



23 August 2012

The Hon Dick Adams MP
Committee Chair
House Standing Committee on Agriculture, Resources, Fisheries and Forestry
Joint Committee of Public Accounts and Audit
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear Hon Dick Adams MP

**SUBMISSION TO THE INQUIRY INTO THE ROLE OF SCIENCE FOR THE
FUTURE OF FISHERIES AND AQUACULTURE**

Thank you for the invitation for the APVMA to make a submission to the inquiry into the role of science for the future of fisheries and aquaculture being conducted by the House of Representatives Standing Committee on Agriculture, Resources, Fisheries and Forestry.

This submission will inform the Committee of the APVMA's role in pest and disease management and mitigation and in minimising risks to the natural environment and human health.

Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority responsible for the assessment and registration of agricultural chemicals and veterinary medicines (agvet chemicals) and for their regulation up to and including the point of retail sale. The authority sits within the portfolio of the Australian Government Minister for Agriculture, Fisheries and Forestry.

The APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals and the scheme's legislation in partnership with state and territory governments and a number of Australian government agencies. The system for managing agvet chemicals is a risk management system designed to provide a systematic, structured and scientific, evidence-based approach to our decision-making.

Legislative framework

The APVMA's functions and powers are conferred by *The Agricultural and Veterinary Chemicals (Administration) Act 1992* and by the agvet codes of the states and territories. The Agvet Code makes provision for the evaluation, registration and control of agricultural chemicals and veterinary medicines and related matters.

In most jurisdictions, registered products must only be used for purposes that are specified on the label. In practice, situations often arise where chemicals are needed for a use not specified on the label. The APVMA can consider applications for permits that

allow for the legal use of chemicals in ways different to the uses set out on the product label. In certain circumstances, such as for research purposes, the limited use of an unregistered chemical may also be allowed by permit. The Agvet Code provides for the issuance of permits. The legislative tests for granting permits are the same for granting registration.

Role of the APVMA

We independently evaluate the safety and performance of chemicals intended for sale in Australia, ensuring that the health and safety of people, animals and crops, the environment and trade are protected. Before they can be registered, chemicals and products must be shown to work and be safe for people and the environment. Registered products must also not unduly jeopardise Australia's trade with other nations.

Our role extends beyond registration for veterinary medicines: manufacturers are licensed and audited by us to ensure adherence to contemporary manufacturing standards.

We manage an adverse experience reporting program designed to ensure early detection of problems with registered chemicals when used as intended.

The authority also monitors the market for compliance and reviews registered agvet chemicals to ensure that they continue to meet contemporary high standards. The states and territories are responsible for regulating and managing the use of agvet chemicals once they are sold.

Pest and disease management and mitigation

The aquaculture industry relies on veterinary chemical products to control pests and diseases. Currently, there are no registered products approved for use in aquaculture, as pharmaceutical manufacturers do not find it economically viable to seek registration and support existing industry use patterns. Access to veterinary chemical products is either through permits or through veterinary prescriptions off-label. In contrast, the aquarium fish industry has access to 29 registered agvet chemical products, including seven algicides.

The APVMA has issued permits to the aquaculture industry for minor use, supply and research. Minor use permits have allowed the aquaculture industry access to:

- antibiotics (oxytetracycline and florfenicol) to treat bacterial diseases;
- vaccines to control diseases such as *Vibrio anguillarum* and *Aeromonas salmonicida*;
- hormones to induce spawning in broodstock; and
- industrial chemicals such as hydrogen peroxide and formalin to treat protozoan and metazoan ectoparasites and fungal infections, calcium or sodium hypochlorite to disinfect abalone harvesting equipment to protect stock from disease by abalone viral ganglioneuritis.

These permits impose conditions of use and supply of the products. When assessing applications for minor use permits, the APVMA would consider clinical efficacy and

safety data generated in Australia or overseas and published literature to verify that the scientific information supports the directions for use of the permitted products.

Supply only permits are issued to manufacturers to enable them to supply unregistered prescription animal remedies for use under the directions of a registered veterinarian. The prescribing veterinarian determines the dose, duration of treatment and withholding periods. Through this type of permit, the aquaculture industry has been able to use benzocaine, an anaesthetic, for sedation.

Research permits are issued to individuals (persons or corporations or user groups/associations) to allow research and development of registered and unregistered products. These permits are more restrictive than minor use permits, as they impose greater limitations on persons who are allowed to use the products, places where treatment may occur, the products that can be used, how the products can be used, and the population of animals to be treated during the life of the permit.

Minimising risk to the natural environment and human health

Each application for a minor use or research permit is assessed for the impact of its permitted product(s) on the environment and human health.

The Natural Environment

The Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) is the external agency which advises the APVMA whether an agvet product would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. The APVMA refers each permit application for a new or different use pattern to DSEWPaC, who determines whether a detailed assessment of the environmental impact is required. If a detailed assessment of the application is required, DSEWPaC would consider:

- the extent to which the environment is exposed to the chemical and its metabolites;
- what happens to the chemical when it enters the environment (physiochemical degradation, biodegradation, mobility);
- the effects of the chemical on aquatic fauna and flora (birds, fish, aquatic invertebrates, algae, diatoms and aquatic plants); and
- the effects of the chemical on terrestrial invertebrates and soil microorganisms.

During an assessment, DSEWPaC would have accessed scientific information such as:

- the physical and chemical properties of the chemical;
- metabolism and bioavailability studies;
- hydrolysis and photolysis studies;
- aerobic and anaerobic aquatic metabolism studies;
- soil adsorption and desorption studies;
- leaching studies;
- field dissipation studies; and
- acute toxicity exposure studies.

From these studies, DSEWPaC determines the predicted no effect concentration (PNEC) and the predictive effect concentration (PEC) from which the Risk Quotient – the ratio of the PEC and PNEC on non-target organisms – is derived.

These considerations are followed by an environmental risk assessment, which takes into account the various aquaculture production systems, the concentration of the chemical in the water column and sediment when applicable, and the Risk Quotient. Risk to the environment is deemed to be acceptable when the Risk Quotient is less than one. Conversely, a Risk Quotient greater than one indicates an unacceptable risk.

Environmental risks could be mitigated through conditions of the permits. Mitigation measures may include the requirement of lease holders to:

- collect and analyse water and sediment samples for chemical residues;
- hold treated waters in retention ponds for a specific period before releasing into waterways;
- incorporate the chemical in a particular way into feed to prevent leaching of the chemical into the environment; and
- implement mechanisms to prevent over-feeding of medicated-feed.

Human Health

The Office of Chemical Safety (OCS) is an agency within the Department of Health and Ageing, which advises the APVMA whether an agvet product would not be likely to have an effect that is harmful to human beings, and whether the product would not be an undue hazard to the safety of people exposed to it during its handling.

OCS characterises the toxicity profile of a chemical and its product based on observations from a suite of acute and chronic toxicity studies conducted with the chemical. These toxicology studies provide OCS with information required for the agency to establish the health standards (acceptable daily intake¹ and acute reference dose²) for a chemical, safety directions and first aid instructions for the product. Acceptable daily intakes and acute reference doses are based generally on no observable effect levels obtained from the toxicity studies to which OCS add safety factors for inter- and intraspecies variation and for uncertainty in the data set. The overall safety factor could be as low as 100 fold or as high as 1000 fold. OCS uses the lowest observable effect levels when no observable effect levels are unavailable.

Consumers of aquaculture commodities are further protected from unsafe concentrations of residues of a chemical when producers observe withholding periods (WHPs) in degree days for commodities consumed domestically. The export slaughter interval (ESI) is observed for the commodities that are exported. WHPs are based on

¹ The acceptable daily intake is the amount of a chemical (expressed as mg/kg bodyweight per day) a person can ingest daily in food or drinking water during a lifetime without being affected adversely by the chemical.

² The acute reference dose is an estimate of an amount of a chemical (expressed as mg/kg bodyweight) a person can ingest in food or drinking water over a short time (usually in one meal or during one day) without an appreciable health risk to the person.

maximum residue limits³ (MRLs) which the APVMA establishes from residues data showing the residues decline profile of the product in the host species. ESIs are established from the same data set and are based on the MRLs or tolerances set by the most sensitive of the top importing countries for aquaculture commodities.

Calculations of chronic and acute dietary exposure to a chemical are benchmarked against the health standards. When dietary exposures exceed 100% of the health standards, the risk to human health is unacceptable. This could result in the use pattern not being supported, whereas the use pattern is supported when dietary exposures are substantially less than 100% of the health standards.

Summary

The aquaculture industry in Australia is dependent on several agvet products to treat and control various pests and diseases in aquaculture species. None of these products are registered for this purpose. Industry is able to use these products legally through the APVMA permit system.

Seasonal treatments of aquaculture host species with agvet products increase the environmental exposure to these products. Ecotoxicity studies provide the platform for determining whether the exposures are acceptable. Measures to mitigate the risk are imposed through conditions of the permit.

Workers in the aquaculture industry are exposed to agvet chemicals by direct contact while consumers are exposed by ingesting residues of the chemical in their diet. Toxicological studies are required to establish the health standards for agvet chemicals. Safety factors are included in the health standards, further reducing the risk to human beings. Where required, safety directions and first aid instructions are recommended for the safe use and handling of the chemicals.

Residues studies in conjunction with the health standards are important for the APVMA to determine maximum residue limits, withholding periods, export slaughter intervals and the extent to which a person is exposed to residues of a chemical in the diet. Each standard and each mitigating measure adds an additional layer of protection to human health.

In conclusion, the APVMA's decision to grant a permit to the aquaculture industry or to register a product for use in aquaculture will be based on scientific data. Permits or registrations will not be granted if the APVMA is not satisfied that the health and safety of people, animals and crops, the environment and trade are protected.

Yours sincerely

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Chief Executive Officer

³ Maximum residue limits are regulatory standards which individual countries either establish or adopt to help monitor that a product has been used as directed on an approved label.