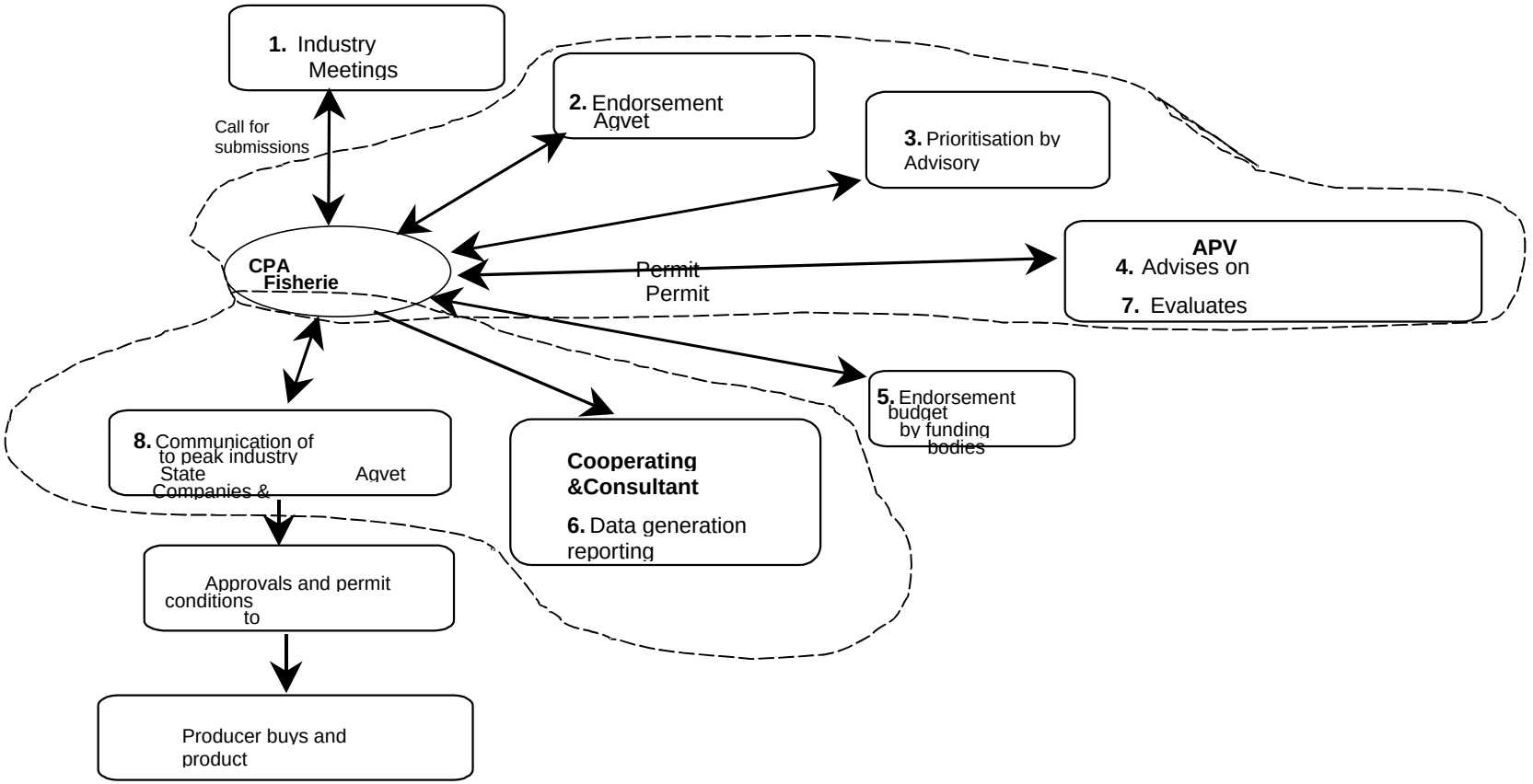
– **Fees**

Proposed System Requirements

- *Producer / Industry driven*
- *Funded – industry / government*
- *Maintained*
- *Communicative*
- ***Simple (for client industry)***

COMMUNICATION

- ***Web,***
- ***Email***
- ***Post***
- ***News Items***



CPA RESEARCH FISHERIES

- Collects requests for registration of items from industry group meetings. Compiles information on use, application rates, other
- Negotiates with AgVet companies for
- Distributes list of items and associated information to advisory committee for prioritisation
- Negotiates data requirements with
- Secures funding approval for trials/analyses (if
- Writes trial protocols, commission's trials and analyses, conducts QA on trial
- Compiles submissions and applies to APVMA for
- Communicates outcomes and information on permits to
- Maintains system for permit review and

LIKELY COSTS

Project – specific costs:

- ***New Permit (no data reqd)*** **$750.00**
- ***Renewal (no data reqd)*** **$500.00**
- ***New Permit (residue data)*** **$1500.00**
- **+ Residue Trial costs** $??
- **+ Chemical Analyses** $1000 - $2000
- ***Registration*** **$10,000**
- **+ Residue and Efficacy data generation** ? $50,000-$100,000 +
- **+ APVMA Fees** ? $2060 - $10,310

System Maintenance: ***? $5,000 pa (approx)***

- **Will depend on hours input**

ISSUES – DISCUSSION SESSION 1

- *LIABILITY*
- *PERMIT OWNER*
- *AVENUES FOR FUNDING*

NOTES

Appendix 4 Text on Liability Issues, originally in draft Blueprint

2.3 Liability

The manufacture, supply and use of agricultural and veterinary substances are fraught with risk. Significant health, environmental and economic damage can flow from the improper use of therapeutic substances, and inevitably lead to litigation that attempts to sheet home responsibility among the parties involved in their manufacture, supply and use.

If a product is ineffective or not properly applied, the grower who uses it will have lost at least the purchase price of the substance, and may also lose the livestock. If the product is defective or misused in other ways, not only can the livestock be lost, but also the environment may be contaminated or damaged. A wide range of other parties may also suffer loss and damage. They include purchasers and consumers of produce that have been damaged or affected by residues, and persons affected by environmental contamination, for example, as downstream users of water.

A person suffering loss and damage arising out of his or her use of a veterinary product may look to the veterinarian who prescribed the product (if applicable) and/or the manufacturer for compensation. Disputes over liability for damage arising out of agrochemical use have the potential to embroil other persons involved in the chain of manufacture, approval and use. We have asked for further legal advice on liability issues with products available only on prescription and will update this section when we have received it.

2.4.1 Liability of Manufacturer

A manufacturer's liability for a defective product may arise in a number of ways: -

- in contract, where liability may arise as a result of an expressed or implied term in the contract for supply of the product. Terms are generally implied by statute that a product is fit for its intended purpose and is of merchantable quantity. The doctrine of privity of contract means that claims based in contract are only likely to be made by the person to whom the product was supplied by the manufacturer.
- in negligence, where the manufacturer of a product is under a duty to avoid causing injury or damage to the user of a product. The duty arises where a reasonable person in the manufacturer's position would have foreseen that the use of the product involved a risk of injury, and that there is an appropriate relationship of proximity between the manufacturer and the person suffering particular loss or damage.
- under Part V of the Trade Practices Act 1974 (and equivalent State legislation dealing with consumer protection), which makes manufacturers liable to consumers in certain circumstances,

including where the goods are not reasonably fit for the purpose for which they were acquired, do not correspond to the description by which they were supplied or are not of merchantable quality.

- under Part V A of the Trade Practices Act 1974 - dealing with liability for defective goods - which makes manufacturers and importers generally liable to compensate for injury and loss or damage to goods or land acquired for personal use caused by or resulting from a defective product. A product is defective if its safety is less than persons are generally entitled to expect. There are a number of criteria by which this is judged. A manufacturer may avoid liability if it can prove that the defect did not exist at the time the goods were supplied, that the state of scientific knowledge at the time the goods were supplied was not such as to enable the defect to be discovered, that the defect in the goods was attributable to the design of or instructions accompanying finished goods in which the goods were comprised or that the goods were defective only because they complied with a mandatory standard.

A manufacturer may be liable to the user of a product if the product is not effective, or is harmful to the crop, and may be liable to persons generally who suffer loss or damage as a result of the use the product. Liability arises principally in tort, in contract and under the Trade Practices Act. While some of these liabilities can be limited contractually, manufacturers cannot contractually limit their liability under the Trade Practices Act. Section 74K of the Act renders void any term of a contract which purports to exclude, restrict or modify, or which has the effect of excluding, restricting or modifying a manufacturer's liability under Part V. Section 75AP has the same effect in relation to contracts which purports to limit, restrict or modify liability under section 75A.

2.4.2 Liability of the APVMA

Section 69H of the Agricultural and Veterinary Chemicals (Administration) Act 1992 gives the APVMA a very broad statutory protection against liability arising out of its approval and registration decisions.

2.4.3 Liability of funding body.

As a general principle, the greater the funding body's involvement in or control over the research outcomes and the uses to which it is applied (such as obtaining a Minor Use Permit), the greater will be its exposure to liability. Likewise, arrangements entered into jointly with an active partner, whether CPAF, a grower organisation or manufacturer, are inherently more likely to expose the funding body to risk than arrangements where it is merely a passive funding body. In each case, the funding body would have options for

managing those risks, and would need to seek its own advice about structuring arrangement to that end, at least in relation to CPAF.

However, if the funding body is simply the provider of funding by means of grants to CPAF, no real prospect of liability on its part arises. It is neither an investor nor a lender in the conventional sense. The terms of any grant are clearly matters for negotiation between the funding body and CPAF. The only risk that might arise for the funding body is if conditions of funding are so specific or prescriptive that the funding body is in fact exercising control over the operations of CPAF.

Appendix 5 Permit 6670

NATIONAL AQUACULTURE COUNCIL
CPA Research Pty Ltd
Level 1, 5 Everage Street
MOONEE PONDS 3039 VIC

OFF-LABEL PERMIT (OLP)
FOR USE OF A REGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - PER6670

This permit is issued under the Agvet Code, of the relevant jurisdictions, to the person stated above. The holder of the permit must comply with all requirements as specified in the Agvet Code. A summary of the key requirements are that the holder must:

- supply any requested information to the APVMA;
- inform the APVMA if they become aware of any relevant information concerning the uses dealt with by this permit; and
- comply with a lawful direction or requirement of an inspector.

This permit for the reason given below, allows any person listed in ***1. Persons*** to use the products listed in ***2. Products*** for the minor off-label use specified in ***3. Directions for Use*** in the jurisdictions listed in ***4. States***.

If this permit were not issued use of the products as specified in this permit would constitute an offence under the Agvet Codes.

The persons listed in ***1. Persons*** must comply with all conditions listed in ***CONDITIONS OF PERMIT*** to be effectively covered by this permit.

THIS PERMIT IS IN FORCE 15th September 2003 to 30th September 2005 .
It is in force until it expires or it is cancelled, suspended or surrendered.

Reason for issue of permit:
There are no registered products available to the decapod crustacea (including prawns, shrimps and crayfish) aquaculture industry for the control of different species of

epicommensal protozoan and metazoan parasites. Formalin has been shown to be effective in controlling such external protozoan and metazoan parasites. It is also used effectively for the elimination of viruses such as Monodon Baculovirus from crustacean broodstock.

There are currently no registered products available to treat freshwater and saltwater food finfish species which have infestations with protozoan and metazoan parasites or fungal infections.Formalin is widely used to control protozoan and metazoan species in finfish and can be applied to eggs at rates high enough to control Oomycete and other fungal infections.

This Permit has been requested by the National Aquaculture Council as a result of Fisheries Research & Development Corporation funded projects to consolidate and facilitate the granting of APVMA permits to support the minor use of veterinary chemicals in aquaculture. It follows the granting of earlier Permits for the use formalin in aquaculture such as Permit 1507 granted to the NSW Silver Perch Growers Association, and incorporates an application from the WA Department of Fisheries.

DETAILS OF PERMIT

1. Persons

Members of the National Aquaculture Council and those determined by the National Aquaculture Council to be bona fide members of the Australian Aquaculture Industry including members of the NSW Silver Perch Growers Association Inc.

2. Products

Registered Veterinary Products: Nufarm Formalin for Footrot in Sheep (37609) and Deltrex Chemicals Formalin for Control of Footrot in Sheep (36715) containing 400.00 g/L FORMALIN as their only active constituent.

3. Directions for Use

For use in Crustacea including Prawns, Shrimps and Crayfish, their broodstock, and newly hatched Nauplii; Freshwater and saltwater Finfish and finfish eggs including Salmonids .

To treat Protozoan and Metazoan ectoparasites, control of Fungi, elimination of viruses and other disease causing organisms.

Use as per the instructions on the attachment following.

Critical Use Comments:

Use strictly in accordance with the permit, attachments and product label instructions as supplied.

Withholding Period:

Fish: Meat – DO NOT USE less than 100 degree days before slaughter for human consumption.

Eggs: Treated eggs must not be used for human consumption.

4. States

ALL States

CONDITIONS OF PERMIT

THIS PERMIT has been granted in response to requests from persons other than the manufacturers of products, which have been included in this permit. When assessing the proposed use the APVMA will often seek advice from these manufacturers. As these manufacturers have not sought this permit, they should not be held responsible for use of their products as specified in this permit.

THIS PERMIT provides for the use of a product in a manner other than specified on the approved label of the product. Unless otherwise stated in this permit, the use of the product must be in accordance with the instructions on its label.

Persons who wish to prepare for use and/or use the products for the purposes specified in this permit must read, or have read to them, the permit particularly the information included in DETAILS OF PERMIT and CONDITIONS OF PERMIT.

The permit holder is specifically requested to:

1. Supply the APVMA with information, which summarises the annual use of formalin, which contains the following components: amount used in each industry sector; the purpose for its use in each sector; and, the number of users authorized under the auspices of the National Aquaculture Council.
2. Ensure that authorized users under this permit are adequately trained in handling hazardous chemicals and are provided with a copy of this permit and attachment plus a copy of the MSDS from the supplier of the product.
3. Monitor the overseas situation regarding the use of formalin in aquaculture and inform the APVMA of any change in status particularly any incidents of environmental contamination and any action taken by overseas regulatory authorities in regard to its use

Issued by

Ken Hoy
Delegated Officer
15th September 2003

Attachment:

Indications:

For the treatment of protozoan and metazoan parasites:

Formalin is used to control a number of protozoan parasites, including *Costia* (now known as *Icthybobo nacator*); *Chilodonella spp.; Brooklynella spp.; Trichodinid spp.; Icthyophirius multifilis; Cryptobia spp.;* Sessile, solitary, ectocommensal ciliates (eg *Apiosoma, Riboscphidia and Ambiphrya);* and Sessile, colonial, ectocommensal ciliates (eg *Epistylis*).

For the treatment of fungal infections:

Formalin is effective in controlling infections in eggs caused by organisms in the Class Oomycetes. The vast majority of pathogens in this Class are from the Family Saprolegniaceae.

Formalin is used for the control of other pathogens including viruses in crustacean broodstock such as Monodon Baculovirus.

Precautions:

Temperatures below 4 degrees C can result in the formation of paraformaldehyde which is very toxic to fish. Paraformaldehyde appears as a white precipitate (sludge) and must be filtered out before use.

DO NOT treat eggs within 24 hours of hatching. Formalin may concentrate in the shell, killing the embryo.

A small number of the group of animals to be treated should be treated to check for unusual sensitivity before the entire group is treated. Formalin is contraindicated if fish have been recently stressed (eg transported) or if skin ulcers are present. Treatment water must be well aerated. Algae and dinoflagellates present in the treated waterbody may die during treatment and water quality problems may result. Remove aquarium plants before treating. Formalin should not be mixed with potassium permanganate.

Used solutions should be diluted to a concentration of 0.025 ml/L or less before discarding. Read the safety directions and the MSDS on the product label before using.

Directions for Use:

SALMONIDS AND SALTWATER AND FRESHWATER FINFISH AND EGGS

FISH:

The dosage and method of application of formalin necessary to control external protozoan parasites will depend on a number of factors (eg water quality, stocking density, water temperature, level of infestation and protozoan species being treated). As a guide, formalin can be used in the following methods:

1. BATH – Add 0.125 to 0.167 or 0.250 mL formalin/L (125 to 250 ppm) to bath water. Treat for up to 60 minutes. Treatment can be repeated 2 to 3 times, however treat only once daily if needed. When water temperatures are high (> 21 degrees C for warm water fish and > 10 degrees C for coldwater fish) DO NOT USE >167 ppm. The maximum dose should be only used every three days. Up to 167 ppm can be used on concurrent days.

2. PROLONGED IMMERSION IN AQUARIA – Add 0.015 to 0.025 mL formalin/L (15 to 25 ppm) to aquarium water. For *Icthyophilius*, use 25 ppm every other day for three treatments. Remove all plants before treatment. Change up to 50% of the water on alternate days. The treatment should be prolonged at low temperatures, can be used as an indefinite treatment.

3. CONSTANT FLOW – Add 0.015 mL formalin/L (15ppm) to raceway water as a constant flow for 25 hours. This can be used to treat *Icthyophirius* in raceways.

EGGS:

As a guide, formalin can be used in the following methods:

1. BATH- Add 1 to 2 mL formalin/L (1000 to 2000 ppm) and treat eggs for up to 15 minutes. If prevailing conditions are favourable for fungal growth, repeat treatment daily of more frequently if needed. Excessive re-treatments may cause egg mortality. OR

2. Add 0.23 mL formalin/L (227 ppm) and treat eggs for up to 60 minutes.

CRUSTACEA INCLUDING PRAWNS, SHRIMPS AND CRAYFISH

1. TANKS OR RACEWAYS- 0.20 – 0.40 ml/L for 4 hours daily until parasite control is achieved, or (earthen ponds only) 0.025ml/L repeated after 5-10 days if necessary.

2. ELIMINATION OF VIRUSES FROM BROODSTOCK –

Bath: 0.20- 0.40 ml/L of water, for 30 minutes to 2 hours, then rinse.
Broodstock Holding Tank: 0.05 ml/L

3. NEWLY HATCHED NAUPLII- Dip 0.20 – 0.40 ml/L for 30 seconds per scoop net of nauplii (< 50 scoops per spawn tank).

WITHHOLDING PERIODS

FISH: Meat – Do not use less than 100 degree days before slaughter for human consumption

Eggs- Treated eggs must NOT BE USED for human consumption.

FIRST AID:

If poisoning occurs, contact a doctor or the Poisons Information Centre. *Phone Australia 131126.* If swallowed do NOT induce vomiting. Give water or milk, then raw egg. If skin contact occurs, remove contaminated clothing and wash skin thoroughly. Remove from contaminated area. Apply artificial respiration if not breathing. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

SAFETY DIRECTIONS:

Poisonous if swallowed. Attacks eyes. The fumes can cause smarting, then watering of eyes. This should be taken as a warning sign. Will irritate throat nose and skin. Repeat exposure may cause allergic disorders. Sensitive workers should use protective clothing. Avoid contact with eyes and skin and clothing. Do not inhale vapour. Protect eyes while using this product. When opening the container and using the product, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves, goggles and a half facepiece respirator with canister specified for formaldehyde. If product on skin, immediately wash area with soap and water. After use, and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles, respirator and if rubber, wash with detergent and warm water and contaminated clothing.

DISPOSAL:

Treated water – No treated water from ponds/tanks/raceways should be released directly into the environment until after it has been held for two days following treatment. Where this is totally impractical, a tenfold dilution factor into receiving waters must occur.

Container – Triple rinse into treatment mix. Recycle container if possible. If not, crush and bury in a local authority landfill or below 500mm depth at an approved disposal site clear of waterways and vegetation roots (check State regulations). Do not burn containers or product.

Appendix 6 - Listing of requests made for permits by aquaculture industries.

Output from the Aquaculture Database

All Aquaculture Minor Use Requests (wishlist report ordered by species)

Crop	Code	Problem	Product	Active	App rate	Timing	Status	Priority	IsProject	Desk	Company	Trialcosts	Labcosts
Abalone	AQC2	Bacterial infec	Not specified	Oxolinic acid	200 ppm,		Proposed	0	No	☐	Not Specified		
APVMA data reqts	Difficultn to get permit. It is not registered for use on any food animal. Significant risk of bacterial resistance												
Abalone	AQC49	Induction of s		Hydrogen Peroxide <1		general cleaning	Prioritised	2	Yes	☐	Not specified		
APVMA data reqts													
Abalone	AQC6	Bacterial infec	Oxytetracycli	Oxytetracycline		WHP 500 degree-days	Proposed	0	No	☐	Agribusiness Products		
APVMA data reqts	Basically approved, but environmental concerns would require monitoring of sediments and effluent water.												
Abalone	AQC8	Bacterial infec	Not specified	Doxycycline			Proposed	0	No	☐	Not Specified		
APVMA data reqts	Likely success depends on activity spectrum(?similar to oxytet?) and scale of use.												
Abalone	AQC33	Sedation and	Not specified	Benzocaine			Proposed	0	No	☑	Not Specified		
APVMA data reqts													
Abalone	AQC3	Bacterial infec	Not Specified	Trimethoprim			Proposed	0	No	☐	Not Specified		
APVMA data reqts	Relatively environmentally friendly.												
Abalone	AQC44	Sedation & An	Not specified	Ethanol 950 ml/lt	1.5% v/v	grading & harvest	Prioritised	2	No	☐	Not specified		
APVMA data reqts													
Abalone	AQC45	Bacterial infec	Not specified	Erythromycin	0.005 gm	hatchout	Prioritised	1	No	☑	Not specified		
APVMA data reqts	No data generation reqd because of low rate and early stage of growth.												
Abalone	AQC46	Sanitising	Vortex	Hydrogen Peroxide <1	2.0 ml/lt	general cleaning	Prioritised	2	Yes	☐	Not specified		
APVMA data reqts	Permit will require only supporting argument												
Abalone	AQC47	Clean in place	CIP-Safe	Sequestrant 10-<30%	0.5-3% v/	general cleaning	Prioritised	2	No	☐	Not specified		
APVMA data reqts													
Abalone	AQC48	Bacterial infec	Not specified	Benzalkonium chloride	0.2-2 pp	larval	Prioritised	1	No	☐	Not specified		
APVMA data reqts													

Crop	Code	Problem	Product	Active	App rate	Timing	Status	Priority	IsProject	Desk	Company	Trialcosts	Labcosts
Abalone	AQC43	Clean in place	Microscan 53	Sulphamic acid	0.5-1.0%	general cleaning	Prioritised	2	No	☐	Not specified		
APVMA data reqts													
ALL	AQC16	General disinf	Not specified	Sodium hypochlorite			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Eels	AQC40	Ectoparasites	Clean fish C	hydrogen peroxide + c	15 ml/100	winter	Proposed	0	No	☐	Ozsea Aquaculture		
APVMA data reqts	Will need to measure silver concentrations												
Fresh and salt w	AQC35	Ectoparasites,	Not specified	Formaldehyde	50mg/L f		Prioritised	1	Yes	☐	Not Specified		
APVMA data reqts	Possibly will require discussion of environmental effects, depending on disposal method for treated effluent												
Fresh and salt w	AQC23	Promotion of	Not specified	GnRHa			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Fresh and salt w	AQC1	Bacterial infec	Not specified	Oxolinic acid		200 ppm, 72 h bath, 25 mg/kg body weight oral	Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Fresh and salt w	AQC12	Protozoan an	Not specified	hydrogen peroxide			In progress	0	Yes	☑	Not Specified		
APVMA data reqts													
Fresh and salt w	AQC34	General sedat	Clove oil	iso-eugenol	10 ml/100	just before handling fish	Prioritised	1	No	☐	Not Specified		
APVMA data reqts	will need supporting data (from overseas?) and will need to be registered. Data protection may induce a company to register.												
Fresh and salt w	AQC38	Bacterial infec	Oxytetracycli	Oxytetracycline	50mg/L f	WHP 500 degree-days	Prioritised	2	No	☐	Agribusiness Products		
APVMA data reqts	Basically approved, but environmental concerns would require monitoring of sediments and effluent water.												
Fresh and Saltw	AQC39	General sedat	Not specified	Benzocaine			Prioritised	5	No	☑	Not Specified		
APVMA data reqts													
Freshwater finfis	AQC41	parasites	salt	sodium chloride			Prioritised	1	No	☑	Not Specified		
APVMA data reqts	Need to address issues of efficacy spectrum, safety to fish and disposal of salty water.												

Crop	Code	Problem	Product	Active	App rate	Timing	Status	Priority	IsProject	Desk	Company	Trialcosts	Labcosts
Freshwater finfis	AQC42	Argulus	Neguvon	trichlorfon	0.2 - 0.3		Prioritised	3	No	☐	Not Specified		
APVMA data reqts	Permit data requirements will depend on scale of use												
Freshwater finfis	AQC36	Ectoparasites,	Not specified	Copper sulphate			Not specified	0	No	☐	Not Specified		
APVMA data reqts													
Kingfish	AQC26	anthelminthic	Droncit	praziquantel			Proposed	0	No	☐	Not Specified		
APVMA data reqts	Will need data.												
Kingfish	AQC7	Bacterial infec	Oxytetracycli	Oxytetracycline		WHP 500 degree-days	Proposed	0	No	☐	Agribusiness Products		
APVMA data reqts	Basically approved, but environmental concerns would require monitoring of sediments and effluent water.												
Not specified	AQC37	Ectoparasites,	Not specified	Copper sulphate			Not specified	0	No	☐	Not Specified		
APVMA data reqts													
Prawns	AQC11	Bacterial infec	BKC	Benzalkonium chloride			Proposed	0	No	☐	Not Specified		
APVMA data reqts	Need more information on use, rates, scale of use												
Prawns	AQC31	Larval mycosi	Not specified	Trifluralin	0.5 ml/10,	preventative in larval tanks	Proposed	0	No	☑	Not Specified		
APVMA data reqts	Simply requires re-application												
Prawns	AQC32	Control of alg	Not specified	Simazine			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Prawns, shrimps	AQC15	Epicommensa	Not specified	Formaldehyde			Prioritised	2	Yes	☐	Not Specified		
APVMA data reqts	Possibly will require discussion of environmental effects, depending on disposal method for treated effluent												
Salmon	AQC5	Bacterial infec	Oxytetracycli	Oxytetracycline		WHP 500 degree-days	Proposed	0	No	☐	Agribusiness Products		
APVMA data reqts	Basically approved, but environmental concerns would require monitoring of sediments and effluent water.												
Salmon	AQC4	Bacterial infec	Not specified	Trimethoprim			Proposed	0	No	☐	Not Specified		
APVMA data reqts	Relatively environmentally friendly.												

Crop	Code	Problem	Product	Active	App rate	Timing	Status	Priority	IsProject	Desk	Company	Trialcosts	Labcosts
Salmon	AQC13	Fungal infecti	Not specified	Malachite green			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC9	Bacterial infec	Not specified	Chloramine-T			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC10	Environmental	BKC	Benzalkonium chloride			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC17	Water disinfe	Not specified	Ozone			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC18	Egg disinfecti	Not specified	Iodine			Not specified	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC19	General sedat	Not specified	Benzocaine			Proposed	0	No	☑	Not Specified		
APVMA data reqts													
Salmon	AQC20	General, Harv	Aqui-S	Iso-eugenol	5-25 ml/1		Already Regi	0	No	☐	NZ Institute for Crop and Food research		
APVMA data reqts													
Salmon	AQC21	General sedat	Clove oil	iso-eugenol			Proposed	0	No	☐	Not Specified		
APVMA data reqts	will need supporting data (from overseas?) and will need to be registered. Data protection may induce a company to register.												
Salmon	AQC22	Harvesting se	Not specified	CO2			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC25	Immunostimul	Not specified	Levamisole			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC27	Immunostimul	Not specified	b-glucans			Proposed	0	No	☐	Not Specified		
APVMA data reqts													

Crop	Code	Problem	Product	Active	App rate	Timing	Status	Priority	IsProject	Desk	Company	Trialcosts	Labcosts
Salmon	AQC28	Salt	Not specified	Gill astringent			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC29	Yersiniosis va	Not specified	Yersiniosis vaccine			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC30	Vibriosis	Anguilvac-C	Vibriosis vaccine	100 ml/L	30 sec and 1 hour	Already Regi	0	No	☐	Not Specified		
APVMA data reqts													
Salmon	AQC24	Production of	Not specified	Testosterone			Proposed	0	No	☐	Not Specified		
APVMA data reqts													
Salmonid fish an	AQC14	Fungal infecti	Not specified	Formaldehyde		>100-degree days pre-slaughter	Proposed	0	Yes	☐	Not Specified		
APVMA data reqts	Possibly will require discussion of environmental effects, depending on disposal method for treated effluent												