Australian Government
Australian Pesticides and
Veterinary Medicines Authority

30 July 2007

Ms Maggie Eibisch
Regulatory Burdens - Primary Sector
Productivity Commission
PO Box 80
BELCONNEN ACT 2616

Dear Ms Eibisch,

Annual Review of the Regulator Burdens on Business – Primary Sector

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator for agricultural and veterinary chemicals. The APVMA notes that comments relating to agricultural and veterinary chemical regulation have featured in a number of submissions that have been made to the Commission.

The APVMA is committed to assisting the Government's objective to minimise 'red tape' and has been integral in driving a number of reforms to reduce the regulatory burdens on the chemical industry. The objective of this submission is to provide context to a number of the submissions that have been made to the Commission.

Background

The APVMA is an Australian Government Statutory Authority within the portfolio of the Department of Agriculture, Fisheries and Forestry. It regulates the release of agricultural and veterinary chemicals into the Australian marketplace. Each State and Territory regulates the use of those chemicals in its jurisdiction. This arrangement is the "National Registration Scheme" (NRS) which was established by the inter-governmental agreement of the Commonwealth, State and Territory agriculture Ministers in September 1995. The NRS is established in this way because of the Constitutional limitations on the Commonwealth's ability to legislate over agricultural and veterinary chemicals. The regulatory framework is a complementary one with a shared division of responsibilities between the Commonwealth and the States and Territories.

The APVMA's mission is to protect the health and safety of people, animals and crops, the environment, and trade and support Australian primary industries through evidence-based effective and efficient regulation of agricultural and veterinary chemicals. It does this through its evaluation and registration of agricultural and veterinary chemical products; its permits scheme; the review of older chemicals or chemicals for which concerns have been raised to ensure they continue to meet contemporary standards; as well as ensuring compliance, both during manufacture and in the market. Agricultural and veterinary chemical products are vital for the efficient production of commodities by the primary sector.

Australian situation

The Australian agricultural and veterinary chemical market is relatively small on a world scale. The Australian market comprises less than 2% of the global distribution of agricultural and veterinary chemicals. Even so, the regulatory system must still deliver outcomes comparable to those of other first world nations in terms of safety to consumers and the environment. It is also imperative that the system be recognised internationally as effective if Australia's export trade in agricultural commodities is to be sustained.

Benchmarking performance

In 2005 the APVMA sought to benchmark key aspects of its operations with those of its counterparts in other countries. Even given the differences in activities between the various agencies and their differing statutory responsibilities, it was apparent that the APVMA compared favourably with the equivalent Canadian, United States and United Kingdom regulatory authorities in terms of application fees, timeframes and timeframe performance. The international competitiveness of the Australian regulatory system for veterinary chemicals has recently been confirmed by a qualitative survey conducted by Business Decisions Limited, *'Benchmarking the Competitiveness of the Australian Animal Health Industry'* which found that respondents perceived that it was the size of the Australian market that was the biggest obstacle to innovation, rather than the regulatory framework. In all other regions covered by the research, respondents identified the regulatory framework as being the biggest obstacle to innovation.

The APVMA actively engages with similar regulators of other OECD countries to facilitate consistency and improved efficiencies wherever possible. We are currently involved in a number of work-share projects with similar regulators of other OECD member countries and have signed memoranda of understanding with a number of our counterparts. This international cooperation is intended to harmonise data assessment procedures and data requirements between comparable regulators to facilitate greater work sharing and improving the international 'portability' of scientific data with respect to chemical products. These activities work to directly reduce the regulatory burden in Australia.

In 2006 the APVMA was the subject of a comprehensive performance audit by the Australian National Audit Office. The performance audit report[1] acknowledged the various initiatives the APVMA had introduced in recent years to improve the effectiveness of its operations and made six recommendations. The APVMA welcomed the report and is implementing each of the recommendations. The arena of chemicals regulation is constantly changing and the APVMA believes that the performance audit has provided valuable recommendations for further improvements to its operations.

Providing context

The APVMA notes that comments relating to agricultural and veterinary chemical regulation have featured in a number of submissions that have been made to the Commission. Several of the submissions perhaps do not relate specifically to the regulatory burdens in the primary sector and may be more relevant to the recently

[1] Available at http://www.anao.gov.au/uploads/documents/2006-07_Audit_Report_14.pdf.

announced review of the chemicals and plastics sector. However the APVMA believes that a number of the submissions raise some very relevant points, particularly in the areas of consistency in the national regulatory framework.

In reviewing the submissions the APVMA has noted some factual inaccuracies in some of the comments about both the APVMA and the regulatory framework itself. There are also some comments where we believe some additional clarity and background information would be of benefit. To assist the Commission we have addressed these matters in Attachment 1.

The APVMA is committed to improving its regulatory efficiency and assisting the Governments objective to minimise 'red tape' without compromising the overall policy objective of the NRS. I attach the APVMA's 2007-08 Operational plan[2], which outlines the APVMA's current key priority reform areas.

The APVMA looks forward to discussing matters relating to the regulation of agricultural and veterinary chemicals with the Commission.

Yours Sincerely,

Dr Eva Bennet-Jenkins
Acting Chief Executive Officer

[2] A copy can also be obtained from the APVMA website at the direct link http://www.apvma.gov.au/publications/cdocs.shtml#corporate.

PRODUCTIVITY COMMISSION
ANNUAL REVIEW OF REGULATORY BURDENS ON BUSINESS – PRIMARY SECTOR

APVMA Comments On Factual Errors And Statements Requiring Further Clarification In Submissions To The Commission

Comment	Correction of error of fact or clarifying comment
Animal Health Alliance	
There is a duplication of requirements between APVMA and AQIS (AQIS assessing for endemic pathogens, APVMA basing decisions on the exotic status of disease).	The APVMA wishes to correct an inaccuracy in this statement and comment on the statement. • AQIS assesses applications for a permit for import of biological materials (vaccines in this case), for the risk that they are contaminated by pathogens that are exotic to Australia. • The APVMA assesses applications for registration of all vaccines, whether imported or manufactured in Australia, for the risk that they are contaminated by pathogens that are endemic to Australia. The APVMA accepts AQIS import permits on the basis of the risk assessment that AQIS perform. At a recent consultative meeting with the chemical industry, the APVMA and AQIS agreed to cooperate with a consultant to do a side-by-side comparison of each other's requirements and procedures, to determine what elements are common, with a view to determining whether a single assessment will serve to fulfil the requirements of each agency. This initiative will reduce the regulatory burden on applicants, to the degree that it eliminates duplication of provision of information for regulatory purposes.
Unnecessarily burdensome requirements: • APVMA's requirement for local efficacy studies for all products intended for use in food producing animals (even when the disease, the genetics of the animals and the environmental conditions have been shown to be no different to those overseas, APVMA will not accept efficacy data generated overseas).	The APVMA wishes to correct an inaccuracy in this statement and then comment on the statement. The APVMA's Manual of Requirements and Guidelines (MORAG) states that Australian efficacy studies are required for products which contain new active constituents and which are designed as herd or flock medications for food-producing species of animals. However, MORAG also states that the APVMA will consider scientific argument that Australian efficacy data not be provided, on a case-by-case basis. This is particularly relevant to the pig and poultry industries, where the genetics, housing, feeding and husbandry are largely standardised the world over. The APVMA has registered a number of products on the basis of overseas efficacy

Comment	Correction of error of fact or clarifying comment
	data only and has directly informed the pig industry that it is prepared to register products for pigs on the basis of overseas efficacy data.
• APVMA's requirement that studies are conducted in several different States or locations, even if there is no scientific reason for this (e.g. for poultry housed in temperature and humidity controlled housing). APVMA are moving towards requesting studies in multiple States, with minimal scientific rational provided other than "environmental extremes".	The APVMA wishes to correct an inaccuracy in this statement and then comment on the statement. If Australian efficacy data are required to fulfil the requirements of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code), that the APVMA be satisfied of the efficacy of a product, the APVMA requires sufficient trials to be conducted in a sufficient range of environments, to prove efficacy of the product in relation to the product's proposed label claims. Environmental factors can significantly impact the efficacy of some products. The APVMA only requires that studies be conducted where there is a valid scientific reason. Data collected in a range of States is only required where warranted to prove a product's efficacy within the range of environments in which it is proposed to be used.
• APVMA's position that products designed to treat or prevent diseases which are exotic to Australia should not be registered. Often multinational companies produce multivalent vaccines. For example, four out of five of the antigens in a vaccine may be relevant to Australia, one of the five may not. Importation of the vaccine may be found by AQIS not to pose a threat to Australia (e.g. killed antigens). APVMA will not allow registration of the vaccine because of the exotic antigen – the company cannot justify producing a vaccine excluding the antigen just for the Australian market and so no product is registered or made available in Australia.	The APVMA notes that this comment does not relate to regulatory burden, but wishes to provide comment. It is true that the APVMA has an operational policy of not registering vaccines which contain antigens for diseases which are exotic to Australia. There are several reasons for this: • each year, the Department of Agriculture, Fisheries and Forestry (DAFF) informs the World Organisation for Animal Health (OIE) of the presence or absence of animal diseases in Australia. If the APVMA were to register a vaccine for a disease that DAFF had informed the OIE does not exist in Australia, it would undermine Australia's international credibility. This could have negative effects on access to international markets that Australia enjoys on the basis of freedom from certain animal diseases. • the presence of exotic pathogens is often monitored through detection of serum antibodies to exotic pathogens in sentinel animals. It is common for vaccination to result in changes to serum antibody levels. Assurance that Australia is free from an exotic pathogen could be compromised by vaccination of sentinel animals. • to a reasonable person, it would seem strange that a regulatory authority would register a product which contains antigens which are there to treat a

Comment	Correction of error of fact or clarifying comment
	disease which is not present in Australia. • it is not good veterinary practice to unnecessarily vaccinate animals against non-existent diseases. The roles of AQIS and the APVMA are different in this manner. AQIS will issue a permit under the Quarantine Act for importation of a killed antigen, if the product poses no risk of introducing an exotic disease into Australia. The APVMA registers products under the Agvet Code if satisfied that they are safe and effective and will not impact Australia's trade when used in accordance with their label instructions. It is important to note that the Agvet Code specifically requires the APVMA be satisfied that the registration of a chemical product "would not unduly prejudice trade or commerce between Australia and places outside Australia".
• Since APVMA took over management of trade risk, requirements have increased dramatically. A straight forward scientific review is now undertaken in place of a more appropriate risk management strategy, which would ensure the protection of trade without placing unreasonable constraints upon applicants.	The APVMA wishes to comment on this statement. The introduction 'Since the APVMA took over trade risk….' is confusing because the Agvet Code has required the APVMA to assess trade risk since it came into force in 1993. Indeed risk to trade is one of the risk elements, along with public health, environment, safety risks and efficacy, of which the APVMA must be satisfied in order to register a product. It is possible that the author is making a comparison between trade risk assessments carried out by the individual states before 1993, and those carried out by the APVMA since its establishment. Alternatively the author could be referring to the setting of export slaughter intervals (ESI's), which until recently was performed by Meat and Livestock Australia (MLA), but is now included in the APVMA residue and trade assessment process. The APVMA agrees that it undertakes a straightforward scientific review of data submitted by the applicant. Trade risk is most commonly related to the presence of chemical residues in exported produce, which may violate importing country tolerances. The APVMA manages the trade risks by setting withholding periods between treatment of animals or crops, and slaughter of the animals, or collection of milk, or harvesting of crops as the case may be. The APVMA believes that its assessment procedures are valid, reproducible and have the support of Australian consumers, Australian processors, overseas importers and overseas import regulatory authorities. In this statement there is no description of what a 'more appropriate risk

Comment	Correction of error of fact or clarifying comment
	management strategy' would comprise, nor are there examples of 'unreasonable constraints' upon applicants.
• APVMA's extended application forms and requirement to approve final printer proof labels has considerable increased the regulatory burden placed upon companies.	The APVMA wishes to correct an error in this statement and provide further background on the requirement to approve final printer's proof labels. The error in this statement relates to 'extended application forms'. Until July 2005, the APVMA had a single registration application form of 13 pages, which applicants had to fill out irrespective of the nature of their application. In July 2005 the APVMA introduced a range of seven application forms, each one specific to the nature of the application. Some of the application forms are now 2 pages long instead of 13 pages in 2005. This represents a significant reduction in the regulatory burden for applicants. The requirement to approve labels in the final form in which they will be printed (rather than in text form) is not an APVMA requirement as such, but rather a requirement of the Agvet Code, by amendments that came into force in October 2003. The APVMA did not seek these amendments. The increased regulatory burden for registrants since October 2003 is that the label that is attached to product containers must be identical to the one that the APVMA has approved. Prior to this time the APVMA registered products on the basis of a text label. Since October 2003 the APVMA has introduced a number of process reforms which greatly decreased the regulatory burden with respect to approval of labels. The APVMA issued a permit (PER6868) that allows registrants to make various administrative label amendments without the need for application to the APVMA. In this respect, the regulatory burden with respect to label amendments is now less than it was in October 2003. In addition, the APVMA has introduced electronic submission of printer's proofs of labels, which has greatly improved efficiency.
• Good Manufacturing Practice certification requirements: APVMA is increasingly prescriptive about the format certification should take, while not recognising that this aspect is virtually beyond the control of the manufacturer and applicant	The APVMA wishes to comment on this statement. The specific intent of this statement is somewhat ambiguous, but in the context of the submission the APVMA believes that the comments may be directed towards the certificates that the APVMA accepts as evidence of compliance with Good Manufacturing Practice (GMP) requirements for products manufactured overseas. The Agvet Code (and regulations[3]) requires the APVMA to be satisfied of a number of matters with respect to the manufacture of chemical products

[3] *Agricultural and Veterinary Chemicals Code Regulations 1995*

Comment	Correction of error of fact or clarifying comment
	(including the keeping of records) and such certificates are necessary for the APVMA to fulfil its legislative obligations. The APVMA does accept various certificates from counterpart authorities to reduce duplication and continues to work (through DFAT) to extend international harmonisation. This is by far the most preferred option as the alternative would be for the APVMA to audit all foreign manufacturing sites, with obvious cost implications. Whilst it is acknowledged that on occasion manufacturers may have problems obtaining acceptable evidence of compliance through the various issuing authorities in their jurisdiction, most manufacturers are able to provide suitable evidence.
ANAO…Recently however, our industry has identified inefficiencies and inconsistencies with our key regulators in their dealings with our member's products. In addition, the recent outcomes of the ANAO audit of APVMA have confirmed most of the shortfalls industry has identified.	The APVMA wishes to clarify this statement and comment on it. In its December 2006 report following a comprehensive performance audit, the ANAO made six recommendations, which may be summarised as: 1. strengthen arrangements of managing conflict of interest for external service providers, and consultative committees; 2. improve arrangements for monitoring and reporting on statutory timeframes; 3. improve registration processes by systematically analysing the types and cause of errors in applications; 4. review arrangements for obtaining scientific advice from Australian government agencies; 5. improve the manufacturer's licensing scheme; 6. improving the effectiveness (throughput and transparency) of the Chemical Review Program. The APVMA conducts regular consultative meetings with its industry stakeholders through its Industry Liaison Committee (ILC) and Industry Technical Committee (ITC) but does not have any record of these issues being raised or identified at any of the meetings. With specific respect to timeframe performance, the ANAO noted that 74% of pesticide and 76% of veterinary medicine applications made to the APVMA contain errors (deficiencies). The ANAO criticised the APVMA for repeatedly giving applicants additional time to correct deficiencies, leading to a prolonged elapsed time for applications. Nevertheless, the ANAO noted that due to APVMA

Comment	Correction of error of fact or clarifying comment
	initiatives, 98% of applications received after 1 July 2005 were finalised within the statutory timeframe.
IFAH benchmark survey has identified three key areas of concern with the existing regulatory platform/process for animal health products in Australia. 1. Regulatory framework increases time, cost & risk for bringing new products to market; prevents market access for advanced product technologies; increases scale of defensive R&D; erodes level of potential returns from existing products. This has occurred over the last 5-8 years. 2. Regulatory factors influenced decisions by companies to introduce fewer breakthrough products; to reduce product availability; to focus on older technologies; & to avoid certain product technologies. 3. Qualitative evidence from companies suggests 3 causes of deterioration in regulatory framework for animal health products: (1.) weakness in process used to manage trade risks; (2.) reduction in social acceptance of risks posed by animal health products leading to greater risk aversion & (3.) inadequacies of regulatory quality with APVMA and the network of risk assessors it manages.	The APVMA wishes to clarify this statement and comment on it. A very short summary of the International Federation of Animal Health (IFAH) benchmarking report of March 2007 is: • the Australian animal health industry is relatively small, but it is essential to the maintenance of Australia' very large animal food and fibre export industries; • the Australian approach to regulation is based on high-quality science, clearly defined processes and well-established rules. It is predictable, open and accessible; • whilst 58% of Australian companies who participated in the survey believe that the Australian regulatory system is an obstacle to innovation, this proportion is less than anywhere else in the world; • 92% of Australian companies who participated in the survey believe that the small size of market segments is the principal obstacle to innovation; • the time and cost to develop products in Australia have risen in the past 5 years; • with some caveats, the quality of scientific risk assessment is the equal of that in the USA, with the exception of assessment of efficacy, which is poor compared to US standards; • overall, the Australian regulatory environment is the most efficient, least obtrusive and lowest cost in the world; • the Australian market is relatively small and is mature (i.e. it does not show consistent growth). Specific regulatory actions which respondents believe have caused increased time to develop products and increased cost to innovation are: • increased residues studies required by APVMA because of socio-political concerns about trade risks; • increase in risk aversion and decrease in the quality of regulatory decision-making at AQIS, the regulatory authority which issues import permits for biological materials (eg vaccines); • greater requirements by APVMA for safety and efficacy testing for companion animal products;

Comment	Correction of error of fact or clarifying comment
	• increased testing requirements by the Office of Chemical Safety (OCS) for reasons of user safety and antimicrobial resistance, and the Department of the Environment and Water Resources (DEW) for reasons of environmental safety; • the APVMA takes social concerns into account by being influenced by advisory bodies such as the Expert Advisory Group on Antimicrobial Resistance (EAGAR) and regulatory agencies such as AQIS; • the APVMA takes the views of users into account in making its regulatory decisions • the APVMA has inadequate expertise and resources. Overall the IFAH survey is relatively complementary about the Australian regulatory framework in comparison to that of other countries, noting that "*In all other regions covered by the research program, companies identified the local regulatory framework as the biggest obstacle to innovation. Australia does not follow this pattern. Qualitative evidence suggests that this reflects recognition of benefits created by regulatory reforms in the 1990s and the impact of the small size of the Australian market on the economics of new product development*".
Red Meat Industry	
…Banning useful chemicals can also lift costs by requiring more expensive treatments.	The APVMA wishes to clarify this point. The APVMA does not 'ban useful chemicals'. The APVMA reviews the registration of agricultural or veterinary chemicals when a concern arises about the safety or efficacy of a chemical. If the APVMA's review finds that there is a legitimate cause for concern over the safety of a chemical, the APVMA takes action to minimise the risk associated with the use of the chemical. That action might be modifying the approved use of the chemical, or applying greater risk mitigation measures such as requiring the use of more stringent personal protective equipment on the label so that the product may continue to be used safely. As prescribed by the legislation the APVMA will only cancel the registration of a chemical if the risks posed by its use cannot be managed by these means.
…Treatments approved for goats are not available because of high registration costs	The APVMA wishes to elucidate this point and highlight a contradiction. Goats are a minor animal species in Australia. The IFAH benchmark survey attached to the Animal Health Alliance submission found that the size of the Australian market is the greatest impediment to the development of products,

Comment	Correction of error of fact or clarifying comment
	rather than high registration costs. It is open to goat producers (industry associations) to apply for a minor use permit[4] to obtain the use of registered products in goats which do not currently have an approved use in goats included on the label.
Victorian Farmers Federation	
Maximum residue levels (MRL's) are set by FSANZ, however MRL's are also set by APVMA. To further complicate things, the Department of Human Services and local councils also have authority in these matters as well. It is in industry's best interest to maintain best practice and to ensure the safety of their produce.	The APVMA wishes to clarify this statement. The APVMA sets MRLs for the products it assesses for use on food crops or animals. The APVMA then notifies FSANZ so that the MRLs can be considered for listing in the Food Standards Code. State departments and local councils do not have any authority in the process of setting MRLs.
CropLife Australia	
The APVMA regulates many non-agricultural products (eg. pool and spa chemicals, pool sanitizing devices and domestic pet repellants), partly because no other agency has the mandate or resources to assess and manage the risks of these products.	The APVMA wishes to clarify this statement and comment on it. The APVMA regulates products if they fall within the definition of an agricultural or veterinary chemical product provided by sections 4 and 5 of the Agvet Code and by Regulations 7 and 8. The APVMA agrees that some of these products would not commonly be thought of as agricultural chemical products (eg swimming pool products, personal insect repellents for humans). The APVMA is the principal driver of a process though a sub-committee of the Primary Industries Ministerial Council to review the scope of products that fall into the National Registration Scheme.
Improved efficiencies and reduced red tape in the APVMA would reduce the costs of registering agricultural and veterinary products and shorten the time taken for manufacturers to deliver new products to the market. Self-assessment of some aspects of applications by approved applicants is one proposal to reduce costs and time of applications.	The APVMA wishes to comment on this statement and provide some information as to its current initiatives in this area. The APVMA agrees that self-assessment of some aspects of applications by approved applicants offers opportunities to reduce regulatory burdens. To this end the APVMA is investigating the potential and feasibility of a 'quality assurance' system that would allow approved registrants to make specified minor variations to registered products without need for application to the APVMA. For some time the APVMA has had a system in place whereby minor variations to veterinary chemical product formulations (in terms of non-active constituents) are permitted

[4] Minor use permits apply to new or small use industries where the use of the product would not produce sufficient economic return to an applicant for registration to meet the costs of registration or data generation. For more information on permits and minor use see http://www.apvma.gov.au/minor_use/subpage_minor.shtml.

Comment	Correction of error of fact or clarifying comment
	with much reduced chemistry data requirements. The APVMA is looking to adapt a similar system for such variations in agricultural chemical products. The APVMA wishes to draw the Commissions attention to its issuance of Permit 6868, which has greatly reduced the regulatory burden with respect to labelling. Permit 6868 allows registrants to make various administrative variations to labels of a specified type without the need for application to the APVMA. In addition to these initiatives the APVMA is currently investigating the feasibility of registrants separately seeking review of efficacy data by approved reviewers prior to making application to the APVMA. This proposal has significant potential to reduce the APVMA assessment time of applications as the APVMA could base its decision on the advice of the approved reviewers report (conforming to set standards) rather than conducting the review itself. Such a proposal (if feasible) would also translate to lower APVMA application fees and timeframes. Similarly the APVMA is participating with other international regulatory authorities in work-sharing data assessments, which is expected to translate to lower APVMA application fees and timeframes.
Government policy in relation to confidentiality of emails and other electronic communications introduces significant inefficiencies in the regulatory processes. Despite requests from industry for electronic communication on routine registration matters, the APVMA is required by government policy to use the postal system, which greatly increases the time taken to register a product when much liaison is required between the APVMA and the registrant. This can, and has in many cases, delay getting products to market by many months.	The APVMA wishes to clarify and comment on this statement. The APVMA only prevents the transmission of X-in-Confidence emails to registrants and not emails that include unclassified material. Other forms of electronic communication such as facsimiles that include X-in-Confidence are permitted. The APVMA must follow the Australian Commonwealth Government's mandatory requirements concerning the transmission of emails that include X-in-Confidence information. These requirements are detailed in the Protective Security Manual 2005 (PSM), the Australian Government Information and Communications Technology Security Manual (ACSI 33) and other documents. In particular the Department of Finance and Administration document entitled 'Implementation Guide for Email Protective Markings October 2005' (available at http://www.agimo.gov.au/__data/assets/pdf_file/46461/Protective_Markings.pdf) specifically prevents the transmission of X-in-confidence information over unprotected public networks. The APVMA is required to comply with these whole-of-government requirements.

Comment	Correction of error of fact or clarifying comment
Growcom	
Sections of APVMA that are responsible for issuing permits are seen to be sufficiently under resourced and therefore are unable to turn around applications in the promoted time frame of 3 months.	The APVMA wishes to comment on this statement. The three-month statutory timeframe only applies to applications requiring no technical assessment. In the 2006/07 financial year applications with three-month timeframes accounted for approximately 44% of the total agricultural chemical permits finalised. The APVMA acknowledges that in some circumstances the statutory timeframes have been difficult to meet and has a number of initiatives in place to enhance its performance in this respect. However in the 2006/07 financial year 83% of agricultural chemical permits were finalised within timeframe. Of those applications with three-month timeframes 87% were finalised within timeframe. In terms of timeframe performance it is important to note the ANAO performance audit observation that 74% of pesticide and 76% of veterinary medicine applications made to the APVMA contain errors (deficiencies) and ANAO's criticism of the APVMA for repeatedly giving applicants additional time to correct deficiencies, leading to a prolonged elapsed time for applications.
Currently, the APVMA is undertaking a review of the chemicals dimethoate and fenthion, which has been occurring for many years. The review is anticipated to have a potentially adverse effect in terms of retaining access to many currently approved use. …Therefore, to preserve uses the onus to generate data is falling on the affected industries. Many of these industries are funding the generation of new insecticide data to maintain the uses or are looking at the development of alternate procedures to satisfy interstate quarantine requirements.	The APVMA wishes to elaborate on this point. The APVMA appreciates the impact that the loss of certain chemicals can have on its industry stakeholders and for this reason engages in extensive consultation throughout the review process, providing early warning of potential regulatory action wherever possible. However the APVMA has an obligation to ensure that the use of registered products does not cause undue harm or pose undue risk to people and the environment. In the case of dimethoate and fenthion (which are organophosphate insecticides) the key concern is chemical residues in treated produce, particularly when applied as a post-harvest treatment. The type of information available on chemical reviews can be obtained via the APVMA website or at the following link http://www.apvma.gov.au/chemrev/chemrev.shtml. The preliminary review findings for fenthion are available at http://www.apvma.gov.au/chemrev/fenthion.shtml. The APVMA is a member of the National Task Force established to consider alternatives to dimethoate and fenthion, reassess trade requirements and consider the potential outcomes of the reviews. The APVMA has actively participated in a number of meetings and two industry forums. In looking to identify ways in

Comment	Correction of error of fact or clarifying comment
	which these chemicals may continue to be used safely the APVMA has outlined the type and nature of information that would be required. The APVMA continues to work with the industry to obtain the necessary information. It is important to note that the APVMA's role is to assess data to determine if chemical products may be used safely and effectively and it that it does not have the legislative ability to generate data. Chemical companies or user groups generate the data.
Growcom wishes to raise a specific issue in relation to inconsistencies between Australian Pesticides and Veterinary Medicines Authority (APVMA) and Food Standards Australia New Zealand (FSANZ) regarding maximum residual limited (MRLs) in fresh produce and food products. The issue for the horticulture industry is that when a new pesticide is registered or an existing pesticide registration is extended by APVMA it is not transposed in the Food Standards Code by FSANZ immediately. There can be lengthy transition periods of up to 15 months, where some fresh produce can technically be a MRL violation despite the fact the chemical is legal. This is a national issue that has been raised by industry stakeholders for many years, however it must be recognised that this issue has still not been rectified.	This statement is correct, however the APVMA wishes to highlight the ongoing reform process. For a number of years the APVMA has been involved in discussions with FSANZ and the Food Regulation Standing Committee (FRSC) to harmonise the MRL setting process. Recent amendments to the Agvet Code and a revised MOU with FSANZ are expected to reduce the lag between product registration and entry of the relevant MRL into the Food Standards Code.
Tasmanian Salmonid Growers Association Ltd	
…the aquaculture industry is actively pursing Minor Use Permit registration with the Australian Pesticides and veterinary medicines Authority of a small number of chemicals specifically for use in aquaculture …we feel that APVMA as the regulating authority could speed up the evaluation of applications and generally improve the evaluation process by: • adopting a more lenient approach to chemicals used in relatively small quantities, and • accepting more readily the published scientific literature and/or approvals granted by reputable authorities in other countries such as UK, Canada, US and Norway … I believe this is a regulatory burden which could be alleviated without undue risk.	The APVMA wishes to clarify this statement and comment on it. There appears to be some confusion between product registration and the seeking/issuing of minor use permit. These are different but the APVMA believes that the author is referring to seeking a minor use permit. In the case of applications for a permit for use of a chemical in aquaculture, the principal assessment is commonly that of environmental safety, because the chemical proposed for use is introduced directly into the aquatic environment. Although the APVMA is the agency responsible for determining whether a permit should be issued or not, it relies on advice from the Department of Environment and Water (DEW) where an environmental assessment is required. Both the APVMA and DEW are confident that the level of environmental assessment represents an appropriate level of protection for the Australian environment. As previously indicated the APVMA does accept overseas data where relevant to the Australian proposal and situation.

Comment	Correction of error of fact or clarifying comment
National Aquaculture Council	
The NAC is concerned over the time taken for various agencies to evaluate applications for minor use permits submitted to the APVMA. The industry appreciates the need for rigorous process but believes the Government should work with industry in shortening the process and in particular providing exemptions with very harmless products that are considered to have little or no risk or in the context of food contamination (eg salt). Various agencies are involved in evaluating applications and the timeframe for approval is very long. This needs to be shortened particularly given the small quantities of chemicals in use.	Whilst this comment has been addressed above, the APVMA wishes to provide further information. The APVMA agrees that Australian Government agencies such as the APVMA should work with industry to understand issues and identify solutions within the legislative parameters. In fact in 2002 the APVMA conducted significant consultations with the Tasmanian Salmonid Growers Association, including a visit from APVMA and DEW delegates to better understand the industry's issues and collaboratively identify means to resolve a particular problems. With regard to the comments relating to exemptions for harmless products, whilst the APVMA cannot 'exempt' products, in 2003 amendments to the Agvet Code provided for a low regulatory scheme for low risk product types. Under those provisions certain products or product types may be proposed by industry for listed registration or reservation. The APVMA will assess such proposals and determine their potential and feasibility and then make a proposal through PSIC to the Minister. Chemical products approved for reservation do not need to be registered with the APVMA provided that they are of a type described in the conditions of reservation and are only supplied for the purposes described in the conditions of reservation. The APVMA also currently does take a practical approach to harmless substances such as salt when proposed for use via either registration or permit. However it is important to note that the APVMA still must be satisfied that the use of any substance will be safe and effective. Even substances that are considered relatively harmless can cause undue harm when applied in particular circumstances - it is the harm aspects that the APVMA assesses.
Australasian Compliance Institute	
Registration of new products containing new/existing active constituents: • It should be noted that veterinary chemical products, other than ectoparasiticides, do not require approval of the "active constituent" if the active component conforms to standards specified in accepted pharmacopoeia.	The APVMA wishes to correct an inaccuracy in this statement. The Agvet Code prohibits the APVMA from granting an application for registration of a chemical product unless it has also granted an application for approval of each active constituent contained in the product. The Agvet Code (at section 14A) does however provide for an alternate approach to active constituent approval, where the active constituent conforms to a standard specified in certain pharmacopoeia. Nevertheless, the Agvet Code requires the APVMA to be 'satisfied' that the use of the active constituent would not be an undue hazard to

Comment	Correction of error of fact or clarifying comment
	the safety of people or have an effect that is harmful to human beings, amongst other things, prior to approving any active constituent.
• Registration of a new product containing an approved active constituent for use in a crop in which the specified active constituent is not already used requires payment of application fee to APVMA of $31,750 and involves an evaluation timeframe of 15 months, i.e. a minimum of two and probably three seasons from the time the application is submitted until registration is granted. This fee is payable and the timeframe applies even if the active constituent is used in other crops/situations.	The APVMA wishes to correct an inaccuracy in this statement. The APVMA believes that the author is referring to application Category 3, which is only relevant to an application for registration of a chemical product containing an approved active constituent, but where there is no registered chemical product containing that active constituent and where a full assessment is required. The majority of applications of a type referred to by the author are assessed through application Category 10, for which a modular assessment period and fee are determined based on the type of assessment required. Examples of the relevant fees and timeframes for applications processed under Category 10 for a range of situations are available in the Category 10 chapter of the APVMA's Manual of Requirements and Guidelines (MORAG) which is available at http://www.apvma.gov.au/MORAG_ag/vol_2/category_10.html#gen12. Example 2 at this link outlines a scenario where an active constituent has previously been registered for use in one crop and is subsequently proposed for use in a different crop. The fee and timeframe are $17,830 and 9 months respectively. Other examples detail lesser fees and timeframes.
• Example: Agricultural chemicals for use in commercial forestry	The APVMA wishes to highlight an inconsistency in the example and comment on it. The author states that agricultural chemical companies are reluctant to register new products in forestry due to small market size (low usage), but asserts that it is costs and delays in obtaining registration that prevents the forestry industry from access to chemicals. The APVMA can only consider products for registration that are proposed for registration by chemical companies. The APVMA has issued numerous permits to authorise the use of chemicals in forestry. The APVMA notes the timeframe assertions in the example but wishes to clarify that the statutory timeframe for such permits will typically range from 3 to 9 months depending on the level of assessment required. As acknowledged by the author, forestry often occurs in areas that are environmentally sensitive and hence the potential environmental safety of the product must be carefully assessed.
Costs of Registration of New Products: • The fees and levies paid are considerably higher than those paid in	The APVMA wishes to comment on this statement. The roles and responsibilities of the APVMA and the Industrial Chemicals

Comment	Correction of error of fact or clarifying comment
relation to industrial chemicals, which must also demonstrate safety to users, bystanders and the environment. • … Similarly, the requirement to register an agricultural or veterinary chemical product can be more expensive than that for the same product when used as an industrial chemical or as an additive in food.	regulator NICNAS are markedly different with respect to the nature and scope of their regulation. For example the NICNAS do not register chemical products, the assessment is chemical entity based and the results of those assessments are used to support a range of other chemicals management legislation, which place controls and restrictions on the use of those chemicals within the industrial setting. The chemical products registered by the APVMA are often applied directly to crops and animals, which enter the food chain. In the case of agvet chemicals there are few other controls or restrictions on use other than those prescribed by the product label. Furthermore agvet chemicals have specific claims and the Agvet Code requires the APVMA to ensure that these claims are justified (i.e. that the products are effective). This is not required for industrial chemicals. Where specific chemicals are approved as additives in food, the APVMA will take such approvals (and assessments) into account when considering their registration as an agvet chemical with respect to the human safety part of the assessment. However this is but one aspect of which the APVMA must be satisfied.
• The cost of generating data can be substantial and can be a disincentive to companies to obtain registration even if they know their products are effective and can be used with confidence. With newer technologies, for which there are no established testing methods to confirm efficacy, the normal delays in registration can be further compounded by the requirement to negotiate suitable testing methods with APVMA. This problem is particularly acute in relation to animal health remedies.	The APVMA wishes to comment on this statement. The APVMA agrees that many manufacturers are convinced of the safety and efficacy of their product. However, the Agvet Code provides that agricultural or veterinary chemical products must be proven to be safe and effective to the satisfaction of a public sector regulator (i.e. the APVMA). The APVMA's standards for the demonstration of efficacy are consistent with other international regulators that are required to consider efficacy and provide an acceptable level of protection to the Australian community.
• Example: Australian company decides not to register new products One small Australian animal health products company has advised it currently has four products it would like to sell in Australia. However, due to cost of registration, the company has decided not to register those products in Australia.	As indicated above, the IFAH benchmark survey attached to the Animal Health Alliance submission found that the size of the Australian market is the greatest impediment to the development of products, rather than high registration costs.
Additional Fees from 1 July 2007: • The imposition of additional fees, as proposed, does not address the underlying organizational deficiencies that result in almost half of all applications finding it necessary to submit additional information.	The APVMA wishes to correct an inaccuracy in this statement and comment on the statement. The APVMA is in the process of finalising public comments on a proposed Legislative Instrument that will allow the APVMA to apply fees (and timeframe) to data that an applicant submits voluntarily during the assessment of an

Comment	Correction of error of fact or clarifying comment
	application. Submission of such data, which often occurs late in the assessment process in response to APVMA advice that it may not be satisfied based on the originally submitted data, can put unrealistic pressure on the APVMA's statutory timeframes, creating an additional workload that detrimentally impacts the progress of other applicant's applications (because the APVMA may have to effectively reassess the application). The APVMA had previously discussed this proposal at a chemicals industry consultative meeting at which the proposal received industry support. If the APVMA specifically requests an applicant to provide additional data, there is no additional fee. The reason that the APVMA may request an applicant to supply additional information is that the information supplied to the APVMA is incomplete, unclear or does not meet the APVMA's published data requirements. It should be noted that the current framework does allow for fees to be applied to new data submitted voluntarily by the applicant and the APVMA is developing a mechanism (through the Legislative Instrument) by which such fees can be recovered. In its recent performance audit, the ANAO criticised the APVMA for expending excessive effort on applications that are incomplete or inadequate. The ANAO recommended that the APVMA more speedily determine (finalise) applications rather than spend time in 'negotiating' with applicants. The APVMA has accepted this recommendation and is moving to implement it, although it is acknowledged that it will result in the APVMA refusing a greater number of applications. The effect of the Legislative Instrument (in the context of this ANAO recommendation) will be to provide applicants with an opportunity to volunteer additional information during the assessment of an application. The submission and assessment of such volunteered information may avoid the APVMA having to refuse the application.
Timeframes in the Regulatory System and their Effect: • The evaluation timeframe for an application, as specified in the Agricultural and Veterinary Chemicals Code Regulations 1995, for a new active constituent with new chemical product is 15 months. This compares with 90 days for a new industrial chemical. In addition to the 15 months evaluation timeframe, there is additional time required for "screening" the application before it enters evaluation and further time	The APVMA wishes to correct an inaccuracy and comment on this statement. As indicated above the roles and responsibilities of the APVMA and NICNAS are somewhat different with respect to the nature and scope of their regulation and the level of assessment required. The author is correct that the Agvet Code does provide for a one-month preliminary assessment (screening) period prior to the commencement of the statutory timeframe. During the preliminary assessment period the APVMA must

Comment	Correction of error of fact or clarifying comment
required for finalisation of the application after evaluation has been completed. The 15 month time frame is suspended each time APVMA asks for additional information. Consequently, the time to obtain approval and registration of a new active constituent and a product containing that new active constituent can be more than 18 months.	ensure that the application has been made properly, containing the necessary information and fee. Applications satisfying all requirements pass the preliminary assessment step in much less than the prescribed period. The author is also correct that the statutory timeframe for an application for the approval of a new active constituent and the registration of an associated chemical product where a full assessment of the active constituent and product is required is 15 months. However the 15 month statutory timeframe includes the finalisation of the application and this is not an additional period as indicated by the author. It is also important to note that the Agvet Code Regulations provide that the APVMA may assess such applications via a modular approach (with reduced fees and time) where less than a full assessment is required. If during the assessment of an application the APVMA discovers errors or omissions in the supporting information to that application it is true that the statutory timeframe is suspended until those errors or omissions are rectified. As discussed previously, the ANAO found that 74% of pesticide and 76% of veterinary medicine applications had one or more 'deficiencies' (errors or omissions), with the number of deficiencies generally increasing with the length of the formal evaluation timeframe (related to the complexity of the application). The ANAO recommended that the APVMA systematically analyse the type and cause of errors or omissions in applications so as to better target its initiatives to improve application quality. The APVMA has accepted this recommendation and has developed initiatives to address this issue.
Conflict between APVMA and Overseas Requirements: Certain countries require a document called a "Certificate of Free Sale" (for example the United Arab Emirates) before the product can be registered in those countries. The APVMA will only issue this Certificate when a product has been registered for sale in Australia. Where a product does not require registration in Australia a Certificate of Free Sale will not be issued, even if the product requires registration in other countries.	The APVMA wishes to correct an inaccuracy in this statement and then comment on the statement. 'Certificates of Free Sale' are government-to-government certificates. The integrity of Australian Government certificates are crucial for the maintenance of all of Australia's trade. Section s69D of the Agricultural and Veterinary Chemicals (Administration) Act gives the APVMA the power to issue such a certificate for a chemical product (i.e. a registered agricultural or veterinary chemical product). Contrary to the assertion, the APVMA will issue a certificate of free sale for a veterinary product, to state that the product does not require registration in Australia and may be freely sold in Australia. This certificate satisfies the great majority of requests for exporters who request such a certificate, however the

Comment	Correction of error of fact or clarifying comment
	APVMA cannot make a statement on the certificate with respect to the constituents of the product, because the APVMA has not had any regulatory dealings with the product. The APVMA also issues certificates of manufacture and free sale for unregistered products that are manufactured in premises licensed by the APVMA. During 2006/7 the APVMA issued 550 certificates of export. Of these, 82 were for unregistered products. In this submission, the Australasian Compliance Institute seems to be arguing for an extension of the APVMA's regulatory scope.
New Technologies – the Missing Benefit Safer or reduced risk compounds are promoted by regulators in other countries due to potential benefits in relation to human health, the environment and international trade. Such countries (as New Zealand and the USA) have introduced programmes to encourage the development of reduced risk products. There is no such system operating for agricultural and veterinary chemical products in Australia; even though one does exist in Australia for certain industrial chemicals.	The APVMA wishes to comment on this issue and to correct an inaccuracy in the statement. The APVMA agrees that more could be done to encourage the development and registration of reduced risk products and is aware of the developments in industrial chemicals in this area (e.g. http://www.nicnas.gov.au/publications/chemical_gazette/pdf/2006nov_whole.pdf). However the APVMA may only operate within its legislative framework. Nevertheless it is important to note that in 2003 amendments to the Agvet Code provided for a low regulatory scheme for low risk product types. Under the new provisions certain products or product type may be proposed by industry for listed registration or reservation. The APVMA will assess such proposals and determine their potential and feasibility and then make a proposal through PSIC to the Minister. Once a particular product type is approved for listed registration a standard is determined and new products may be registered with much reduced application requirements, provided they conform to the determined standard. Chemical products approved for reservation do not need to be registered with the APVMA provided that they are of a type described in the conditions of reservation and are only supplied for the purposes described in the conditions of reservation. The APVMA recognized that the legislative framework for listed and reserved chemical products was not delivering the desired outcomes and has recently proposed a revised system to the Product Safety and Integrity Committee (PSIC) within the existing legislative framework that will achieve results. PSIC has accepted the proposal and the APVMA is moving to implement it.

Comment	Correction of error of fact or clarifying comment
Data Protection – A further disincentive for suppliers. • The lack of data protection given to proprietary information submitted in support of permits can prevent agricultural and veterinary chemical suppliers supporting permit applications. • Example: Timbercorp support for use of Terbuthylazine in Australian forestry Timbercorp developed intellectual property that related to significant commercial advantage in the use of terbuthylazine in forestry. In so doing, the benefits were "shared" with Timbercorp's competitors.	The APVMA wishes to comment on this statement and highlight an irregularity in the example. The current legislative provisions in relation to data protection do not include data submitted with permit applications. The APVMA agrees that this is problematic, particularly where permits are sought to conduct broad-scale trials with new chemistries (as the submission of data negates the potential for data protection when data is later submitted in support of a registration application). However the APVMA may only operate within its legislative framework. The example cited is somewhat unclear and it would appear that the purpose of data protection has not been clearly understood. The intent of data protection is to limit the use of data, preventing it from being used to register other products (or approve other active constituents) or from being used to vary (add uses to) other products. Data protection effectively provides a period in which an innovator (a registrant generating/obtaining data for the purposes of registering or extending their product) may have exclusive right to the use of that information and obtain a return on their investment (in the data). Data protection is not intended to limit the use of a particular product to one particular user or a group of specific users. In the example cited, had the data have been used to grant registration of a chemical product or to add a use to the label of a chemical product, the product would be available on the market and hence could be purchased by anyone who wished to use it.
Compatibility of Australian requirements with overseas countries. • While APVMA ensures compliance with overseas residue requirements, APVMA also makes demands that go beyond requirements made in other countries. This can significantly impact availability of agricultural and veterinary chemical products in Australia	The APVMA wishes to comment on this statement. The APVMA believes that the statement relates to its management of trade risk due to its reference to overseas residue requirements. As indicated in response to comments made by Animal Health Alliance on this topic, the APVMA undertakes a straightforward scientific review of data submitted by the applicant in its assessment of trade risk. This is consistent with other similar overseas regulators. The APVMA believes that its assessment procedures are valid, reproducible and have the support of Australian consumers, Australian processors, overseas importers and overseas import regulatory authorities.
• Of significant concern is the Quality Assurance Scheme for active constituents used in agricultural chemical products. … The APVMA requires that the identity of the manufacturing facility that produces an Active constituent be disclosed in documentation supplied to	The APVMA wishes to comment on this statement and correct an inaccuracy. The APVMA is required to ensure the quality of products within the scope of its regulation that are supplied for sale. To this end the registration of many agricultural chemical products is conditional that the registrant must not supply the

Comment	Correction of error of fact or clarifying comment
the registrant of a formulated product.	product unless the active constituent contained in the chemical product complies with the standard for that active constituent and was manufactured at a site of manufacture listed in the APVMA record of approved active constituents. This information can be provided directly to the APVMA and does not have to be provided to the registrant. In 2003-4 the APVMA put forward a proposal to reform the arrangements relating to active constituents and allow supply from any source provided that the active constituent complied with the APVMA standard for that constituent. However sustained industry lobbying at the time resulted in the system remaining unchanged.
• While the Australian requirement for residue data to be generated under Good Laboratory Practice (GLP) is similar to that in other developed countries, its implementation is different to those in other countries. In particular, the Australian system requires that data be generated, including field applications of products, be conducted by NATA registered facilities. There are few NATA approved facilities for generating residue data. • In contrast with Australian requirements, the USA requires that studies comply with GLP requirements. Furthermore, in submitting an application to US EPA, deviations from GLP can be noted and need not invalidate a study.	The APVMA wishes to comment on this statement. Whilst the US EPA audits and accredits laboratory facilities, in Australia due to the small size of the chemical industry, such an accreditation system would be extremely costly. If the APVMA were to administer such a system, under the current cost-recovery framework such costs would likely be recovered from industry. In Australia, the National Association of Testing Authorities (NATA) is the Australian Government endorsed provider of accreditation for laboratories and similar testing facilities. NATA is Australia's GLP compliance monitoring authority for the OECD Principles of GLP and represents Australia on the OECD GLP Working Group.
The Australasian Compliance Institute recommendations	The APVMA notes that a number of the recommendations are not supported by reasoning or detail in the body of the submission and wishes to comment on the following matters:
• 1. Permits issued for minor uses be automatically converted to registrations if no adverse effects are noted during the permit period. Such conversion should attract the minimum fee possible (currently $540) to encourage registrants of products to add those uses to their labels.	The APVMA does have a practice of encouraging the adoption of uses that have been previously authorised by permit on to product labels where it is satisfied that it is appropriate to do so. Due to the restrictions and limitations (and known limited use) associated with the issue of minor use permits the APVMA is often able to issue a permit with the condition that additional confirmatory data be generated during the life of the permit. Over several seasons sufficient information may become available for the APVMA to be satisfied to grant full registration (which is unrestricted) of a particular use. In these situations the APVMA will write to the relevant product registrants (or the permit holder who can then advise the registrants) and offer the adoption of the use on their product label as a minor

Comment	Correction of error of fact or clarifying comment
	label variation application for which the fee is nil. It is important to note however that the APVMA cannot force registrants to seek registration of such use patterns. As such, an automatic conversion of permits to registration would not be feasible.
• 4. Applicants for approval and/or registration of substances be permitted to submit assessment reports from overseas regulatory authorities to enable further reductions in the fees payable to APVMA for registration of new active constituents or new agricultural and veterinary chemical products. • 5. (b) Accepting and relying on evaluations conducted by other regulatory authorities with effective regulatory systems. Such reliance would then allow the APVMA to concentrate on Australia specific issues.	The APVMA is involved in a number of work-share projects with similar regulators of other OECD member countries. Under these projects individual countries take the lead on a specific aspects of the application and provide a hazard assessment report to all the participants. A country such as Australia then takes that hazard assessment and in conjunction with its advising agencies such as the Office of Chemical Safety (OCS) and DEW sets standards and applies risk mitigation. The setting of standards (such as public health standards) and the application of risk mitigation are country specific due to societal differences in the acceptance of risk. In this context the APVMA does accept evaluations conducted by other competent regulatory authorities. However it is critical to the success of international work sharing and more importantly to the protection of intellectual property (data protection) that applicants submit full copies of the data submitted to overseas authorities for the purposes of their evaluation. The APVMA cannot rely on a published evaluation of another country if it has not had submitted to it the data on which that evaluation is based as to do so could potentially breach obligations with respect to intellectual property protection.
• 5. (a) Eliminating the need for chemical substances that are only used in the workplace (e.g. commercial agricultural production) to be Scheduled as Scheduling imposes a significant delay in the approval process for new active constituents. Scheduling is not required for other chemical substances used in the workplace only. Scheduling can remain a requirement for veterinary chemicals and agricultural chemicals sold to consumers.	The APVMA wishes to correct an inaccuracy in this statement. Industrial chemicals are subject to the requirements of poison scheduling, except where otherwise considered and exempted. The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) lists 9 schedules according to the degree of control recommended to be exercised over the availability of drugs and poisons to the public. Schedules 2, 3, 4 and 8 apply to therapeutic drugs (including veterinary medicines). Schedules 5, 6 and 7 apply to agricultural, domestic and industrial poisons. Schedule 9 applies to substances only available for medical or scientific research. In many cases, poisons whether used for agriculture, veterinary or industrial uses are scheduled on the basis of the active constituent and not the use pattern.
• 5. c) Outsourcing evaluations where internal resources are inadequate in the same way that other authorities (for example, the EU and USA)	The APVMA currently does outsource the evaluation of aspects of applications made to it. It routinely contracts OCS, DEW, State Departments of Primary

Comment	Correction of error of fact or clarifying comment
use external resources for initial evaluations	Industry and a range of other appropriate consultants to provide it with the advice necessary to determine applications. Under a Ministerial Agreement the APVMA has also sought tenders for outsourcing of human health data assessment.
• 5 (d) Streamlining the process for registration by increased grouping of products. …for example, products that are known to control a particular pest species might be able to be registered for use on any crop due to the similarity of the behaviour of the pest on all crops and the susceptibility of the pest to application. In other situations, it may be necessary to demonstrate efficacy on individual situations/crops/animals	The APVMA can only register uses that are proposed for registration by an applicant/registrant. The APVMA encourages the broadening of use patterns by 'grouping' where it can be demonstrated that it is appropriate to do so (i.e. the product can be used safely and effectively) and the APVMA is satisfied of its legislative obligations. The example cited by the author only refers to efficacy. It is important to note that the consideration for use of a product on another crop also involves other factors including, but not limited to, chemical residues, environmental exposure and occupational health risks.
• 9. Establishing an independent audit or review panel to review APVMA decisions as small business is deterred from challenging decisions by the cost of the existing legal process.	The APVMA wishes to comment on this statement. Applicants who disagree with an APVMA decision to not grant an application can seek a reconsideration of that decision from the CEO of the APVMA. There is no cost for a reconsideration and where such a request is made the decision is revisited by someone other than the original decision-maker. If the applicant disagrees with the result of a reconsideration the applicant can seek to have the decision reviewed by the Administrative Appeals Tribunal (AAT). The APVMA will only make a decision not to grant an application for a chemical product if it cannot be satisfied that the product: • would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; • would not be likely to have an effect that is harmful to human beings; • would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; • would not unduly prejudice trade or commerce between Australia and places outside Australia; • would be effective All APVMA decisions are scientific decisions and the APVMA maintains its regulatory science quality and relevance through a range programs, including a Science Fellows Program involving external scientists.

Comment	Correction of error of fact or clarifying comment
Northern Territory Horticultural Association	
The NTHA supports a science based approach to chemical registration however we submit that the application processes for chemical registration, minor use and emergency use permits are excessively cumbersome for industry to manage. There is insufficient support for industries to obtain or develop scientific data to support applications.	The APVMA would like to comment on this statement and highlight current initiatives in this area. The APVMA believes, noting the author and the reference to "industry" that this comment is related primarily to the permits system and growers and/or grower associations obtaining minor-use and emergency permits. The APVMA acknowledges the difficulties of the 'minor-use' issue, which is also experienced internationally. Although additional to its core business, in 2004 the APVMA appointed a Minor-Use Co-ordinator to engage and provide a contact point for grower groups. It has also more recently contributed to a recent initiative (in conjunction with DAFF) of the Minor Use Liaison Office. This office was established in August 2006 with objectives to progress initiatives for minor uses and to develop a long-term strategy for addressing minor use. In addition the APVMA chairs an OECD Expert Group on Minor Uses which is seeking to develop ways to share international data, reducing the costs to Australian growers of producing data to support minor uses.
Also of major concern is that chemical reviews do not adequately take into consideration impact of withdrawal (trade restrictions etc). Nor do they reasonably consider time frames and resource constraints for industry to develop alternative pest and disease management strategies.	The APVMA wishes to elaborate on this point. As previously indicated the APVMA appreciates the impact that the loss of certain chemicals can have on its industry stakeholders and for this reason engages in extensive consultation throughout the review process, providing early warning of potential regulatory action wherever possible. However the APVMA has an obligation to ensure that the use of registered products does not cause undue harm or pose undue risk to people and the environment.
VMDA	
Greater Risk management by APVMA to reduce regulatory burden • Risk management is considered a key part of APVMA activities, particularly during product registration assessment, yet there is very little detail on how this assessment is performed. … The APVMA should develop clear guidance on the preparation and evaluation of risk/benefit analysis;	The APVMA wishes to comment on this statement and correct an inaccuracy. The APVMA acknowledges that its framework for risk assessment is not well understood. To rectify this and improve transparency the APVMA is in the advanced stages of finalising a document that describes the APVMA's framework of risk assessment. This document once completed will be published to the APVMA website. The Agvet Code does not provide for risk/benefit analysis. The APVMA must be satisfied that products are safe and effective before they are registered.
• Currently the APVMA requires certain products be trialled across several States, this is often not justified.	The APVMA wishes to correct an inaccuracy in this statement and then comment on the statement.

Comment	Correction of error of fact or clarifying comment
	As previously indicated, if Australian efficacy data are required to fulfil the requirements of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code), that the APVMA be satisfied of the efficacy of a product, the APVMA requires sufficient trials to be conducted in a sufficient range of environments, to prove efficacy of the product in relation to the product's proposed label claims. Environmental factors can significantly impact the efficacy of some products. The APVMA does not require that products be trialled across several states without justification. Data collected in a range of States is only required where warranted to prove a product's efficacy within the range of environments in which it is proposed to be used.
• Animal ethics considerations encourage researchers to use a few animals as possible, yet MORAG insists all products for use on food producing animals be efficacy tested in Australia, even when they may have been tested overseas unless strong justification is put forward.	The APVMA wishes to correct an inaccuracy in this statement and then comment on the statement. As previously indicated the APVMA's MORAG does state that Australian efficacy studies are required for products which contain new active constituents and which are designed as herd or flock medications for food-producing species of animals. However it is important to note that MORAG also states that the APVMA will consider scientific argument that Australian efficacy data not be provided, on a case-by-case. The APVMA has registered a number of products on the basis of overseas efficacy data only.
• The APVMA has signed a number of agreements with overseas regulators allowing for more co-operations between agencies. This co-operation should be used to reduce data requirements.	The APVMA wishes to provide some additional background to this comment. The APVMA has invested significant effort into international engagement with similar regulatory authorities to optimise international consistency and harmonisation where possible. The APVMA has now signed memorandum of understanding with the Agricultural Compounds and Veterinary Medicines group (ACVM) of the New Zealand Food Safety Authority (NZFSA), the United Kingdom Pesticides Safety Directorate (PSD) and the Canadian Veterinary Drugs Directorate (VDD). In addition the APVMA is involved in a number of work-share projects with similar regulators of other OECD member countries. This international cooperation is intended to harmonise data assessment procedures and data requirements between comparable regulators, where the legislative obligations of the regulators allow (facilitating greater work sharing and improving the international 'portability' of information with respect to

Comment	Correction of error of fact or clarifying comment
	chemical products). However proponents of chemical products in Australia (and in other countries) will still be required to make full data submissions with respect to their applications. The APVMA cannot rely on a published evaluation of another country if it has not had submitted to it the data on which that evaluation is based as to do so could potentially breach international obligations with respect to intellectual property protection.
• The recent ANAO report on the APVMA entitled "Regulation of Pesticides and Veterinary Medicines" strongly recommends the use of greater risk management by this regulator.	The APVMA wishes to correct an inaccuracy in this statement and then comment on the statement. The ANAO report did not 'strongly recommend' the use of greater risk management by the APVMA. Whilst the ANAO report does frequently use the word 'risk', this is most frequently with respect to the APVMA's financial reserves. The report's reference to risk management is with respect to the scope of products in the National Registration Scheme: 'For example, the APVMA has proposed changes to the type of chemicals to be covered by its regulation. The intent behind this proposal is to more closely align regulatory processes and resources with the inherent risks posed by different types of chemicals. This proposal has been endorsed by the Committee and has been included in its Work Plan for 2005–06 to 2007–08.' The APVMA's assessment of applications for registration of a product, variation of a registered product or issue of a permit are underpinned by hazard identification and characterisation and risk management. As previously indicated the APVMA is in the advanced stages of finalising a document that describes the APVMA's framework of risk assessment.
Inconsistent application by APVMA staff and outsourced advisors of guidelines and regulations.	The APVMA notes a number of issues are raised under this heading. Whilst a lack of detail surrounding several of the examples prevents the APVMA from responding on them, the APVMA wishes to provide comment on the following:
• It is appreciated that APVMA has guaranteed to respond without recrimination to individual industry complaints, although it is not clear what form those responses might take.	The APVMA has always adopted a very consultative approach and been willing and open to meet with applicants, registrants and industry representatives to discuss issues and complaints. The APVMA believes that it is very clear what form any response to a complaint raised with it might take. The APVMA is very transparent in providing explanations as to why certain actions or activities have occurred and proactive in

Comment	Correction of error of fact or clarifying comment
	taking any remedial action warranted. It provides detailed responses to concerns raised with it. This is underpinned by its Service Charter (a copy can be obtained from http://www.apvma.gov.au/about_us/pdf/charter_2004.pdf).
• Companies that seek approval of trial protocols before undertaking field trials have had no guarantee in the past that the reviewer who approved the original trial protocol will be the reviewer who reviews the trial report once the trial is completed. This has led to the ludicrous situation where a company has had their trial protocol approved, only to be advised following review of the final report that the trial was of unsatisfactory or unacceptable design.	The APVMA offers the assessment of a trial protocol as a service to industry (on a fee for services basis). The objective of a potential applicant in having a trial protocol assessed it to determine whether a trial conducted in accordance with the protocol would be likely to yield the sort of information necessary to support product registration. Of course a number of factors (such as environmental factors, presence/absence of disease) can impact the actual conduct of the trial meaning that it does not yield appropriate data. The APVMA has amended its process of assessment of trial protocols to make it clear that the assessment of a trial protocol is the APVMA's assessment, even if the assessment is outsourced to an external expert.
• Failure of the APVMA internal evaluators to interpret and/or amend 'requirements letters' generated by external reviewers	The APVMA wishes to correct an error in this statement. External efficacy reviewers do not generate 'requirements letters'; the APVMA generates 'requirements letters'.
• *Failure of APVMA staff to respond within statutory timeframes* … It has been a not infrequent complaint that APVMA have not responded with prescreen or other advice within the statutory time-frame for that advice. This view is enhanced by the lack of transparency in how the time to complete a review is computed.	The APVMA wishes to correct an error in this statement. The statutory timeframe for making an initial determination at screening of an assessment is one month. APVMA statistics show that in approximately 95% of applications, the initial screening determination is made within the one month statutory timeframe.
• *Failure of APVMA to respond at all* … It is our request that APVMA should take the steps that are necessary to ensure that APVMA officers always respond in an appropriate and timely manner.	As previously mentioned, the APVMA has a customer service charter detailing its service standards (copy available at http://www.apvma.gov.au/about_us/pdf/charter_2004.pdf). Telephone calls are returned within 24 hours and written correspondence (including email) acknowledged within 10 working days. The APVMA acknowledges that the timeliness of responses to phone calls and emails was raised in Registrant Satisfaction Surveys that it conducted during 2005/06. Following those surveys a range of initiatives have been implemented to address the concerns raised. The results of the surveys and the respective APVMA initiatives are available at http://www.apvma.gov.au/registration/regsurvey.shtml. The APVMA is happy to investigate any circumstances where industry believe the APVMA's service standards have not met the expectations of the customer service

Comment	Correction of error of fact or clarifying comment
	charter.
• *Inability of reviewers to respond in other than the maximum allowable time* …Although appreciating the difficulties faced by APVMA in finding reviewers and using external agencies, Industry believes the time frames, in general, are unnecessarily long and frustration increases when those timeframes are apparently exceeded. This view is enhanced by the lack of transparency in how the time to complete a review is computed.	The APVMA believes that this comment primarily relates to the efficacy reviewers contracted by the APVMA. The APVMA disagrees that there is a lack of transparency in how the time taken to complete a review is computed. Section 2.5 (Timeliness of assessments) in the 'Manual for efficacy and safety reviewers' (available from http://www.apvma.gov.au/publications/manual_efficacy_reviewers_v4.pdf) provides this information. The recent ANAO performance audit of the APVMA noted that whilst the Australian Government agencies (OCS and DEW) from which the APVMA seeks advice generally met assessment timeframes, almost half of the efficacy and safety assessments conducted by State Government departments or private consultants exceeded the timeframe. The ANAO suggested that the APVMA identify opportunities to improve this performance and the APVMA is working to address this.
• *Requesting technical explanation of data at screening* … during screening, companies sometimes receive requests for technical detail which has already been provided in the dossier and would be recognisable to the external reviewer. This quasi-technical review at screening may be undertaken by individuals not technically qualified to understand the data or their significance. This leads to delays in processing of the application as the clock is stopped whilst the company responds to an unnecessary request.	The APVMA wishes to correct an error in this statement. The purpose of screening of technical data is to ensure that the company has provided all data according to the APVMA's published data requirements. If the applicant has provided inadequate data, the application can either not be assessed, or if it is assessed, is likely to be refused. Whilst the APVMA does not investigate the quality of the data supplied in detail at screening, where flaws are noticed it is obliged to raise these with the applicant. The APVMA is preparing a proposal to present to industry consultative forums that the APVMA will screen data and identify deficiencies to applicants, but if they wish, the applicant may request the APVMA proceed to assess the application despite the deficiencies.
Virginia Horticultural Centre	
• Why are reviews from leading countries ignored in the use of assessing chemicals; • Resources from leading authorities in different countries need to be incorporated as there research and data is ahead of the APVMA	The APVMA wishes to correct an error and comment on this statement. The APVMA does not conduct research and collect data of its own accord for the purposes of registering products or issuing permits. The APVMA assesses data submitted to it to determine the safety and effectiveness of chemical products. As previously discussed the APVMA will consider overseas information (data) and is involved in a number of work sharing projects with international regulators

Comment	Correction of error of fact or clarifying comment
	whereby it would accept hazard assessments conducted by those regulators. It is generally not possible for the APVMA to be satisfied of a product's efficacy and safety merely by the presence of a particular use on a label in another country. Environmental, agronomic and cultural differences (and differences in the products themselves) in Australia can greatly impact whether a use approved overseas would be safe and effective in Australia.
• Chemical registration is critical as often industry will need a chemical immediately but have to wait months for the registration process to occur;	The APVMA wishes to comment on this statement. Where a chemical is required immediately due to an emergency (such as an incursion of an unexpected pest/disease) the APVMA can issue 'emergency' permits which the Regulations specify that the APVMA must determine "as soon as practicable". Of course the APVMA must still be satisfied that the product proposed for use can be used safely and effectively and information must be submitted or otherwise available to support this.