SUBMISSION 005
Received 16/01/13

HILLS ORCHARD IMPROVEMENT GROUP INC.

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

House Standing Committee on Agriculture, Resources, Fisheries and Forestry

Comments by the Hills Orchard Improvement Group Inc. on the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 referred on 29 November 2012 to the House of Representatives Standing Committee on Agriculture, Resources, Fisheries and Forestry for inquiry and report.

Terms of Reference

The Terms of Reference comprise the text of the Bill and without limiting the scope of these terms of reference the Committee has resolved to target a number of key areas for consideration:

1. Initial assessment and registration processes (Schedule No. 1 of the Bill), including:
   a. Factors that affect efficient regulation, including the risk assessment process;

2. Re-approval and re-registration of agricultural and veterinary chemicals (Schedule No.2 of the Bill), including:
   a. The need for re-approval/and re-registration;
   b. The process and practical effects (including the financial impacts) for all stakeholders including the regulator;

3. International comparisons and trade issues, including the effect on small companies; and

4. Consultation processes and outcomes:
   a. Including intergovernmental consultations.

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The content of the submission we acknowledge is protected by privilege but only after the committee has accepted it, however if it is rejected then no such protections arise.

The submission becomes a committee document, and must not be disclosed to any other person until it has been released ('published') by the committee. Once a committee has authorised the release of a submission, subsequent publication of it is protected by parliamentary privilege.

The content of a submission may be published in another form or for another purpose before the submission is released by the committee, but this publication will not be protected by parliamentary privilege.

It is our belief that the submission does not reflect adversely on any other person or make any accusation of lying or corrupt behaviour.

HOIG has produced this document in good faith for the purpose of putting forward its views on the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 to the Parliament of Australia.

Executive Summary

The Hills Orchard Improvement Group Inc. (HOIG) was formed in 1982 and today has a membership of about 100 Western Australian growers with orchards in the Perth Hills district.

Perth Hills fruit growers produce more than $40 million a year of stone fruits, apples and pears. HOIG's members became gravely concerned last year about the Australian Pesticides and Veterinary Medicines Authority (APVMA) recommendation to ban fenthion on some fruits.

Mediterranean fruit fly is an endemic pest in the Perth Hills and poses a catastrophic threat to the industry without access to fenthion.

Fenthion is the only effective treatment that kills fruit fly in all stages of the life cycle – from larvae to adult. The fenthion ban was introduced for home gardeners in October 2012 and we fear that suburban fruit trees will become a breeding ground for a massive explosion in the fruit fly population.

Our initial dealings with the APVMA suggested to us that they had failed to apply the legal rules of procedural fairness and natural justice or the principles of scientific method.

HOIG members seek efficiency and performance improvements within the APVMA. We do, however, remain concerned that the reforms proposed in this Amendment Bill fail to deliver any real efficiency or reduction in red tape.

A number of reviews have highlighted shortcomings in the APVMA's structure and performance.

The APVMA's dysfunction has had a significant impact on the supply of new products to the production animal market. The same dysfunction has limited Australia's capacity to fund animal and plant health research, reducing our international competitiveness.

Under its current legislation, the APVMA takes no account of issues such as standard orchard practice, Australia's food security and supply or the social and economic impact of its decisions.

HOIG's submission comments from an industry and public policy perspective on the proposed amendments contained in the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012.

HOIG is generally supportive of the proposed amendments, with some reservations detailed in this submission.

HOIG submits trade and efficacy must remain mandatory considerations for products used in all trade exposed industries. The requirement to consider efficacy is critical to ensure that only chemicals which are fit for purpose are registered, which in turn will reduce chemical content in food production processes and reduce the risk of unacceptable residues.

HOIG understands that the Department of Agricultural Food and Forestry (DAFF) is proposing to place the burden of proof for a re-approval or re-registration on the presence of adverse outcomes. This is would be welcomed by HOIG after its dealings with the APVMA on fenthion. Clearly if there is evidence of problems with product safety and/or environmental

impact of old products it is necessary and reasonable that they be withdrawn. There are many old products that are used in combinations, and in rotations with new products that are important to productivity and managing biosecurity, food security and animal health and welfare.

HOIG's major objection to the amendments concerns the proposed re-approval and re-registration of generic medicines and chemicals for which patents have expired. In these cases no individual company will have sufficient financial incentive to carry out necessary studies to collect data for re-registration, which is likely to cause considerable damage to many agricultural industries.

It is HOIG's experience that the APVMA cannot manage its current regulatory responsibilities adequately. The APVMA has struggled to maintain a timely and effective regulatory regime, let alone introduce internal reform to its widely criticised performance.

The APVMA's record highlights what can happen if a regulator acts without accountability.

As industry members dependent for our livelihoods on the APVMA's decisions, HOIG believes piecemeal legislative reforms are unlikely to fix the well identified failings of the APVMA.

Introduction

The Hills Orchard Improvement Group Inc. (HOIG) was formed in 1982 by 8 fruit growers and 2 officers of the Western Australian Department of Agriculture. Today it has a membership of about 100 Western Australian horticulturists with orchards in the Perth Hills district.

The objective of the group is to promote modern fruit growing methods. This has been achieved in many ways over the past 30 years. HOIG will be hosting its 29th Karragullen expo this year. The wide range of horticultural products on display at the one venue is seen to be of great benefit to horticulturists, vignerons, flower growers and fruit growers in the Hills and nearby regions.

HOIG has also been active in liaising with local and overseas growers and grower organisations sharing information, technology and new methods of crop and tree cultivation. The group has regular meetings with guest speakers from both government departments and from industry who inform members on a variety of industry-related matters.

HOIG endeavours to support modern fruit growing methods in the Perth Hills district. It has an enduring commitment to promoting nutritional awareness and maintaining a fresh and healthy balanced diet, in schools and in the community.

HOIG is not a peak industry body or a lobbying organisation for the stone fruit industry. Its members aim to produce high standard horticultural crops that are pest and disease free. It strives to increase the nation's agricultural productivity, sustainability and food security.

HOIG has not until recently seen any role for itself in lobbying government. However, it became gravely concerned about The Australian Pesticides and Veterinary Medicines Authority (APVMA) recommendation to ban fenthion in the horticultural industry.

Mediterranean fruit fly is an endemic pest in the Perth Hills and poses a catastrophic threat to the industry without access to fenthion.

Fenthion is the only effective treatment that kills fruit fly in all stages of the life cycle – from larvae to adult. The fenthion ban was introduced for home gardeners in October 2012 and we fear that suburban fruit trees will become a breeding ground for a massive explosion in the fruit fly population.

The APVMA announced just days before this season's crop was to be picked in the Hills district that it would ban the chemical fenthion on a wide range of fruits on October 31. Perth Hills fruit growers produce more than $40 million a year of stone fruits, apples and pears. HOIG predicted the total destruction of the stone fruit crop and the loss of 80 per cent of the apple crop in the south west of Western Australia should fenthion be banned.

Although the APVMA assured growers that their submissions would be taken into account before a decision was made about banning fenthion, prior to the submission period closing we were advised by the Western Australia Department of Agriculture and Food, pesticide manufacturers and by the Minister's office that the ban would proceed.

There are 600 growers in Western Australia who would have been affected by the ban, not just HOIG members. The industry is committed to phasing out the use of chemicals as much as possible but it will take time and millions of dollars to set up Area Wide Management (AWM) of fruit fly. The Western Australian Minister for Agriculture wants AWM established throughout the state but when pressed on who is going to pay for it he remains silent.

While the APVMA may say that it is not their responsibility to develop alternatives to fenthion it has to be pointed out that it is beyond the scope of horticulturists to develop new pesticides and chemical manufacturers have so far not been able to develop one in spite of their best efforts.

Although HOIG members were contributors to the various industry levies and part of grower industry bodies our interests and concerns were not adequately put forward by representative bodies or state departments and agencies to the APVMA fenthion review.

Our initial dealings with the APVMA suggested to us that they had failed to apply the legal rules of procedural fairness and natural justice or the principles of scientific method - the body of techniques for investigating phenomena, acquiring new knowledge, or correcting and integrating previous knowledge which is based on empirical and measurable evidence subject to specific principles of reasoning.

The scientific method appeared to be replaced with bias and preconceived assumptions. HOIG was told that fenthion had been banned in the United States and the European Union and would therefore be banned in Australia.

HOIG representatives pointed out to APMVA staff at a public meeting held at the Canning Vale Markets that fenthion, which is sold under the brand name Lebaycid, has been used safely in the horticulture industry to control Mediterranean fruit fly for more than 50 years with no reported health effects among workers or consumers. A senior staff member of the authority responded in front of an audience of growers: “You want to harm small children, do you?”

APVMA officers told HOIG members that there was no point seeking political influence to overturn the ban because the APVMA’s decisions were not subject to ministerial approval or veto. However, once HOIG raised its concerns with the Minister, the Shadow Minister, members of the Rural and Regional Affairs and Transport Committee, the MHR for Canning and other Members and Senators, the APVMA’s approach changed and became far more conciliatory and collegiate.

These actions resulted in a one-year permit being issued for the use of fenthion on certain fruit crops. The proposed ban on fenthion by the APVMA has seen us turn our attention to examining the APVMA’s activities and record.

The APMVA does not appear to communicate on a regular basis with growers or consumers. It regards its stakeholders as chemical companies, industry peak bodies and government instrumentalities. Its decisions take no account of issues such as standard orchard practice, food security and supply or economic impact.

HOIG sponsors stewardship activities to ensure the safe use of herbicides, insecticides and fungicides that are critical to maintaining and improving Australia’s agricultural productivity to meet global food security challenges in coming decades.

Each of these products is thoroughly assessed to ensure they present no unacceptable risk to users, consumers and the environment.

Without access to these tools, farmers may lose at least 50 per cent of their annual production to pests and weeds. Crop protection products must be used meticulously, sparingly, carefully and responsibly. HOIG believes the responsible use of agricultural chemicals must be supported by a regulatory scheme that maximises the benefits

associated with their responsible use, while minimising the costs from excessive, inappropriate and ineffective regulation.

Horticulturists demand these products because of the benefits they provide to their businesses. While it is important for governments to provide for appropriate regulation of pesticides, any regulator must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation and delivering poorer safety, health and environmental outcomes.

Horticulture Australia Limited (HAL) commissioned Growcom's 2011 review of food security issues, which identified a diverse range of threats that may impact on Australia's domestic food security and will have important consequences for the $7.3bn per year horticulture industry.

The report found that Australia is not as food secure as suggested by simplistic examinations of the relevant data. Australia already imports 34 per cent of fruit consumed and 19 per cent of vegetables. The report found that the sources of these imports could disappear as world population heads for 9 billion people by 2050.

The world will need to double food production by 2050 just to ensure that the number of hungry does not increase from its current level of one billion people. The report recommended that this challenge to feed more people with the same or less land and water will require an increase in research and development funding from the current three per cent of the gross value of agricultural production to five per cent.

Dr Giles Oldroyd of Global Food Security predicted last year that food prices will continue to increase substantially and spike unpredictably, as they did in 2008. In that year staple food prices soared – wheat up 130%; sorghum up 87% and rice 74%. These events caused riots in 36 countries and the government of Haiti was toppled as people took to the streets. He highlighted that more people die each year from hunger and malnutrition than from AIDS, tuberculosis and malaria combined, and the World Bank estimates that cereal production needs to increase by 50% and meat production by 85% between 2000 and 2030 to meet demand.

Australia also has a role in ensuring food security in a changing world. Australia is currently a net exporter of food, with considerable expertise in food production under resource constraints and in the face of climate variability. However we face increased challenges to this important Australian industry including: land degradation, population growth, long-term climate change, competition for arable land, scarcity of water, and nutrient and energy availability.

Food security is not just about having enough food in a typical year. It means having reliable and sustainable access to acceptable, nutritious, and affordable food at all times. Australians expect this security, and about 40 million non-Australians internationally rely on Australia to secure their food.

There are many factors that affect food production. The post-war 'second agricultural revolution' in developed countries, and the 'green revolution' in developing nations in the mid-1960s transformed agricultural practices and raised crop yields dramatically, but the effect is leveling off and is unlikely to meet projected demand.

At the same time, many pests are becoming resistant to insecticides, but many of the most effective chemical agents are now banned under environmental regulations. Climate change

is bringing new microbial diseases to food-growing regions along with more extreme and unpredictable weather patterns.

Estimates vary, but around 25% of crops can be lost to pests and diseases, such as insects, fungi and other plant pathogens. But without suitable pesticides to counter these problems crop losses are likely to be much higher.

The Report for the Prime Minister's Science, Engineering and Innovation Council on Food Security in 2010 said "that experience of the Australian veterinary and agricultural chemical industries suggests that many large international companies are not prepared to pay for the efficacy testing of chemicals to register products in Australia through the APVMA.

This limits the range of opportunities for productivity improvement by Australian farmers. As food security issues continue to emerge, the regulatory environment in Australia will need to be more flexible and responsive. This will ensure that innovations which underpin productivity and efficiency improvements are delivered effectively". HOIG would add to that recommendation that the regulatory environment in Australia must also be internationally cost competitive if our small domestic market is to have access to innovation in chemical control of pests.

The APVMA's charter does not take into account the impact of its decisions on Australia's food security.

The regulator has to adopt a broad view of its responsibilities not a narrow one. Imminent harm to humans, livestock or the environment cannot be tolerated but blind observance to a mathematical formula to justify banning a pesticide should not be acceptable. It nearly was in the case of fenthion and still may be.

The current situation with fenthion has illustrated the risk of not scrutinising the APVMA appropriately. Providing it with independence is one thing but allowing it to place in jeopardy at least half of the nation's stone fruit industry could be said to border on irresponsibility.

The Authority is due to rule this year on whether this important chemical for treating Mediterranean and Queensland fruit fly can continue to be used. There is still no effective alternative pesticide treatment to fenthion (Summerfruit Australia 2010). HOIG knows firsthand that unchallenged the APVMA would have banned fenthion with no alternative available and on the acknowledged basis that there has never been harm to humans from the use of the pesticide in the horticultural industry.

HOIG would like to see all sides of this vexed question come together to address this significant problem but it does require more leadership from the lead agency than has been exhibited in recent times.

HOIG accepts that the government is attempting to improve the performance of the APVMA but does not believe the Amendment Bill is designed to address the multitude of problems that have been identified with its performance.

On 15 June 1993, the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Admin Act) became law and provided the legal framework for the establishment of the APVMA as an independent, fully cost recovered Commonwealth Statutory Authority. The APVMA is responsible for assessing agricultural and veterinary chemicals intended by companies for supply and use in Australia. With feedback from three Commonwealth agencies responsible for Human Health, the Environment and Occupational Health and Safety, the APVMA undertakes the evaluation, registration and review of chemical products

and their control up to the point of retail sale. The States and Territories are responsible for control of use aspects such as licensing of pest control operators and aerial spraying, and for undertaking field compliance and surveillance work as tasked by the APVMA.

The Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) is the primary Act regulating agricultural chemicals in Australia. As a result, HOIG and its members have a strong interest in any proposed amendments to the Agvet Code. HOIG welcomes efforts to reform the Agvet Code to improve its efficiency, as well as improve the performance of the APVMA. HOIG endorses the objective 'to cut red tape and increase the efficiency and effectiveness of agricultural and veterinary (Agvet) chemicals regulation'.

HOIG members seek efficiency and performance improvements within the APVMA. We do, however, remain concerned that the reforms proposed in this Amendment Bill fail to deliver any real efficiency or reduction in red tape. Our assessment reveals that there will be additional functions and processes that are likely to further hinder efficiency aims and deliver no additional health, safety or environmental outcomes.

Unnecessary increases in the regulatory burden on applicants, registrants and approval holders will increase the total administrative and regulatory costs of the registration system, which is already resulting in a loss of safe and useful products.

The current Amendment Bill arises from the Australian Government Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper. Released in November 2010, the paper provided stakeholders with details of the government's thinking around its commitment to reform the Commonwealth regulation of Agvet chemicals and to start the process of actively engaging with stakeholders.

Submissions were called for and then in November 2011, the Minister for Agriculture, Fisheries and Forestry, Senator Joe Ludwig, and the Minister Assisting on Deregulation, Senator Nick Sherry, announced a comprehensive package of reforms to Agvet chemicals regulation. The reforms were included in a draft Agricultural and Veterinary Chemicals Legislation Amendment Bill. Further submissions were received and the government released a revised draft legislation package and invited comment from industry and the community on 25 September 2012.

Again comment was sought from stakeholders and the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 was introduced into the House of Representatives by Parliamentary Secretary Sid Sidebottom on 28 November 2012. This Bill included further changes in response to submissions made by stakeholders on the revised draft legislation.

It is HOIG's experience that the APVMA cannot manage its current regulatory responsibilities adequately. The APVMA has struggled to maintain a timely and effective regulatory regime, let alone introduce reform to its widely criticised performance. Piecemeal legislative amendment or reforms are unlikely to fix "what ails" the APVMA.

The APVMA's dysfunction has had a significant impact on the supply of new products to the production animal market. The same dysfunction has limited Australia's capacity to fund animal and plant health research.

Since 2000 there have been a number of reports and reviews looking at the performance of the APVMA, including reports by:

- the Agriculture and Resource Management Council of Australia and New Zealand;

- the Australian Academy of Technological Sciences and Engineering;
- the Allen Consulting Group; and
- the Environment Protection and Heritage Council National Chemicals Taskforce.

They all considered the management of Agvet chemicals and arrived at similar conclusions. There was general agreement that the assessment and approval system was effective, and its strengths should be retained. However, there were structural shortcomings:

- varying approaches to control of use between States / Portfolios;
- lack of overall policy integration, formal links and interfaces; and
- fragmented and limited monitoring of outcomes.

Seven principles were identified that were considered essential to the design of an effective Australian Agvet chemicals risk management system. They were:

- a seamless system;
- strong feedback loops;
- flexibility to respond to emerging issues;
- provision for continuous improvement;
- confidence in the regulatory and management process;
- effectiveness and efficiency; and
- international confidence.

Since these principles were agreed upon little has changed and many have not been adopted. The APVMA has demonstrated that it has inadequate capacity for reform, despite all of the reform initiatives that the APVMA itself has identified, or have been identified by Veterinary Chemicals Producers, other industry associations, the Australian National Audit Office and the Productivity Commission.

In 2004, the Australian government endorsed a recommendation of the Uhrig Review into corporate governance (Commonwealth Government, 2003). As a result of this review, in July 2007 amendments to the *Agricultural and Veterinary Chemicals Code Act* came into force that had the effect of abolishing the APVMA's governing Board. The APVMA's Chief Executive Officer (CEO) then reported directly to the Minister of Agriculture, Fisheries and Forestry, whereas under the governing Board model, the CEO reported to the governing Board, whose Chairman reported to the Minister.

In HOIG's limited dealings with the APVMA we were surprised at their repeated assertion that their decisions were not subject to review or ministerial oversight. They failed to mention that their decisions could be overruled by an administrative tribunal or through a court decision.

We also understand that in certain circumstances the Act does provide the Minister with the opportunity to intervene in the decisions of the Authority.

To confuse this matter further the Operational Plan of the APVMA in 2010-2011 says the APVMA is guided by the policy direction of the Australian, state and territory governments for the regulation of agricultural and veterinary chemicals (Agvet) as determined by the Primary Industries Ministerial Council (PIMC).

Ministerial councils are established under the auspices of COAG to play an important role in bringing together Commonwealth, state and territory ministers (and in this instance New Zealand).

The establishment of independent regulatory authorities such as the APVMA leads to the question of how much autonomy it should have. HOIG is of the view that the APVMA should arrive at its conclusions without fear of interference and then recommend to Government a particular course of action. It is very important to have a regulatory body independent from all interested parties in order to ensure fair and transparent processes.

HOIG believes the ultimate objective of regulation is an effective regulatory framework which enables the market to become competitive and stimulate technological advances to enhance efficiency so that consumers benefit and the environment is safe. The APVMA's current exercise of its "independence" is in fact impeding Australian primary industry competitiveness.

To achieve this independence, accountability has to be of the highest order and enshrined in the philosophical underpinnings of the regulator. Many independent regulators are empowered to make recommendations to Government, which under the Westminster system gives the final decision and accountability to the responsible Minister. Few have the unabridged power to make decisions enjoyed by a body such as the Reserve Bank.

In the case of the APVMA, the independent regulator is a statutory authority of the government, which requires that its actions are monitored and that it is held accountable for them. HOIG believes that sound governance requires a tension between the independence and accountability of a regulator. Independence has to be qualified - to working within, rather than independently of, Government. The Amendment Bill does not address this shortcoming of the legislation.

In December 2006, the Australian National Audit Office (ANAO) published ANAO Audit Report No.14 2006–07 titled *Regulation of Pesticides and Veterinary Medicines: Australian Pesticides and Veterinary Medicines Authority*.

The report stated that the objective of the audit was to assess whether the APVMA was performing its key regulatory functions effectively. In particular, the audit examined the APVMA's provisions for:

- planning and overseeing the delivery of regulatory functions;
- registering pesticides and veterinary medicines in a timely manner;
- obtaining external scientific advice to support the registration function;
- monitoring the quality of pesticides and veterinary medicines approved for sale in Australia; and
- administering its cost recovery framework.

The ANAO report made a number of recommendations about corporate governance that the APVMA has implemented. However, the APVMA has not implemented two important recommendations directed towards improving timeframes:

- Recommendation 2(c): establish processes to verify the accuracy of time entries.
- Recommendation 3: improve registration processes by systematically analysing the type and cause of errors in applications, to better target initiatives to improve the quality of applications.

Both recommendations are aimed at streamlining assessments and reducing delays. It is difficult to understand why such procedural improvements have not been implemented and that undue delays continue.

In February 2007, the Australian Government asked the Productivity Commission (PC) to undertake over five years a series of annual reviews of the burdens on business from the

stock of Commonwealth regulation. The reviews were to categorise areas where regulation needs to be improved, consolidated or removed in order to raise productivity while not compromising the underlying policy objectives (Productivity Commission, 2007).

One of the terms of reference required the PC to identify specific areas of Australian Government regulation that:

- are unnecessarily burdensome, complex or redundant; or
- duplicate regulations or the role of regulatory bodies, including in other jurisdictions.

The Animal Health Alliance submitted to the report that because of the regulatory burden related to Agvet chemicals:

- Australian producers have fewer products with which to combat disease;
- increased reliance on currently-registered antibiotics was leading to antimicrobial resistance issues;
- premium pricing on products that are available;
- increased livestock production costs and livestock management issues;
- reduced competitiveness of Australian produce in domestic and international markets; and
- a lack of affordable preventative products leading to an increased incidence of disease and animal welfare issues.

The PC report noted that it had become clear that many issues need to be scrutinised and a detailed public study was warranted including:

- timeliness and complexity of national registration procedures; and
- differences among the states in rules for use of chemicals.

In August 2008 the PC's Chemical and Plastics Regulation Research report pointed out that the effectiveness and efficiency of APVMA assessments could be improved and suggested a number of reforms, including introducing a formal obligation on the APVMA to ensure that the costs of chemical assessments was commensurate with the risks of the chemicals concerned and that APVMA assessment priorities should be directed to the most efficient management of aggregate risks of all agricultural and veterinary chemical products.

In November 2008, ACIL Tasman prepared a report jointly for the Animal Health Alliance and CropLife Australia, on the APVMA's proposed cost recovery policy. The report provided a critique of the uncapped sales levy, the current cost recovery system, and discussed an economic case against mandatory efficacy evaluations for new veterinary medical products (VMP) when generic fair trading and consumer law obligations assign significant liabilities to manufacturers of ineffective or dangerous products.

The report also discussed the significant commercial disincentives for suppliers of products which lead to trade risks, disincentives that constitute reasons why the Agvet Code's trade risk criterion for registration of VMPs is not necessary.

Business Decisions Limited prepared a 2007 report comparing the performance of regulatory agencies in the United States of America, the European Union, Japan, Canada and Australia. The report found that uncertainty, inconsistency and protracted timeframes in APVMA evaluations caused a considerable cost burden on Australian applicants which led to:

- inordinate delays in getting innovative new products to market;
- reduced research and development in Australia; and
- increased costs which are passed on to consumers.

In December 2008, the AHA commissioned a study to fully analyse the costs associated in treating the major diseases of the beef, sheep, swine, poultry and dairy industries, as well as understanding the associated production loss to farmers and producers when such diseases occur.

The study concluded that over the previous four years 19 products of significant innovation were delayed due to new difficulties in the regulatory process; and the average delay period was 28 months longer than considered reasonable.

Products were available elsewhere in the world but not in Australia. Some 20 major products of significant innovation were available in other competitive markets but were not contemplated for launch in Australia due to costs and characteristics in the Australian regulatory process.

There were many cases where products were not available in Australia for protracted periods of time or were not made available at all but in similar, competitive markets access was available, clearly disadvantaging Australian producers.

The Animal Health Alliance submission on the National Food Plan Green Paper reported the results of a major global survey that found 89% of respondents in Australia agreed the regulatory environment was a significant obstacle to successful innovation, compared with 53-86% elsewhere in the developed world. Australia was the only country where the regulator received a negative rating for its impact on the industry's ability to innovate.

If Australia is to remain competitive globally, it is critical that we provide an attractive location for R and D investment and bringing new products to market. This requires a responsive and efficient regulatory environment and not the one HOIG has experienced.

HOIG can only presume that the impact on Australia's R and D capacity will be significant and long lasting. According to the Animal Health Alliance, ddomestic expenditure on R and D in animal medicines has decreased by around one fifth from between 9-10% of total turnover in 2006 to 7.7% in 2011. Australia has a history of being at the forefront of scientific discovery in animal and plant health. This requires skilled researchers, scientists and academics, and solid financial investment.

The slow and unpredictable nature of the APVMA is highlighted in statements made by Professor Frank Dunshea, the Head of Melbourne University's Agriculture and Food Systems Department, who reported in the media in December 2012 his firsthand account of APVMA delays:

> *"One of my PhD students had to gain approval from the APVMA to undertake what was a relatively straightforward experiment as part of his thesis, which focused on pig production," he said.*
>
> *"We had difficulty with frequent changes to the staff managing the application and lack of clear direction in correspondence form the APVMA. After two years of waiting for consent, we didn't want to waste any more time and withdrew the application. As a result, he had to change the focus of his project."*

In early 2010, the then Minister for Agriculture, Fisheries and Forestry decided that a 10 per cent increase in fees would be applied from 1 July 2010, pending development of a revised cost recovery impact statement. The 10 per cent increase applied to the annual fee on product registrations, new application fees for evaluation and approval, hormonal growth

promotants, notification number application and renewal fees, Certificate of Export fees, new good manufacturing practice licences and database information fees. Levies did not change. These changes were given effect by a variation to the 2005 Cost Recovery Impact Statement (CRIS).

The 10 per cent increase was an interim measure. Further changes to the APVMA's cost recovery arrangements were to be considered in the context of expected reforms to the operation of the APVMA announced in the government's August 2010 election commitment for the “Better Regulation of Agricultural and Veterinary Chemicals”.
In December 2011, a discussion paper that proposed further interim cost recovery arrangements for the APVMA in 2012-15 was released. The paper focused on ensuring appropriate and sustainable revenue to enable efficient and effective administration of Agvet chemical regulation and to minimise risks while a longer-term First-principles Review was being undertaken by the Department of Agriculture, Fisheries and Forestry.

The discussion paper also proposed a number of changes to the current arrangements for the recovery of costs associated with the assessment of compliance with Good Manufacturing Practice (GMP), which affects manufacturers of veterinary medicines in the Australian marketplace and registrants of imported veterinary products. Following consultation with a number of veterinary medicines industry groups an alternative proposal for the recovery of costs associated with the assessment of compliance with GMP was presented in a supplementary discussion paper on the Cost Recovery of Compliance with GMP in May 2012. Submissions were received until the middle of June 2012.

A Cost Recovery Impact Statement (CRIS) was then developed based on the two discussion papers and the consultation undertaken. The Minister for Agriculture, Fisheries and Forestry approved the CRIS in November 2012.

The Federal Government has undertaken a series of reviews of the APVMA, focusing on its structure and funding. The amendment Bill currently before the Parliament is one of the outcomes of the reviews and there are likely to be more reforms over the next few years.

Following stakeholder consultation in 2010, a range of measures was developed and considered by the Australian Government and amendments were proposed to the suite of Acts covering the functioning and administration of the APMVA. The amendments are aimed at:

- providing a transparent and comprehensive risk framework to deliver more predictable outcomes;
- providing a more efficient way to look at ‘chemicals of concern’;
- modernising the APVMA’s compliance and enforcement powers;
- using the science and studies from overseas to their full extent;
- establishing an independent science panel; and
- improving the APVMA’s operational and administrative functions.

HOIG believes that the APVMA could have administratively commenced many of the reform proposals some time ago. From our experience with the APVMA we see its managers claim to strive continuously for improvement in general, and improved managerial performance in particular. In contrast to the stated aim, we have an impression gained from those we have met and spoken to that many APVMA bureaucrats are reactionary and show excessive caution. They rarely indicate a willingness to listen to an alternative point of view. They initially rejected any submission from HOIG, not because it was necessarily wrong but because it challenged the routine and traditional processes. They appeared closed, and would find excuses as to why alternative practices could not be contemplated.

From its experience, HOIG can say that the APVMA seems to adopt a tick the box approach to its regulatory responsibilities and even this approach lacks consistency. In the case of fenthion, the APVMA agreed to reduce the withholding period while the product was under review, resulting in higher residue levels for consumers.

HOIG understands why the government has taken a legislative approach to improve the performance of the APMVA. It is only in the Parliament that such reforms can be made. But we contend that the APVMA has deep-seated cultural, attitudinal, communication, procedural and processing issues that will continue to impede its task as a regulator and that these shortcomings will need to be addressed by different processes.

Philosophical position on regulation

The Agvet product approval process in Australia requires reform so that Australian industries can continue to remain competitive, safe and produce the highest quality product.

Regulatory systems, almost by definition, impose costs on the private sector and consumers. Their major intent is to require people to do things in the public interest that might not be done in the absence of a regulator. As a result, they may be viewed as extra costs imposed by society, that society is willing to pay to manage any associated risks.

A perfect system of pesticide and product testing and registration is yet to be found. There are substantial structural differences in the systems that exist throughout the world. In some the intent of the legislation that creates them is to protect health. In others, it includes a health protection component, but also has objectives that relate to trade, thereby requiring regulators to explicitly consider a balance. The Australian system does not require the regulator to consider the economic or social impacts of its decisions or the likelihood of replacement pesticides or methods being available to guarantee the production of crops.

Other structural differences in the systems include internal disciplines designed to facilitate approval processes. For example, there is no appeal mechanism or drop dead date so as to restrict the length of assessment.

There are substantial differences in fees charged by regulators and for what purpose.

Every effort should be made to keep fees to a minimum. Fee-charging could be a process of consultation with stakeholders prior to establishing a fee. The fee would be levied on the basis that there is a clear benefit to the fee. If the parties cannot agree on a fee then there should be a mechanism to establish an independent resolution system. To ensure accountability of the regulator, performance benchmarks should be set in exchange for the fee charged. There should also be provisions for fee reductions when performance standards are not met.

The characteristics of a stringent, yet timely product registration program for Australia should be focused around a set of characteristics organised around the following:

- objectives of the legislation;
- procedures for market approval;
- applicant tasks;
- costs and incentives;
- transparency;
- consistency; and
- perceived costs and benefits

An overview of the product approval system suggests that it has the potential to get out of the control of Parliament and the Government. The legislation and regulations have been developed piecemeal. There is no - or very little - reference to any economic or trade objectives in the deliberations of the APVMA. It does not balance the narrow concept of risk prevention with the promotion of innovative advancements in health methodologies and products. By the same token, there is very little in the legislation that allows the public, through Parliament and its offices such as the Auditor-General, to hold regulators accountable for the economic consequences of their decisions. At a time when government says it wants to increase "value adding", "productivity" and or "technology", it must put regulatory processes in place that are consistent with this policy.

HOIG is of the view that the public expects all public officials, including regulators, to serve them. The support of those with an interest in what is being regulated should be a primary objective to achieving legitimacy for anything that the regulator attempts to do. The support of stakeholders is a necessary condition for successful policy adoption and effective policy implementation.

Regulators must be sensitive and responsive to their various constituents, perhaps especially those who fund their regulatory function.

US President Franklin Roosevelt said regulatory bodies must be a "Tribune of the people... getting the facts and doing justice to both the consumers and investors".

The actions and procedures of a regulator should be open, allowing public observation and public participation. Providing a platform to ensure that people feel in touch and able to influence a regulator is an essential tool for any regulator.

Regulatory discretion in part involves assigning relevance and weight to the opinions expressed in both evidentiary and public hearings.

In matters of regulation, public needs and wants often do not align. The regulator has to exemplify fairness, interpretability, and practicality. They must strike the balance between competing interests of the parties but always ensure safety and predictability in decision making. Public understanding and acceptance are weighed against other criteria, including revenue recovery, efficiency, and stability. Balance must also be found and that is a lot about demeanour and approachability.

Regulators make decisions and policy in the ruckus and disharmony of clamour and criticism. Politics may well turn up the degree of difficulty of the task but it should always be considered.

Some opinions may be unheard; some decisions are unpopular and met with some political resistance although still regarded as legitimate and necessary. Public interest must be informed by public opinion, but not defined by it. Regulation cannot take place in a vacuum and independence does not necessitate isolation or barring all avenues of input from stakeholders, the public and political institutions.

Decisions must be supported by evidentiary record, based on merit and constructed in accordance with due process, and opportunity should be available for giving consideration to more and better data and information.

Policy demands associated with urgency, or rapid economic and technological change may not be suited to the plodding pace of regulation. Participatory and collaborative approaches

may assist in quickening response times and improving the acceptability of regulatory decisions. Adaptation and modernisation are not reasons to abandon regulation's fundamental principles.

Technical complexity does not justify exclusion of interests or exemption of issues from healthy and open public debate about values, preferences, and priorities. Many voices should have the chance to speak to public policy, not just those who are most powerful or who most often bend its ears.

More inclusive processes for policy development are more demanding, but also fairer and better informed. Diversity enriches the record by which policy decisions are made. Regulators are well advised to place a priority on engaging in constructive dialogue with the public, stakeholders and policymakers in similar agencies and with their peers in other state and federal agencies with which they share geopolitical boundaries, markets, or jurisdiction.

Role of the Australian Pesticides and Veterinary Medicines Authority

Pesticides and veterinary medicines are used widely in Australia to protect crops, livestock, and plants from pests and diseases, and to treat animals, including household pets, for illnesses and conditions. In 2004–05, sales of pesticides and veterinary medicines in Australia totalled in excess of $2.3billion.

Although pesticides and veterinary medicines provide benefits to users, they can also be hazardous if manufactured or used incorrectly-potentially causing illness or death to humans or animals, or damage to crops and the environment. Also, high levels of chemical residues in food or livestock can jeopardise trade to export markets.

The National Registration Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia. It is a partnership between the Australian, State and Territory governments. Under the Scheme, APVMA is responsible, on behalf of the Australian Government, for: registering pesticides and veterinary medicines for use in Australia, having satisfied itself that such products are safe and effective for humans, animals, crops and the environment, and are not a trade risk; and assessing the ongoing quality of products following registration, and monitoring compliance with regulations on the importation, manufacture, supply and advertising of pesticides and veterinary medicines, up to the point of retail sale.

State and Territory governments are responsible for controlling the use of registered products, following retail sale. Policy on the management of pesticides and veterinary medicines is formally determined by the Primary Industries Ministerial Council.

The APVMA's principal activity is the evaluation of applications to register pesticides and veterinary medicines for use in Australia. These are required to be processed within statutory timeframes. The APVMA also conducts various activities to monitor product quality and compliance. These include a licensing scheme for manufacturers of veterinary medicines, and a program to review whether products registered in previous years meet contemporary standards of safety and efficacy. In delivering its regulatory functions, the APVMA obtains scientific advice and services from external providers, mainly Australian and State government departments.

The APVMA operates on a cost recovery basis. Its principal source of revenue is a levy on the sale of pesticides and veterinary medicines, which it collects annually from registrants. In

2005–06, the APVMA collected revenue of $24.3 million, and incurred expenses of $21.2 million.

The APVMA assesses Agvet chemical products and decides on their subsequent registration. Its assessment covers risks to health, environment and trade, and reviews product efficacy. The APVMA combines risk assessment with risk management and standard setting. The effectiveness of the Agvet arrangements is enhanced by state and territory implementation via the template Agvet Code and their commitment to the National Registration Scheme. However, the states and territories can also have their own control-of-use regulations.

Manufacturers incur significant costs in having chemicals assessed by the APVMA. The costs include the expensive data requirements (which often duplicate international assessments), delays and the risk averse approach adopted by the APMVA. The small size of the Australian market restricts the ability of manufacturers to recoup these costs. Accordingly, some international companies claim the high cost of registration discourages the introduction of new chemicals that may be more beneficial to industry and the environment.

The Productivity Commission recommended that delays and data costs of assessments could be reduced through the greater recognition of appropriate overseas schemes, and more extensive utilisation of international data and modelling tools. The APVMA is explicitly required by its legislation to manage risk within a cost-benefit framework but routinely rejects overseas research used to support registration in other comparable jurisdictions.

The procedures for assessing and registering low regulatory concern chemicals has been claimed to be inefficient. They are time consuming and demanding and, as a result, the Agvet sector is reluctant to introduce some chemicals, despite their potential benefits.

The APVMA sets maximum chemical residue limits (MRLs) in food (taking into account dietary impacts) as a way of monitoring good agricultural practice. It also makes a recommendation to Food Standards Australia New Zealand (FSANZ), which undertakes its own processes before incorporating an MRL in the Food Standards Code (for health reasons). This takes more than a year or more to occur, leaving farmers faced with the dilemma of being able to use the Agvet chemical concerned, but not being legally able to sell the relevant produce during this time.

HOIG submits trade and efficacy must remain mandatory considerations for products used in all trade exposed industries. The requirement to consider efficacy is critical to ensure that only chemicals which are fit for purpose are registered, which in turn will reduce chemical content in food production processes and reduce the risk of unacceptable residues.

Bills to be amended

The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill) amends the Agricultural and Veterinary Chemicals Act 1994 (Agvet Act), Agricultural and Veterinary Chemicals (Administration) Act 1992 (Admin Act), the Agricultural and Veterinary Chemicals Code Act 1994 (Code Act) and the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 (Collection Act).

Comments on the Amendment Bill

To assist the committee in its deliberations HOIG has taken the comments from the overview of amendments in the explanatory memorandum and added its submission under each relevant heading.

Overview of amendments

Approvals, registrations, permits and licences

Simplification, reorganisation and modernisation of the Agvet Code

The Bill simplifies, reorganises and modernises the Agvet Code to reduce uncertainty and complexity in the legislation, and improve the operation and understanding of the legislation. The Bill also includes other amendments to remove redundant provisions and amend out of date provisions in all Commonwealth agricultural and veterinary chemical legislation.

The existing Agvet Code largely reflects legislative drafting standards of the early 1990s. These revisions bring these areas of the Agvet Code up to contemporary standards for legislative drafting. The improvements in comprehension and utility delivered by these changes are significant, with benefits particularly for improved efficiency in complying with and administering the Agvet Code.

Some highlights of this are revision of the explanation sections; consolidation of existing 'legislative tests' for approval and registration, variation, reconsideration and elsewhere into four 'meets the X criteria' tests; a single set of general provisions relating to all applications except those for licences and consolidated notice provisions. The Bill also substantially simplifies provisions around 'interested persons' and 'approved persons' to address some inconsistencies in the Agvet Code.

The Bill also simplifies provisions related to listed registration, 'mainstreaming' these registrations with other registrations of chemical products and approvals of labels, but with simpler criteria for registration.

HOIG response: Supported with reservations

HOIG welcomes the government decision to streamline the operation of the APVMA's assessments. This includes restricting the information that the APVMA can take into account when considering an application. Restricting the amount of information that the APVMA can consider prevents applicants constantly seeking to provide additional information and data to support an application and delaying assessment processes.

This highlights how essential it is for the APVMA to clearly specify what information will be required in advance of these provisions commencing. Sufficiently detailed information on necessary requirements for the full scope of potential applications will be essential.

Despite these measures, it is unlikely that the APVMA will be able to prepare guidelines that cover every potential application that it might receive. An appropriate level of flexibility will be essential to ensuring that the application process is capable of accommodating innovative new products.

HOIG considers it will be difficult for the APVMA to anticipate the sort of information and data that it may need to adequately assess a particularly innovative new active constituent. In these circumstances, a more collaborative approach may need to be adopted by both the APVMA and the applicant.

Without this additional flexibility, the APVMA may be restricted to applying an inappropriate risk assessment model that is unsuited to the innovative new product, resulting in a risk assessment outcome that is not ideal. The Government may wish to consider, at least for more complex application categories (such as for a new active constituent), whether greater flexibility in the information that the APVMA can take into account will result in better risk assessment outcomes.

HOIG commends the government on the proposed regulations under this Act that would specify the time period under which the APVMA must make a determination about a particular application. The special arrangements for global joint reviews and 'time shift' applications have been developed.

The APVMA must continue to be able to accept scientific argument to address a particular concern.

HOIG stresses that for complex application categories, flexibility in information that the APVMA can take into account is essential and necessary.

HOIG is concerned about the meaning in Section 1A of the intent to base decisions on 'relevant science'. It is considered to be another ambiguous term which might allow the APVMA to apply an interpretation inconsistent with industry best practice risk assessment processes.

HOIG is further concerned that the code will be implemented in a manner that reflects 'contemporary principles' based on 'relevant science'. What does 'contemporary principles' mean and what are they? Surely they have to be spelt out and then a process agreed on as to how to manage their impact on the Code.

HOIG cannot support the reference to 'unmanageable risks'. If that is the case then surely the product cannot be registered.

The meaning of the phrase 'undue hazard' is unclear and imprecise and perhaps should be reviewed.

Enhanced consistency and transparency of assessments

The Bill includes amendments that improve the efficiency and effectiveness of Agvet chemical regulation through increased transparency and predictability of decision-making. The amendments provide for the APVMA to make, publish and have regard to guidelines. These are to form part of an overarching risk-based compendium that would be developed, maintained and published by the APVMA. The compendium will improve transparency by detailing all relevant guidelines, standards and methods which would guide regulatory decisions.

The compendium assists in communicating the APVMA's acceptable level of risk and regulatory posture in regulating agricultural and veterinary chemicals. The compendium also allows the APVMA and its regulatory partners to determine the scale of an assessment appropriate to the decision by better matching regulatory effort to risk. Providing a comprehensive reference to the risk assessment process improves the predictability of regulatory decisions, and therefore increases certainty and consistency for applicants and the community.

HOIG response: Supported

HOIG agrees with the amendments to enable the APVMA to make guidelines. Effective, comprehensive guidelines are essential to providing certainty to applicants about the way

their application will be treated. While the current Manual of Requirements and Guidelines is useful, it is not specific nor detailed enough to effectively operate as a sufficient guide. APVMA guidelines must also apply to risk assessment advice sought from external agencies.

The behaviour of external agencies who unilaterally revise requirements without adequate consultation with affected stakeholders is unacceptable.

Improving assessment efficiency and effectiveness

The Bill also includes amendments to address concerns about the time taken by the APVMA to complete applications and reconsiderations. The current assessment timeframes do not take into account the total time elapsed for considering an application or finalising a reconsideration (known as chemical review). This does not provide for certainty and predictability in assessment timeframes for applicants or the APVMA. In addition, applicants may provide data for the APVMA's consideration at any time. These existing arrangements unnecessarily frustrate the finalisation of assessments for applications and reconsiderations.

The amendments require the APVMA to refuse inferior or deficient applications so that it only needs to assess applications that are of the required standard. The reforms also introduce timeframes for assessments that include the total time elapsed, including the time taken to provide more information. This increases certainty around when applications will be finalised.

The reforms introduce timeframes for reconsiderations (also known to the community as chemical reviews). Along with other reforms to reconsiderations, this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes.

The reforms would ensure that there is no undue impediment to the use of overseas data and assessments by the APVMA, where conducted by comparable agencies and while recognising differences in national approaches. The reforms enable the APVMA to require electronic communication between it and applicants. This electronic communication would also streamline the APVMA's internal administrative processes.

HOIG response: Supported with reservations
HOIG welcomes measures that allow the APVMA to better manage application processes. However, amendments that penalise applicants, approval holders and registrants for APVMA failures are not supported.

HOIG is concerned with sub-section 29E (3) if the APVMA is not able to complete a preliminary assessment within two months, the application must be refused. This would be an undesirable interpretation. Where the APVMA is not able to meet its obligations under sub-section 29E (1), applicants should not be disadvantaged through an unfair and inappropriate refusal of an application.

HOIG supports measures to allow applicants, approval holders and registrants to give information to the APVMA electronically. This has the capacity to minimise the cost to the APVMA in handling information. The reduction in storage costs for hard copy material should be of benefit to the APVMA.

The amendments that will see the APVMA, where appropriate, adopt decisions and evaluations made by overseas regulators are supported by HOIG. It would be of assistance to industry for the APVMA to advise which overseas regulators it believes has a compatible regulatory regime.

HOIG welcomes the prospect of the APVMA setting timeframes for considering establishing work plans for finalising reconsiderations. Reconsiderations that take a long time to finalise should not result in the cancellation of the products. Products must be reconsidered on the basis of can they be used safely and sustainably.

HOIG believes that approval holders and registrants of active constituents and products under reconsideration should be required to declare their intention within a prescribed time limit to support their product or not. Unless this occurs delays will continue in the reconsideration process. Approval holders and registrants that do not wish to participate in any information and data generation would then have their approvals and registrations cancelled, allowing for a recall of the product.

Data collection is often a particularly time consuming process. In some circumstances longitudinal residue and/or efficacy data can be required to satisfy the APVMA that a particular active constituent or product meets safety criteria. The APVMA must retain the power to extend the timelines to conclude evaluations.

Schedule II Re-approval and re-registration

Australia currently has no requirement for existing agricultural and veterinary chemicals to be regularly reviewed. Australia has an ad hoc reconsideration system whereby chemicals of concern are brought to the regulator's attention by the community, by industry itself or on the regulator's own initiative. This existing approach is not consistent with international best practice.

Consistent with international practice and coupled with Commonwealth funding to mitigate start-up costs, the Bill provides for a mandatory scheme for re-approval and re-registration. Re-approval and re-registration will increase the scrutiny of chemical constituents and products through a scheme that minimises impacts on industry. The scheme provides a greater level of assurance that existing chemicals and products do not pose an undue risk to human health or the environment, and further promotes public confidence in Agvet chemical regulation.

HOIG response: Opposed

HOIG recommends that a rigorous and independent cost-benefit analysis be carried out on this proposal before it is implemented. After HOIG's experiences with the APVMA and fenthion it is nervous that introducing a scheme to re-approve active constituents and re-register products builds another layer of bureaucracy without providing any meaningful improvement in human health, safety or environmental protection.

While HOIG understands that introduction of a re-approval and re-registration scheme was part of a commitment given by the government prior to the 2010 election, it is our belief that this commitment has resulted in poor policy. The need for a re-approval and re-registration scheme stems from an assumption that the APVMA is currently not properly managing the existing chemical product portfolio.

HOIG understands that the Department of Agricultural Food and Forestry (DAFF) is proposing to place the burden of proof for a re-approval or re-registration on the presence of adverse outcomes. This is would be welcomed by HOIG after its dealings with the APVMA on fenthion. Clearly if there is evidence of problems with product safety and/or environmental impact of old products it is necessary and reasonable that they be withdrawn. There are many old products that are used in combinations, and in rotations with new products that are important to productivity and managing biosecurity, food security and animal health and welfare.

HOIG's major objection to the amendment concerns the proposed re-approval and re-registration of generic medicines and chemicals for which patents have expired. In these cases no individual company will have sufficient financial incentive to carry out necessary studies to collect data for re-registration, which is likely to cause considerable damage to many agricultural industries.

HOIG is aware of a number of reviews that have identified excessive delays under the APVMA's existing chemical review program. Creating an additional bureaucratic process to select, guide and add additional chemical products to the existing review priority list will not address concerns about the time taken to complete reconsideration. The measures proposed in the Amendment Bill appear not to target the central problems associated with the current chemical review program – why reviews are excessively delayed. Instead, an additional tier of bureaucratic work is created and there is likely to be less capacity for the APVMA to deliver timely, professional chemical reviews given the enormous number of registered chemical constituents that would fall under this re-registration provision.

HOIG supports measures to provide for notice - both publicly and to registrants and approval holders - that the end of an active constituent approval or end of a product registration is approaching. This process will allow all parties to consider seeking re-approval or re-registration, or to invest in the development and approval of alternatives.

A comprehensive risk framework describing the criteria through which active constituents and products would be assessed is essential. This is particularly the case when the new Section 1A introduces novel, undefined, vague and imprecise concepts such as 'contemporary principles', 'relevant science' and 'unmanageable risks'. Approval holders and registrants require certainty about the standards against which their active constituents and products will be assessed.

The costs of a re-approval and re-registration mandatory scheme are estimated to be approximately $2 million each year to administer. This figure does not include the costs to applicants which would at least be similar to the APVMA's costs. The question to warrant consideration is will the community see an improvement in health, safety or environmental benefits that make this expenditure worthwhile. There appears little evidence to suggest that this will be the reality.

The new administrative functions will create an additional workload for the APVMA and may distract it from its core functions.

Schedule III Enforcement

The APVMA currently lacks a modern graduated compliance regime. The current legislation provides no intermediate measures between the extremes of warning letters and criminal prosecution. In addition, some provisions limit the APVMA's ability to respond when new information becomes available during the course of an investigation.

The Bill modernises Agvet chemical regulation by introducing provisions that allow for a graduated and contemporary approach to compliance and enforcement. These improve the ability of the APVMA to efficiently administer its regulatory decisions, and protect public health and safety and the environment. The measures are comparable to those available to other regulators under other Commonwealth laws.

HOIG response: Supported

HOIG supports the compliance measures proposed for the APVMA. Guaranteeing the APVMA has a wide ranging set of compliance procedures that permit proportionate responses to compliance issues is important.

An effective compliance regime must ensure that the APVMA is not excessively focused on technical compliance by registrants, but focused on compliance by the entire industry, including those seeking to avoid regulatory controls. Importantly, the APVMA should deploy its monitoring, compliance and enforcement resources in a manner that allows it to focus its resources on those individuals and organisations that present the greatest risk.

Controlling and monitoring Australia's agricultural chemical industry is an administratively complex task for the APVMA. Penalties imposed must reflect the risk of harm that results from any breach.

HOIG supports the APVMA having adequate compliance powers. Compliance effort and resources should be focused on individuals and organisations that seek to avoid regulatory scrutiny by deliberately avoiding compliance with the Agvet Code. Attention should be focused on those that seek to import and supply products directly, avoiding registration requirements.

HOIG backs the APVMA having all necessary powers to properly manage the agricultural chemical range of products. HOIG accepts that the APVMA has to be able to suspend or cancel a product in circumstances where there is an imminent risk of death, serious injury or illness, or intentionally providing false or misleading information to the APVMA.

HOIG believes that there should be a stricter compliance regime. The APVMA may suspend or cancel a product because of use practices that may be permitted by state and territory use regulations, but not assessed by the APVMA at registration. This potentiality poses significant risks to registrants. The APVMA has to work in closer contact with state instrumentalities and growers.

New offences and civil penalty provisions

The Bill includes a number of new offence provisions. The new offences either align with existing or previous offences or are consistent with A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers (published by the Attorney-General's Department) (the Guide) and include:

- *offences (30 penalty units) for not complying with the directions of APVMA inspectors, which align with the 30 penalty unit offence in the previous section 131 of the Agvet Code (sections 69EAC, 69EBA and 69EBC of the Admin Act and sections 131A, 132A and 132C of the Agvet Code)*
- *offences (30 penalty units) for not complying with a notice to produce or attend (section 130B)*
- *new offences (30 penalty units) for failing to provide assistance to APVMA inspectors (section 69EFA of the Admin Act and section 138D of the Agvet Code)*
- *offences for not complying with enforceable directions (section 145H of the Agvet Code (30 or 120 penalty units) consistent with the 30 penalty unit offence in the previous section 131*
- *offences (50 penalty units) for not complying with substantiation notices (sections 69ENB of the Admin Act and section 145GB of the Agvet Code), which is consistent with existing and previous penalties in Agvet chemical legislation*
- *offences (50 penalty units) for not complying with a requirement to answer questions or produce documents to an APVMA inspector executing a warrant (sections 69EAH and 69EC of the Admin Act and sections 131F and 132G of the Agvet Code), which is consistent with other penalties in Agvet chemical legislation*

The offence in section 99 has been amended to address an inconsistency and provide that this section applies in relation to active constituents as well as to chemical products, with no change in the penalty amount. A new offence has also been included in section 116 to deal with non-compliance with permit conditions with a penalty that is consistent with other offences in the Agvet Code that deal with non-compliance with conditions. New offences have also been included in sections 143D of the Agvet Code and section 69EHD of the Admin Act, which apply to APVMA inspectors and warrants.

The Bill also provides for existing offence provisions to also be civil penalty provisions, and to allow the APVMA to apply to the court for a civil penalty order against a person who has contravened a civil penalty provision. The financial disincentives to misconduct provided by civil penalties are a more proportionate and effective enforcement tool, reflecting the practice of other areas of (particularly, corporate) regulation under Commonwealth legislation.
A number of current offences in Agvet chemical legislation place an evidential or legal burden on a defendant in certain circumstances. The new civil penalty provisions within the Bill place the same evidential or legal burden on a defendant in the same circumstances as the existing offences. With two exceptions, the amendments in the Bill ensure minimal changes to existing offences so as not to disturb the existing provisions dealing with the evidential burden and legal burden. The exceptions are new section 45C of the Agvet Code (Schedule 3 of the Bill) and to a lesser degree new section 47E (Schedule 2 of the Bill).

Section 47E mirrors old section 54. New section 47E contains the same defence as in old section 54 with the same evidential burden for the defence. The old (pre-amendment) sections 45A and 55 have been amalgamated into new sections 45A, 45B and 45C. Just as is provided for in old sections 45A and 55, new section 45C provides for a strict liability offence for possessing, having custody of, or other dealing with a suspended active constituent or chemical product in contravention of the instructions in the notices provided to persons or notices which have been published. The defences in the old subsections 55(5) and (6) have been retained as subsections 45C(3) and (4). The defence and the reversal of the onus of proof in subsection 45C(4) mirrors the current defence and onus of proof in old subsection 55(6).

The approach of aligning the defences and burdens of proof in the new provisions with those in the old provisions results in the least impact on all parties to which the old and new offence provisions relate (see the Statement of Compatibility with Human Rights below for more detail on this measure).

HOIG response: Supported
The new offences which appear to be as a result of not complying with directions, notices, failing to provide assistance to APVMA inspectors, not complying with enforceable directions and not complying with the requirement to answer questions or produce documents when an APVMA inspector is executing a warrant are in general terms acceptable to HOIG. The circumstances and nature of the dangers that might face the community in rare cases probably justify these powers.

HOIG as a general principle does not oppose the use of civil penalties. A financial penalty imposed by a government agency as restitution for misconduct is not new. A civil fine is not considered to be a criminal punishment.

Providing for civil penalty, increasing the penalties and providing for new offences should not be a method to increase revenue to the APMVA but a deterrent for non-compliance.

The defence and the reversal of the onus of proof in subsection 45C(4) mirrors the current defence and onus of proof in old subsection 55(6).

There are numerous examples in law where Australian Governments have reversed the onus of proof. Some argue this reveals the government's preparedness to ignore basic legal rights. This is not a theme central to our submission but an issue that should never be overlooked. The fact that it exists in current legislation does not sanctify its existence in the Amendment Bill.

HOIG supports the general Common Law view that the onus of proof should be on the authority making the accusation. Reversing the onus of proof could provide the APVMA with an unfair level of power because the innocent accused is compelled to prove a negative.

HOIG is aware of the removal of offences relating to counterfeit activities. These offences are now covered by the revised definitions of '*registered chemical product'* and *'approved active constituent'* in sub-section 3(1) of the Agvet Code. Nevertheless, it will still be important to send a strong signal that counterfeit products remain illegal in Australia.

Penalty increases

The penalties for some offences have been increased in the Admin Act (sections 69E, 69EA and 69EP), the Collection Act (sections 15, 20 and 36) and the Agvet Code (sections 88, 89 and 170A) to ensure that the penalty remains proportionate to the potential gain from non-compliance and to align with the penalties for other similar offences. The penalties for these offences have been increased from either 20 or 30 penalty units to 50 penalty units.

HOIG response: Supported
HOIG supports the aim of encouraging compliance with the Act and of properly penalising those who offend. Increasing the monetary penalty should not be an alternative source of increased revenue to the APMVA.

Abrogation of privilege against self-incrimination for certain notices

Consistent with the Guide, the Bill includes a new Division 2 in Part 9 that deals with notices requiring people to attend, give information and produce documents or things. This new division provides for the more efficient collation of information to provide a response that is complete and allows persons to consider their rights and obligations and seek appropriate legal advice before providing information, documents or answers to questions. The new division aligns with old section 144 but includes a new section 130C that abrogates the privilege against self-incrimination for the purposes of a notice under section 130 (see the Statement of Compatibility with Human Rights below for more detail on this measure).

HOIG response: Supported with reservations
HOIG supports measures that require approval holders and registrants to submit relevant information, reports, results and samples.

Currently, approval holders and registrants that choose not to participate in data generation activities suffer no penalty in relation to their approval or registration. In a situation where the APVMA requires trials or laboratory experiments all approval holders and registrants should be given a limited opportunity to indicate that they will participate in any data generation or trial program. Approval holders and registrants that do not indicate they wish to participate should have their registrations and approvals cancelled. This would share incentives and responsibilities across the industry.

While the new sub-section (5) will provide an incentive, ensuring that only those approval holders and registrants with a commitment to developing data should be allowed to maintain their approval or registration.

The Statement of Compatibility with Human Rights included with the memorandum says the Bill engages the following rights:

- *the right to health and a healthy environment (Article 12) in the International Covenant on Economic, Social and Cultural Rights (ICESCR)*
- *the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights (ICCPR)*
- *fair trial and fair hearing rights including the right to be free from self-incrimination and the right to the presumption of innocence in Article 14 of the ICCPR.*

Division 2 of Part 9 addresses this by requiring information, documents or things to be provided through notices that allow persons to prepare the information in a specified time or be accompanied by a lawyer, and by providing a use and derivative use immunity for those persons that provide the information, documents or things. The abrogation of the privilege against self-incrimination and the safeguards are considered reasonable, necessary and proportionate and are consistent with the legitimate objective of ensuring the regulator has complete information to enable it to protect human health and the environment. This approach is also consistent with the existing section 34 of the Collection Act in relation to giving information or producing a document under that Act and with Commonwealth therapeutic goods legislation. The memorandum concludes that the Bill is compatible with human rights to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate. In addition, the limitations on human rights have appropriate safeguards in place and are appropriate in the context of protecting the community and the environment from inappropriate agricultural and veterinary chemical products.

Bearing in mind the potential impacts that non-compliance with this Act could inflict on people, animals and the environment, HOIG supports the removal in certain instances of the right against self-incrimination, subject to determination by a judge/magistrate of the Federal Court.
The APVMA should not have the power or authority to decide such matters. Their purpose is to act as a regulator not as a court.

Suspension or cancellation to prevent imminent risk to persons of death, serious injury or serious illness

New sections 35A and 119A allow the APVMA to suspend or cancel, respectively, a registration or a permit where it considers this is necessary to prevent imminent risk to persons of death, serious injury or serious illness. The APVMA may exercise this authority whether or not the product is being used in accordance with its instructions for use or conditions of the permit.

This measure provides for the APVMA to only take action in those situations where action is strictly necessary to protect people. For example, where the APVMA needs to take action as part of a whole of government response to an emergency or major public health incident, where other agencies are taking commensurate and parallel action. There must be an imminent risk of death or serious illness or serious injury to a human that relates to use of a registered Agvet chemical product or to a permit. The imminent risk must be able to be addressed (even in part) by cancelling or suspending the registration or permit. Suspension or cancellation of the registration/permit must be necessary (and thus proportionate to the risk and the most appropriate course of action to take) to address the imminent risk.

HOIG response: Supported
HOIG supports the APVMA having all necessary powers to properly manage the agricultural chemical portfolio.

HOIG recognises the need for the APVMA to be able to suspend or cancel a product in circumstances where there is an **imminent risk of death, serious injury or illness,** or intentionally providing false or misleading information to the APVMA. This would not preclude the APVMA from taking other regulatory or compliance action, such as recalls or reconsidering an active constituent or product. In the case of fenthion, 50 years of use in orchards has not resulted in a reported case of harm to human health. As such, HOIG would oppose the use of sections 35A and 119A generally to justify suspension of chemicals that have a safe history of use.

Powers for persons assisting APVMA inspectors

Persons assisting can exercise powers while inspectors are exercising powers but they cannot exercise these powers once an APVMA inspector has completed the execution of the warrant. A guard can be placed to guard evidence but can only act in accordance with the directions of an inspector. However, other laws generally provide for police to attend premises to support APVMA inspectors. Police would act independently of APVMA inspectors and may choose to take action in respect to relevant Commonwealth, state or territory laws.

HOIG response: Opposed
HOIG is not convinced that this delegation is appropriate. The securing of evidence that is to be relied upon in any subsequent action is not a function that should be delegated to third parties. The securing of evidence or the performance of other functions should not be potentially compromised by the power for such a direction.

The APVMA Inspector's Procedural Manual (Compliance Monitoring and Surveillance) does not currently have this provision and HOIG questions whether there has been any requirement for the provision of such assistance.

Currently Inspectors are appointed under the provisions of section 69F (1) and (2) of the Admin Act and the Act distinguishes between Commonwealth and State/Territory department employees.

The APVMA may by writing appoint a member of its staff or a person employed under the Commonwealth Public Service Act 1922, or other persons having appropriate qualifications to be Inspectors for the purposes of a relevant law referred to in the document of appointment.

State and Territory employees are by signed writing authorised by the Chief Executive Officer of the APVMA to exercise the powers and perform the functions of Inspectors for the purposes of a particular relevant law.

An Inspector is a person appointed or authorised under one of the above sections.

HOIG believes that the current provisions provide adequate scope for the appointment of Inspectors and this extension of powers is unwarranted.

Costs of investigation

A new section 149A has been included to allow the APVMA to apply to a court to have a person pay certain costs incurred in investigation of the offence or civil penalty provision. While this provision is not consistent with the Guide, a provision to allow for offsetting costs in particular situations avoids inappropriate drains on the APVMA's resources (which are almost fully cost recovered from industry). The measure minimises the impact on compliant industry participants by providing for convicted industry participants to be responsible for

reasonable costs and expenses. Safeguards have been included by limiting a court order to reasonable costs and expenses that the court considers just and equitable.

HOIG response: Opposed
HOIG has referred to the Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers and has seen that the "Commonwealth has taken the view that in most circumstances that it is undesirable to include provision in Commonwealth legislation allowing for the recovery of investigation costs from a convicted defendant. Provisions allowing for recovery of investigation costs have been perceived as having the following drawbacks:

- they may lead to the unwanted precedent that acquitted defendants might seek or be awarded costs for criminal proceedings;
- the ability to recover investigation costs on conviction may distort investigation priorities; and
- there is potential for injustice to a poorer defendant, who may be more inclined to admit guilt rather than risk the prospect of having to pay investigation costs.

HOIG sees little justification to grant this additional punitive power. The safeguards mentioned in the explanatory memorandum seem minimal.

Any such recovery should be:

- subject to review, assessment or taxation by a court of the APMVA's claim for its costs of investigation; and
- limited to cases in which a contravention has been found by a court, a person has been convicted of a criminal offence or an admission of a breach has been sealed by the court.

Any costs orders, whether relating to legal, investigative or other costs, should be taken into account when assessing the level of penalty to be imposed.

Certainty, transparency and fairness require that costs sought by the APMVA in relation to an investigation fall within defined parameters.

The payments of monies to the APVMA may give rise to a perception of impropriety. Where the exercise of power by a regulator involves the acceptance of money from a member of the regulated community there is a specific need for transparency and accountability.

Infringement notices

Section 69EK of the Admin Act and section 145DA of the Agvet Code provide for infringement notices to be issued where there are reasonable grounds to believe a civil penalty provision has been contravened. Sections 69EKA and 145DB provide for a scale of infringement notice penalty amounts to apply for alleged contraventions and for this scale to be detailed in the regulations. While the provision for a scale of amounts is not consistent with the Guide, this scale is intended to provide for a proportionate response to contraventions based, for example, on the amount of substance concerned or the number of containers implicated in an alleged contravention. These provisions also specify that the infringement notice penalty must be less than one-fifth of the maximum that a court could impose, which provides a safeguard as to the maximum amount that could be imposed.

HOIG response: Supported
HOIG supports the new compliance and enforcement powers provided for in the Bill.

The APVMA will have the ability to issue the authorised domestic agent of an overseas company with an infringement notice. The agent may then be liable for paying any penalty specified in the infringement notice even when they may not have had any knowledge or control of the actions of the registrant or approval holder.

The government could consider cancelling or suspending the approval holder's registrations rather than imposing fines on their domestic agents. It could of course take both actions if the circumstances warranted.

Schedule IV Data protection

Data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. As investment in regulatory data can require significant resources and because the time taken to collect such data and have it assessed by the regulator diminishes its value, the protection of these data encourages innovation in agricultural and veterinary chemicals. In the case of new chemical products this means that the APVMA cannot rely on data it holds to register a product without the data owner's permission and before the protection period has elapsed.

The current data protection provisions are overly complex and do not provide meaningful access to data protection for information provided to a reconsideration. By enhancing data protection provisions, the Bill removes disincentives to invest in innovative product development and to improve the productivity of Australia's agri-food industries.

The Bill includes amendments to improve data protection provisions by making them simpler and more consistent, and therefore easier for industry and the APVMA to interpret and for the APVMA to administer. The reforms also reduce the disincentives to generating and providing data by extending data protection eligibility to a greater range of data. In the case of reconsiderations, some amendments have been made to improve the system whereby the data owners and other registrants can share the costs of any data required.

The Bill includes amendments to improve the mechanism by which data owners can obtain compensation for information submitted in relation to a reconsideration. These reforms would more closely align the data protection for new products and reconsiderations, and reduce the disincentive to providing data as part of these reconsiderations.

HOIG response: Supported

HOIG is of the view that any data submitted to the APVMA as part of reconsideration should be protected. Better protection for information and data submitted under reconsideration should be confirmed through the protection period and should start when the APVMA makes a decision to affirm the approval or registration of an active constituent or product under review. The protection period should run for 10 years as is the case in Sections 10 and 27 for information presented to the APVMA.

HOIG supports the amendments to Division 4A that allows information presented to the APVMA in connection with an application under Sections 10, 27 or 161 to be protected in accordance with the provisions of this Division. HOIG also supports that this Division will operate even if an application is denied; information is protected unless it is also subject to one of the exemption categories specified in the proposed new Section 34J.

HOIG is concerned by sub-section 29E (3) which states that if the APVMA is not able to complete a preliminary assessment within two months, the application must be refused. The treatment of any commercially sensitive data that may be submitted with a re-approval or re-registration application that is refused under these circumstances must be protected.

Levy collection

The Bill amends the current levy collection provisions to allow alternative arrangements to be implemented. The APVMA is one of a number of Australian Government regulators funded by fees, charges and levies imposed on the industry it regulates. Chemical companies pay fees for the APVMA to, for example, evaluate product registration proposals and pay a levy based on the value of wholesale sales of chemical products.

Amendments in the Bill provide for any Commonwealth agency to be able to issue notices regarding levy assessments and receive levy payments, should it be cost effective to do so. Such a change would allow the government to respond to perceptions of a conflict of interest arising from the current arrangements for collection of this levy. No change to the levy structure or rate is proposed by the Bill.

HOIG response: Supported
HOIG supports the most efficient and effective administrative arrangements for collecting the sales levy.

Schedule V Retrospective application

Schedule 5 includes provisions that validate past actions in relation to signing notices of assessment for levies payable under the Collection Act, that is, under subsection 16 (12). Together with a new section 38E, these provisions correct an anomaly in the Collection Act for delegations and provide for limited delegations that were understood to apply because of section 44 of the Admin Act (which provides that the Chief Executive Officer may delegate all or any of his or her powers). The new provisions specify that notices issued under the old law by purported delegates are valid and effective, irrespective of whether these notices were issued by a person with the authority to sign these notices. Further provisions have been included to ensure that rights and liabilities of parties are not affected where a court has heard and determined proceedings between parties.

HOIG response: Opposed
HOIG has the belief that in general, relief should be not be provided for breaches of provisions of the Act that may have already taken place. In other words, we generally do not agree with providing the power to grant retrospective relief. The amendment Bill is fixing poor administrative practices of the past.

The extent of the legitimacy of purported delegations power in relation to signing notices of assessment for levies is clearly a retrospective action designed to take away the consequences of past conduct by the APVMA and as a general rule this should not be allowed.

Relief may be considered in circumstances where:

- no mischief has yet occurred; and
- the regulatory detriment of the breach is minimal and clearly outweighed by the commercial benefit which would result from giving the proposed relief.

The paramount consideration in exercising such a power in these circumstances is whether anyone has already been adversely affected by the APMVA's previous breach; something that HOIG is not aware of.

Schedule VI Other amendments

Legislative instruments

The Bill also updates the Agvet Act and the Code Act to specifically provide for legislative instruments made under the Agvet Act or the Code Act, including orders, to remain subject to disallowance with two exceptions (Part 1 of Schedule 6). These provisions override subsection 44(1) of the Legislative Instruments Act 2003 which provides that the disallowance provisions don't apply if the enabling legislation for the instrument facilitates the establishment or operation of an intergovernmental body or scheme involving the Commonwealth and one or more States; and the enabling legislation authorises the instrument to be made by the body or for the purposes of the body or scheme (such as it does in this case).

All the legislative instruments are enabled by legislation which facilitate the establishment and operation of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), established in 1994 between the Commonwealth and the states, and which provides for the APVMA (a Commonwealth agency) to regulate chemicals on the states' behalf. The legislation exists for the NRS. This measure is intended to preserve Parliamentary oversight of legislative instruments made for the NRS.

HOIG response: Supported
The preservation of Parliamentary oversight of the NRS that is overseen by the APVMA is welcomed by HOIG but it is our contention that the Government and the Minister should have clearly defined powers of oversight because of the very significant impact APVMA decisions can have on Australian industry and the economy. The APVMA's narrow focus on reviewing and regulating chemicals without consideration of the broader implications of its actions demands that government assume greater oversight of its decisions.

Retrospective application

Schedule 6 includes provisions that deal with transitional, application and savings measures for amendments made by the Act. To ensure a comprehensive transitional approach can be adopted the Bill provides for regulations to take effect before they are registered and this may have some retrospective application of certain measures. A safeguard measure has been included to ensure that a court must not convict a person of an offence, or order the person to pay a pecuniary penalty, in relation to the conduct on the grounds that the person contravened a provision because of a retrospective effect of the regulations.

HOIG response: Opposed
HOIG believes good governance requires that legislation be prospective and cannot support this step. Transitional issues that are caused by timing can easily be resolved by delaying implementation.

HOIG is unconvinced as to why there is a need for haste in this particular matter. We are reminded of the words of Lord Chesterfield (Philip Dormer Stanhope, 4th Earl of Chesterfield) who said "Whoever is in hurry shows that the thing he is about is too big for him." HOIG hopes this is not the case.