Registration of Aquaculture Chemicals

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FISHERIES RESEARCH & DEVELOPMENT CORPORATION

Project 96/314

Registration of Aquaculture Chemicals

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March 2001

Disclaimer Note that all information presented in this Report was valid as @ February 2000. National Registration Authority (NRA) requirements will change from time to time. Therefore, the NRA should be contacted by anyone developing an application for an exemption from registration, registration or minor use permit to ensure the latest requirements are met.

ISBN: 0-646-41396-1

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1. NON-TECHNICAL SUMMARY

1996/314 Registration of Aquaculture Chemicals

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OBJECTIVES:

1. To identify the most appropriate and industry accepted drugs and chemicals and their use patterns for each sector of the Australian aquaculture industry.

2. To maximise the cost-effectiveness and efficiency of the drug or chemical registration process by the Australian aquaculture industry to the NRA.

3. To establish registration of at least twelve of the drugs and chemicals identified in objective 1. (NB Each registered drug or chemical may be used by a number of aquaculture sectors in a number of different ways)

OUTCOMES ACHIEVED

The project has increased NRA staff understanding of the aquaculture industry and the industry's needs with regard to the use of medication chemicals. This will assist the NRA in reviewing and finalising future aquaculture industry applications for chemical use exemptions, permits or registrations. The project has also increased industry understanding of the need for NRA regulation of chemical use and the processes to be followed in achieving legal use of appropriate medication chemicals. During the course of the project this increased understanding has been limited to those industry sectors that were actively assisted in preparing and attaining exemptions, registration or minor use permits. However, the dissemination of this report is expected to achieve a broader understanding by the aquaculture industry of these issues. Increased understanding will form the basis of further exemptions, permits or registrations for appropriately used medication chemicals in the aquaculture industry.

Appropriate legal use of medication chemicals will improve the confidence of government regulators, veterinarians and the public in the aquaculture industry to use these compounds with minimal environmental impact and with maximum safety to staff, aquaculture species being treated and the end consumer.

Australian governments and agri-food industries are placing greater emphasis on marketing Australia as a supplier of high quality fresh produce. It is important that these "clean food" activities are underpinned by appropriate mechanisms that ensure the integrity of Australian product. Residue detection and any associated food safety

issues will continue to attract considerable public interest. The challenge for the aquaculture industry, governments and regulatory authorities is to develop strategies that combine efficient production methods without detrimental effects to food products, the environment, the safety of target animals, and the safety of persons who administer the compounds.

The National Strategy on Aquaculture in Australia (1994), developed in cooperation with industry by the Commonwealth, State and Territory governments sets the strategic framework for future aquaculture development. The strategy identified chemical registration in the aquaculture industry as a priority issue. Consequently in 1995, the Aquaculture Committee (AC) operating under the auspices of the Standing Committee on Fisheries and Aquaculture (SCFA) established a National Taskforce (The Taskforce) comprising industry and government representatives to address the issue.

Under the Chemical and Veterinary Chemicals Code Act 1994, all chemicals which fit the definition of agricultural and veterinary chemicals in the Act[1] must be registered by the National Registration Authority (NRA) before they can be supplied, sold or used in Australia. Many chemicals currently used by aquaculture industries fit these definitions, yet none of these chemicals were registered specifically for use in aquaculture. Like most other farmers, aquaculture producers need access to a range of safe and effective agricultural and veterinary chemicals so they can control pests and diseases on their farms, and maintain water quality. Yet, because it is a relatively small industry and the quantities of chemicals used are quite small and often out of patent, most chemical manufacturers are reluctant to register products for aquaculture use as the registration costs are hard to justify in view of the small potential market.

Based on the results of an extensive industry survey of drug and chemical usage in the Australian aquaculture industry conducted in 1995, this project has undertaken an assessment of the most appropriate drugs and chemicals and their use patterns for each sector of the industry (Objective 1).

This project has also developed and tested a cost-effective and efficient process in conjunction with NRA for attaining a legal basis for drug or chemical usage by the Australian aquaculture industry. This process is based on usual NRA requirements, but enables the legal use of appropriate chemicals where detailed information is not available (Objective 2).

[1] The legal definition of a veterinary chemical product stated in the Agvet Code is: A substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly (a) preventing, diagnosing, curing or alleviating a disease or condition in an animal or an infestation of an animal by a pest; or (b) curing or alleviating an injury suffered by an animal; or (c) modifying the physiology of an animal: (i) so as to alter its natural development, productivity, quality or reproductive capacity; or (ii) so as to make it more manageable; or (d) modifying the effect of another veterinary chemical product (for more detail see section A-1.3.1 "Definition of a veterinary chemical product" in The NRA Requirements Manual for Veterinary Chemicals)

The project has selected representative chemicals from those identified by industry and achieved the following (Objective 3):

Registered	Aqui-S	Anaesthetic/sedative
Minor Use Permits (approved)	Formalin in salmonids	External protozoan parasites
	Formalin in native fish	External protozoan parasites
	Methyltestosterone/Methyldihydrotestosterone in salmonids	Sex reversal
	Trifluralin in prawns	Larval mycosis
	Simazine in prawn ponds	Control of algae
	Benzocaine in finfish and abalone	Anaesthetic/sedative
	Amoxycillin in salmonids	Bacterial infections
	Oxytetracycline in salmonids	Bacterial infections
Minor Use Permits (pending approval)	Formalin in prawns	External protozoan parasites
	Sulfadiazine/trimethoprim in salmonids	Bacterial infections
	Ovaprim in finfish	Spawning induction
	OvaRH in finfish	Spawning induction
	LHRHa in finfish	Spawning induction
Exemptions	A Calcium carbonate, Calcium hydroxide, Calcium oxide, Calcium/Magnesium carbonate in ponds	Increase water pH Increase sediment pH Increase pH buffering Calcium/magnesium nutrient source Accelerate decomposition of organic matter Detoxify pond sediments
	B Calcium sulphate in ponds	Calcium source when pH high
	C Zeolite in ponds	Adsorption of toxic ammonia and sulphide compounds
	D Aluminium sulphate, Ferric chloride in ponds	Flocculation of suspended clay
	E Inorganic fertilisers , Organic fertilisers in ponds	Stimulation of phytoplankton growth
	F Astaxanthin, Canthaxanthin, Beta carotene in feeds	Tissue pigmenters
	G Propionic acid in feeds	Antifungal agent
	H Ethoxyquin in feeds	Antioxidant
	I Sodium chloride in feed	Flavour/preservative

The Australian aquaculture industry, consumers, governments and regulators all benefit from strategies that combine efficient production methods without detrimental effects to food products, the environment, the safety of target animals, and the safety of persons who administer the compounds. Industry will benefit directly from this project by having access to a number of safe registered or NRA permitted drugs and chemicals.

The extent of the benefits flowing from this project have been limited to some degree by the lack of available information to support applications for registrations or minor use permits, and the reluctance of drug companies to become involved with the aquaculture industry due to the small size of the market.

It is essential that a mechanism is established to continue the work undertaken by this FRDC project. Unfortunately the TaskForce has not been active since 1998. However, the Taskforce or a similar industry-inclusive group needs to play a lead role in continuing this work, otherwise once again the momentum will be lost on this issue.

Key points identified by the TaskForce in December 1998 include:

i The Taskforce consider the broader issue of increasing industry and veterinary awareness and education on the safe, appropriate and minimal use of drugs and chemicals.

ii The Taskforce facilitate and encourage veterinary education and involvement in the supply and prescription of drugs and chemicals to Australia's aquaculture industry.

iii The Taskforce encourage the development of management and husbandry practices which decrease the requirement for drugs and chemicals.

iv The Taskforce ensure minor use permits are maintained and renewed, minor use permit conditions and requirements are adhered to and approval for minor use permits or registration is pursued as and if more drugs and chemicals are required by Australia's aquaculture industry. This is to be carried out in conjunction with awareness and education campaigns for industry and veterinarians.

v That the Taskforce encourage Australia's participation in the international forum addressing the issues of harmonisation of information on the use of drugs and biologics in aquaculture. This international forum aims to assist countries involved in gaining registration and obtaining minor use permits by sharing information and data required for approval.

KEYWORDS: aquaculture, chemical, drug, registration, permit, exemption

2. BACKGROUND

The National Strategy on Aquaculture in Australia, developed in cooperation with industry by the Commonwealth, State and Territory governments sets the strategic framework for future aquaculture development. The strategy identified chemical registration in the aquaculture industry as a priority issue. Consequently in 1995, the AC operating under the auspices of the SCFA established a Taskforce comprising industry and government representatives to address the issue.

The Taskforce developed an agreed strategy to register drugs and chemicals and has been instrumental in fostering a cooperative approach between the aquaculture industry and the NRA. The Fisheries and Aquaculture Branch, DPIE [now Agriculture Fisheries and Forestry – Australia (AFFA)] provided funding for a consultant to survey industry drug and chemical requirements and associated use patterns. The consultancy was the first of a three stage strategy in achieving registration or 'minor use permits' for priority drugs and chemicals required by the aquaculture industry. The three stages were:

Stage 1 — Identify aquaculture industries, industry groups, essential chemicals, quantities used, use patterns, existing maximum residue limits and withholding periods.

Seek NRA advice on the best approach to achieve legal use of these chemicals.

Stage 2 — Access existing information to address deficiencies identified by the NRA. Prepare and submit applications to achieve an approved legal basis for the use of these chemicals.

Stage 3 — Establish new information to address deficiencies in existing information required to achieve an approved legal basis for the use of those chemicals not yet approved.

Stage one of the strategy was completed successfully in December 1995, with a comprehensive review of the aquaculture industry's drug and chemical requirements and associated use patterns being submitted to the Taskforce.

Under the Chemical and Veterinary Chemicals Code Act 1994, all chemicals which fit the definition of agricultural and veterinary chemicals in the Act must be registered by the NRA before they can be supplied, sold or used in Australia. Many chemicals currently used by aquaculture industries fit these definitions, yet none of these chemicals were registered specifically for use in aquaculture. Like most other farmers, aquaculture producers need access to a range of safe and effective agricultural and veterinary chemicals so they can control pests and diseases on their farms, and maintain water quality. Yet, because it is a relatively small industry and the quantities of chemicals used are quite small and often out of patent, most chemical

manufacturers are reluctant to register products for aquaculture use as the registration costs are hard to justify in view of the small potential market. Even with the resources of this FRDC project, it has often been difficult to find drug companies that will participate in the project. In these cases, industry organisations have needed to act as the applicant in seeking ‘minor use permits’ from the NRA.

The NRA has supported, and had considerable input into the current strategy. Despite the resources available in countries like the USA, Canada and parts of Europe, and the relatively substantial sizes of their aquaculture industries, there are still only a handful of registered products in these countries. Within the NRA there was a lack of understanding on how aquaculture operations function. Without this understanding it was difficult for them to come to grips with the industry that they were dealing with. Therefore the aquaculture industry and drug companies have needed to assist the NRA wherever possible.

3. NEED

Australian governments and agri-food industries are placing greater emphasis on marketing Australia as a supplier of high quality fresh produce. It is important that these “clean food” activities are underpinned by appropriate mechanisms that ensure the integrity of Australian product. Residue detection and any associated food safety issues will continue to attract considerable public interest. The challenge for the aquaculture industry, governments and regulatory authorities is to develop strategies that combine efficient production methods without detrimental effects to food products, the environment, the safety of target animals, and the safety of persons who administer the compounds.

The detection of residues from unregistered chemicals may jeopardise the “clean green” image of Australian seafood. In a worst case scenario a complete shutdown of an aquaculture industry could occur if residues of unregistered chemicals were detected in aquaculture produce. This could be particularly damaging for export dependent products (with possible detrimental spillover effects in the wild caught sector and Australian food exports in general).

Aquaculturists across Australia have over the last ten years expressed the need to have access to suitable chemicals. Several reports and industry surveys have taken place (Herbert Report 1990, Heasman Report 1992, Percival Report 1995) however at the commencement of this FRDC project no drugs or chemicals (except Chorulon – finfish spawning induction agent) had been registered for use in Australian aquaculture. This highlighted the need for dedicated and specialist resources to undertake the next step and achieve registrations.

4. OBJECTIVES

4. To identify the most appropriate and industry accepted drugs and chemicals and their use patterns for each sector of the Australian aquaculture industry.

5. To maximise the cost-effectiveness and efficiency of the drug or chemical registration process by the Australian aquaculture industry to the NRA.

6. To establish registration of at least twelve of the drugs and chemicals identified in objective 1. (NB Each registered drug or chemical may be used by a number of aquaculture sectors in a number of different ways)

5. METHODS

Taskforce members provided advice and guidance to the principal investigator during the project. The principal investigator's role was to contribute to the guidance of the project through his industry and veterinary experience and to undertake the major component of the activities outlined below.

Activities

1. During July 1996 a familiarisation visit was undertaken to prawn, barramundi and government aquaculture facilities in North Queensland. This provided an opportunity for two NRA staff to better understand the activities and requirements of aquaculture companies.

2. In August 1996 a two day seminar/workshop was conducted in Canberra where many key aquaculture staff, industry veterinarians and other aquatic animal health experts presented information to, and met with, a wide range of government officials involved in the chemical registration process. This provided a further opportunity for government officials to better understand the activities and requirements of the aquaculture industry, and for aquaculture representatives to better understand the registration process.

3. Using the Percival Report (1995) "Registration of chemicals for use in the Australian aquaculture industry" as a basis, priority drugs and chemicals, and common use patterns were identified and prioritised.

4. In consultation with industry and the NRA, the most appropriate drugs and chemicals and their use patterns were established. This included discussions with the National Health and Medical Research Council (NHMRC), Worksafe (OH&S) and the Commonwealth Environmental Protection Agency (CEPA – environmental aspects) to identify agency information requirements.

5. The cost-effectiveness and efficiency of applications for registrations or minor use permits was maximised. This was achieved, where possible by:

- Including, all the industry sectors that required a particular drug or chemical and all the associated use patterns for that drug or chemical in a single application to the NRA.
- Submitting applications through appropriate drug companies or industry organisations.

6. Wherever possible, drug companies were encouraged to be the minor use permit applicant with the principal investigator preparing applications to the NRA. This involved contacting and meeting with drug company representatives and where applicable identifying other sources of information (eg. literature review/industry/government).

7. Where no drug company was interested in being the applicant, industry organisations were encouraged to be the minor use permit applicant with the principal investigator preparing applications to the NRA. This involved seeking information from relevant sources (eg. literature review/industry/government).

8. The principal investigator facilitated the education and awareness of NRA and other regulatory agency staff on aquaculture practices. This involved interactive sessions with NRA staff to enhance the information base for decision makers involved in the assessment of aquaculture chemical registration applications.

9. Where current information is insufficient for obtaining registration for priority drugs and chemicals, mechanisms for establishing additional information were identified.

10. A watching brief was maintained for newer, safer and/or more effective products.

11. As part of this final report, an outline of the protocol for registration or minor use permit applications has been prepared, as well as a copy of the minor use permits obtained to date.

12. During the project, the principal investigator also participated in the international effort to harmonise the registration of aquaculture drugs and chemicals.

13. During the project the principal investigator also participated as a volunteer member of the Therapeutics Advisory Committee to the Australian Veterinary Association. This provided an opportunity to ensure that the needs of the aquaculture industry were considered when developing veterinary industry policy.

6. RESULTS/DISCUSSION

6.1 Introduction

Based on the information in the Percival Report (1995) "Registration of chemicals for use in the Australian aquaculture industry", the Taskforce sought advice from the NRA, on the best approach to achieve legal permission for the use of key drugs and chemicals required by the aquaculture industry in Australia.

Three options are available for each particular drug or chemical:

- Full registration
- Permit (minor use, emergency or trial)
- Exemption from the need to obtain registration or a minor use permit based on the known innocuous characteristics of the compound and/or its use pattern

Legal use of chemicals can also occur under the prescription of a registered veterinarian depending on individual State legislation. However where this occurs, the individual veterinarian takes responsibility for any problems that may or may not result from the prescribed use.

Table 1 shows the main drugs and chemicals identified by the aquaculture industry in the 1995 survey according to the purpose of the use pattern. Applications to the NRA for registration or minor use permits were prepared for thirteen compounds from this list, selected according to the following criteria.

- availability of information to support the application
- availability of a drug company or industry organisation prepared to act as the applicant
- importance of the drug or chemical to the aquaculture industry
- appropriateness of the use pattern(s)
- the likelihood of success in obtaining the registration or minor use permit
- that the list of applications covered one or more compounds in all categories of therapeutic use identified in the table.

The drugs and chemicals selected were:

Ovaprim. LHRH and OvaRH (spawning induction agents)
Aqui-S and Benzocaine (anaesthetics/sedatives)
Aquacil, Sulfatrim and Tetraplex (antibacterial agents)
Formalin (antiparasitic agent – external protozoan parasites)
Dichlrovos (antiparasitic agent – metazoan parasites)
Trifluralin (antifungal agent)
Simazine (control of microalgae in prawn ponds)
Methyltestosterone/Methyldihydrotestosterone (Sex reversal agents)

Following is an outline of the:

(i) Requirements for seeking registrations, permits or exemptions from registration or minor use permit.

(ii) Status of applications undertaken as part of this FRDC project for the above selected drugs and chemicals

TABLE 1. The main drugs and chemicals identified by the aquaculture industry in the 1995 survey according to the purpose of the use pattern

Category	Drug/Chemical	Use Pattern
Hormones	Domperidone	Induction of spawning in finfish broodstock
	Human Chorionic Gonadotrophin	Induction of spawning in finfish broodstock
	LHRH analogues	Induction of spawning in finfish broodstock
	Methyldihydrotestosterone	Sex reversal in salmonid eggs or fry (for broodstock use only)
	Methyltestosterone	Sex reversal in salmonid eggs or fry (for broodstock use only)
	SGnRH + analogues	Induction of spawning in finfish broodstock
Anaesthetics	AQUIS	Anaesthesia of aquaculture spp. for the purpose of weight checks, health inspection etc. and to reduce stress at harvest.
	Benzocaine	Anaesthesia of finfish spp. for the purpose of weight checks, health inspection etc. and abalone spp. to remove from surfaces to which they are adhered.
	Metomidate hydrochloride	Anaesthesia of finfish spp. for the purpose of weight checks, health inspection etc.
	Phenoxyethanol	Anaesthesia of finfish spp. for the purpose of weight checks, health inspection etc.
	Tricaine methane sulphonate	Anaesthesia of finfish spp. for the purpose of weight checks, health inspection etc.
Antibacterials	Amoxycillin	Treatment of infections due to susceptible organisms in all stages of finfish spp. and in the hatchery stages (only) of molluscs and crustacea
	Benzalkonium chloride	Treatment of a number of bacterial or environmental conditions of juvenile and adult prawns, and hatchery stages of finfish production
	Erythromycin	Treatment of infections due to susceptible organisms in all stages of finfish spp. and in the hatchery stages (only) of molluscs and crustacea
	Florphenicol	Treatment of infections due to susceptible organisms in all stages of finfish spp. and in the hatchery stages (only) of molluscs and crustacea
	Oxolinic acid/ Sarafloxacin/ Enrofloxacin	Treatment of infections due to susceptible organisms in juvenile and broodstock stages (only) of finfish spp. and in the hatchery stages (only) of molluscs and crustacea
	Oxytetracycline/ Doxycycline	Treatment of infections due to susceptible organisms in all stages of finfish spp. and in the hatchery stages (only) of molluscs and crustacea
	Trimethoprim/ Sulphadiazine (+ Trimethoprim only)	Treatment of infections due to susceptible organisms in all stages of finfish spp. and in the hatchery stages (only) of molluscs and crustacea
Antiparasitics	Cypermethrin	Treatment of external metazoan parasites of finfish spp.
	Dichlorvos	Treatment of external metazoan parasites of finfish spp.
	Formalin	Treatment of external protozoan parasites in juvenile and broodstock stages of finfish and juvenile, adult and broodstock stages of prawn spp.
	Hydrogen peroxide	Treatment of external crustacean parasites in finfish spp.
	Malachite green	Treatment of external protozoan parasites in juvenile and broodstock stages of finfish spp.
	Ronidazole	Treatment of external protozoan parasites in all stages of finfish spp.
Antifungals	Amphotericin	Treatment of fungal infections in the eggs and juvenile stages of finfish spp. and hatchery stages of prawn spp.
	Formalin	Treatment of fungal infections in the eggs and juvenile stages of finfish spp.
	Hydrogen peroxide	Treatment of fungal infections in the eggs of finfish spp.
	Malachite green	Treatment of fungal infections in the eggs and juvenile stages of finfish spp.
	Trifluralin	Treatment of fungal infections in the hatchery stages of prawn spp.
Herbicides	Simazine	Selective herbicide for control of algal blooms in pond aquaculture
	Glyphosate	General purpose herbicide for controlling weeds in and on the banks of aquaculture ponds
Immunostimulants	β glucans	Feed additive for all aquaculture species to improve their ability to resist infections and therefore requirements for other treatments
Piscicide	Teaseed cake (Saponin)	Control of predators in prawn ponds

6.2 Requirements for seeking registration, a minor use permit or an exemption from registration or minor use permit

(NB. Much of the information presented in this report is based on information drawn from NRA publications)

6.2.1 Registration

In most cases registration of chemicals used in aquaculture is not a realistic proposition due to the lack of fundamental data available to support such an application and the high costs of generating this data in relation to the small potential market for the product. Following is an outline of the information required for a registration application. More detailed information can be found in the NRA manual "The Requirements Manual for Veterinary Chemicals".

The following data is required to register new active constituents. Less data is required to register a product that contains an approved active constituent or a product that is not intended for use on food-producing animals.

Part 1 Application Overview
A brief overview of the entire application.

Part 2 Chemistry and Manufacture
Data to identify the active constituent (eg. common name, chemical name CAS registry number, manufacturer's code number, structural formula/diagram, empirical formula and molecular weight); its manufacturer, composition, batch analysis, analytical methods, process chemistry, and quality control. Data to clearly identify the product; its chemical and physical properties; formulator; formulation composition, process, stability and analysis; and packaging.

Part 3 Toxicology
Results of toxicity studies (acute, short-term and long-term); reproduction studies; developmental studies; genotoxicity studies; and studies of the toxicity of metabolites and impurities, other adverse effects and toxicology of mixtures. Data on human toxicology, the no observable effect level, acceptable daily intake (for humans), and proposed first aid and safety directions.

Part 4 Metabolism and Toxicokinetics
Results of metabolic studies in target crops and animals. Metabolic and toxicokinetic studies in laboratory animals. Database of all metabolic studies considered.

Part 5a Residues
Complete, detailed proposed use-pattern for the product, including dose rate and regime and proposed withholding period. Data showing the nature, level and safety of residues and metabolites resulting from the proposed use-pattern of the product and the effect of any major variables. Included should be residues in aquaculture animals and/or products. Fate of residues during storage, processing and cooking. A proposed

maximum residue limit (MRL) and data on MRLs in Australia, other countries and Codex.

Part 5b Overseas Trade Aspects of Residues in Food
Information about the overseas registration status of the product/active constituent, use patterns and MRLs overseas, export intervals, labelling, compliance with overseas MRLs, authorities and growers views on use as proposed, and gazettal/trade advice notices. The NRA also needs to know what are the current/potential export markets for the product and that approval will not have implications that will adversely affect trade.

Part 6 Occupational Health and Safety
Data on potential occupational exposure of workers to the active constituent, end-use product and residues. Health conditions contraindicating use of the product. Occupational health monitoring, including atmospheric and biological monitoring (as applicable). Safety information to be provided on the label, Material Safety Data Sheets and through education/training.

Part 7 Environmental Studies
An assessment of the extent of, and potential for, environmental exposure during manufacture, use, disposal and through accident. Results of laboratory studies on the degradation of the chemical in water and by light; the metabolism of the chemical (both aerobic and anaerobic); bioaccumulation in fish, aquatic organisms and other species; and mobility in soil. Results of field studies to determine degradation (persistence) and leachability. Ecotoxicity studies of birds, mammals and other vertebrates; aquatic organisms and non-target invertebrates and native vegetation.

Part 8 Efficacy and Safety
Comprehensive data from laboratory and field trials which show that the product is effective for the purposes claimed and safe for the intended species and non-target species.

Part 9 Other Trade Aspects
Data on the trade aspects of a product relating to matters other than residues in food; e.g. environmental concerns about residues in wool.

Part 10 Special Data Requirements
For some types of products, evidence has to be shown that approval has been obtained from other agencies (eg. NHMRC Working Party on Antibiotics, Genetic Manipulation Advisory Committee, Australian Quarantine and Inspection Service, Australian National Parks and Wildlife Service.

For complete details outlining these requirements, NRA and other publications that should be consulted include:

- Standards for the Uniform Scheduling of Drugs and Poisons

- Maximum Residue Limits in Food and Animal Foodstuffs
- Code of Practice for Labelling Veterinary Chemical Products
- The Requirements Manual for Veterinary Chemicals
- Food Standards Code
- Code of Practice for labelling Agricultural Chemical Products
- The Requirements Manual for Agricultural Chemicals

For more information about these publications or any of the material covered in them contact:

National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E240
Kingston ACT 2604

Ph: (02) 6272 5852
Fax: (02) 6272 5249

NB. For contact details for State and Territory coordinators and other relevant agencies see Appendix 11.8.

6.2.2 Permits

6.2.2.1 Introduction

In certain circumstances the NRA may issue a permit to allow the use of an unregistered chemical product or an unapproved active constituent. In many cases this will be the most appropriate system for drugs and chemicals used in aquaculture due to the small quantities used and the lack of detailed information that is available to support a registration application.

A permit may be issued to:
- undertake research trials with unregistered products or active constituents
- allow the treatment of emergency disease outbreaks or pest infestations
- enable the treatment of a minor farmed species or crop not listed on the label of a registered product;
- allow the importation of an unregistered chemical or an unapproved active constituent into Australia.

Possession, supply and use of unregistered chemical products or unapproved active constituents are illegal unless the NRA has issued a permit that allows a person or organisation to legally use that product. State regulatory authorities control the use of chemicals (see section 6.2.2.3 – State "Control of Use" Legislation).

To obtain a permit, applicants must generally satisfy the same criteria as those for product registration. As the extent or degree of use of a chemical under permit is generally less than with registration, it is possible to undertake appropriate risk assessment with less data than is generally required for registration purposes.

It must be emphasised however, that the permit system is not intended to be used to circumvent the normal process of registering products and approving labels. It is therefore the responsibility of the applicant to provide justification to the NRA as to why the product and/or use should be considered as minor and suitable for consideration under permit requirements.

6.2.2.2 Types of Permits

Permits can generally be divided into two main types. Permits issued for minor use or emergency use situations are termed 'off-label permits'. Permits issued to allow research trials to be undertaken are termed 'trial permits'.

(i) Off-label Permits

The NRA categorises off-label uses as follows:

- minor use; and
- emergency use.

Minor uses include uses not listed on the registered label of a product because the cost of their inclusion would exceed the economical return of the product to its manufacturer or distributor. The cost of inclusion is comprised of the cost of registration and the cost of research to generate the necessary data for registration.

Examples of a minor use include, but are not limited to, situations in which:

- a product is used on a specialty animal grown by only a few producers on a small scale (minor animal);
- a product is used infrequently, its use is for control of a minor disease in a major animal enterprise (minor use in a major animal); and/or
- a variation is made to a registered use in special circumstances, such as approval of bath application of a chemical which is only registered for parenteral use.

The acceptability of a use as a minor use is at the discretion of the NRA. However (as mentioned above) it is the responsibility of the applicant to provide justification to the NRA as to why the product and/or use should be considered as minor and suitable for consideration under permit requirements. Minor use permits are only granted for specific periods and require renewal at the end of that period. Renewal can continue to occur, so long as the use can continue to be justified as a minor use.

An application for an **emergency use** is essentially an application for an off-label use that must be evaluated quickly to meet a genuine emergency. An example is use of an unregistered product to control a contagious disease outbreak for which no registered product exists. Poor planning and late submission of a permit application does not constitute justification for an emergency.

By their very nature, applications for an emergency use may not be subject to the same requirements or the same processing procedures as those for minor uses. In all cases of genuine emergency the NRA will consider requests urgently, and verification with the appropriate State coordinators whether the 'emergency' is genuine will be conducted.

(ii) Trial Permits

Research trials with agricultural and veterinary chemicals can vary greatly with respect to the size, numbers of people involved, and the potential human or environmental risks. These variations are used by the NRA to categorise trial permits.

The trial permit categories used by the NRA are:

- small-scale trials (*ie*. laboratory and small plot screening trials);
- field trials (*ie*. small scale field trials, under operator control/supervision, may be limited to < 1% total industry); and
- product evaluation trials (*ie*. large scale field/grower evaluation, < 5% industry).

6.2.2.3 State 'Control of Use' Legislation

It is an offence against State legislation to possess and use an unregistered chemical product or to use a registered chemical product for an unapproved purpose. The relevant legislation in each State may, however, differ about the types of actions with a registered chemical product that are deemed to be offences. For example, application of a product at lower-than-label-rate may not be an offence in certain States. Therefore, issue of a permit for such an application may not be necessary in all States.

A permit may not be required in the following instances:

- when products are used at lower rates or lower concentrations or are applied at lower frequencies than those indicated on the approved label;

- when additional conditions are set on how the chemical is applied, such as buffer zones, time of day or season for application etc.

- when veterinarians exercise their 'right to prescribe'.

It should be noted that the above examples may not be deemed to be non-offences in all States. Furthermore, the list is not exhaustive as there may be other situations in which use of an agricultural or veterinary product may not require a permit.

The NRA or the appropriate State Coordinator (see Appendix 3) should be contacted if there is any doubt about whether a proposed use is an offence and therefore requires a permit.

6.2.2.4 Lodging an Application

Applications for permits should be made to the NRA. Applications may be lodged by any person or organisation, including individual growers, grower organisations, government departments and authorities, and manufacturers or suppliers of agricultural and veterinary chemicals.

The NRA will initially examine an application and then consult with State coordinators or other experts, as required.

The NRA's permit application form (see Appendix 4) can be obtained from the NRA. While it is not essential that the permit application form be used, it is important that complete and adequate information is supplied in the required format. Application information can be submitted on computer disk or by electronic mail, if appropriate.

The time taken for the NRA to finalise applications can be found in the NRA manual "Permits for Agricultural and Veterinary Chemical Products". Generally the time taken depends on the type of application and the extent of information supporting it. Inadequately supported applications will invariably lead to delays, thus it is in an applicant's best interests to ensure that complete and relevant information accompanies each application.

One application may include a number of uses or trials, provided that:

- the uses or trials are conducted with the same active constituents or chemical product; or
- a number of active constituents or products are being used or tested for the same purpose.

There is usually a fee payable upon submission of an application for a minor use permit. However in certain circumstances no fee is payable, including if:

- the applicant is a grower of aquaculture products (*ie*. primary producer);
- the applicant is a producer organisation;
- the applicant is an officer or employee of the Commonwealth, a State or Territory, or of an authority of the Commonwealth, a State or Territory;
- The application is for an emergency use.

6.2.2.5 Completing an Application

The NRA manual "Permits for Agricultural and Veterinary Chemical Products" outlines the information that needs to be provided in an application for an off-label or trial permit.

This includes general information on the applicant, the product or chemical to be used, type of permit, use or trial details, starting and finishing dates for use or trial, quantity of product to be used, location of proposed use or trial. In addition to this general

information the application must satisfy the NRA that the proposed chemical is effective for the intended purpose and that the proposed use will not:

- be an undue hazard to the safety of the people exposed to the chemical during its handling or people using anything containing its residues;
- be likely to have an effect that is harmful to human beings;
- be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- unduly prejudice trade or commerce between Australia and its trading partners.

To support an application for a permit, applicants should where possible provide data and/or evidence in relation to the above criteria as outlined below.

Where possible, the same data as outlined for registration of chemicals in Section 6.2.1 should be provided in support of off-label and emergency use applications. This includes the following sections:

Part 1 Application Overview

Part 2 Chemistry and Manufacture

Part 3 Toxicology

Part 4 Metabolism and Toxicokinetics

Part 5a Residues

Part 5b Overseas Trade Aspects of Residues in Food

Part 6 Occupational Health and Safety

Part 7 Environmental Studies

Part 8 Efficacy and Safety

Part 9 Other Trade Aspects

Part 10 Special Data Requirements

However, often there is little data available in relation to off-label or emergency uses. In these cases, the applicant must satisfy the NRA through indirect evidence and argument as to why the proposed use should be permitted.

Examples of the information used to support an application for a minor use permit is presented in Appendix 5. The information presented in these applications was collected from public sources. In some cases however, particularly where the applicant was a drug company, the principal investigator was required to sign confidentiality agreements so as to access the company'' confidential records and research results. This information was combined with publicly available information in the preparation of applications, but cannot be presented in this report.

6.2.3 Exemptions

When the particular use of a chemical is considered to be innocuous, it may not be necessary to apply for either registration or a permit. Applying for exemptions simply requires the submission of a letter to the NRA requesting the exemption in conjunction supporting information to justify the request. Examples of the information used to justify exemptions is presented in Appendix 6.

6.3 Status of applications undertaken as part of this FRDC project for the above selected drugs and chemicals (as @ February 2000).

6.3.1 Registered Products

6.3.1.1 AQUI-S

AQUI-S is an aquatic anaesthetic that is now registered in Australia for use in the handling and harvesting of salmonids by or under the direction of a registered veterinarian. It can also be used off-label in other aquatic animal species under veterinary prescription. AQUI-S has been developed by the New Zealand Institute for Crop and Food Research and is manufactured and distributed under licence by AQUI-S New Zealand Ltd.

For further information on AQUI-S contact your local fish veterinarian or
AQUI-S New Zealand Ltd., PO Box 44-269, Lower Hutt, New Zealand.
Ph: (0011) 644 569 3852
Fax: (0015) 644 566 5601

6.3.1.2 Chorulon (HCG)

Chorulon is a spawning induction agent registered for use in finfish species under veterinary prescription. The product was registered by Intervet (Australia) Pty. Ltd. prior to the commencement of this FRDC project.

For further information on Chorulon contact your local fish veterinarian or Intervet (Australia) Pty. Ltd., Unit 13/14, 5 Hudson Avenue, Castle Hill, NSW 2154.
Ph: (02) 899 3522
Fax: (02) 899 3091

6.3.2 Minor Use Permits (approved)

6.3.2.1 Formalin

- A minor use permit has been granted to the Victorian Trout Association permitting the use of formalin to treat protozoan and metazoan ectoparasites of salmonid fish and fungal infections of salmonid eggs under certain conditions (see Appendix 7 – Permit Number 1260).

For further information contact your local fish veterinarian or the Victorian Trout Association, PO Box 258, Alexandra, Victoria 3714.
Ph: (03) 57 732483
Fax: (03) 57 732486

- A minor use permit has been granted to the NSW Silver Perch Growers Association permitting the use of formalin to treat protozoan and metazoan ectoparasites in native finfish and fungal infections in native finfish eggs.

For further information contact your local fish veterinarian or the NSW Silver Perch Growers Association, Mulquinneys Road, Braunstone, NSW 2460 or Locked Bag 5, Grafton, NSW 2460
Ph: (066) 493528
Fax: (066) 493528

6.3.2.2 Methyltestosterone or Methyldihydrotestosterone

- A minor use permit has been granted to the Victorian Trout Association permitting the use of methyltestosterone or methyldihydrotestosterone for the purpose of producing sex reversed broodstock in salmonid species under certain conditions (see Appendix 7 – Permit Number 2484).

For further information contact your local fish veterinarian or the Victorian Trout Association, PO Box 258, Alexandra, Victoria 3714.
Ph: (03) 57 732483
Fax: (03) 57 732486

6.3.2.3 Trifluralin

- A minor use permit has been granted to the Australian Prawn Farmers Association Inc. permitting the use of trifluralin to treat larval mycosis in prawns under certain conditions (see Appendix 7 – Permit Number 977).

For further information contact your local fish veterinarian or the Australian Prawn Farmers Association Inc., 27 Peel Street, South Brisbane, Queensland, 4101.

6.3.2.4 Simazine

- A minor use permit has been granted to the Australian Prawn Farmers Association Inc. permitting the use of simazine to control blue-green algae in prawn ponds under certain conditions (see Appendix 7 – Permit Number 491. This permit expired in November 1998, with the Australian Prawn Farmers Association Inc. intending to seek renewal of the permit. As yet this has not occurred.

For further information on the status of this application contact the Australian Prawn Farmers Association Inc., 27 Peel Street, South Brisbane, Queensland, 4101.

6.3.2.5 Benzocaine

- A minor use permit has been granted to Aquatic Diagnostic Services International Pty. Ltd. permitting the use of benzocaine as a sedative/anaesthetic in finfish and abalone species under certain conditions (see Appendix 7- Permit Number 1827).

For further information contact your local fish veterinarian or Aquatic Diagnostic Services International Pty Ltd, 29 Lincoln Street, Wilston, Queensland, 4051.
Ph: (07) 38305039
Fax: (07) 33655799

6.3.2.6 Aquacil (amoxycillin)

- A minor use permit has been granted to Novartis Animal Health Australasia Pty. Ltd., permitting the use of Aquacil (amoxycillin) to treat salmonid diseases caused by organisms sensitive to amoxycillin trihydrate under certain conditions and only under veterinary prescription (see Appendix 7 – Permit Number 1015). Unfortunately Novartis Animal Health Australasia has notified the Task Force that they no longer wish to pursue business in the aquaculture industry and therefore did not seek to renew these permits when they expired in August 1999. It is therefore necessary to find an alternative drug company or industry organisation to continue this permit.

6.3.2.7 Tetraplex (oxytetracycline)

- A minor use permit has been granted to Novartis Animal Health Australasia Pty. Ltd., permitting the use of Tetraplex (oxytetracycline) to treat salmonid diseases caused by organisms sensitive to oxytetracycline hydrochloride under certain conditions and only under veterinary prescription (see Appendix 7 – Permit Number 1014). Unfortunately Novartis Animal Health Australasia has notified the Task Force that they no longer wish to pursue business in the aquaculture industry and therefore did not seek to renew these permits when they expired in August 1999. It is therefore necessary to find an alternative drug company or industry organisation to continue this permit.

6.3.3 Minor Use Permits (pending approval)

6.3.3.1 Formalin

- A minor use permit application has been submitted by the Australian Prawn Farmers Association Inc. proposing to permit the use of formalin to treat external protozoan parasites of prawns and to eliminate viruses from prawn broodstock. Approval of this application is expected in the near future, but is still pending.

For further information on the status of this application contact the Australian Prawn Farmers Association Inc., 27 Peel Street, South Brisbane, Queensland, 4101.

6.3.3.2 Sulfatrim (sulfadiazine/trimethoprim)

- A minor use permit has been submitted by Novartis Animal Health Australasia Pty. Ltd., proposing to permit the use of Sulfatrim (sulfadiazine/trimethoprim) to treat salmonid diseases caused by organisms sensitive to sulfadiazine and trimethoprim under certain conditions and only under veterinary prescription. Unfortunately Novartis Animal Health Australasia has notified the Task Force that they no longer wish to pursue business in the aquaculture industry and therefore do not wish to pursue this application any further. It is therefore necessary to find an alternative drug company or industry organisation to be the applicant for this permit application.

6.3.3.3 Ovaprim (salmon gonadotrophin releasing hormone + domperidone)

- A minor use permit has been submitted by Syndel Laboratories Inc., proposing to permit the use of Ovaprim (salmon gonadotrophin releasing hormone + domperidone) as a spawning induction agent in finfish species. Approval of this application is expected in the near future, but is still pending.

For further information on the status of this application contact Syndel Laboratories Inc., 9211 Shaughnessy Street, Vancouver, British Columbia, Canada V6P 6R5.
Ph: (0011) 1 604 321 7131
Fax: (0015) 1 604 321 3900

6.3.3.4 OvaRH (salmon gonadotrophin releasing hormone)

- A minor use permit has been submitted by Syndel Laboratories Inc., proposing to permit the use of OvaRH (salmon gonadotrophin releasing hormone) as a spawning induction agent in finfish species. Approval of this application is expected in the near future, but is still pending.

For further information on the status of this application contact Syndel Laboratories Inc., 9211 Shaughnessy Street, Vancouver, British Columbia, Canada V6P 6R5.
Ph: (0011) 1 604 321 7131
Fax: (0015) 1 604 321 3900

6.3.3.5 LHRHa (Leutinising hormone releasing hormone analogue)

- A minor use permit has been submitted by Syndel Laboratories Inc., proposing to permit the use of LHRHa (leutinising hormone releasing hormone analogue) as a spawning induction agent in finfish species. Approval of this application is expected in the near future, but is still pending.

For further information on the status of this application contact Syndel Laboratories Inc., 9211 Shaughnessy Street, Vancouver, British Columbia, Canada V6P 6R5.
Ph: (0011) 1 604 321 7131
Fax: (0015) 1 604 321 3900

6.3.3.6 Dichlorvos

Following the submission of applications proposing the use of dichlorvos to treat external metazoan parasites in salmonids, barramundi and native finfish, the NRA instigated a detailed review of the use of dichlorvos in all animal species. Any application to use dichlorvos needs to conform with the outcome of that review.

- A minor use permit application was prepared for the Victorian Trout Association proposing to permit the use of dichlorvos to treat external metazoan parasites, however the association decided not to pursue the application as dichlorvos is no longer considered to be an important requirement by the industry.

- A minor use permit application was prepared for the Australian Barramundi Farmers Association proposing to permit the use of dichlorvos to treat external metazoan parasites, however the association decided not to pursue the application as dichlorvos is no longer considered to be an important requirement by the industry.

- A minor use permit application was prepared for the NSW Silver Perch Growers Association proposing to permit the use of dichlorvos to treat external metazoan parasites, however the association decided not to pursue the application as dichlorvos is no longer considered to be an important requirement by the industry.

NB. For contact details for State and Territory coordinators and other relevant agencies see Appendix 11.8.

6.3.4 Exemptions

The following chemicals have been granted an exemption from the need to be registered or obtain a permit for the following use patterns.

- Calcium carbonate (agricultural limestone)
  Calcium hydroxide (hydrated lime, builders lime, slaked lime, burnt lime)
  Calcium oxide (quick lime, unslaked lime, burnt lime)
  Calcium/Magnesium carbonate (dolomite)

  Exempted Use – prawns, freshwater crayfish and native fish. Usually incorporated into soil of earthen ponds prior to filling with water to:
  raise pH of pond water;
  raise pH of pond sediments to mobilise nutrients (eg. N. P and K);
  increase buffering capacity of pond water;
  supply a source of calcium and magnesium nutrients;
  accelerate decomposition of organic matter on the pond bottom and provide a potential food source;
  detoxify pond bottoms between growout cycles.

- Calcium sulphate (gypsum)

  Exempted Use – prawns, freshwater crayfish and native fish. Incorporated into soil of earthen ponds prior to filling with water, or added to water, to provide source of calcium when pH is high and use of lime is inappropriate.

- Zeolite (hydrated alkali aluminium sulphates)

  Exempted Use – prawns, freshwater crayfish and native fish. Added to water in earthen ponds to absorb toxic ammonia and sulphides from pond water and sediments.

- Aluminium sulphate (Alum)

Ferric chloride

Exempted Use – prawns, freshwater crayfish and native fish. Added to pond water and pond effluent to flocculate suspended clay particles.

- Inorganic fertilisers (urea, superphosphate, potassium chloride, ammonium sulphate, sodium nitrate, phosphoric acid, diammonium phosphate)

  Exempted Use - Prawns, freshwater crayfish and native fish. Usually incorporated into soil of earthen ponds prior to filling with water, or added to water subsequent to filling, to stimulate the growth of phytoplankton/zooplankton which is a source of food for aquaculture species.

- Organic fertilisers (eg. animal manures, lucerne pellets, dynamic lifter, OR 90, blood and bone, chaff, hay and straw).

  Exempted Use – prawns, freshwater crayfish and native fish. Usually incorporated into soil of earthen ponds prior to filling with water to stimulate the growth of phytoplankton/zooplankton which is a source of food for aquaculture species.

- Astaxanthin
  Canthaxanthin
  Beta carotene

  Exempted Use – flesh colouring agents in aquaculture feeds.

- Propionic acid
  Sorbic acid

  Exempted Use – antifungal agents in aquaculture feeds.

- Ethoxyquin

  Exempted Use – antioxidant in aquaculture feeds

- Sodium chloride

  Exempted Use – flavour/flavour enhancer in aquaculture feeds.

The principal investigator has continued to assist drug companies and producer organisations in finalising minor use permit applications still pending, however, it is essential that a permanent mechanism is established to maintain the progress made by this project (see section 8 – Future Developments).

7. BENEFITS

The Australian aquaculture industry will benefit directly from this project by having access to a number of safe registered or NRA permitted drugs and chemicals. Availability of appropriately registered or permitted products and the information that is associated with such products, encourages consistent good practice throughout the industry which helps to ensure that high quality is a hallmark of the Australian aquaculture industry in domestic and overseas markets.

The Australian aquaculture industry, consumers, governments and regulators all benefit from strategies that combine efficient production methods without detrimental effects to food products, the environment, the safety of target animals, and the safety of persons who administer the compounds.

The extent of the benefits flowing from this project have been limited to some degree by the lack of available information to support applications for registrations or minor use permits. The project has also been limited by the reluctance of drug companies to become involved with the aquaculture industry due to the small size of the market, even where the principal investigator was available to prepare applications on behalf of the company.

In the initial stages of the project, twenty-three drug companies expressed an interest in participating in the project. However, only two companies maintained their interest in the project once they understood the limited market potential, the resources required to support an application and/or the potential detrimental consequences should there be an adverse impact resulting from the use of a product that they had supported.

When the information presented in applications is not subject to confidentiality, the applications themselves provide a very good overview of the issues relating to the use of that chemical. Thus these applications could be used as an effective component of industry education programs.

8. FURTHER DEVELOPMENTS

It is essential that a mechanism is put in place to continue the work undertaken by this FRDC project. The TaskForce on Aquaculture Drugs and Chemicals held a teleconference on the 3rd December 1998 to consider the future direction this issue. The minutes of this meeting are attached in Appendix 8.

Key points from that meeting include:

vi The Taskforce consider the broader issue of increasing industry and veterinary awareness and education on the safe, appropriate and minimal use of drugs and chemicals.

vii The Taskforce facilitate and encourage veterinary education and involvement in the supply and prescription of drugs and chemicals to Australia's aquaculture industry.

viii The Taskforce encourage the development of management and husbandry practices which decrease the requirement for drugs and chemicals.

ix The Taskforce ensure minor use permits are maintained and renewed, minor use permit conditions and requirements are adhered to and approval for minor use permits or registration is pursued as and if more drugs and chemicals are required by Australia's aquaculture industry. This is to be carried out in conjunction with awareness and education campaigns for industry and veterinarians.

x The TaskForce emphasise the importance to industry of using registered or permitted chemicals in preference to chemicals that are unregistered or do not have exemptions or minor use permits. If the aquaculture industry does not support companies that attain registration or permits, companies willing to expend the time and money to apply to the NRA will become harder to find.

xi That the Taskforce encourage Australia's participation in the international forum addressing the issues of harmonisation of information on the use of drugs and biologics in aquaculture. This international forum aims to assist countries involved in gaining registration and obtaining minor use permits by sharing information and data required for approval.

However, the TaskForce has not been active since the above meeting. If the Taskforce were not to continue, the Australian Aquaculture Forum (AAF) or other national coordinating body representative of all aquaculture industries [eg. Australian Seafood Industry Council (ASIC) or Seafood Services Australia (SSA)], in a position to liase closely with industry, government and the NRA and with access to veterinary expertise needs to address the issues of drug and chemical use in future, for the following reasons:

- It is inefficient for individual industry organisations to apply for and maintain minor use permits and develop awareness and education campaigns separately, as duplication occurs with separate applications being written for the same product (this slows down the NRA approval process);
- Individual industry organisations should not be expected to be responsible for minor use permits used by industry participants that are not members of their organisation as the responsibilities associated with the minor use permit conditions are too great.
- Issues of drug and chemical use in aquaculture are all national issues and would be most efficiently and effectively be coordinated by a national organisation;
- Such a national organisation would be in a position to most efficiently and effectively facilitate and coordinate:
  - the development of applications for registration and minor use permits;
  - the maintenance and renewal of minor use permits;
  - the collation and dissemination of information to stakeholders on drug and chemical use;
  - the nomination of a veterinarian to represent the aquaculture/seafood industry on the Australian Veterinary Association's Therapeutics Advisory Committee.

The development of codes of practice and standards for the use of chemicals in the aquaculture industry based on existing and future efforts on this issue would be beneficial.

Chemical use issues relating to capture fisheries were not included in this project, however they also need to be addressed. Any future mechanism for addressing chemical use in aquaculture should include capture fisheries to avoid duplication.

9. CONCLUSION

The project has undertaken an assessment of the most appropriate, but industry accepted drugs and chemicals and their use patterns for each sector of the Australian aquaculture industry.

The project has also developed and tested a cost-effective and efficient process in conjunction with NRA for attaining a legal basis for drug or chemical usage by the Australian aquaculture industry (see Section 6.2 and Appendix 11.4). It must be noted however, that for various reasons, not all drugs and chemicals used by the aquaculture industry will necessarily achieve registration or permits. In these cases it is imperative that the industry assess and/or develop effective and safe alternative treatments.

The Australian aquaculture industry, consumers, governments and regulators all benefit from strategies that combine efficient production methods without detrimental effects to food products, the environment, the safety of target animals, and the safety of persons who administer the compounds. The Australian aquaculture industry's philosophy of minimising chemical usage will help ensure this objective is achieved.

The project has not established twelve registered drugs and chemicals, however the project has achieved the following:

Registered	Aqui-S	Anaesthetic/sedative
Minor Use Permits (approved)	Formalin in salmonids	External protozoan parasites
	Formalin in native fish	External protozoan parasites
	Methyltestosterone/Methyldihydrotestosterone in salmonids	Sex reversal
	Trifluralin in prawns	Larval mycosis
	Simazine in prawn ponds	Control of algae
	Benzocaine in finfish and abalone	Anaesthetic/sedative
	Amoxycillin in salmonids	Bacterial infections
	Oxytetracycline in salmonids	Bacterial infections
Minor Use Permits (pending approval)	Formalin in prawns	External protozoan parasites
	Sulfadiazine/trimethoprim in salmonids	Bacterial infections
	Ovaprim in finfish	Spawning induction
	OvaRH in finfish	Spawning induction
	LHRHa in finfish	Spawning induction
Exemptions	A Calcium carbonate, Calcium hydroxide, Calcium oxide, Calcium/Magnesium carbonate in ponds	Raise water pH Raise sediment pH Increase pH buffering Calcium/magnesium nutrient source Accelerate decomposition of organic matter Detoxify pond sediments
	B Calcium sulphate in ponds	Calcium source when pH high
	C Zeolite in ponds	Adsorption of toxic ammonia and sulphide compounds
	D Aluminium sulphate, Ferric chloride in ponds	Flocculation of suspended clay
	E Inorganic fertilisers , Organic fertilisers in ponds	Stimulation of phytoplankton growth
	F Astaxanthin, Canthaxanthin, Beta carotene in feeds	Tissue pigmenters
	G Propionic acid in feeds	Antifungal agent
	H Ethoxyquin in feeds	Antioxidant
	I Sodium chloride in feed	Flavour/preservative

Despite the good record of most aquaculture companies, it is vital that this issue is properly addressed without the use of chemicals within the industry becoming a major issue in the public arena. The cooperative strategy over the last few years has provided a good opportunity to achieve chemical registrations or 'minor use permits' without the stimulus of a major residue, environmental or human health incident. However, with the conclusion of this FRDC project it is essential that government and industry develop a mechanism for continuing this effort into the future.

10. REFERENCES

Heasman, M., 1992. Rationale for Regulation and Registration of Aquacultural Chemicals and Drugs in Australia. Report to the Working Group on Aquaculture reporting to the Standing Committee on Fisheries; 128 pp.

Herbert, 1988. Review of Use of Chemicals in Aquaculture in Australia – The Herbert Report. Report to the Working Group under the Standing Committee on Agriculture and the Standing Committee on Fisheries; 28 pp.

Percival, S., 1995. Registration of Chemicals For Use in the Australian Aquaculture Industry. Report to Fisheries Policy Branch of the Department of Primary Industry and Energy in Canberra; 174 pp.

11. APPENDICES

11.1 Intellectual Property

No intellectual property has been generated from this project.

11.2 Staff

I would especially like to acknowledge the contribution of Jayne Gallagher, Ian Hill and Iska Sampson from the Fisheries and Aquaculture Branch of the then DPIE, and Ken Hoy and Graham Savage from the NRA. However, there have been many other people who have also contributed to the project over its term, including:

Members of the Aquaculture Committee
Damien Ogburn (NSW Fisheries, Chairman of the TaskForce on Aquaculture Chemical Registration)
Roger Hall (Tasmanian DPIWE)
Robert Heard (NRA)
Narelle Clegg (NRA)
Jack Holland (CEPA)
Ian Hamdorf (BRS)
Rosalie Schnick (National Aquaculture NADA Coordinator – USA)
Rob Armstrong (Salmonid Health Consortium – Canada)
Eva-Maria Bernoth (Office of the Chief Veterinary Officer, Canberra)
Mark Kelly (AQIS)
Heloisa Mariath (National Residue Survey – NRS)
Paula Shoulder (Agriculture, Fisheries and Forestry – Australia, Fisheries and Aquaculture Branch)
Simon Bennison (Aquaculture Council of Western Australia)
Edward Meggitt (Victorian Trout Association)
Liz Evans (Australian Prawn Farmers Association)
Bruce Malcolm (NSW Silver Perch Growers Association)
Calvin Terry (NSW Silver Perch Growers Association)
Brian Jeffriess (Australian Tuna Boat Owners Association)
Glen Hurry (Agriculture, Fisheries and Forestry – Australia)
Darryl Hudson (Aquatic Diagnostics Services International Pty Ltd)
Don Bell (Aqui-S New Zealand)
Jan Holland (Aqui-S New Zealand)
Paul Hardy Smith (Tasmanian DPIF)
John Klose (Heriot Agvet Chemicals)
Jim Brackett (Syndel Laboratories Inc.)
Rick Bradshaw (Syndel Laboratories Inc.)
Alison Turner (DPIE)
Greg Hooper (NRA)
Harry King (SALTAS)
Phil Reed (NSW Fisheries)
Chris Robertson (QDPI)
Patrick Hone (SARDI)

Kirsten Rough (ATBOA)
Barry Munday (UTAS)
Ian Anderson (QDPI)
Mike Heasman (NSW Fisheries)

11.3 NRA Minor Use Permit Application Form (* Note this application form will be updated from time to time)

National Registration Authority
For Agricultural & Veterinary Chemicals

MINOR USE / EMERGENCY USE PERMIT APPLICATION FORM

FOR AGRICULTURAL OR VETERINARY CHEMICAL PRODUCTS

***Note*: An application is not accepted until all relevant parts are completed and all necessary supporting information and any required fee are submitted.**

Request is for: ☐ a minor use ☐ a genuine emergency use			
A fee is: ☐ attached. Amount: ☐ not attached. Reason: exempt or not required. *(Includes primary producers or officers of the Crown.)*			
Applicant Name			
Street Address			
Postal Address			
Name & position of contact person			
Telephone		Facsimile	

e-mail:	

PRODUCT(s) to be used	
Product is: ☐ registered in Australia. ☐ not registered in Australia. If product is unregistered attach the following information: Full formulation details, including active constituent(s) and all inert ingredients; If the product is imported, additional information detailing: **Quantity imported; Port or location entering Australia; Importing agents; Manufacturer of product; Estimated date of arrival.**	
ONLY ONE PRODUCT: - Indicate the brand name; **OR** **MORE THAN ONE PRODUCT**:- Indicate the **name** and **strength** of the active constituent(s) or all the brand names.	
PROPOSED USE	
Crop, animal or situation	
Pest or purpose	
Rate / dose	
Timing and frequency of sprays or doses	
Method of application	

Period between last application and harvest, grazing, slaughter or milking (Withholding Period)	
Any special precautions	

JUSTIFICATION:

Are any products currently registered or approved for the requested use?

☐ YES ☐ NO

If YES, indicate separately on attachment or in covering letter why the requested use should be considered over the currently registered products.

Use is to occur in:

☐ All states

☐ ACT ☐ NSW ☐ NT ☐ QLD

☐ SA ☐ VIC ☐ TAS ☐ WA

Specific locations (*if applicable*)

Proposed first date of use:

Likely duration of use:

Persons to be covered by the permit

Please indicate the most relevant and **attach appropriate details** where necessary.

☐ "All persons" - (includes everyone), ie no restrictions.

☐ A specific group (eg. Pest Control Operators, members of a particular association, etc..). *Please specify details below*.

☐ One or more nominated individuals. *Please attach details below*.

Details of end users (*if applicable*)

Supplier details: If the product is **unregistered** please indicate the name and address of the supplier of the product:	

IMPORTANT:

The NRA will only issue an off-label permit if it satisfied that the use would not cause an undue hazard to people (directly or through food residues), the environment, plants and animals. The use must also be effective and not prejudice Australia's trade. Please indicate, by marking the appropriate box, whether any data has been submitted with your application to support the proposed minor/emergency use in regard to:

- ☐ chemistry and manufacture
- ☐ toxicology
- ☐ metabolism and toxicokinetics
- ☐ residues
- ☐ overseas trade aspects of residues in food
- ☐ occupational health and safety
- ☐ efficacy and crop/animal safety.

If there is insufficient space on this request form please attach additional information.

Please forward this application, together with the appropriate fee and any supporting information, to:

NATIONAL REGISTRATION AUTHORITY
PO BOX E240
KINGSTON ACT 2604
Ph: (02) 6272 3216 Fax: (02) 6272 3218

I declare that the information contained in this application and accompanying documentation is complete and true to the best of my knowledge

Printed name: **Position:**

Signature: **Date:**

As part of the Government's regulatory reform strategy all Commonwealth Departments and agencies are required to have time boxes included on their external forms.

Optional: For organisations with less than 20 people - in an effort to simplify paperwork on small business, the Government needs to track the time it takes to complete existing forms. ***Please estimate:***

- ♦ the time actually spent reading the instructions, working on the question and obtaining the information, and
- ♦ the time spent by all employees in collecting and providing this information

…….days……hours…….minutes

11.4 Examples of Information used to Support an Application for a Minor Use Permit.

Following are four examples of the information used to support an application for a minor use permit. These applications were not subject to confidentiality agreements and therefore can be presented in this FRDC Report. Applications which were subject to confidentiality agreements included sulfatrim (sulfadiazine/trimethoprim), Tetraplex (oxytetracycline), Aquacil (amoxycillin), Ovaprim (salmon gonadotrophin releasing hormone + domperidone), OvaRH (salmon gonadotrophin releasing hormone) and LHRH analogue. In general, these application contained much more detailed information than that presented in the following examples.

11.4.1 Formalin for use in prawns to control external protozoan parasites

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1.1 INTRODUCTORY INFORMATION

1.1.1 APPLICANT DETAILS

1.1.1.1 Industry Organisation

1.1.1.2 Street Address

Postal Address

1.1.1.3 Contact Officer

1.1.2 PURPOSE OF APPLICATION

All species of cultured crustacea are susceptible, worldwide, to sessile ciliates which use the crustacean as an attachment substrate. Thirty-eight species of epicommensal ciliates belonging to nine genera (*Zoothamnium*, *Epistylus*, *Vorticella*, *Rhabdostyla*, *Myschiston*, *Pseudocarchesium*, *Intrastylum*, *Vaginicola* and *Cothurnia*) have been observed on penaeid shrimp [Chen, 1992 (p.51)]. *Zoothamnium*, *Vorticella* and *Epistylus* are the most common. They are ubiquitous in the aquatic environment. Adult ciliates feed on organic matter and bacteria suspended in the water column. Free-swimming teletrophs are the transmission stage. Fatal infestations often occur in larvae due to their small size. High levels of organic waste and or high bacterial counts in culture water result in increased ciliate numbers. Heavy fouling by epicommensal protozoa on the surfaces of gill and appendages may cause mortalities. Heavy infestations also interfere with locomotion, feeding and moulting [Anderson, 1989 (p. 111-112); Chen, 1992 (p.51); Fulks and Main, 1992 (p.10-11, 17); Lightner, 1988 (pp. 76-77, 80 - 81); Lightner, 1993 (p.448-449); Owens, 1989 (p.229, 231); Paynter, 1989 (pp.161-163); Percival, 1995 (pp. 114-115]. There are no approved treatments available to the prawn aquaculture industry for control of epicommensal protozoa. Formalin has been shown to be effective in controlling external protozoan parasites in cultured prawns.

Viral diseases can be devastating in prawn aquaculture, killing whole populations of prawns in a single outbreak. A number of these viruses are transmitted by prawn broodstock which are collected from the wild. However, viruses such as Monodon Baculovirus can be eliminated from broodstock through the application of appropriate quarantine and treatment before being placed in the hatchery. Formalin is one such agent [Chen et al., 1992 (p. 182); Lee and Wickins, 1992 (p.130, 156); Momoyama, 1992 (p.190); Percival, 1995 (p.109); Sano and Momoyama, 1992 (p.171)].

Nufarm Formalin is currently registered for treatment of footrot in sheep and the preservation of colostrum and drink milk in calves [see References - Nufarm formalin information sheet; IVS 1996 (p. 399)]. The use of formalin for treatment of epicommensal protozoan infestations in prawns, and viral infections in prawn

broodstock is therefore a different use pattern. However, there are three formalin products (ie. Formalin-F, Paracide-F and Parasite-S) in the USA approved for aquaculture use patterns, one being approved for use in prawns [Bell, 1992 (p. 312); Carpenter, 1994 (p. 26)]. It is proposed that Nufarm Formalin be granted a Minor Use Permit for use in the whole prawn aquaculture industry up to a stipulated total quantity in Australia of 8000 L per year of active formaldehyde.

1.1.3 OTHER RELATED SUBMISSIONS CURRENTLY UNDER REVIEW

Separate Minor Use Permit applications will be submitted for use of formalin in salmonids and native fish aquaculture.

1.1.4 CLAIMS FOR USE

External protozoan parasites

The proposed treatment is 50-100 ppm formalin for 4 hours daily in tanks or raceways until parasite control is achieved or a single dose in earthen ponds at 25 ppm which may be repeated in 5 to 10 days if needed [See References - FOI Summary NADA 140-989 (p.2); Liao et al., 1992 (p.117-118);

Elimination of viruses from broodstock

The proposed treatment is 200-400 ppm formalin for 30 minutes to 2 hours, then rinse [Chen et al., 1992 (p. 182); Lee and Wickins, 1992 (p.130, 156); Percival, 1995 (p.109)].

<u>USE PATTERN</u>

Hatchery Use

The dilution rate that is usually used in Australian hatcheries is 20-40ml/100litres of water for dip treatment and 500ml/ 10,000litre tank for broodstock holding treatment

Treatment tank sizes are 50-100litres for nauplii and broodstock dip. Treatment tank sizes are 10,000-20,000litres when treating broodstock holding tanks.

Formalin is added to treatment tanks by measured amount poured into the tank which is aerated.
No top ups are needed.

One treatment tank (50-100litres) would be prepared and used when new shipments of broodstock arrive at the hatchery (4-5 times per year) for a dip bath before placing in broodstock holding tanks. One treatment tank (50-100litres) would be prepared and used when nauplii are newly hatched for a dip bath before placing in larval rearing tanks. Frequency of both treatments depends on hatchery batch stage - one batch (cycle) takes 40 days and so these treatments would most likely occur in the first 7-10 days of a batch then not occur again until a new cycle is begun.

Australian hatcheries tend to run 3-4 concurrent batches then dry out the hatchery for two months and start again. Broodstock tanks (10,000-20,000 litres) could be treated on a weekly basis if required whilst holding broodstock - generally broodstock are held for up to two months, then a new shipment is brought in. This treatment is not commonly used as it is preferable to get new broodstock rather than treat.

A hatchery technician would take 10 minutes to prepare a dip treatment tank. Broodstock dip treatment takes 30 seconds per broodstock animal (10-30 per shipment) to place into and out of treatment tank. Nauplii dip treatment takes 30 seconds per scoop net of nauplii (<50 scoops per spawn tank). Broodstock holding tanks take 10 minutes to treat one tank.

Treatment tanks are located indoors in a separate room to the rest of activities in hatchery as broodstock require low light intensity to avoid stress. Spawning tanks are also isolated from rest of hatchery. No other workers are in the room during treatment.

Broodstock animals are placed into and out of dip treatment tanks by hand. Nauplii are held in scoop net and dipped into treatment tank. Broodstock in holding tanks are not removed - treated in tank if required.

Rubber gloves and face mask are used.

1.1.5 DRAFT LABEL

Not Applicable

1.2 CHEMISTRY AND MANUFACTURE

Nufarm Formalin is 400 g/L Formaldehyde (See References - Nufarm Formalin Information Leaflet). No additional information supplied.

1.3 TOXICOLOGY

No additional information supplied. A maximum of 8000 L total per year in Australia of active formaldehyde is proposed for use in the whole prawn aquaculture industry. The maximum used on any one site would be 3000 L per year.

Formalin is already scheduled S6 in Australia [See References - Standard for uniform scheduling of drugs and poisons, 1996 (p. 151)] and formalin products approved for aquaculture uses are sold over the counter in the U.S.A. [See References - FOI Summary NADA 140-989, 1993 (p.2); Bell, 1992 (p.312)].

1.4 METABOLISM

No additional information supplied.

1.5 RESIDUES

The recommended withdrawal period by the US Food and Drug Administration, for formalin is zero-hour for prawns [See References - FOI Summary, NADA 140-989]. In prawns, residue data indicated that the mean concentrations of formalin residues at 12 hours after the last treatment were not significantly different from naturally-occurring formaldehyde, which is a product of autolysis. It is proposed that a 100 degree day withdrawal period apply to the use of formalin in prawn spp.. Residues are not an issue with regard to treatment of broodstock as they will not be sold for human consumption.

1.6 OCCUPATIONAL HEALTH AND SAFETY

Formalin is already scheduled S6 in Australia [See References - Standard for uniform scheduling of drugs and poisons, 1996 (p. 151)] and approved formalin products are sold over the counter in the U.S.A. [See References - FOI Summary, NADA 140-989, 1993 (p.2)].

A maximum of 8000 L total per year in Australia of active formaldehyde is proposed for use in the whole prawn aquaculture industry. The maximum used on any one site would be 3000 L per year.

However, formalin is known to be toxic. Therefore safety precautions should be taken during use [See References - Standard for the uniform scheduling of drugs and poisons, 1996 (p. 216,223, 196, 197 and 202)].

Safety directions include:

* Avoid contact with eyes
* Avoid contact with skin
* Avoid breathing dust (or) vapour (or) spray mist

Standard statements include:

* If poisoning occurs, contact a doctor or Poisons Information Centre
* If skin contact occurs, remove contaminated clothing and wash skin thoroughly.
* Remove from contaminated area. Apply artificial respiration if not breathing.

In addition to the above, there are a number of other statements made on the current label for Nufarm Formalin with regard to Safety Directions, First Aid, Handling, Fire Hazard and Spills, which should be followed (See References - Nufarm Formalin Label).

Solutions should be tightly sealed during storage and not allowed to contact human skin. Formalin should only be used in well ventilated areas.

1.7 ENVIRONMENTAL CHEMISTRY AND FATE, AND ENVIRONMENTAL TOXICOLOGY

Prawn hatcheries in Australia can use one of two effluent disposal methods. Waste water from larval rearing tanks is directed into an evaporation/holding pond or is directed into earthen channels which also carry water from the prawn grow out ponds. These channels discharge under state EPA license, into adjoining brackish water river/estuary.

Water from earthen grow-out ponds is discharged into earthen channels which run around the perimeter of the prawn ponds (1-2ha) on farm thus a discharge channel can be from 100 meters plus long depending on how many ponds on the farm. Water is discharged under state EPA license into adjoining brackish water river/estuary.

Formalin degrades in the soil into biodegradable products and therefore does not cause residue problems (See References - Nufarm Formalin Information Leaflet). The US Food and Drug Administration concluded that formalin treatment will not have a significant impact on the environment when used at 100 ppm in raceways or at 25 ppm in ponds to treat shrimp. There are three formalin products approved for use in finfish aquaculture in the U.S.A., one of which is also approved for prawns.

A maximum of 8000 L total per year in Australia of active formaldehyde is proposed for use in the whole prawn aquaculture industry. The maximum used on any one site would be 3000 L per year.

Formalin is already scheduled S6 in Australia [See References - Standard for uniform scheduling of drugs and poisons, 1996 (p. 151)] and formalin products approved for aquaculture uses are sold over the counter in the U.S.A. [See References - FOI Summary, NADA 140-989, 1993 (p.2)].

Used formalin solutions should be diluted to at least 25 ppm before discarding [Noga, 1995 (p.286)].

1.8 EFFICACY AND SAFETY TO TARGET SPECIES

1.8.1 EFFICACY

The antiparasitic action of formalin solutions is based on their disinfectant properties which bring about reduction and protein precipitation. At the same time an irritation of the mucous membranes of the macro-organism takes place which favours the antiparasitic action to some extent [Schaperclaus, 1991 (p. 237)].

The US Food and Drug Administration has stated that formalin, when used as directed is effective in the treatment and control of external protozoan parasites on prawns [See References - FOI Summary NADA 140-989] and formalin is widely recommended in the literature for this purpose [Avault and Hunter, 1985 (p.18);

Chen, 1992 (p. 51); Fulks and Main, 1992 (p.11, 17, 19, 23, 24, 25, 28); Lightner, 1988 (pp. 77-78, 81); Lightner, 1993 (p. 451-452); Moore and brand, 1993 (p.337-338); Owens, 1989 (p.229, 231); Park, 1992 (p. 164); Paynter, 1989 (p.163)].

Formalin is also recommended to control the spread of viruses on wild broodstock introduced into the hatchery [Chen et al., 1992 (p. 182); Lee and Wickins, 1992 (p.130, 156); Momoyama, 1992 (p.190); Percival, 1995 (p.109); Sano and Momoyama, 1992 (p.171)].

For the success of the disinfectant and antiparasitic actions, it is important to bear in mind that formalin solutions are transformed at temperatures below 5-8°C more or less into the ineffective paraformaldehyde [Schaperclaus, 1991 (p. 237)]. Formalin solutions have the advantage that their efficacy is not reduced by soaps, detergents, acids or oils.

1.8.2 SAFETY TO TARGET SPECIES

The US Food and Drug Administrated states that formalin has an adequate margin of safety when used as directed [See References - FOI Summary NADA 140-989].

Treatment of ponds with phytotoxic substances such as formalin may lead to oxygen depletion [Romaire, 1985 (p.427)]. Formalin can be irritating to gills, and lower water dissolved oxygen levels, therefore water should be well aerated during treatment.

Formalin should be stored in the dark and above 4°C to inhibit paraformaldehyde formation. Paraformaldehyde is very toxic to prawns and must be filtered out prior to use. Formalin should never be used for treating prawns if paraformaldehyde is present. Methanol (12 to 15%) can be added to formalin to inhibit paraformaldehyde formation. Formalin should not be mixed with potassium permanganate.

1.9 TRADE

A standard of no detectable residues of formalin in exported product should be adopted unless otherwise indicated by importing country. However, due to the very short residue time of formalin this is unlikely to be an issue.

1.10 SPECIAL DATA

Not Applicable

1.11 REFERENCES (Note – copies of references should be included in the application)

Anderson, I., 1989. Hatchery health problems and hygiene management. In: Invertebrates in Aquaculture, Proceedings 117, Post Graduate Committee in Veterinary Science, University of Sydney: pp. 11-112, 116.

Avault, J., and Hunter, J., 1985. Crawfish culture in the United States. In: Crustacean and Mollusk Aquaculture in the United States, Eds. J. Brown and E. Brown, Publ. Van Nostrand Reinhold: p.18.

Bell, T., 1992. Drugs and chemotherapeutants for shrimp diseases: Their present status in the United States, with an overview of research and approval processes. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: p. 312, 314.
Carpenter, C., 1994. Guide to drug, vaccine and pesticide use in aquaculture. Prepared by the Federal Joint Subcommittee on Aquaculture: p.26.

Chen, D., 1992. An overview of the disease situation, diagnostic techniques, treatments and preventives used on shrimp in China. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: p. 51.

Chen, S., Chang, P., and Kou, G., 1992. Infection route and eradication of *Penaeus monodon* Baculovirus (MBV) in larval Giant Tiger Prawns, *Penaeus monodon*. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: pp. 182-183.

Freedom of Information Summary, NADA 140-989, 1993. PARASITE-S.

Fulks, W., and Main, K., 1992. Introduction. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: pp. 10-11, 17, 19, 23-25, 28.

IVS, 1996: p. 399.

Lee, D., and Wickins, J., 1992. Techniques: species/groups. In: Crustacean Farming, Blackwell Scientific Publications: pp. 130, 156.

Liao, I., Su, M., and Chang, C., 1992. Diseases of *Penaeus monodon* in Taiwan: A review from 1977 to 1991. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: pp. 117-118.

Lightner, D., 1988. Protozoan fouling diseases of Penaeid shrimps. In: Disease Diagnosis and Control in North American Marine Aquaculture, Developments in Aquaculture and Fisheries Science, Volume 17, Eds. C. Sindermann and D. Lightner, Publ. Elsevier: pp. 76-81.

Lightner, D., 1993. Diseases of cultured penaeid shrimp. In: CRC Hanbook of Mariculture, 2nd Edition, Volume 1, Crustacean Aquaculture, Ed. J. McVey, Publ. CRC Press: p. 448, 450-453.

Momoyama, K., 1992. Viral diseases of cultured Penaeid shrimp in Japan. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: p. 190.
Moore, D., and Brand, C., 1993. The culture of marine shrimp in controlled environment superintensive systems. In: CRC Hanbook of Mariculture, 2nd Edition, Volume 1, Crustacean Aquaculture, Ed. J. McVey, Publ. CRC Press: pp. 337-338, 342.

Nufarm Formalin Information Leaflet.

Owens, L., 1989. Common diseases of freshwater prawns and crayfish relevant to Australia. In: Invertebrates in Aquaculture, Proceedings 117, Post Graduate Committee in Veterinary Science, University of Sydney: pp. 229, 231.

Park, M., 1992. The status of culture and diseases of penaeid shrimp in Korea. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: p. 164.

Paynter, J., 1989. Penaeid prawn diseases. In: Invertebrates in Aquaculture, Proceedings 117, Post Graduate Committee in Veterinary Science, University of Sydney: pp. 161-163.

Percival, S., 1995. Registration of drugs and chemicals for use in the Australian aquaculture industry. Report of the Task Force on Aquaculture Drug Registration, DPIE, Canberra: pp. 30, 36, 71, 76.

Romaire, R., 1985. Water quality. In: Crustacean and Mollusk Aquaculture in the United States, Eds. J. Brown and E. Brown, Publ. Van Nostrand Reinhold: p.427.

Sano, T., and Momoyama, K., 1992. Baculovirus infection of penaeid shrimp in Japan. In: Diseases of Cultured Penaeid Shrimp in Asia and the United States. Eds. W. Fulks and K. Main, Publ. The Oceanic Institute, Honolulu, Hawaii: p. 171.

Schaperclaus, W., 1991(a). Therapy of fish diseases. In: Fish Diseases, Eds. Schaperclaus, Kulow and Schreckenback, Publ. A.A. Balkema/Rotterdam: 237-238.

Standard for the Uniform Scheduling of Drugs and Poisons, No. 11, 1996: 151, 196-197, 202, 216, 223.

11.4.2 Benzocaine used in finfish and abalone as a sedative/anaesthetic agent

APPLICATION OVERVIEW

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Sedation/ anaesthesia of finfish spp. to enable one of a number of handling procedures to be carried out without undue stress to the fish

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PROPOSED USE PATTERN (NO 1)

Sedation/ anaesthesia of finfish spp. to enable one of a number of handling procedures to be carried out without undue stress to the fish.

1. Justification for proposed use

Handling of small subsamples of cultured finfish populations is necessary from time to time to carry out one of a number of procedures. These procedures include: checking the health of the fish (especially gill health), weight checking, tagging, sampling blood, cannulation of broodstock, injection of hormone implants into broodstock, application of topical treatments, vaccination, surgery, research purposes and euthanasia (Ingram, 1988; Percival et al., 1988; Gilderhus, 1990; Brown, 1993; Stoskopf, 1993; Sedgewick, 1995; Gurney, 1996).

Sedation or anaesthesia of fish decreases the stress associated with such handling for both the fish and the operator, due to less physical damage to fish, less injury to the operator, decreased oxygen consumption by the fish due to reduced activity, lowered fish metabolic rate which results in less waste products and carbon dioxide production, and minimal changes in physiological parameters (Brown, 1993; Stoskopf, 1993; Gurney, 1996).

It is also sometimes necessary to transport certain stages of cultured finfish spp. from one site to another (eg. from the hatchery to a growout site). Sedation of fish prior to transport has a number of advantages in certain circumstances (Ferreira et al., 1984; Needham, 1988). Sedation reduces the stress of transporting fish, reduces physical injury to fish, decreases activity which reduces oxygen consumption, lowers metabolic rate which results in less waste products and carbon dioxide (Ferreira et al., 1984).

The use of sedation/ anaesthesia in both the above cases consequently results in a reduced effect on growth rates and mortality and minimises the need to treat stressed or damaged fish or abalone with antimicrobial agents following routine handling procedures

There are currently no registered sedative or anaesthetic agents available for these purposes in cultured finfish spp. in Australia. (Except for a permit for the use of MARINIL in salmonids at the Snobs Creek Hatchery in Victoria) Because only small samples of fish are sedated or anaesthetised, the quantities of benzocaine used are very small. Consequently there is little commercial incentive for drug companies to register benzocaine for the above-mentioned purposes. A number of anaesthetic/ sedative agents are required by the aquaculture industry in Australia so that individual operators are able to use the most appropriate agent for the particular species and application. Benzocaine should be one of these agents.

Benzocaine is considered to be one of the most effective all-round anaesthetics for use in finfish spp. (Ferreira, 1979; Gilderhus, 1987; Needham, 1987; Stoskopf, 1993) and can be used for marine, freshwater, temperate and tropical fish spp. (Gurney, 1996).

2. Proposed use details

2.1 Aquaculture species

Finfish spp

2.2 Situation

Benzocaine is dissolved in ethanol or methanol to make a stock solution. The stock solution is added to a plastic bin containing freshwater or seawater (as appropriate). Fish are immersed in the solution until the appropriate level of sedation or anaesthesia is reached for the purpose of the handling or transport procedure.

2.3 Purpose

Anaesthesia/ sedation of finfish spp. (See section 1 - Justification for proposed use)

2.4 Dose rate

10 - 100 ppm depending on the species, water temperature, the level of anaesthesia and the type of handling procedure to be performed. However, various recommendations are made regarding dosage. Ross et al., (1979) suggests that for warmwater species whose sensitivity to benzocaine is unknown, a starting point concentration of 100 ppm at 25°C should be used. Gurney, (1996) suggests that lower concentrations of 50 and 80 ppm have been demonstrated to anaesthetise carp and tilapia, and that rainbow trout have been induced to a "handleable state" at a concentration of 35 ppm within 3 minutes. Lower doses are required for active fish (eg. salmonids) and higher doses (up to 200 ppm) required for carp to achieve anaesthesia in acceptable time (Needham, 1988).

Whenever any anaesthetic agent is being used for the first time by an operator on a particular species or in a particular application, the sensitivity of small trial batches of fish should be tested with the agent before large scale use.

Dose (ppm)	Purpose	Induction (min)	Maintenance	Recovery (min)
5-12.5	Examination workup	1-3		3-15
12.5	Transport	5	24 hrs	3-15
20-30	Gentle handling	1-3	Excellent	3-15
50	Deep anaesthesia	1-3	Excellent	3-15
80	Surgery in recirculating system	1-15	Excellent	1-10
100	Surgery at higher water temperature	1-15	Excellent	1-10

(Table taken from Needham, 1988)

2.5 Method of application

Bath treatment

2.6 Critical comments

Benzocaine appears to have hypoxic effects on fish. Therefore aeration or oxygenation of the induction solutions throughout induction and anaesthesia is important (Clark, 1990; Stoskopf, 1993). Higher doses of benzocaine are required in warmer water, presumably because of the metabolism of the drug by fish; however, benzocaine is also more toxic in warmer water, a fact that narrows the margin of safety. The efficacy of benzocaine is not affected by water hardness, alkalinity or pH (Gurney, 1996; Stoskopf, 1993). Sedated or anaesthetised fish should be released into a safe environment (eg. where they cannot get hooked up or caught in net pockets) with adequate oxygen levels for recovery (Ingram, 1988).

Close observation is required to ensure that fish only reach the required level of anaesthesia. If fish are left in the benzocaine for too long, particularly at higher doses they may overdose and die. (Needham, 1987; Stoskopf, 1993)

Benzocaine is hydrolysed to para-aminobenzoic acid. This compound is used in laboratories as a sulphonamide antagonist. Therefore caution should be exercised when administering benzocaine to fish being treated with sulphonamides (Stoskopf, 1993; Merck Index, 1989).

3. Difference between proposed use and currently registered use

Topical anaesthetics such as benzocaine are frequently included in oral preparations to control nausea and vomiting caused by gastrointestinal irritation (Jenkins, 1988). A number of products containing benzocaine are registered for use in humans as oral, otic and rectal preparations (MIMS, 1995) including products such as sunburn relief lotions and throat lozenges. Benzocaine is also contained in a topical antibiotic powder registered for topical use in animals (MIMS, IVS Annual, 1996). These uses are all designed to relieve pain. The use in finfish is as a sedative/ anaesthetic.

4. Earliest and latest dates of proposed use

Indefinitely

5. Total area/ quantity/ number of animals to be treated

Benzocaine is required widely throughout the finfish aquaculture industry. However, procedures requiring benzocaine sedation or anaesthesia only involve small numbers (subsamples) of fish (1-100). Therefore the quantities used are relatively small. Most finfish hatcheries or growout operations would use < 5 kg of benzocaine powder annually, with many using < 1kg annually (Percival, 1995).

6. Maximum number of applications and withholding period (WHP)

Very few fish would be treated with benzocaine more than once as sampling regimes are usually completely random within large populations and only a limited number of procedures are performed in the course of a production cycle.

Benzocaine is highly soluble in fat and its retention in body tissues is directly related to their fat levels (Gurney, 1996; Stoskopf, 1993). The drug accumulates in mature, older fish and gravid females, which can result in prolonged recovery times and the need for longer withdrawal periods. Otherwise a withdrawal time of

only 24 hours is necessary for trout and large-mouth bass, but salmon require longer (Stoskopf, 1993). The withdrawal period of benzocaine for Atlantic salmon is 21 days in Norway (Nordmo, 1993).

The only fish to routinely receive more than one application are broodfish. Withdrawals periods are not applicable in these fish unless they are sold for human consumption.

7. States in which use is proposed

All states

8. Details of end-users

All operators and researchers involved in the aquaculture of finfish spp.

9. Residues in produce

There is little information available on withdrawal periods or residues for benzocaine in aquatic animals. Allen, (1988) found that benzocaine residues in muscle tissue were below the control values after 8 hours in largemouth bass and after 4 hours in rainbow trout when given a dose of 50 ppm. Most use of benzocaine occurs when the fish are small and therefore a considerable period exists between the time of use and the time of harvest. If benzocaine is used close to harvest, then a conservative withdrawal period should be used until expected residues patterns are confirmed through residue studies.

The Norwegian withdrawal period is 21 days in Atlantic salmon (Nordmo, 1993) (remembering that water temperatures in Norway are less than in Australia, so the residues will remain in the flesh longer in Norway).

10. Efficacy

Benzocaine is widely used and recommended internationally as a sedative/ anaesthetic agent for finfish (Booth, 1988; Ingram, 1988; Needham, 1988; Percival et al., 1988; Clark, 1990; Summerfeldt, 1990; Brown, 1993; Butcher, 1993; Stoskopf, 1993; Wall, 1993; Alderman et al., 1994; Stickney, 1994; Sedgewick, 1995; Gurney, 1996)

11. Safety to target species

As with any anaesthetic, close supervision is required to ensure good control over the level of anaesthesia. Whenever any anaesthetic agent is being used for the first time by an operator on a particular species or in a particular application, the sensitivity of small trial batches of fish should be tested with the agent before large scale use. However, benzocaine is widely used with good results.

Benzocaine may itself affect water quality, changing pH, carbon dioxide, alkalinity and conductivity. These changes revert to normal over time (Gurney, 1996). For water treated with 50 ppm of benzocaine, water quality returns to pretreatment levels within an hour. Gurney (1996) recommends that for transportation of fish, a sedative dose of 25 ppm be used which allows the resumption of pretreatment water quality within 30 minutes. At the end of 30 minutes the fish can be safely added.

12. Human and occupational health

It is argued that toxicological information should not be needed for benzocaine since benzocaine is already registered as an active constituent for veterinary preparations and is used in human therapeutics, both topically and orally (MIMS, 1995; MIMS, 1996: Jenkins, 1988)

Benzocaine has been shown to induce methemoglobinemia in certain animal spp. following topical application (Davis et al., 1993). A permit should recommend the use of impervious gloves when using benzocaine to prevent methemoglobinemia and anaesthesia of the hands.

Gloves and a face mask should be worn when preparing stock solutions.

13. Environmental safety

The environmental impacts from disposal of benzocaine treated water are considered to be low (Alderman, 1994) due to a number of reasons including:

* Benzocaine is used in small amounts (10-100ppm) in relatively small volumes of water in containers (50-1000 litres). The dilution effect is considerable if this treated water is released into waterways.

* The use of benzocaine is an intermittent procedure (ie. weekly or monthly usage).

* Benzocaine treated water is contained during use, therefore it is usually possible to dispose of the benzocaine at an appropriate land site.

It may be possible to use an activated carbon filtration system to remove benzocaine from the water (Howe et al., 1990), but the necessity and practicality of this requirement would need to be assessed.

14. Trade implications

There should be no trade implications so long as there are no residues of benzocaine in exported aquaculture products.

PROPOSED USE PATTERN (NO 2)

Sedation/ anaesthesia of abalone to allow their removal from the substrate they are attached to so that one of a number of handling procedures can be carried out.

1. Justification for proposed use

Abalone strongly adhere to the growing surfaces in aquaculture holding facilities. During the production cycle however, it is necessary to remove the abalone from these surfaces for a number of purposes, particularly grading (Fallu, 1991). While physical removal is possible, sedation/ anaesthesia prior to removal considerably minimises the potential stress and physical damage which can be associated with handling. Consequently growth rates are less affected, mortalities reduced and the need for remedial treatments minimised.

There are no permitted products available to the abalone farming industry in Australia (Except for permits issued by the Health Department in South Australia for individual growers in that state). The quantities used are very small and consequently there is little commercial incentive for drug companies to register benzocaine for use in abalone.

2. Proposed use details

2.1 Aquaculture species

Abalone

2.2 Situation

Benzocaine powder is dissolved in ethanol to make a stock solution. The stock solution is then added to a container of seawater.

2.3 Purpose

Anaesthesia/ sedation of abalone (See section 1 - Justification for proposed use)

2.4 Dose rate

50-100 ppm for 10-20 minutes (Fallu, 1990; Percival, 1995)

2.5 Method of application

Abalone together with attached substrate are immersed in the benzocaine bath to sedate/anaesthetise them before handling or the benzocaine stock solution is introduced to a static tank.

2.6 Critical comments N/A

3. Difference between proposed use and currently registered use

Topical anaesthetics such as benzocaine are frequently included in oral preparations to control nausea and vomiting caused by gastrointestinal irritation (Jenkins, 1988). A number of products containing benzocaine are registered for use in humans as oral, otic and rectal preparations (MIMS, 1995) including

products such as sunburn relief lotions and throat lozenges. Benzocaine is also contained in a topical antibiotic powder registered for topical use in animals (MIMS, IVS Annual, 1996). These uses are all designed to relieve pain. The use in finfish is as a sedative/ anaesthetic.

4. Earliest and latest dates of proposed use

Indefinitely

5. Total area/ quantity/ number of animals to be treated

All abalone on the farm may need to be anaesthetised 2-3 times annually. Larger abalone farms may produce in excess of 5 million abalone annually. The quantity of benzocaine used depends on the number of abalone being cultured, but individual farms use significantly < 10 kgs annually (Percival ,1995). There are currently less than 20 companies farming abalone in Australia.

6. Maximum number of applications and withholding period (WHP)

All abalone on the farm may need to be anaesthetised 2-3 times annually.

Benzocaine residues have been shown to disappear quickly from the body tissues in fish. Because benzocaine is fat soluble, longer residue times tend to occur in fatter individuals. Abalone are likely to have shorter residue times due to the low fat nature of their body tissues, although this may be counteracted to some extent by their low metabolic rate. In most cases benzocaine is not used on abalone within 6 months of harvest. In view of the lack of information on benzocaine use in abalone, perhaps a conservative withdrawal period could be set under a Minor Use Permit with a requirement for a residue study within the next 2 years.

7. States in which use is proposed

All states

8. Details of end-users

All aquaculture operations farming abalone (sea based and land based)

9. Residues

Benzocaine residues have been shown to disappear quickly from the body tissues in fish. Because benzocaine is fat soluble, longer residue times tend to occur in fatter individuals. Abalone are likely to have shorter residue times due to the low fat nature of their body tissues, although this may be counteracted to some extent by their low metabolic rate. In most cases benzocaine is not used on abalone within 6 months of harvest. In view of the lack of information on abalone, perhaps a conservative withdrawal period could be set under a Minor Use Permit with a requirement for a residue study within the next 2 years.

10. Efficacy

Benzocaine is widely used for the sedation/ anaesthesia of abalone (Fallu, 1991; Percival, 1995) because it has proved to be effective without undue side effects on the subsequent performance of the abalone.

11. Safety to target species

As with any anaesthetic, close supervision is required to ensure good control over the level of anaesthesia, however benzocaine is widely and effectively used in abalone.

Benzocaine may itself affect water quality, changing pH, carbon dioxide, alkalinity and conductivity. These changes revert to normal over time (Gurney, 1996). For water treated with 50 ppm of benzocaine, water quality returns to pretreatment levels within an hour. Gurney (1996) recommends that for transportation of fish, a sedative dose of 25 ppm be used which allows the resumption of pretreatment water quality within 30 minutes. At the end of 30 minutes the fish can be safely added.

12. Human and occupational health

It is argued that toxicological information should not be needed for benzocaine since benzocaine is already registered as an active constituent for veterinary preparations and is used in human therapeutics, both topically and orally (MIMS, 1995; MIMS, 1996: Jenkins, 1988)

Benzocaine has been shown to induce methemglobinemia in certain animal spp. following topical application (Davis et al., 1993). Gloves and a face mask should be worn when preparing stock solutions.

13. Environmental safety

The environmental impacts from disposal of benzocaine treated water are considered to be low (Alderman, 1994) due to a number of reasons including:

* Benzocaine is used in small amounts (10-100ppm) in relatively small volumes of water in containers (50-1000 litres). The dilution effect is considerable if this treated water is released into waterways.
* The use of benzocaine is an intermittent procedure (ie. 2-3 times annually).

* Benzocaine treated water is often contained during use, therefore it may be possible to dispose of the benzocaine at an appropriate land site.

It may be possible to use an activated carbon filtration system to remove benzocaine from the water (Howe et al., 1990), but the necessity and practicality of this requirement needs to be assessed.

14. Trade implications

There will be no trade implications so long as there are no residues of benzocaine in exported aquaculture products.

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11.4.3 Formalin for the treatment of external protozoan parasites in salmonids and fungal infections in salmonid eggs

APPLICATION OVERVIEW

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1.1 INTRODUCTORY INFORMATION

1.1.1 APPLICANT DETAILS

1.1.1.1 Industry Organisation

1.1.1.2 Street Address

Postal Address

1.1.1.3 Contact Officer

1.1.2 PURPOSE OF APPLICATION

Finfish species are sometimes prone to infestation by one or more of a number of protozoan parasites and fungal infections. These conditions cause a variety of clinical signs [Noga, 1995 (p. 93, 95, 99-100, 102, 103, 109-110, 112-113, 116); Schaperclaus, 1991 (p. 604, 636-638, 643-645, 705-706, 722-723, 742-750, 758-761, 767-768, 896); Schlotfeldt and Alderman, 1995 (p. 28, 30, 31, 32)], and can lead to large losses in performance and mortality if left untreated.

There are currently no registered products available to salmonid aquaculturists to treat these conditions. However, formalin has been widely used and recommended as an effective means of controlling these parasites in finfish species and fungi in finfish eggs [See Section 1.8.1].

Nufarm Formalin is currently registered for treatment of footrot in sheep and the preservation of colostrum and drink milk in calves [see References - Nufarm formalin information sheet; IVS 1996 (p. 399)]. The use of formalin for treatment of protozoan and metazoan infestations in salmonids, and fungal infections in salmonid eggs is therefore a different use pattern. However, there are three formalin products (ie. Formalin-F, Paracide-F and Parasite-S) in the USA approved for aquaculture use patterns [Carpenter, 1994 (p. 26)]. The volumes of formalin used in salmonid aquaculture in Australia are small compared with existing registered uses. It is proposed that Nufarm Formalin be granted a Minor Use Permit for use in the salmonid industry up to a stipulated total quantity in Australia of 500 L per year of active formaldehyde.

1.1.3 OTHER RELATED SUBMISSIONS CURRENTLY UNDER REVIEW

Separate Minor Use Permit application will also be submitted for use of formalin in native fish and prawn aquaculture.

1.1.4 CLAIMS FOR USE

Formalin is an effective parasiticide for bath treatment of most ectoparasitic protozoa and monogeneans in finfish (See Section 1.8.1 for details). It has

moderate-to-weak antibacterial activity. It also has moderate-to-strong action against water moulds on eggs but is not antifungal at doses that are non-toxic to fish [Noga, 1995 (p.286)].

Treatment of protozoan and metazoan ectoparasites

Formalin is effective in controlling a number of protozoan parasites, including *Costia* (now known as *Ichthybodo necator*); *Chilodonella spp.*; *Brooklynella spp*.; *Trichodinid spp; Ichthyopthirius multifilis; Cryptobia spp.;* Sessile, solitary, ectocommensal ciliates (e.g. *Apiosoma*, *Riboscphidia* and *Ambiphrya*)*;* and Sessile, colonial, ectocommensal ciliates (e.g. *Epistylis*).

The dosage and application regime of formalin necessary to control external protozoan parasites will depend on a number of factors (e.g. water quality, stocking density, water temperature, level of infestation and protozoan species being treated). As a guide formalin can be used in the following regimes [Munday, 1996 (p. 188, 192, 194); Noga, 1995 (286-287)].

(i) Bath

Add 0.125 to 0.250 ml formalin/L (= 125 to 250 ppm) and treat for up to 60 minutes. This can be repeated two to three times once daily if needed. When water temperatures are high (> 21°C for warmwater fish and > 10°C for coldwater fish) do not use > 167 ppm. The maximum dose should only be used every 3 days. Up to 167 ppm can be used on concurrent days.

(ii) Prolonged immersion in aquaria

Add 0.015 to 0.025 ml formalin/L (= 15 to 25 ppm). For *Ichthyophthirius*, 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 water temperatures.

(iii) Constant flow

Add 0.015 ml formalin/L (= 15 ppm) as a constant flow for 24 hours. This can be used to treat *Ichthyopthirius* in raceways.

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.

As a guide, formalin can be used in the following regimes for treatment of eggs [Munday, 1996 (p.192); Noga, 1995 (286-287)].

(i) Bath

Add 1 to 2 ml formalin/L (= 1000 to 2000 ppm) and treat eggs for up to 15 minutes. This can be repeated as needed.

OR

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

Precautions

Formalin is volatile and irritating. It causes cancer in laboratory rodents and can cause contact hypersensitivity and lung damage in humans; solutions should be tightly sealed during storage and not allowed to contact human skin. Formalin should only be used in well ventilated areas.

Formalin should be stored in the dark and above 4°C to inhibit paraformaldehyde formation. Paraformaldehyde is very toxic to fish and must be filtered out prior to use. Formalin should never be used for treating fish if paraformaldehyde is present. Methanol (12 to 15%) can be added to formalin to inhibit paraformaldehyde formation. Formalin should not be mixed with potassium permanganate.

Formalin can be irritating to the gills, and lowers water dissolved oxygen levels, therefore water should be well aerated during treatment. Formalin is more toxic in soft, acid water and at high temperatures. Formalin is usually contraindicated if the water temperature is > 27°C. Some fish are sensitive to formalin, so it is best to do a test treatment on a small number of fish before using it on untested species. Formalin is contraindicated if fish have been recently stressed (e.g. transported) or if skin ulcers are present.

Formalin is algicidal and toxic to macrophytes (e.g. aquarium plants).

Used formalin solutions should be diluted to at least 25 ppm before discarding.

1.1.5 DRAFT LABEL

Not Applicable

1.2 CHEMISTRY AND MANUFACTURE

Nufarm Formalin is 400 g/L Formaldehyde (See References - Nufarm Formalin Information Leaflet). No additional information supplied.

1.3 TOXICOLOGY

No additional information supplied. A maximum of 500 L total per year in Australia of active formaldehyde is proposed for use in the salmonid aquaculture industry. The maximum used on any one site would be 100 L per year. Formalin

usage in salmonid aquaculture is small compared to the volumes used by the sheep industry to control footrot.

Formalin is already scheduled S6 in Australia [See References - Standard for uniform scheduling of drugs and poisons, 1996 (p. 151)] and approved formalin products are sold over the counter in the U.S.A. [See References - FOI Summary, NADA 140-989, 1993 (p.2)].

1.4 METABOLISM

No additional information supplied.

1.5 RESIDUES

The recommended withdrawal period for approved formalin products is zero-hour for prawns [See References - FOI Summary, NADA 140-989] and fish [Munday, 1996 (p. 195)]. In prawns, residue data indicated that the mean concentrations of formalin residues at 12 hours after the last treatment were not significantly different from naturally-occurring formaldehyde, which is a product of autolysis. It is proposed that a 100 degree day withdrawal period apply to the use of formalin in salmonid spp.. Residues are not an issue with regard to treatment of eggs due to the long period and large size increase between treatment and harvest.

It is argued that the use of formalin in salmonid species should receive a Table 5 entry in the MRL standard. Firstly, formaldehyde is a natural component of body tissues in all animals (Mc Gilvery, 1970). Secondly, enclosed is a copy of information obtained for us from Public Master File No. 5228 in the USA which clearly supports the premise that residues of formaldehyde in a variety of fish species treated with formalin are indistinguishable from background levels of formaldehyde in tissues.

1.6 OCCUPATIONAL HEALTH AND SAFETY

Use Pattern

* The dilution rate varies depending on the type of treatment. Recommended dilution rates of formalin for treatment are as follows:

  Bath - < 250 ppm formalin (note: formalin is 37% formaldehyde)
  Prolonged immersion in aquaria - < 25 ppm formalin
  Continuous flow - 15 ppm formalin

* The product label for Nufarm Formalin is enclosed. A copy of the Minor Use Permit with all associated conditions would be supplied to subsequent aquaculture users of the product.

* Bath sizes will vary depending on the biomass of fish/eggs to be treated. The volume of water to be treated can vary from a few litres (treatment of eggs) to many thousands of litres (treatment of fish).

* For bath treatments, the formalin would usually be added directly to the treatment tank or raceway. For continuous flow systems, the formalin is usually added to the water supply for the tanks/raceways to be treated which then transports the formalin into appropriate tanks/raceways to be treated.

* The appropriate dose should be administered without the need for top-ups.

* The number of treatments per day will vary significantly depending on the system of water flow through the farm, the stage of the life cycle to be treated and the biomass to be treated. For example, a large biomass of fish could be treated from a single application point of the water supply, whereas if individual tanks or raceways only need treatment, the number of application points may increase according to the number of tanks/raceways to be treated, but the total volume of water to be treated would be less.

* Other activities may be carried out around the farm, however fish being treated are unlikely to be handled during treatments.

* Baths/raceways could be located either indoors or outdoors, however the volume of water to be treated indoors is likely to be significantly less than in outdoor situations.

* In most cases, the eggs/fish are treated in situ (ie. they are not handled during the treatment). This minimises the stress of treatment on what are already sick/stressed animals.

* Workers administering concentrated formalin to the water should be wearing protective clothing such as gloves and a face mask (for chemical vapours).

Formalin is already scheduled S6 in Australia [See References - Standard for uniform scheduling of drugs and poisons, 1996 (p. 151)] and approved formalin products are sold over the counter in the U.S.A. [See References - FOI Summary, NADA 140-989, 1993 (p.2)].

A maximum of 500 L total per year in Australia of active formaldehyde is proposed for use in the salmonid aquaculture industry. The maximum used on any one site would be 100 L per year. Formalin usage in salmonid aquaculture is small compared to the volumes used by the sheep industry to control footrot.

However, formalin is known to be toxic. Therefore safety precautions should be taken during use [See References - Standard for the uniform scheduling of drugs and poisons, 1996 (p. 216,223, 196, 197 and 202)].

Safety directions include:

* Avoid contact with eyes
* Avoid contact with skin

* Avoid breathing dust (or) vapour (or) spray mist

Standard statements include:

* If poisoning occurs, contact a doctor or Poisons Information Centre
* If skin contact occurs, remove contaminated clothing and wash skin thoroughly.
* Remove from contaminated area. Apply artificial respiration if not breathing.

In addition to the above, there are a number of other statements made on the current label for Nufarm Formalin with regard to Safety Directions, First Aid, Handling, Fire Hazard and Spills, which should be followed (See References - Nufarm Formalin Label).

Solutions should be tightly sealed during storage and not allowed to contact human skin. Formalin should only be used in well ventilated areas.

1.7 ENVIRONMENTAL CHEMISTRY AND FATE, AND ENVIRONMENTAL TOXICOLOGY

Formalin degrades in the soil into biodegradable products and therefore does not cause residue problems (See References - Nufarm Formalin Information Leaflet). The US Food and Drug Administration concluded that formalin treatment will not have a significant impact on the environment when used at 100 ppm in raceways or at 25 ppm in ponds to treat shrimp. There are three formalin products approved for use in finfish aquaculture in the U.S.A..

Used formalin solutions should be diluted to at least 25 ppm before discarding [Noga, 1995 (p.286)].

It is argued that there will be no significant environmental impacts associated with the proposed use of formalin in salmonids.

Salmonid farms in Australia can use one of two effluent disposal methods. Waste water is directed into evaporation/ holding/ sedimentation ponds or it is directed into earthen channels or pipes which also carry water from the rest of the salmonid tanks or ponds. These channels/pipes discharge under State government guidelines into adjacent freshwater/ brackish waterways. The volumes of treated water and dilution rates of formalin treated water vary from farm to farm depending on the biomass of stock to be treated and the characteristics of the waterway. However, treatment is usually only required in young fish or eggs. This means the volumes of treated water are reduced and waste treatment water is often significantly diluted by waste (untreated) water from the remainder of the farm prior to discharge into adjacent waterways. The characteristics of adjacent waterways will vary to some extent between farms, however by necessity, farms need to be located on waterways with significant water volumes and flows to maintain the farms operations. These characteristics will facilitate the rapid dilution and dispersal of waste water from the farm.

1.8 EFFICACY AND SAFETY TO TARGET SPECIES

1.8.1 EFFICACY

The antiparasitic action of formalin solutions is based on their disinfectant properties which bring about reduction and protein precipitation. At the same time an irritation of the mucous membranes of the macro-organism takes place which favours the antiparasitic action to some extent [Schaperclaus, 1991 (p. 237)].

Formalin is an effective parasiticide for bath treatment of most ectoparasitic protozoa and monogeneans. It has moderate-to-weak antibacterial activity. It also has moderate-to-strong against water moulds on eggs but is not antifungal at doses that are non-toxic to fish [Noga, 1995 (p. 93, 95, 99, 101, 103, 108, 111, 112, 114, 116, 286); Schaperclaus, 1991 (p. 606, 639, 646, 706, 723, 752, 762, 768, 896), Schlotfeldt and Alderman, 1995 (p. 28, 30, 31, 32)].

For the success of the disinfectant and antiparasitic actions, it is important to bear in mind that formalin solutions are transformed at temperatures below 5-8°C more or less into the ineffective paraformaldehyde [Schaperclaus, 1991 (p. 237)]. Formalin solutions have the advantage that their efficacy is not reduced by soaps, detergents, acids or oils.

1.8.2 SAFETY TO TARGET SPECIES

The toxicity of formalin solutions to fish is high, so that the therapeutic index has the value 2-3. Nevertheless, when the treatment is done carefully, no therapy mishaps occur, especially since small fish can recover quickly after immersion in formalin baths, while sensitive parasites suffer irreparable damage [Schaperclaus, 1991(a) (p. 237)].

Formalin should be stored in the dark and above 4°C to inhibit paraformaldehyde formation. Paraformaldehyde is very toxic to fish and must be filtered out prior to use. Formalin should never be used for treating fish if paraformaldehyde is present. Methanol (12 to 15%) can be added to formalin to inhibit paraformaldehyde formation. Formalin should not be mixed with potassium permanganate.

Formalin can be irritating to the gills, and lower water dissolved oxygen levels, therefore water should be well aerated during treatment. Formalin is more toxic in soft, acid water and at high temperatures. Formalin is usually contraindicated if the water temperature is > 27°C. Some fish are sensitive to formalin, so it is best to do a test treatment on a small number of fish before using it on untested species. Formalin is contraindicated if fish have been recently stressed (e.g. transported) or if skin ulcers are present [Noga, 1995 (p.286)].

Formalin is algicidal and toxic to macrophytes (e.g. aquarium plants).

1.9 TRADE

There should be no detectable residues of formalin in exported product unless otherwise indicated by importing country. However, due to the very short residue time of formalin this will not be an issue.

1.10 SPECIAL DATA

Not Applicable

1.11 REFERENCES *(Note – copies of references should be included in the application)*

Carpenter, C., 1994. Guide to drug, vaccine and pesticide use in aquaculture. Prepared by the Federal Joint Subcommittee on Aquaculture: p.26.

IVS, 1996: p. 399.

Freedom of Information Summary, NADA 140-989, 1993. PARASITE-S.

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McGilvery, 1970. Part IV - The Nitrogen Economy. In: Biochemistry - A Functional Approach, Publ. W. B. Saunders: pp. 412-414, 424, 430-431, 443-444.

Munday, B., 1996. Treatment of finfish diseases. In: Fish Health Workshop, Proceedings 265, Post Graduate Foundation in Veterinary Science, University of Sydney: pp. 188,192, 194, 195.

Noga, E., 1995(a). Part II. Problem List. In: Fish Disease: Diagnosis and Treatment, Publ. Mosby: 93, 95-97, 99-104, 108-120.

Noga, E., 1995(b). Part II. Problem List. In: Fish Disease: Diagnosis and Treatment, Publ. Mosby: 286-287.

Nufarm Formalin Information Leaflet and Label.

Percival, S., 1995. Registration of drugs and chemicals for use in the Australian aquaculture industry. Report of the Task Force on Aquaculture Drug Registration, DPIE, Canberra: pp. 30, 36, 71, 76.

Schaperclaus, W., 1991(a). Therapy of fish diseases. In: Fish Diseases, Eds. Schaperclaus, Kulow and Schreckenback, Publ. A.A. Balkema/Rotterdam: 237-239.

Schaperclaus, W., 1991(b). . In: Fish Diseases, Eds. Schaperclaus, Kulow and Schreckenback, Publ. A.A. Balkema/Rotterdam: 601-607, 633-646, 702-706, 716-723, 737-752, 755-762, 764-768, 892-897.

Schlotfeldt, H., and Alderman, D., 1995. A practical guide for the freshwater fish farmer. Supplement to the Bulletin of the European Association of Fish Pathologists, 15(4): pp. 28, 30, 31, 32.

Standard for the Uniform Scheduling of Drugs and Poisons, No. 11, 1996: 151, 196-197, 202, 216, 223,

11.4.4 Trifluralin for the treatment of larval mycosis in prawn larvae

APPLICATION OVERVIEW

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1.1 INTRODUCTORY INFORMATION

1.1.1 APPLICANT DETAILS

1.1.1.1 Industry Association

1.1.1.2 Street Address

Postal Address

1.1.1.3 Contact Officer

1.1.2 PURPOSE OF APPLICATION

Fungal diseases are common in shrimp culture and can cause mass mortalities, especially in hatcheries, where the disease larval mycosis has proven to be deadly. Larval mycosis is usually caused by either *Lagenidium callinectes*, *Sirolpidium* sp. or *Haliphthoros* sp., and mortalities can reach 100% within 24-48 hours after the onset of infection. There are currently no registered products available to prawn farmers to control this disease. However, trifluralin has been shown to be an effective means of controlling this disease.

Nufarm Trifluralin Selective Herbicide is currently registered as a pre-emergence herbicide for the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops. The use of trifluralin as a fungicide in the hatchery stages of prawn aquaculture is therefore a completely different use pattern. However, the volume of trifluralin used in prawn hatchery aquaculture in Australia will be very small compared to its use as a registered herbicide.

1.1.3 OTHER RELATED SUBMISSIONS CURRENTLY UNDER REVIEW

Not Applicable

1.1.4 CLAIMS FOR USE

Trifluralin is used to control larval mycosis caused by the fungi *Lagenidium callinectes*, *Sirolpidium* sp. or *Haliphthoros* sp. in hatchery stages of prawn culture. Chemotherapy destroys infective zoospores, thereby limiting the development and/or spread of infection, however treatment of already infected larvae is not successful [Anderson, 1989 (p.111)].

The dosage and application regime of trifluralin necessary to control larval mycosis depends on a number of factors (eg. water quality, stocking densities, level of zoospores etc.). Trifluralin can be added regularly (twice daily, daily or alternate days) or continuously to culture water during hatchery stages (approximately 12-15 days). The recommended dose is 10-100 ppb.

Spawners are sometimes dipped in trifluralin prior to entry to the hatchery to reduce contamination of hatchery systems.

The dilution rate of trifluralin is 0.5ml/10,000 Litres of water x 2 treatments/day applied as new water is added to tanks. Note: The dosage of trifluralin used in prawn hatcheries (ie. 100 ppb) is only one fifth of the Maximum Residue Limit for trifluralin in water (0.5 ppm) which already exists in the Food Standards Code.

Treatment bath sizes vary according to larval tank sizes in the hatchery - 5,000 Litre to 30,000 Litre tanks are used in Australian hatcheries. Small hatcheries may have 5 to 10 larval rearing tanks, large hatcheries may have 20 to 30 larval rearing tanks.

The length of time a single dose treatment will last is dependant on how long the trifluralin takes to volitalise. Half-life is known to be 30 - 138 minutes and as algae is present in the larval tanks, the speed of decay is increased. The rate of decay would also be dependant on the rate of aeration and water temperature also.

1.1.5 DRAFT LABEL

Not Applicable

1.2 CHEMISTRY AND MANUFACTURE

Nufarm Trifluralin Selective Herbicide (Nufarm Trifluralin Product Label - see references). No additional information supplied.

1.3 TOXICOLOGY

No additional information supplied. A maximum of 100 L per year of Nufarm Trifluralin Selective Herbicide is proposed for this Minor Use Permit. This volume would be used over a number of sites and is very small compared to the use of this product as a registered herbicide.

1.4 METABOLISM

No additional information supplied.

1.5 RESIDUES

The existing MRL for trifluralin in water set by the National Food Authority is 0.5 ppm (Food Standards Code - see references) which is higher than the treatment dose in the rearing water of prawn hatcheries. Apart from carrots which have an MRL of 0.5 ppm, other meat and vegetable products have an MRL of 0.05 ppm (Food Standards Code - see references).

It is extremely unlikely that any trifluralin will remain in harvested prawns. Treatment occurs when the prawns are < 4.5 mm in length and at least 100 days prior to harvest [Bell, 1991 (p.23)]. Williams et al. [1988 (p.191-192)] found no detectable tissue residues in small juvenile shrimp that had been exposed to trifluralin as larvae.

1.6 OCCUPATIONAL HEALTH AND SAFETY

It is argued that no additional toxicological or OH&S data should be required for the use of trifluralin in prawn hatcheries as trifluralin is already registered as a herbicide. A maximum of 100 L per year of Nufarm Trifluralin Selective Herbicide is proposed for this Minor Use Permit. This volume would be used over a number of sites and is very small compared to the use of this product as a registered herbicide. In addition, the existing MRL for trifluralin in water set by the National Food Authority is 0.5 ppm (Food Standards Code - see references) which is higher than the treatment dose in the rearing water of prawn hatcheries.

Trifluralin is added to the rearing water in very small regular volumes using a syringe. All safety directions stated for the registered product should be applied for the preparation and use of trifluralin in prawn hatcheries.

Taken from NUFARM Trifluralin Product Label (Product Label - see references):

Harmful if swallowed. Will irritate the eyes and skin. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and using the prepared spray wear cotton overalls, buttoned to the neck and wrist and a washable hat and elbow length PVC gloves and face shield or goggles. 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, face shied or goggles and contaminated clothing.

Sensitive workers should take similar precautions when working around aquaculture tanks being treated with trifluralin.

1.7 ENVIRONMENTAL CHEMISTRY AND FATE, AND ENVIRONMENTAL TOXICOLOGY

Extensive information is already available on the environmental issues associated with the use of trifluralin as a herbicide.

Prawn hatcheries in Australia can use one of two effluent disposal methods. Waste water from larval rearing tanks is directed into an evaporation/ holding pond or is directed into earthen channels which also carry water from the prawn growout ponds. These channels discharge under state EPA license into adjoining brackish water river/estuary.

Trifluralin rapidly decays in water, with a half-life of 30-138 minutes and levels drop rapidly in the presence of algae blooms [Williams et al., 1986 (p.8); Bell, 1991 (p.23)]. In fact the reason regular or continuous treatment of rearing water is necessary is due to the inherently unstable nature of trifluralin [Lightner, 1993 (p.435)]. Trifluralin can be absorbed in sediments and is rapidly accumulated from water by fish [Alderman et al., 1994 (p.64)]

Fungistatic doses of trifluralin used to control larval mycosis (10-100 ppb) are less than the current MRL for trifluralin in water (0.5 ppm). The dose is so small that the dilution effect upon release into a waterway and the rapid breakdown of the chemical would result in a negligible environmental impact.

A maximum of 100 L per year of Trifluralin Selective Herbicide is proposed for this Minor Use Permit. This quantity would be used over a number of sites and is very small compared to the use of this product as a registered herbicide.

1.8 EFFICACY AND SAFETY TO TARGET SPECIES

1.8.1 EFFICACY

Trifluralin is widely used to control larval mycosis in prawns [Lightner, 1988 (p.60); Anderson, 1989 (p.111*)*; Paynter, 1989 (p.159); Bell, 1991 (p.23); Fulks et al., 1992 (p. 9,25,367,369); Shariff et al., 1992 (p.42); Flegel et al., 1992 (p.79); Bell, 1992 (p.315,317); Lea Master, 1992 (p.350); Lightner, 1993 (p.434-435); Alderman et al., 1994 (p.64); Percival, 1995 (p.111)].

1.8.2 SAFETY TO TARGET SPECIES

Excessive dosage of trifluralin can affect larval prawn survival [Bland et al., 1976 (p.454)], therefore recommended doses should be adhered to, however there appears to be a reasonable margin of safety [Bell, 1991 (p.23)].

1.9 TRADE

As residues are not an issue in harvested product following the use of trifluralin, there are no expected trade implications.

1.10 SPECIAL DATA

Not Applicable

1.11 REFERENCES *(Note – copies of references should be included in the application)*

Alderman, D., 1994. Chemicals used in Mariculture. International Council for the Exploration of the Sea (ICES), Cooperative Research Report No. 202: 64-65.

Anderson, I., 1989. Hatchery health problems and hygiene management. In: Proceedings 117 - Invertebrates in aquaculture, Postgraduate Foundation in Veterinary Science, University of Sydney: p. 111**.**

Bell, T.A., 1992. Drugs and chemotherapeutants for shrimp diseases: Their present status in the United States, with an overview of research and approval processes. In: Diseases of cultured penaeid shrimp in Asia and the United States, Proceedings of workshop in Honolulu, Hawaii, April 27-30, 1992: p. 315 and p. 317.

Bell, T.A., 1991. Overview of diseases and drug needs for major aquaculture species: shrimp. Veterinary and Human Toxicology, Proceedings of the IR-4/FDA Workshop for minor use drugs: Focus on Aquaculture, 33, Supplement 1: 22-23.

Bland, C.E., Ruch, D.G., Salser, B.R. and Lightner, D.V., 1976. Chemical control of Lagenidium, a fungal pathogen of marine crustacea. Proc. World Mariculture Soc., 7: 445-472.

Flegel, T., Fegan, D.F., Kongsom, S., Vuthikomudomkit, S., Sriurairatana, S., Boonyaratpalin, S., Chantanachookhin, C., Vickers, J.E. and MacDonald, O.D., 1992. Occurrence, diagnosis and treatment of shrimp diseases in Thailand. In: Diseases of cultured penaeid shrimp in Asia and the United States, Proceedings of workshop in Honolulu, Hawaii, April 27-30, 1992: p.79.

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Fulks, W. and Main, K., 1992. Introduction. In: Diseases of cultured penaeid shrimp in Asia and the United States, Proceedings of workshop in Honolulu, Hawaii, April 27-30, 1992: p. 9 and p. 25.

Fulks, W. and Main, K., 1992. Discussion group summaries. In: Diseases of cultured penaeid shrimp in Asia and the United States, Proceedings of workshop in Honolulu, Hawaii, April 27-30, 1992: p. 9 and p. 25.

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Lightner, D., 1988. Larval mycosis of penaeid shrimp. In: Developments in aquaculture and fisheries science, Vol 17 - Disease diagnosis and control in North American marine aquaculture, Eds. C.J. Sinderman and D.V. Lightner: 58-61.

Lightner, D., 1993. Diseases of cultured penaeid shrimp. In: CRC Handbook of Mariculture, Ed. J.P. McVey: 433-435.

Merck Index, 11th Edition, 1989.

NUFARM Trifluralin Product Label.

Paynter, J., 1989. Penaeid prawn diseases. In: Proceedings 117 - Invertebrates in aquaculture, Postgraduate Foundation in Veterinary Science, University of Sydney: 158-159.

Percival, S., 1995. Registration of drugs and chemicals for use in the Australian aquaculture industry. Report of the Task Force on Aquaculture Drug Registration, DPIE, Canberra: p. 111.

Shariff, M. and Subasinghe, R.P., 1992. Major diseases of cultured shrimp in Asia: An overview. In: Diseases of cultured penaeid shrimp in Asia and the United States, Proceedings of workshop in Honolulu, Hawaii, April 27-30, 1992: p. 42.

Williams, R.R., Bell, T.A. and Lightner, D.V., 1986. Degradation of trifluralin in seawater when used to control larval mycosis in penaeid shrimp culture. J. World Aqua. Soc., Vol 17: 8-12.

Williams, R.R. and Lightner, D.V., 1988. Regulatory status of therapeutants for penaeid shrimp culture in the United States (Extract only). J. World Aqua. Soc., Vol 19: 191-192.

11.5 Examples of information used for support applications for exemptions

Soil/Water Treatments

Calcium carbonate	***(Agricultural limestone)***
Calcium hydroxide	***(Hydrated lime, Builders lime, Slaked lime, Caustic lime)***
Calcium oxide	***(Quick lime, Unslaked lime, Burnt lime)***
Calcium/Magnesium carbonate	***(Dolomite, Calmag)***

Proposed exempt use pattern

For application to the soil or water in earthen pond aquaculture systems (liming).

Rationale for use

Liming is conducted to improve the health of the soil and/or water environment in earthen ponds for a number of aquaculture species, including: prawns, freshwater crayfish, native fish etc.. Liming is used to manipulate the acid-base relationship in soils or water within the earthen pond for one or a combination of the following purposes:

* To raise the pH of the water
* To raise the pH of the pond sediment to mobilise important nutrients eg. nitrogen, phosphorous and potassium
* To increase the buffering capacity of the pond water, preventing significant fluctuations in water pH
* To supply a source of calcium (and magnesium) as nutrients (eg. shell growth)
* To accelerate the decomposition process of organic matter, providing a potential food source more rapidly
* To detoxify pond bottoms between growout cycles. A build up of uneaten feed and waste products on the pond bottom contributes to anaerobic conditions in the sediment. Liming in conjunction with sun drying and exposure to air conditions the pond for re-use

The quantity of lime required depends on a number of factors, but mainly soil pH and soil type.

Basis of application for exemption

These compounds are widely available commodities and extensively used in commercial and domestic agriculture and horticulture. The total quantities used in aquaculture are very small by comparison to these other uses.

Zeolite

Proposed exempt use pattern

For application to earthen pond aquaculture systems for the purpose of adsorbing toxic ammonia and sulphide compounds from the system.

Rationale for use

Zeolite is distributed in earthen ponds to improve the health of the culture environment by adsorbing ammonia and sulphides from pond water and sediments. If the levels of ammonia and/or sulphides become too high in the pond, these compounds are toxic to the aquatic species being farmed.

Basis of application for exemption

"Zeolites are naturally occurring compounds found in sedimentary and volcanic rocks, altered basalts, ores and clay deposits. Some 40 known zeolite minerals and a great number of synthetic zeolites are available commercially. They are used as molecular sieves, filters, adsorbents, catalysts, drying agents, cation exchangers, dispersing agents and detergent builders" (Merck Index, 11th Edition, 1989).

Calcium sulphate (Gypsum)

Proposed exempt use pattern

For application to earthen ponds as a source of calcium, when the pH is high (ie. liming compounds are contraindicated).

Rationale for use

Gypsum is a good source of calcium, but will not affect pH. It is therefore useful when water is deficient in calcium (soft water), but the pH is high.

Basis of application for exemption

Gypsum is a widely available commodity and extensively used in commercial and domestic agriculture and horticulture. The total quantities used in aquaculture are very small by comparison to these other uses.

Water Treatments Only

Fertilisers (Organic and Inorganic)

Proposed exempt use pattern

For application to the water in aquaculture systems for the purpose of stimulating phytoplankton multiplication.

Rationale for use

A number of aquaculture species feed on natural populations of zooplankton which have fed on natural populations of phytoplankton. The maintenance of dense populations of appropriate phytoplankton species therefore forms the basis of the food chain within the aquaculture system. The nutrients required for the growth of phytoplankton are supplied via the application of fertilisers (organic and inorganic) to the water. The appropriate quantity of fertiliser to be added to the system, is mostly dependant on the available nutrient content of the soil.

Organic fertilisers are manures or agricultural by-products that slowly release nutrients when decomposing.

chaff, hay, straw, animal manures (poultry, cow, horse, etc.), lucerne pellets, (We need to specify all types the industry wants to use), Dynamic Lifter, OR 90 etc.

Inorganic fertilisers are compounds that dissolve in water releasing nutrients.

Urea, superphosphate, muriate of potash, ammonium sulphate etc.

Basis of application for exemption

These substances are widely available and extensively used in commercial and domestic agriculture and horticulture. The total quantities used in aquaculture are very small by comparison to these other uses.

Aluminium sulphate (Alum)

Proposed exempt use pattern

For application to freshwater pond water and pond effluent to flocculate suspended clay particles.

Rationale for use

Poor water quality due to high levels of suspended solids can be detrimental to the health of aquatic species. By flocculating and settling out these substances from the water column, water quality is improved.

Basis of application for exemption

Commonly used to flocculate clay particles in drinking water for human consumption before treatment with sodium hypochlorite.

Ferric chloride

Proposed exempt use pattern

For application to freshwater pond water and pond effluent to flocculate suspended clay particles.

Rationale for use

Poor water quality due to high levels of suspended solids can be detrimental to the health of aquatic species. By flocculating and settling out these substances from the water column, water quality is improved.

Basis of application for exemption

Commonly used to flocculate clay particles in drinking water for human consumption before treatment with sodium hypochlorite.

Feed Additives

Astaxanthin
Canthaxanthin
Beta-carotene

Proposed exempt use pattern

For incorporation into aquaculture feeds as tissue pigmenters

Rationale for use

Pigments are a natural component of the diet of many wild aquatic animals. In an aquaculture situation however, where the feed is manufactured, it is essential to incorporate pigments to maintain healthy stock and to ensure high quality product. In a number of cases this includes looking like its wild counterpart, eg. the red flesh colour of salmon.

Basis of application for exemption

Astaxanthin, canthaxanthin and beta-carotene are all listed in PART 2-COLOURANTS/PIGMENTERS AND MICROTRACERS of the Veterinary Chemical Products (Excluded Stockfood Non-active Constituents) Order 1995 No.59. This Order states that stockfood non-active constituents are not declared to be veterinary chemical products. These three compounds are widely found in nature in organisms consumed by humans

11.6 Copies of approved Permits

PERMIT - 1827

FOR SUPPLY AND MINOR USE OF AN UNREGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - 1827

THIS PERMIT IS IN FORCE FROM 17 AUGUST 1999 TO 17 AUGUST 2000.
It is in force until it expires or it is cancelled, suspended or surrendered.

DETAILS OF PERMIT

1. Permit Holder & Supplier of Product
AQUATIC DIAGNOSTIC SERVICES INTERNATIONAL PTY LTD
29 Lincoln Street
WILSTON QLD 4051

2. Product
BENZOCAINE SEDATIVE/ANAESTHETIC
Containing: 1000.00 mg/g BENZOCAINE as their only active constituent.

3. States
ALL States

4. Permitted Users
Registered veterinarians who may only prescribe to aquaculture farmers producing finfish and/or abalone.

5. Directions for Use

Animal	Purpose	Rate
FINFISH AND ABALONE	SEDATION & ANAESTHESIA	Refer to label for dosage and administration.

Critical Use Comments: Read product label and leaflet before use.
Withholding Period: Do Not Use less than 500 degree days before harvesting fish or abalone for human consumption.

6. Conditions of Use
6.1. This product is only available on veterinary prescription for use by aquaculture farmers growing finfish and abalone.

6.2. The maximum amount of benzocaine which can be imported and used during the life of this permit is 300kg.

6.3. The permit holder must inform the NRA of any overseas incidents of environmental contamination or any action taken by overseas regulatory authorities in regard to use of benzocaine in aquaculture.

6.4. No treated water should be released directly to the environment unless dilution factors ensure concentrations are less than 2 mg/L in receiving waters, (for example, tenfold for 20 mg/L solutions) or can be held in tanks or settling ponds for at least 2 days.

6.5. It is the responsibility of the permit holder, the prescribing veterinarian and the aquaculture farmer to ensure that produce from, or associated with the application of this product to finfish and abalone will not be sold, until or unless the residues in the produce are at or below the temporary MRL of 0.5 mg/kg for finfish or abalone. To achieve this, the withholding period on the permit and the label must be complied with.

6.6. It is the responsibility of the permit holder, the prescribing veterinarian and the aquaculture farmer to ensure that residue levels in treated produce comply with the relevant MRL's of the importing country.

6.7. An interim shelf life of 12 months is allocated for this product.

6.8. Upon application for renewal of this permit, the permit holder must declare the total quantity of this product supplied for use during the period that this permit is in force.

7. General Conditions

7.1. 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 NRA;
- inform the NRA if they become aware of any relevant information concerning the uses dealt with by this permit;
- comply with a lawful direction or requirement of an inspector; and
- provide copies of the permit to persons who wish to prepare for use and/or use the product for the purpose specified in this permit.

7.2. The supplier must supply the product in a container that complies with the requirements of section 18(1) of the Agricultural and Veterinary Chemicals Code Regulations. Attached to this container must be a label which is identical in content and format to the label in Attachment 1.

8. Reason for issue of permit:

The various Aquaculture associations and State and Federal government departments recognised that the Aquaculture industry needed access to various chemicals. The National Taskforce on Aquaculture Drugs and Chemicals was established in May 1995 to examine the approval process for chemical use in Australian Aquaculture. This taskforce determined which chemicals were required most by the industry.

In conjunction with the NRA, a process was established to achieve approval for the use of these chemicals through the provision of minor use permits with the view to future registration. Funding from the Fisheries Research and Development Corporation was secured

by the taskforce in 1996 to fund a project to prepare minor use permit applications for presentation to the NRA for assessment.

Benzocaine was nominated for inclusion in the minor use permit program because of its safety and effectiveness for a wide range of finfish species and abalone. It also offers a fast induction and recovery time and is ideal for manipulating fish during disease checks, spawning induction procedures and other activities requiring direct handling of fish.

Issued on 1 April, 2001

Senior Product Evaluator

NOTES:
This permit allows the person listed in ***1. Supplier*** to undertake the following actions with the product listed in ***2. Products*** in the jurisdiction listed in ***3. States***:

- ***(i)*** to have the product in their possession or custody for the purposes of supply;
- ***(ii)*** to supply, or cause or permit to supply, the product to the persons listed in ***4. Permitted Users***;
- ***(iii)*** to supply the product in a container that does not have an approved label attached; and
- ***(iv)*** to claim that the product can be used for the purposes as outlined in ***5. Directions for Use.***

This permit also allows persons listed in ***4. Permitted Users*** to have this product in their possession and to use this product for the purposes specified in ***5. Directions for Use***.

If this permit were not issued, possession, custody, supply and use of the product, as specified above, would constitute an offence under the Agvet Codes.

In making a decision, whether or not to issue a permit, the NRA must often balance the need for the permit against known and uncertain scientific and other factors. This is particularly the case in respect of the stability and efficacy of a product for a particular purpose, and the extent to which use of the product might jeopardise trade.

It is therefore important before using an active constituent or a chemical product under a permit issued by the NRA that users make their own judgment as to the suitability, effectiveness and safety of the chemicals for the intended use, and the effect that use of the chemical may have on trade, and do so at their own risk.

PERMIT - 1260

VICTORIAN TROUT ASSOCIATION.
PO BOX 258
ALEXANDRA VIC

PERMIT

FOR MINOR OFF-LABEL-USE OF A REGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - 1260

General
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 NRA;
- inform the NRA 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 2 JUN 1999 TO 2 JUN 2000.
It is in force until it expires or it is cancelled, suspended or surrendered.

Reason for issue of permit:
Salmonid fish are sometimes prone to infection by one or more of a number of protozoan ectoparasites. These infestations cause a variety of clinical signs and can lead to large losses in performance and mortality if left untreated.

Salmonid eggs are also susceptable to fungal infections which can lead to a reduction in the number of viable eggs.

There are currently no registered products available to salmonid aquaculturists to treat these conditions. Formalin has been widely used and recommended overseas, with three formalin products in the USA approved for aquaculture use patterns.

Nufarm Formalin is currently registered for the treatment of footrot in sheep and the preservation of colostrum and drink milk in calves.

DETAILS OF PERMIT

1. Persons

Members of the Victorian Trout Association.

2. Products

NUFARM FORMALIN FOR FOOTROT IN SHEEP
Containing: 400.00 g/L FORMALDEHYDE as the only active constituent.

3. Directions for Use

Animal	**Pest**	**Rate**
SALMONID FISH	PROTOZOAN AND METAZOAN ECTOPARASITES	1) Bath:- 0.125 to 0.250 mL formalin/L (= 125 to 250 ppm). 2) Prolonged immersion in aquaria:- 0.015 to 0.025 mL formalin/L (=15 to 25 ppm). 3)Constant flow:- 0.015 mL formalin/L (=15 ppm).
SALMONID EGGS	FUNGAL INFECTIONS	Bath - 1 to 2 mL formalin/L (=1000 to 2000 ppm) for up to 15 minutes OR, 0.23 mL formalin/L (=227 ppm) for up to 60 minutes.

Critical Use Comments:
READ ATTACHMENT 1 BEFORE USING THIS PRODUCT.

Withholding Period:
MEAT: DO NOT USE less than 100-degree days before slaughter for human consumption.
EGGS: Treated salmon eggs must NOT BE USED for human consumption.

4. States

ACT, NSW, QLD, SA, TAS, VIC, WA

CONDITIONS OF PERMIT

General Conditions

1. A copy of attachment 1 is to be made available to all workers handling or using this product.
2. A copy of the amended MSDS must be obtained from Nufarm when available and is to be made available to all workers handling or using this product.
3. All workers using the product must be adequately trained in handling hazardous substances.
4. The permit holder is to monitor the overseas situation and advise the NRA of any changes to the registration status of formaldehyde, particulary in relation to the use pattern described on this permit.
5. No treated water from ponds/tanks/raceways should be released directly to 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.
6. This permit allows use of this product in freshwater only.
7. The permit holder must monitor the quantities used and provide realistic estimates when applying for an extension to this permit.

Issued by

Senior Product Evaluator
1 April, 2001

NOTE

In making a decision, whether or not to issue a permit, the NRA must often balance the need for the permit against known and uncertain scientific and other factors. This is particularly the case in respect of the stability and efficacy of a product for a particular purpose, and the extent to which use of the product might jeopardise trade.

It is therefore important before using an active constituent or a chemical product under a permit issued by the NRA that users make their own judgement as to the suitability, effectiveness and safety of the chemicals for the intended use, and the effect that use of the chemical may have on trade, and do so at their own risk.

PERMIT - 2484

VICTORIAN TROUT ASSOCIATION
PO BOX 258
ALEXANDRA VIC

PERMIT

FOR SUPPLY AND MINOR OFF-LABEL USE OF AN UNREGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - PER2484

General
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 NRA;
- inform the NRA if they become aware of any relevant information concerning the uses dealt with by this permit;
- comply with a lawful direction or requirement of an inspector; and
- provide copies of the permit to persons who wish to prepare for use and/or use the product for the purpose specified in this permit.

This permit for the reason given below, allows the person listed in ***1. Supplier*** to undertake the following actions with the product listed in ***2. Products*** in the jurisdiction listed in ***3. States***:

(i) to have the product in their possession or custody for the purposes of supply;
(ii) to supply, or cause or permit to supply, the product to the persons listed in ***4. Permitted Users***;
(iii) to supply the product in a container that does not have an approved label attached; and
(iv) to claim that the product can be used for the purposes as outlined in ***5. Directions for Use.***

This permit also allows persons listed in ***4. Permitted Users*** to have this product in their possession and to use this product for the purposes specified in ***5. Directions for Use***.

If this permit were not issued possession or custody, supply and use of the product, as specified above, would constitute an offence under the Agvet Codes.

The persons listed in ***1. Supplier*** and ***4. Permitted Users*** must comply with all conditions listed in ***CONDITIONS OF PERMIT*** to be effectively covered by this permit.

THIS PERMIT IS IN FORCE FROM 1 JUNE 1999 TO 1 JUNE 2000.
It is in force until it expires or it is cancelled, suspended or surrendered.

Reason for issue of permit:
To allow the indirect production of female fish populations, allowing the Salmonid industry to harvest fish in winter.

DETAILS OF PERMIT

1. Supplier.
Australian Laboratory Services, PO BOX 193 Rockdale, NSW 2216

2. Products
Unregistered veterinary chemical products
Containing: Either METHYLTESTOSTERONE or
METHYLDIHYDROTESTOSTERONE as their only active constituent.

3. States
ALL States

4. Permitted Users
Persons from Salmonid hatcheries having a legal presription from a registered veterinary surgeon for methyltestosterone and methyldihydrotestosterone for use in breeding salmonids, and having a copy of this permit.

5. Directions for Use

Animal	**Purpose**	**Dose**
SALMONIDS (TROUT AND SALMON SPECIES)	PRODUCTION OF FEMALE FISH STOCKS	BATH: 400ug/L water (ova). FEED: 1-3mg/kg feed (fry) or as directed by the dispensing veterinarian.

Critical Use Comments:
Bath treatments are applied twice to the same fish.
Feed treatments are given from 600 to 900 degree days
For use in breeding fish only, not to be used in fish for human consumption.

Withholding Period:
DO NOT USE in fish destined for human consumption

CONDITIONS OF PERMIT

General Conditions
1. This permit only allows import and use of 100mg methyltestosterone and 100mg of methyldihydrotestosterone.
2. This product may only be supplied to permitted users having a legal prescription from a registered veterinarian.
3. The supplier must supply the product in a container that complies with the requirements of section 18(1) of the Agricultural and Veterinary Chemicals Code Regulations. The supplier must supply the product in a container which must:
   (a) be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and

(b) have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and
(c) if it is intended to be opened more than once-be able to be securely and readily closed and reclosed; and
(d) have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and
(e) enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:
(i) harm any person; or
(ii) have an unintended effect that is harmful to the environment.

4. Attached to this container must be a label which carries the S4 signal heading and the statement "**FOR ANIMAL TREATMENT ONLY**". It must also contain information and instructions on:
- product name, and amount supplied
- the Restraint statement "**NOT TO BE USED in fish destined for human consumption.**"
- adequate directions for use
- suitable storage information.
- name, address and contact details of the registered veterinary surgeon who wrote the prescription.

The label must not contain any information that contradicts any details or conditions included in this permit.

5. A copy of this permit must be supplied to all users of the permit, who must comply with all conditions listed.
6. A record of all persons issued with a copy of the permit, and the amounts of products being used by those persons, is to be kept by the Victorian Trout Association. This record is to be made available to the NRA apon request. The record must be supplied to the NRA when the permit has expired, or before a new permit is issued.
7. Treated water **MUST NOT** be discharged into groundwater, streams, sewers etc. Unused treated feed is to be disposed of by incineration or deep burial.

Issued by

Senior Product Evaluator
1 June 1999

NOTE

In making a decision, whether or not to issue a permit, the NRA must often balance the need for the permit against known and uncertain scientific and other factors. This is particularly the case in respect of the stability and efficacy of a product for a particular purpose, and the extent to which use of the product might jeopardise trade.

It is therefore important before using an active constituent or a chemical product under a permit issued by the NRA that users make their own judgment as to the suitability, effectiveness and safety of the chemicals for the intended use, and the effect that use of the chemical may have on trade, and do so at their own risk.

PERMIT - 977

AUSTRALIAN PRAWN FARMERS ASSOCIATION INC
27 Peel St
South Brisbane QLD 4101

PERMIT

FOR MINOR OFF-LABEL-USE OF A REGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - 977

General
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 NRA;
- inform the NRA 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 20 AUGUST 1999 TO 20 AUGUST 2000.
It is in force until it expires or it is cancelled, suspended or surrendered.

Reason for issue of permit:
No registered product available

DETAILS OF PERMIT

1. Persons
Registered members of the Australian Prawn Farmers Association Inc

2. Products
NUFARM TRIFLURALIN SELECTIVE HERBICIDE
Containing: 400 g/L TRIFLURALIN as the only active constituent.

3. Directions for Use
For the treatment of larval mycosis in prawn larvae.

Critical Use Comments:
Users must read this permit, the attachments and the product label carefully before using this product. A period of at least 100 days should elapse between the treatment of the larvae and harvest of the prawns for human consumption. It is the resposnibility of the User to satisfy themselves as to the efficacy and safety of the product for this use.

4. States
ALL States

CONDITIONS OF PERMIT

General Conditions
Permitted Users:
1. This permit has been granted in response to requests from persons other than the registrant of the product. When assessing the proposed use the NRA will often seek advice from these manufacturers. As the registrant has not sought this permit, they should not be held responsible for the use of their product as specified in this permit.
2. 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 instructions on its label.
3. The maximum amount of product permitted for this use on each hatchery is 10Litres.
4. Users must be experienced in handling agricultural chemicals.
5. Users must also comply with the conditions specified in attachmenst 1 and 2.

Issued by

Senior Product Evaluator
1 April, 2001

NOTE

In making a decision, whether or not to issue a permit, the NRA must often balance the need for the permit against known and uncertain scientific and other factors. This is particularly the case in respect of the stability and efficacy of a product for a particular purpose, and the extent to which use of the product might jeopardise trade.

It is therefore important before using an active constituent or a chemical product under a permit issued by the NRA that users make their own judgement as to the suitability, effectiveness and safety of the chemicals for the intended use, and the effect that use of the chemical may have on trade, and do so at their own risk.

Permit - 1015

NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY LTD
8 MOSRAEL PLACE
ROWVILLE VIC 3178

PERMIT

FOR SUPPLY AND USE OF AN
UNREGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - 1015

General
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 NRA;
- inform the NRA if they become aware of any relevant information concerning the uses dealt with by this permit;
- comply with a lawful direction or requirement of an inspector; and
- provide copies of the permit to persons who wish to prepare for use and/or use the product for the purpose specified in this permit.

This permit for the reason given below, allows the person listed in ***1. Supplier*** to undertake the following actions with the product listed in ***2. Products*** in the jurisdiction listed in ***3. States***:

(i) to have the product in their possession or custody for the purposes of supply;
(ii) to supply, or cause or permit to supply, the product to the persons listed in ***4. Permitted Users***;
(iii) to supply the product in a container that does not have an approved label attached; and
(iv) to claim that the product can be used for the purposes as outlined in ***5. Directions for Use.***

This permit also allows persons listed in ***4. Permitted Users*** to have this product in their possession and to use this product for the purposes specified in ***5. Directions for Use***.

If this permit were not issued possession or custody, supply and use of the product, as specified above, would constitute an offence under the Agvet Codes.

The persons listed in ***1. Supplier*** and ***4. Permitted Users*** must comply with all conditions listed in ***CONDITIONS OF PERMIT*** to be effectively covered by this permit.

THIS PERMIT IS IN FORCE FROM 7 AUGUST 1998 TO 7 AUGUST 1999.
It is in force until it expires or it is cancelled, suspended or surrendered.

Reason for issue of permit:
There are currently no registered antimicrobial products for use in aquaculture.

DETAILS OF PERMIT

1. Supplier

Novartis Animal Health Australasia Pty Ltd

2. Product

200KG AQUACIL ANTIMICROBIAL FEED ADDITIVE POWDER
Containing: 500 G/KG AMOXYCILLIN AS THE TRIHYDRATE as the only active constituent.

3. States

ALL States

4. Permitted Users

Registered veterinarians who may only prescribe to aquaculture farmers producing salmonid fish for human consumption.

5. Directions for Use

Animal	Purpose	Dose
SALMONIDS	FOR THE TREATMENT OF SALMONID DISEASES CAUSED BY ORGANISMS SENSITIVE TO AMOYCILLIN TRIHYDRATE	AS DIRECTED

Critical Use Comments:
USE ACCORDING TO DIRECTIONS ON THE ATTACHED LABEL
READ THE PERMIT BEFORE USING THIS PRODUCT

Withholding Period:
DO NOT USE less than 50 degree days before slaughter for human consumption. Samples of treated populations should be tested for residue levels prior to harvest to ensure compliance with standards in Australia and export countries.

6. General Conditions

6.1. The maximum amount of amoxycillin which can be imported and used during the life of this permit is 100kg, which equates to 200kg of product.

6.2. This product is only available on veterinary prescription for use by aquaculture farmers growing salmonid fish for human consumption.

6.3. The veterinarian should consider all available means of controlling the disease and not rely on use of antibiotics alone. Good fish health and 'farm' management practices should be in use before repeat treatments are prescribed. Not more than one outbreak should be treated in the one location per batch of salmonid to minimise environmental impact.

6.4. The permit holder must inform the NRA of any overseas incidents of environmental contamination or any action taken by overseas regulatory authorities in regard to use of amoxycillin in aquaculture.

6.5. It is the responsibility of the permit holder, the prescribing veterinarian and the aquaculture farmer to ensure that produce from, or associated with, the use of this product in salmonids will not be sold, supplied or otherwise made available for human consumption in Australia until or unless the residues of amoxycillin

in such produce are at or below the MRL of *0.01mg/kg. It is also their responsibility to ensure compliance with the residue standards in export market countries

6.6. An interim shelf life of 18 months is allocated for this product.

6.7. A copy of the adapted market label must be provided to the NRA before the first batch is released for sale.

Issued by

Senior Product Evaluator
1 April, 2001

NOTE

In making a decision, whether or not to issue a permit, the NRA must often balance the need for the permit against known and uncertain scientific and other factors. This is particularly the case in respect of the stability and efficacy of a product for a particular purpose, and the extent to which use of the product might jeopardise trade.

It is therefore important before using an active constituent or a chemical product under a permit issued by the NRA that users make their own judgment as to the suitability, effectiveness and safety of the chemicals for the intended use, and the effect that use of the chemical may have on trade, and do so at their own risk.

Permit - 1014

NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY LTD
8 MOSRAEL PLACE
ROWVILLE VIC 3178

PERMIT

FOR SUPPLY AND USE OF AN
UNREGISTERED AGVET CHEMICAL PRODUCT

PERMIT NUMBER - 1014

General
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 NRA;
- inform the NRA if they become aware of any relevant information concerning the uses dealt with by this permit;
- comply with a lawful direction or requirement of an inspector; and
- provide copies of the permit to persons who wish to prepare for use and/or use the product for the purpose specified in this permit.

This permit for the reason given below, allows the person listed in ***1. Supplier*** to undertake the following actions with the product listed in ***2. Products*** in the jurisdiction listed in ***3. States***:

(i) to have the product in their possession or custody for the purposes of supply;
(ii) to supply, or cause or permit to supply, the product to the persons listed in ***4. Permitted Users***;
(iii) to supply the product in a container that does not have an approved label attached; and
(iv) to claim that the product can be used for the purposes as outlined in ***5. Directions for Use.***

This permit also allows persons listed in ***4. Permitted Users*** to have this product in their possession and to use this product for the purposes specified in ***5. Directions for Use***.

If this permit were not issued possession or custody, supply and use of the product, as specified above, would constitute an offence under the Agvet Codes.

The persons listed in ***1. Supplier*** and ***4. Permitted Users*** must comply with all conditions listed in ***CONDITIONS OF PERMIT*** to be effectively covered by this permit.

THIS PERMIT IS IN FORCE FROM 7 AUGUST 1998 TO 7 AUGUST 1999.
It is in force until it expires or it is cancelled, suspended or surrendered.

Reason for issue of permit:
There are currently no registered antimicrobial products for use in aquaculture.

DETAILS OF PERMIT

1. Supplier

Novartis Animal Health Australasia Pty Ltd

2. Product

200KG TETRAPLEX ANTIMICROBIAL FEED ADDITIVE POWDER
Containing: 500 G/KG Oxytetracycline (as the hydrochloride) as the only active constituent.

3. States

ALL States

4. Permitted Users

Registered veterinarians who may only prescribe to aquaculture farmers producing salmonid fish for human consumption.

5. Directions for Use

Animal	Purpose	Dose
SALMONIDS	FOR THE TREATMENT OF SALMONID DISEASES CAUSED BY SENSITIVE ORGANISMS	AS DIRECTED

Critical Use Comments:
USE ACCORDING TO DIRECTIONS ON THE ATTACHED LABEL
READ THE PERMIT BEFORE USING THIS PRODUCT

Withholding Period:
DO NOT USE less than 500 degree days before slaughter for human consumption. Samples of treated populations should be tested for residue levels prior to harvest to ensure compliance with standards in Australia and export countries.

6. General Conditions

6.1. The maximum amount of OXYTETRACYCLINE which can be imported and used during the life of this permit is 100kg, which equates to 200kg of product.

6.2. This product is only available on veterinary prescription for use by aquaculture farmers growing salmonid fish for human consumption.

6.3. The veterinarian should consider all available means of controlling the disease and not rely on use of antibiotics alone. Good fish health and 'farm' management practices should be in use before repeat treatments are prescribed. Not more than one outbreak should be treated in the one location per batch of salmonid to minimise environmental impact.

6.4. The permit holder must inform the NRA of any overseas incidents of environmental contamination or any action taken by overseas regulatory authorities in regard to use of OXYTETRACYCLINE in aquaculture.

6.5. It is the responsibility of the permit holder, the prescribing veterinarian and the aquaculture farmer to ensure that produce from, or associated with, the use of this product in salmonids will not be sold, supplied

or otherwise made available for human consumption in Australia until or unless the residues of oxytetracycline in such produce are at or below the MRL of *0.2mg/kg. It is also their responsibility to ensure compliance with the residue standards in export market countries

6.6. An interim shelf life of 18 months is allocated for this product.

6.7. A copy of the adapted market label must be provided to the NRA before the first batch is released for sale.

6.8. The permit holder must provide the NRA with annual returns of sales and supplies on request.

Issued by

Senior Product Evaluator
1 April, 2001

NOTE

In making a decision, whether or not to issue a permit, the NRA must often balance the need for the permit against known and uncertain scientific and other factors. This is particularly the case in respect of the stability and efficacy of a product for a particular purpose, and the extent to which use of the product might jeopardise trade.

It is therefore important before using an active constituent or a chemical product under a permit issued by the NRA that users make their own judgment as to the suitability, effectiveness and safety of the chemicals for the intended use, and the effect that use of the chemical may have on trade, and do so at their own risk.

11.7 Minutes of the National TaskForce Meeting on Aquaculture Drugs and chemicals (Teleconference 3/12/98

NATIONAL TASKFORCE ON AQUACULTURE DRUGS AND CHEMICALS
Teleconference Thursday 3rd December 1998
3.30pm Eastern Summer Time

MINUTES

Participants

Damian Ogburn (Chair) – NSW Fisheries
Steve Percival – ADVS
Roger Hall - DPIWE
Pheroze Jungalwalla - TSGA
Paul Hardy-Smith - DPIWE
Robert Heard - NRA
Ken Hoy - NRA
Edward Meggit - VTA
Bruce Malcolm – NSW SPFA
Dan Liszka – marine fish industry
Eva-Maria Bernoth - OCVO
Mark Kelly - AQIS
Heloisa Mariath - NRS
Paula Shoulder – AFFA
Jayne Gallagher - SeaQual
Liz Evans - APFA
Simon Bennison - ACWA
Brian Jeffriess - ATBOA
Iska Sampson (Secretariat) - AFFA

Agenda item 1
Opening address by Taskforce Chair Mr Damian Ogburn

The Chairman opened the meeting at 3:30pm Eastern Standard Summer Time.

a) Previous role and objectives of the Taskforce.

Taskforce was established in May 1995 to examine the approval process for drug and chemical use in Aquaculture. The taskforce achieved this by:

- determining which drugs and chemicals were required most by the industry and describing their use pattern;
- working with the National Registration Authority (NRA) to establish a method of achieving approval through the provision of minor use permits (MUPs) and registration applications, as well as gaining exemption status for those chemicals considered by the NRA to be exempt from registration;
- securing funding from the FRDC in 1996 for the project *Registration of Aquaculture Chemicals* lead by Dr Steve Percival.

a) Aim of teleconference.

As the project *Registration of Aquaculture Chemicals* is nearing completion, a meeting of the taskforce via teleconference was called to:

- review the progress to date on drug and chemical approvals;
- examine methods for continuing the work achieved by the taskforce previously and the *Registration of Aquaculture Chemicals* project;
- develop a list of taskforce recommendations for decision by Aquaculture Committee at their next meeting in 1999.

Agenda item 2
Progress report of FRDC project 96/314 *Registration of Aquaculture Chemicals* by project leader Dr Steve Percival;

a) Summary of project achievements.

See Annex A- Progress report of FRDC project 96/314 *Registration of Aquaculture Chemicals* by project leader Dr Steve Percival.

Ken Hoy noted that assessment of the MUP applications submitted to the NRA should be completed by March 1999.

Steve Percival advised that he will continue replying to information requests by the different agencies assessing the MUP applications submitted as part of the project until all assessments have been completed.

Once the NRA has completed assessing all MUP applications, Steve will;
- prepare a document describing the application process for MUPs and registrations and the type and format of information required by the NRA;
- communicate the project's results to industry through the Australian Aquaculture Forum (AAF) and Austasia Aquaculture;
- disseminate information to veterinarians through Steve's voluntary membership of the Australian Veterinary Association's Therapeutics Advisory Committee.
- Submit a final report of the project to the FRDC.

a) Summary of application process – Steve Percival.

See agenda item 3a).

b) Recommendations to the Taskforce on future objectives and projects – Steve Percival.

xii The taskforce consider the broader issue of increasing industry and veterinary awareness and education on the safe, appropriate and minimal use of drugs and chemicals.

xiii The taskforce facilitate and encourage veterinary education and involvement in the supply and prescription of drugs and chemicals to Australia's aquaculture industry.

xiv The taskforce encourage the development of management and husbandry practices which decrease the requirement for drugs and chemicals.

xv The taskforce ensure minor use permits are maintained and renewed, minor use permit conditions and requirements are adhered to and approval for minor use permits or registration is pursued as and if more drugs and chemicals are required by Australia's aquaculture industry. This is to be carried out in conjunction with awareness and education campaigns for industry and veterinarians.

xvi That the taskforce encourage Australia's participation in the international forum addressing the issues of harmonisation of information on the use of drugs and biologics in aquaculture. This international forum aims to assist countries involved in gaining registration and obtaining minor use permits by sharing information and data required for approval.

If the taskforce were not to continue, the AAF or similar national coordinating body representative of all aquaculture industries, in a position to liase closely with industry, government and the NRA and with access to veterinary expertise needs to address the issues of drug and chemical use in future, for the following reasons:

- It is inefficient for individual industry organisations to apply for and maintain MUPs and develop awareness and education campaigns separately, as duplication occurs with separate applications being written for the same product (this slows down the NRA approval process);
- Separate industry organisations are not in a position to hold MUPs for others as the responsibilities associated with the MUP conditions are too great.
- Issues of drug and chemical use in aquaculture are all national issues and would be most efficiently and effectively be coordinated by one national industry organisation such as the AAF;
- Such a national industry organisation would be in a position to most efficiently and effectively facilitate and coordinate:
  - the development of applications for registration and MUPs;
  - the maintenance and renewal of MUPs;
  - the collation and dissemination of information to stakeholders on drug and chemical use;
  - the nomination of a veterinarian to represent the aquaculture/seafood industry on the Australian Veterinary Association's Therapeutics Advisory Committee.

Agenda item 3
Obtaining and maintaining registration and minor use permits (MUP) for those drugs and chemicals required by Australia's aquaculture industries;

a) Summary by the NRA of approval process and minor use permit details.

i Minor use permit (MUP) system
Ken Hoy explained that the MUP system was devised to enable the use of drugs and chemicals required by the aquaculture industry for which there is inadequate data to satisfy the NRA requirements for registration. The system was devised mainly for the aquaculture industry, and so far there have been very few MUPs issued to other livestock industries (some have been issued for bees). MUPs are a temporary approval system for drugs and chemicals until sufficient data is available to enable full registration.

Applications submitted to the NRA undergo several screening processes which may involve assessment by other agencies in addition to the NRA such as Worksafe Australia, the Department of

Health, and Environment Australia. Further information is often requested from the applicant during these screening processes to allow proper assessment and approval by the relevant agency.

The taskforce noted the following regarding the MUP system:

- The preparation of MUP and registration applications is a detailed and time consuming process. It is important that applicants have access to veterinary expertise, an understanding of the application process and are able to compile and format the information required by the NRA. A national industry organisation would greatly facilitate the application process through the provision of general information regarding the requirements of the NRA and providing assistance with data sources;

- As one drug or chemical may be used by more than one industry sector (for example formalin in native finfish, salmonids and prawns), collaboration between the sectors involved would greatly assist the approval process. A national organisation would provide an essential link between the industry sectors which may allow one single MUP application to be submitted instead of separate ones. This would greatly assist the NRA in processing the application more efficiently.

- Some industry sectors experience difficulties with the dissemination of information regarding MUP requirements, conditions of use and general information on drug and chemical use to all users due to limited resources.

i MUP conditions and residue testing programs

The conditions associated with MUPs are designed to ensure that the use of the drug or chemical preparation is only that for which has been approved by the NRA, based on information available to them at the time of issue. These conditions may include a limited MUP duration (usually 12 months), limited volumes approved for use, specified users and use patterns, and requirements for residue testing and data collection. The NRA relies on compliance with these conditions to justify approval of the MUP.

Steve Percival explained that residue testing and data collection requirements associated with MUPs aim to generate the information required by the NRA for the least possible cost. The NRA understands that proper residue studies are expensive, therefor MUP testing programs are designed to fit in with commercial operations. For example, if the withholding period (WHP) of a drug is extrapolated from data from use in other species, residue testing may be required of a few fish at the appropriate time (eg the end of the WHP) to ensure levels are below the maximum residue limit (MRL). Results from such data is then assessed by the NRA to ensure that an appropriate WHP and MRL is set.

ii *MUP holders*

Ken Hoy explained that if a drug company is the MUP applicant, then that drug company would also be responsible for the maintenance and renewal of the MUP.

If an industry organisation is the MUP holder, the MUP may restricted for use by only those farmers who are members of the organisation. If the MUP holder is one farm or a collection of farms, use may be restricted to the MUP holders only.

Responsibilities of MUP holders:

- to ensure the MUP requirements and conditions are communicated clearly to the permitted users;

- to ensure that the MUP requirements and conditions are adhered to by the users. This includes any testing or data collection requirements specified on the MUP.

i Registered products

Registered products have no restrictions on availability or volume except for products requiring prescription. Prescription drugs and chemicals may only be prescribed by a registered veterinary surgeon (as is the case with terrestrial animal prescription drugs and chemicals).

a) Role of industry, the Taskforce and Government in the registration and minor use permit (MUP) application, maintenance and renewal process.

See agenda item 3(a) for discussion details.

Ken Hoy recommended a (commonwealth) government veterinarian in a position to liase with industry, State/Territory governments and the NRA would be useful in facilitating the application, maintenance and renewal process for MUPs and the dissemination of general information regarding drug and chemical use.

Steve Percival advised that a national industry group would be more appropriate than a government officer as the registration/MUP process would be less subject to the effects of departmental reorganisation regularly experienced by government officers. There would also be a sense of industry ownership if a national industry organisation were involved.

The taskforce recommended that a national industry organisation with access to veterinary expertise, representative of all aquaculture industry sectors and in a position to liase closely with government, industry and the NRA (as Steve Percival did for the FRDC project) assist industry with the application, maintenance and renewal of MUPs.

- If a single industry organisation requires the MUP, then they are responsible for the application and the national industry organisation would provide an assisting role.
- If more than one industry organisation requires the MUP, then the national organisation may act as MUP holder and coordinate the separate industries in developing one single application.
- One national organisation would assist in the dissemination of information widely to industry regarding the MUP system, conditions and responsibilities.

Agenda item 4
Current issues relating to drug and chemical use in each sector represented by teleconference participants;

a) Prawn industry – Liz Evans

The Australian Prawn Farmers Association (APFA)has applied for 3 MUPs:

1. Simazine – a MUP originally for 2 years expired in November 1998. MUP renewal application currently under assessment by the NRA;
2. Trifluralin – MUP awaiting approval by the NRA;
3. Formalin – MUP awaiting approval by the NRA.

Information about MUPs and approval status is disseminated by Liz Evans (Executive Officer, APFA) to the members of the APFA. Liz consults prawn farmers directly as required when responding to requests for information from the NRA.

Liz Evans explained that prawns were the aquaculture species chosen by the National Residue Survey (NRS) to be examined as part of their levy funded residue monitoring scheme. As a result of incorporation with this funding scheme, the residue testing conditions associated with the simazine MUP (flesh, pond water and sediment) were satisfied at no extra cost to the producers. If further testing is required and the NRS levy funds were not available to the APFA, the cost to the producers may be too great to justify the use of simazine, and alternative husbandry methods will need to be adopted.

Liz Evans noted that at this stage oxytetracycline is the only other drug for which a MUP may be required (for use in hatcheries).

a) Trout industry - Edward Meggit

The Australian Trout and Salmon Farmers Association (now Victorian Trout Association) has applied for 3 MUPs:

1. Methyltestosterone – a MUP renewal application is currently under assessment by the NRA;
2. Dihydromethyltestosterone– a MUP renewal application is currently under assessment by the NRA;
3. Formalin – a MUP application is awaiting approval by the NRA.

The sedative/anaesthetic agent *AQUI-S* registered for use in salmonids and has been widely adopted by the industry.

Edward Meggit recently attended the British Trout Association conference where he learned that development is underway on a product called *Pyceze* which has the potential to be a safe and effective alternative to malachite green. Work is underway to achieve approval for *Pyceze* in the UK and if it is proven cost effective it would be highly desirable to Australia's aquaculture industry.

a) Tasmanian Salmonid Growers Association - Pheroze Jungalwalla

Pheroze Jungalwalla recommended that government and industry work together to gain approval for a cost effective alternative to malachite green as a priority.

b) Native Fish industry – Bruce Malcolm

Bruce Malcolm noted that the availability and approval of a financially viable and effective alternative to malachite green as an external parasitide is a high priority to the native fish industry.

Bruce Malcolm recommended that priority be given to the dissemination of information regarding the risks associated with the use of malachite green.

c) Tuna industry – Brian Jeffriess

AQUI-S was used last year through an external research contractor.

Brian Jeffriess noted that the tuna industry currently has no plans to seek registration or MUPs for any drugs or chemicals. The tuna industry would like to be kept informed about issues of drug and chemical use in aquaculture as developments occur.

d) Marine fish industry – Dan Liszka

Dan Liszka explained that the marine fish industry is a relatively new aquaculture industry and most farmers are unaware of drug and chemical issues. Drug and chemical use at this stage is negligible and includes only those for which MUP applications have already been submitted to the NRA.

Dan Liszka noted that the marine fish industry is keen for marine fish species to be included on existing MUP use patterns.

e) Australian Quarantine and Inspection Service (AQIS) – Mark Kelly

Mark Kelly recommended that the taskforce address the issue of drug and chemical use in the live fish trade (specifically the export trade) as a matter of priority. Refer to agenda item 6.5.

f) National Residue Survey (NRS) – Heloisa Mariath

Heloisa Mariath noted that the NRS residue testing program on freshwater crayfish is nearing completion. Once analysis of the final results is complete, a report of the program will be made available to the Taskforce. The aquaculture product to be examined in 1999 is due to be nominated by industry (Australian Seafood Industry Council and Fishing Industry Advisory Council) at the end of December 1998. Once the product has been nominated, the NRS will select the chemical to be tested.

Heloisa Mariath recommended to the taskforce that the aquaculture industry nominates the product to be tested as far in advance as possible. This is to allow sufficient time for the development of a well designed testing program which complies with international standards and generates data most required by the industry sector concerned.

Brian Jeffriess explained that the difficulties associated with nominating one single product is that the levy system is applied to all aquaculture producers and is based on a c/kg basis. Discussions are currently under way between the NRS and the aquaculture industry to determine the most appropriate levy and testing program to satisfy the requirements of all sectors of the industry.

Heloisa Mariath noted that the problems associated with the use of unregistered products or those for which no MUPs issued. If residues of such drugs and chemicals are detected, as there is no maximum residue limit set, such a detection could potentially result in enormous financial and market access losses to the industry concerned.

i) SeaQual – Jayne Gallagher

Jayne Gallagher explained that the original funding for SeaQual runs out on the 31st March 1999. An application for further funding has been submitted to the FRDC and the Queensland Commercial Fishermen's Organisation to set up an establishment loosely called the Australian Seafood Centre. The proposed centre is to be based in Queensland and will be established firstly with capabilities in seafood quality and safety, called *SeaQual Australia*.

One of the key aims of *SeaQual Australia* is to work with each State/Territory for a national approach to the establishment of industry standards on issues identified as a priority, such as product development, market access, and seafood research.

Jayne Gallagher noted that issues of drug and chemical use may potentially be addressed by SeaQual Australia providing funding is approved.

Agenda item 5
Australia's strategic aquatic animal health plan, AQUAPLAN;

a) Summary of AQUAPLAN (Paula Shoulder).

See Annex B - AQUAPLAN summary.

b) Current status of the programs under AQUAPLAN and how drug and chemical issues are included in the strategy (Paula Shoulder).

Current Status of the AQUAPLAN programs
See Annex A - AQUAPLAN summary.

I*ssues of drug and chemical use identified in AQUAPLAN*
Paula Shoulder explained that the issues of drug and chemical use are identified in AQUAPLAN program 5 – Awareness. One of the objectives of this program is to encourage the development of aquatic animal health management practices which decrease the reliance on drugs and chemicals ensuring their appropriate and minimal use.

It is recognised in the AQUAPLAN strategy that there is a not only a need for the ongoing registration and MUP approval of drugs and chemicals for use in aquatic animals, but also the need for increased industry and veterinary awareness and education on their safe, minimal and effective use.

Paula Shoulder noted that Agriculture, Fisheries and Forestry Australia (AFFA) is able to play an ongoing coordinating role in the progression of the issues of drug and chemical use through AQUAPLAN programs. If it is decided that the Taskforce is to continue, AFFA will continue its support and assistance to the Taskforce projects and activities.

Agenda item 6
Specific issues of drug and chemical use for discussion. Does the Taskforce have a role in addressing these issues;

The taskforce recommended that the taskforce continue as it is the only national coordinating body which links the many different industry groups, government and the NRA in addressing the issues of drug and chemical use which threaten to jeopardise the success of Australia's rapidly growing aquaculture industry and live fish market. However the work of the taskforce would benefit enormously from the assistance of national industry organisation.

The taskforce recommended that the following issues be addressed as a matter of priority. If these issues are not addressed, all aquaculture sectors and the live fish industry are susceptible to massive economic losses, through loss of markets, if residues of drugs or chemicals are detected.

6.1 Veterinary education and involvement in the supply and prescription of drugs and chemicals for Australia's aquaculture farmers;

Steve Percival explained that he has been a voluntary representative of the aquaculture industry on the Australian Veterinary Association's Therapeutics Advisory Committee. However in future he will be unable to continue this representation.

Steve Percival recommended that a veterinarian be nominated by industry to represent all aquaculture industry sectors on the Australian Veterinary Association's Therapeutics Advisory Committee. It is important that aquaculture is represented as currently 'off label' veterinary prescribing legislation is under review.

The taskforce noted that veterinarians could potentially lose the right to prescribe drugs and chemicals 'off label', and that the Australian Veterinary Association's Therapeutics Advisory Committee is an excellent forum through which to disseminate information to the veterinary community on drug and chemical use in aquaculture and aquatic animal species.

Eva-Maria Bernoth explained that a project is being developed under the AQUAPLAN *Awareness* program is underway to increase the profile of aquatic animal health in veterinary and aquaculture undergraduate and postgraduate education. The project, in the initial stages of development, has not specifically included issues of drug and chemical use, however these issues could be legitimately incorporated in close consultation with the Taskforce.
Paul Hardy-Smith explained that as part of the AQUAPLAN *Awareness* program, he recently presented a successful week of formal lectures and practical tutorials to veterinary students at Melbourne University. The success of this lecture and tutorial series was in part due to the enthusiasm and support of the Dean, Ivan Caple. As a result of the lecture series, 12 veterinary undergraduates will be gaining practical experience on fish farms in Tasmania this summer. This figure compares to none in previous years. Some later year undergraduates will be working with Paul to gain practical aquatic animal field veterinary experience.

Lectures are planned again for next year at Melbourne University to include:

- information on production systems to first year veterinary students;
- information on nutrition and economics to second year veterinary students;
- information on fish health management (including therapeutic treatments) to third year veterinary students;
- project style aquaculture and aquatic animal health teaching to final year veterinary students.

It is hoped that the example set at Melbourne University will encourage other universities to include courses in aquaculture and aquatic animal health management in the near future.

6.2 Industry and Government education and awareness to promote safe and appropriate use of drugs and chemicals in aquaculture;

The taskforce noted that *Seafood Training Australia* is developing a National Seafood Industry Training Package which will include competency training in drug and chemical use in aquaculture.

6.3 Promoting the use of management and husbandry practices which reduce the need for drugs and chemicals wherever possible in the aquaculture industry;

The taskforce noted the possibility of government and industry working together to develop and widely disseminate a manual or code of practice for the use of drugs and chemicals in aquatic animals.

6.4 Liaison with, and participation in the international community on issues relating to drug and chemical regulation and use in aquaculture;

Steve Percival noted that the international community is a tremendous source of information on drug and chemical use which saves a lot of time and money in the long run.

The taskforce agreed that given experience and contacts, Eva-Maria Bernoth and the Office of the Chief Veterinary Officer may be the most appropriate to advise on liasing and engaging with the international community on issues of drug and chemical use.

6.5 Drug and chemical use in the live fish industry.

Mark Kelly noted that AQIS is required to certify live fish for export. Difficulties arise for AQIS and the exporters when drugs and chemicals are used about which there is little information. The chemicals of concern at this stage are water treatments used in the transportation of finfish, primarily coral trout, to markets overseas. The water treatments are used to remove ammonia or nitrites from the water during transport. It is not known whether these compounds are innocuous or if they cause residues in the flesh which may potentially be detected by the importing country.

Ken Hoy noted that no drugs or chemicals are approved for use in the live fish trade. As the fish may be potentially eaten immediately upon arrival, there can only be a very short if any withholding period set, which precludes the use of many drugs and chemicals.

The taskforce recommended that the issues of drug and chemical use in the live fish industry (both export and domestic) be addressed as a matter of priority. The export and domestic market for live fish, when combined, is very substantial and the approval of drugs and chemicals and dissemination of information relating to the dangers of unapproved use must be urgently addressed.

Agenda item 7
Suggestions for the future membership, role and objectives of the Taskforce;

The taskforce noted that the previous goals and objectives of the taskforce have been achieved. However there remains many issues of drug and chemical use, some of which are ongoing, and many of which need to be addressed urgently.

The taskforce recommended that the taskforce continue in its present form until there is a national coordinating body representative of all aquaculture industries in a position to liase closely with industry, government and the NRA, to address the issues of concern, disseminate information widely and assist with the application, maintenance and renewal of MUPs. This key representative body must have or have access to veterinary expertise which is required in addressing many of the issues of drug and chemical use.

a) Membership.
The current membership of industry and government representatives remains until there is a national coordinating body as described above.

b) Role.
To provide a national coordinating body which links the many different and emerging aquaculture industry groups, government and the NRA in addressing issues of drug and chemical use in aquaculture and seafood industries. The taskforce will disseminate information widely to industry and government stakeholders regarding current issues.

c) Objectives.

To address the issues identified as a priority by industry, government and the taskforce which include those listed in agenda item 6 and the following:

- The use of malachite green - identify a cost effective alternative before phasing out its use;
- The nomination of a veterinarian to represent the aquaculture industry on the Australian Veterinary Association's Therapeutics Advisory Committee.

Agenda item 8
Recommendations of the Taskforce for presentation to Aquaculture Committee.

Recommendation 1 (Agenda items 2c)iv) & vi), 3b); pages 2-5) that Aquaculture Committee facilitate the development of a national industry organisation with access to veterinary expertise, representative of all aquaculture industry sectors and in a position to liase closely with government, industry and the National Registration Authority (NRA). It is recommended that this organisation:

- assist industry sectors by facilitating and coordinating the application, maintenance and renewal of minor use permits (MUPs);
- act as MUP holder if more than one industry organisation requires a MUP for the same drug or chemical
- disseminate information to industry sectors regarding the MUP system, conditions and responsibilities, and other issues of drug and chemical use.

Recommendation 2 (Agenda item 7; page 10) that the taskforce continue in its present form until there is a national coordinating body described in recommendation 1. This is to ensure that the priority issues of drug and chemical use are addressed with national coordination and minimal duplication. Once a national industry body is active, the taskforce may reduce considerably in membership and with the use of the national industry body's assistance may continue to ensure that issues of drug and chemical use are addressed as required.

Recommendation 3 that the following issues be addressed as a matter of priority:

- Issues listed in agenda item 6 especially the use of drugs and chemicals in the live fish industry (Agenda items 2c) 6; pages 3,4,8);
- The issues associated with malachite green - identify a cost effective alternative before phasing out its use (Agenda items 4b),c),d); 7c); pages 6,11);
- The nomination of a veterinarian to represent the aquaculture industry on the Australian Veterinary Association's Therapeutics Advisory Committee (Agenda items 2c); 6.1;7c); pages 2, 9, 11).

The teleconference closed at 5:30pm.

Annex A: Progress report of FRDC project 96/314, *Registration of Aquaculture Chemicals* by project leader Dr Steve Percival
Annex B: AQUAPLAN Summary
Annex C: Teleconference Participants

National Taskforce on Aquaculture Drugs and Chemicals Secretariat
3 December 1998

ANNEX A: Progress report of FRDC project 96/314
***Registration of Aquaculture Chemicals* by project leader Dr Steve Percival**

1. 16 compounds have been considered by the National Registration Authority (NRA) to be exempt from requiring registration or minor use permits (MUPs) and are able to be used legally by the industry. These are:

Calcium carbonate	Zeolite
Calcium hydroxide	Ethoxyquin
Calcium oxide	Astaxanthin
Calcium/ Magnesium carbonate	Canthaxanthin
Calcium sulphate	Beta carotene
Aluminium sulphate	Propionic acid
All inorganic fertilisers	Sodium chloride
All organic fertilisers	Ferric chloride

2. Applications for MUPs or registration were written and submitted to the NRA with the aim of gaining approval for 2 to 3 compounds from each class of treatment required by the industry;

a) Hormones

Ovaprim, LHRH analogue and OvaRH - MUPs for the use of these spawning induction agents in salmonids is currently awaiting approval by the NRA. Information requested by the NRA has been provided and completion of MUP assessment is anticipated in March 1999.

Methyltestosterone and Dihydromethyltestosterone - a MUP for use in trout and salmon was approved early on in the project and has since expired. A MUP renewal application was submitted to the NRA 6 months ago and is awaiting approval.

b) Anaesthetics

AQUI-S – full registration has been achieved for this sedative and anaesthetic agent for use in salmonids. AQUI-S may be used 'off label' in other species in those States/Territories in which veterinary prescribing legislation allows 'off label' use of registered products in food producing animals.

Benzocaine – MUP application awaiting approval by the NRA. Information requested by the NRA has been provided and completion of MUP assessment is anticipated in March 1999.

c) Antibacterials

Trimethoprim/Sulphadiazine combination – MUP application awaiting approval by the NRA. Information requested by the NRA has been provided and completion of MUP assessment is anticipated in March 1999.

Amoxycillin and Oxytetracycline – MUPs have been approved for the use of both these antibacterials in salmonids. As more information becomes available regarding their use, it is planned to extend the MUP to include use in all finfish species.

The MUP sponsor for these compounds is a drug company which has recently been taken over by an international company. The drug company is currently assessing whether it will continue with its involvement in aquaculture. If the drug company ceases its involvement, there is another company which may be interested in becoming a sponsor of the MUPs. No efforts will be made to extend the MUPs' use until the current drug company sponsor makes a decision.

d) Antiparasitics

Formalin – a MUP for the treatment of protozoan parasites in prawns, native finfish and salmonids. Three separate MUP applications are awaiting approval by the NRA. Information requested by the NRA has been provided and completion of MUP assessment is anticipated in March 1999.

Dichlorvos – for the treatment of metazoan parasites in finfish. Applications were prepared and ready for submission to the NRA when it was announced that dichlorvos is under a national review of its use in all animal species. It was decided to wait for the results of the review before pursuing the application further.

e) Antifungals

Trifluralin – for use in prawn hatcheries. A MUP application is awaiting approval by the NRA. Information requested by the NRA has been provided and completion of MUP assessment is anticipated in March 1999.

f) Herbicides

Simazine – for the treatment of filamentous algal blooms in prawn ponds. A MUP was approved for the use of simazine for a period of 2 years. The MUP expired in November 1998 and a renewal application has been submitted to the NRA.

Liz Evans advised that most prawn farms are now using husbandry methods to control blue-green algal blooms instead of simazine. However a MUP renewal application was submitted as some prawn farmers still use simazine.

ANNEX B – AQUAPLAN Summary

AQUAPLAN is a broad, comprehensive strategy which outlines objectives and projects to improve the management of aquatic animal health in Australia. AQUAPLAN was developed in response to the Report of the National Task Force on Imported Fish and Fish Products, 1996 (Higgins Report) and the report on quarantine arrangements by Nairn 1997. Funding was allocated to the Commonwealth Department of Primary Industries and Energy (now Agriculture, Fisheries and Forestry – Australia, AFFA) to coordinate the development of the five year strategy.

AQUAPLAN has been jointly developed by government and industry and seeks to build capacity for the management of aquatic animal health issues and establish links between State/Territory government and industry initiatives.

The AQUAPLAN strategy comprises of eight key programs under which government and industry have identified priority projects to achieve the program objectives. Together these objectives will assist in maximising Australia's ability to control aquatic disease outbreaks, maintain market access, support quality assurance and improve the productivity and sustainability of Australia's aquatic animal production industries. Wherever possible, AQUAPLAN projects link into existing terrestrial animal health arrangements in order to avoid duplication to maximise resources.

For more details on AQUAPLAN, contact Paula Shoulder, Agriculture, Fisheries and Forestry – Australia, Fisheries and Aquaculture Branch, Aquaculture and Aquatic Animal Health Section,
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NATIONAL TASKFORCE ON AQUACULTURE DRUGS AND CHEMICALS
TELECONFERENCE PARTICIPANTS
3/12/98

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11.8 Contact Details for State and Territory Coordinators, other Agencies and Key NRA Staff

11.8.1 State and Territory Coordinators

State/Territory	Postal Address	Street Address	Telephone and Facsimile
NEW SOUTH WALES	Manager, Pesticides Unit NSW Environmental Protection Authority PO Box A290 SYDNEY SOUTH, NSW 1232	59-61 Goulburn Street SYDNEY NSW 2000	Ph: (02) 9995 5803 Fax: (02) 9995 5936
VICTORIA	State Coordinator (Ag & Vet Chemicals) Chemicals Standards Branch, DNRE 475 Mickleham Road ATTWOOD VIC 3049	475 Mickleham Road ATTWOOD VIC 3049	Ph: (03) 9217 4200 Fax: (03) 9217 4225
QUEENSLAND	Ag Manager Chemical Services Department of Primary Industries GPO box 46 BRISBANE QLD 4001	3rd Floor Primary Industries Building 80 Ann Street BRISBANE QLD 4000	Ph: (07) 3239 3936 Fax: (07) 3211 3293
WESTERN AUSTRALIA	Chemicals Coordinator Agricultural and Veterinary Chemicals Section Department of Agriculture 3 Baron-Hay Court SOUTH PERTH WA 6151	Department of Agriculture 3 Baron-Hay Court SOUTH PERTH WA 6151	Ph: (08) 9368 3688 Fax: (08) 9474 2408
SOUTH AUSTRALIA	Farm Chemicals Program Department of Primary Industries GPO Box 1671 ADELAIDE SA 5001	14th Floor Grefell Street ADELAIDE SA 5000	Ph: (08) 8226 0551 Fax: (08) 8226 1844
TASMANIA	Executive Officer Agvet Chemical Standards Branch Department of Primary Industry, Water and Environment GPO Box 192B HOBART TAS 7001	6th Floor Marine Board Building 1 Franklin Wharf HOBART TAS 7000	Ph: (03) 6233 3565 Fax: (03) 6233 3843

NORTHERN TERRITORY	Chemicals Coordinator Department of Primary Industry and Fisheries PO Box 79 BERRIMAH NT 0828	Berrimah Agricultural Research Centre Berrimah Farm Makagon Road BERRIMAH NT 0828	Ph: (089) 992 272 Fax: (089) 992 111
AUSTRALIAN CAPITAL TERRITORY	Environment Protection Environment ACT Department of Urban Services PO Box 144 LYNEHAM ACT 2602	Level 2 South Wing Macarthur House 12 Wattle Street LYNEHAM ACT 2602	Ph: (02) 6207 5311 Fax: (02) 6207 6610

11.8.2 Other Agencies

Government Agency	Postal Address	Street Address	Telephone and Facsimile
National Registration Authority for Agricultural and Veterinary Chemicals	National Registration Authority PO Box E240 KINGSTON ACT 2604	Level 1, Computer Services House 10 National Circuit BARTON ACT 2600	NRA General Inquiries Ph: (02) 6272 5158 Fax: (02) 6272 4753 Agricultural Registration Ph: (02) 6271 6384 Fax: (02) 6272 3218
Chemicals and Non-prescription Drug Branch	Department of Health and Family Services GPO Box 9848 CANBERRA ACT 2601	Juliana House Bowes Street WODEN ACT 2611	Scientific Director Ph: (02) 6289 7040 Fax: (02) 6289 7211
National Drugs and Poisons Schedule Committee (NDPSC)	The Secretary National Drugs and Poisons Schedule Committee (NDPSC) Department of Health and Family Services GPO box 9848 CANBERRA ACT 2601	Therapeutic Goods Administration Laboratories Narrabundah Lane SYMONSTON ACT 2609	Secretariat: Ph: (02) 6232 8722 Fax: (02) 6232 8659

Worksafe Australia (National Occupational Health and Safety Commission)	Agricultural and Veterinary Chemicals Section Worksafe Australia GPO Box 58 SYDNEY NSW 2001	92 Parramatta Road CAMPERDON NSW 2050	General Inquiries Ph: (02) 6577 9555 Fax: (02) 6577 9202
Environment Australia	Risk Assessment and Policy Section Environment Australia Environment Protection Group 40 Blackall Street BARTON ACT 2600	Tourism House 40 Blackall Street BARTON ACT 2600	General Inquiries Ph: (02) 6274 1643 Fax: (02) 6274 1610
NHMRC Advisory Committee on Antibiotics	Chemistry Section Therapuetic Goods Administration Laboratories PO Box 100 WODEN ACT 2606	Therapeutic Goods Administration Laboratories Narrabundah Lane SYMONSTON ACT 2609	Secretariat Ph: (02) 6239 8452 Fax: (02) 6239 8450
Genetic Manipulation Advisory Committee (GMAC)	The Secreatriat Gentic Manipulation Advisory Committee Department of Industry, Science and Tourism GPO Box 2183 CANBERRA ACT 2601	6th Floor 51 Allara Street CANBERRA CITY ACT 2601	Secretariat Ph: (02) 6276 2134 Fax: (02) 6276 1302
Australian Quarantine and Inspection Service (AQIS)	Australian Quarantine and Inspection Service GPO box 858 CANBERRA ACT 2607	Edmund Barton Building Kings Avenue BARTON ACT 2600	Biologicals Officer Ph: (02) 6272 4578 Fax: (02) 6273 2097
Australian Nature Conservation Agency (ANCA)	Australian Nature Conservation Agency Wildlife Protection Authority GPO Box 636 CANBERRA ACT 2601	Nature Conservation House 153 Emu Bank BELCONNEN ACT 2617	Duty Officer Ph: (02) 6250 0300 Fax: (02) 6250 0303