

# HILLS ORCHARD IMPROVEMENT GROUP INC

## Submission 9 - Hills Orchard Improvement Group Inc - Regulator Engagement with Small Business – Commissioned study

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## Terms of reference

I, David Bradbury, Assistant Treasurer, pursuant to Parts 2 and 4 of the *Productivity Commission Act 1998* hereby request that the Productivity Commission undertake a research study to benchmark the extent to which the different approaches to regulator engagement with small business have the potential to affect the costs (including time and effort) incurred by these businesses. This request follows agreement by COAG's Business Regulation and Competition Working Group that the Productivity Commission undertake a study of this type.

Small business stakeholders consistently raise with Governments their view that compliance approaches and the regulatory posture adopted by regulators with respect to small business, and the degree to which regulators recognise and accommodate the particular circumstances of small business, can have a significant impact on regulatory burden.

Approaches to the regulation of small business can be wide ranging, with some regulators adopting a facilitative role, assisting small businesses to meet their compliance responsibilities, recognising that regulatory compliance activities impose a disproportionate cost on smaller firms. Other regulators adopt a more traditional compliance based regulatory posture.

In undertaking this study, the Productivity Commission is asked to:

- identify the nature of the regulatory posture of Commonwealth and state and territory regulators with respect to small business, including the extent to which facilitative and educative approaches are appropriately combined with compliance based approaches, and the extent to which approaches vary according to the nature and objectives of the regulations
- in doing so, the Commission should draw where appropriate on examples of the various approaches that are used in shaping regulatory culture (including by incorporating regulatory objectives into legislative instruments).
- identify the levels of assistance and education that jurisdictions provide to small business and consider whether this be better targeted
- identify the extent to which regulators apply a risk based approach to enforcement and compliance, including the mandating of information requirements, in regulating small business
- clarify the extent to which regulators consider the size and nature of a business when undertaking compliance and enforcement and compliance based information-gathering activities
- identify whether particular approaches to the exercise of regulatory roles have the capacity to reduce unnecessary compliance costs incurred by small business, while sustaining good regulatory outcomes, and could therefore be described as best practice
- have regard to leading practices in overseas jurisdictions.

In order to undertake this study, the Commission will also need to consider and determine a definition of what constitutes a small business, noting that different regulators and jurisdictions use different definitions. As a starting point, the Commission may wish to consider whether there would be benefit in broader adoption of the Australian Bureau of Statistics (ABS) definition of a small business to provide for ease of comparison with ABS data.

A report is to be completed within nine months of the receipt of this Terms of Reference. The Commission is to provide both a draft and final report, and the reports will be published.

**David Bradbury**  
**Assistant Treasurer**

## **Disclaimer**

The Hills Orchard Improvement Group Inc. (HOIG) has made every effort to ensure that the content of this document is correct in law. It shall not be liable to any person or entity in relation to any claim, action or proceeding whatsoever (whether in contract, negligence or other tort or in proceedings seeking any other form of legal or equitable remedy or relief) for any inadequacy, error or mistake or for any deficiency in the whole or any part of this document.

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 submission in good faith for the purpose of putting forward its views to the Productivity Commission to assist it with its enquiry "Regulator Engagement with Small Business".

## **Executive summary**

The Hills Orchard Improvement Group Inc. (HOIG) was formed in 1982 and 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. HOIG is not a peak industry body or a lobbying organisation for the stonefruit industry. Its members aim to produce high standard horticultural crops that are pest and disease free. HOIG members are classic representatives of small business operators in the horticulture industry. They typically run and own orchards of about 20ha, grow mixed stonefruit and pome crops. Orchards are run by a family or group of families who in many cases have farmed the property for three and four generations.

This Productivity Commission enquiry into the approaches taken by regulators to engage with small business and the resultant costs provides us with the opportunity to relate our experiences with the Australian Pesticides and Veterinary Medicines Authority (APVMA) and hopefully give the Commission some insight into the impact that a regulator can have on small business.

Agricultural and veterinary (Agvet) chemicals are regulated by the APVMA, which conducts an independent assessment of agricultural and veterinary chemical products before registering them for use in Australia. A product is only registered if the APVMA is satisfied that all the risks to human health, worker safety, the environment and trade can be safely managed.

This assessment considers the hazards presented by the active ingredients contained within the product. Provided the hazards can be safely and effectively managed, agricultural chemicals may be registered and used in Australia. Instructions for use are developed to minimise risks and are included on product labels. The APVMA, with advice from the Federal Departments of Health and Ageing (DOHA) and Sustainability Environment, Water, Population and Communities (DSEWPaC) conducts professional risk assessments and approves product labels to ensure safety (including workplace user safety).

HOIG has not until recently seen any role for itself in lobbying government. However, it became gravely concerned about the APVMA's recommendation to ban the pesticide fenthion for use on some fruits and vegetables, including stonefruit.

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 APVMA announced just days before the 2012 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 stonefruits, apples and pears. HOIG predicted the total destruction of the stonefruit crop and the loss of 80 per cent of the apple crop in the south west of Western Australia should fenthion be banned.

Our growers would accept this decision if there was demonstrable harm from the use of fenthion on food crops. However, fenthion has been in use in horticulture for more than 50 years without evidence of harm to orchard workers or consumers. The APVMA acknowledges that the food supply in Australia, including fruit sprayed with fenthion, is safe.

Lobbying by HOIG convinced the APVMA to permit the continued use of fenthion on a restricted basis for one year. The current permit expires in October 2013, days before our next crop will be ready to pick.

There are 600 growers in Western Australia who would have been affected by the ban, not just HOIG members. As an example of regulator impact on small business, it doesn't get any worse than destroying an industry.

This experience led HOIG – a small grower organisation – to examine the record of the APVMA in dealing with other Agvet chemical-using industries. The APVMA has conducted similar reviews of registered chemicals with similar outcomes and has been widely criticised by industry for the uncertainty, cost and lack of timeliness in its discharge of its duties.

Industry peak bodies have given evidence to recent Senate and House of Representatives inquiries that the APVMA's regulatory approach has denied Australian producers access to the latest, most effective and least toxic Agvet chemicals, harming their competitiveness.

The potential economic cost of APVMA decisions which provide no demonstrable protection to health or the environment is clearly not well understood by government or, we believe, it would act to reform the agency.

On its current path, the APVMA is making regulatory decisions that could profoundly damage agriculture in Australia.

Growers faced with the loss of effective chemical tools and subsequent income loss will in the short term abstain from investment and pursuing innovations or creating new jobs, reducing production and profits. These effects have repercussions in the broader society in general, in the form of a net loss in primary production, closure of businesses, job losses, increased bankruptcies and people walking off their properties.

The longer term impact will be the loss of primary production land to other uses and increased reliance on food imports.

Government's policy objective of making Australia the food bowl of Asia is in direct conflict with the approach taken by the APVMA to regulating Agvet chemicals.

## 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 stonefruit 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.

This Productivity Commission enquiry into the approaches taken by regulators to engage with small business and the resultant costs provides us with the opportunity to relate our experiences with the Australian Pesticides and Veterinary Medicines Authority (APVMA) and hopefully gives the Commission some insight into the impact that a regulator can have on small business.

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This assessment considers the hazards presented by the active ingredients contained within the product. Provided the hazards can be safely and effectively managed, agricultural chemicals may be registered and used in Australia. Instructions for use are developed to minimise risks and are included on product labels. The APVMA, with advice from the Federal Departments of Health and Ageing (DOHA) and Sustainability Environment, Water, Population and Communities (DSEWPaC) conducts professional risk assessments and approves product labels to ensure safety (including workplace user safety).

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory authority within the portfolio of the Commonwealth Minister for Agriculture, Fisheries and Forestry.

It obtains policy direction from the Primary Industries Ministerial Council (PIMC), which is supported by the Primary Industries Standing Committee (PISC) and the Primary Industries Health Committee (PIHC). In turn, the PISC and PIHC obtain policy advice

from the Product Safety and Integrity Committee (PSIC), whose members include representatives from the:

- Commonwealth Government Department of Agriculture, Fisheries and Forestry (DAFF)
- Australian state and territory departments responsible for agriculture
- New Zealand Food Safety Authority
- CSIRO
- Environment Protection and Heritage Council
- Workplace Relations Ministerial Council and
- Australian Health Ministers' Advisory Council.

HOIG members typically run and own orchards of about 20ha, grow mixed stonefruit and pome crops. Orchards are run by a family or group of families who in many cases have farmed the property for three and in some cases four generations.

Although we acknowledge that the Assistant Treasurer has asked the Commission to consider and determine a definition for small business it is our opinion that members of HOIG are small business operators as defined by the The Australian Bureau of Statistics (ABS) which defines a small business as one that employs fewer than 20 people. This business will typically be independently owned and operated. The owner-managers who run the business will also tend to be the principal decision makers and will also contribute and own all or most of the firm's operating capital.

As small businesses, orchardists are vulnerable to the demands, vagaries, fads and whims of regulators. The implications of complying with regulatory demands are not limited to financial and time-consuming consequences, but extend to issues of business confidence, capital raising and continuation in the industry.

HOIG has not until recently seen any role for itself in lobbying government. However, it became gravely concerned about the APVMA's recommendation to ban the pesticide fenthion for use on some fruits and vegetables, including stonefruit.

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 use of fenthion in domestic gardens was banned 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 the 2012 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 stonefruits, apples and pears. HOIG predicted the total destruction of the stonefruit 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.

Lobbying by HOIG convinced the APVMA to permit the continued use of fenthion on a restricted basis for one year. The current permit expires in October 2013, days before our next crop will be ready to pick.



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. Underlying the threat to the industry, there is no scientific evidence that AWM will be as effective as fenthion. It is currently being trialled in conjunction with the restricted APVMA application rate but growers are highly sceptical of its effectiveness. There is growing anecdotal evidence that fruit fly numbers have increased markedly in the Hills this summer which we suspect is coming from untreated home garden fruit trees.

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; ergo it would be banned in Australia.

Pesticides are an integral tool in agriculture and their use into the future is necessary to underpin ongoing increases in productivity to enable farmers to feed the world.

Pesticide application is a complex process starting with product selection and an understanding of the target and best practice to accurately distribute the product. There are numerous variables which when well managed can greatly reduce the risk of drift and off-target contamination. This complex process requires a high level of knowledge and understanding, practical skills, well maintained and up to date equipment, and probably most importantly a desire or will to protect the environment and enable sustainable use of pesticides into the future.

While HOIG acknowledges that the APVMA has an important role to play in protecting public safety it maintains that a regulator has to base its decisions on evidence, experiences and testing and not on ideology, belief, dogma and assumption.

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 direction. However, once HOIG raised its concerns with the Minister, the Shadow Minister, members of the Senate 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 APVMA 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.

The Senate Standing Committee on Rural and Regional Affairs and Transport and the House of Representatives Standing Committee on Agriculture, Resources, Fisheries and Forestry have both conducted inquiries into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012. The Minority Reports in both cases said that the legislation failed to achieve the goal of streamlining regulation and should not be supported. HOIG supports the comments made by the Coalition minority reports' authors.

In support of our submission, HOIG recommends that the Commission review both inquiry minority reports and the evidence and submissions.

The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 introduces mandatory re-registration of existing chemicals. The APVMA expects this to increase registration costs by 30 per cent. The Bill was introduced with no cost benefit analysis undertaken as to the efficacy of the measure. Evidence to the Senate Committee on Regional and Rural Affairs and Transport by Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, (Committee Hansard, 4 February 2013) was that "it currently costs the same real dollar amount to register a crop protection product in Australia as it does in the United States, but the Australian market is one-tenth the size of the market in America." This measure will make it more costly to register a chemical in Australia than in the US.

HOIG understands that one of the key factors underpinning Australia's competitive success internationally is the effectiveness of its domestic regulatory structures. Good

regulation can enhance Australia's ability to compete and prosper economically; conversely inappropriate or costly regulation will handicap our performance.

Like many other developed countries, Australia has undergone a relatively rapid rise in regulation over the past couple of decades, in response to a succession of social, environmental and economic needs and pressures.

HOIG believes small business is justified in protesting at the compliance cost and other burdens that this regulatory inflation has entailed.

Regulatory burdens have fallen disproportionately on the economy's many small businesses, which lack the resources to deal with them or to defend themselves from the excesses that can arise.

Shaping regulation to limit the impact on small business and keeping regulatory costs down generally are essential if employment and economic growth are to continue.

Just as regulation naturally develops in response to society's needs, its excesses are largely driven by societal and political pressures. Key among these has been a growing and unsustainable aversion to risk, demanding a rethink about the role of regulation in modern society. Political leadership will be crucial to achieving a better understanding within the Australian community of the importance of a more balanced approach to regulation and to making the changes within government that are essential to a lasting improvement.

## **Diuron**

To assure the Commission that our concerns about the regulatory impact of the actions of the APVMA are not just related to the use of fenthion or to the relationship that exists between HOIG and the APVMA, we have included a short summary of how the APVMA reviewed the use of the crop herbicide diuron. HOIG makes no comment on the scientific background, medical or environmental reasons as to why diuron was assessed. It only wants to point out the approach and attitude of the APVMA to one of its main users, cane growers, in this instance.

Diuron is a long acting (residual) herbicide that has been registered in Australia for more than 20 years but has been manufactured since 1966. Diuron kills weeds by inhibiting the process of photosynthesis, the conversion of sunlight energy to growth. Diuron is absorbed by the plant via the root system. Most of the uses are in agriculture to control all types of weeds in sugarcane, cotton, broadacre crops (oats, wheat, and barley), citrus and some horticultural crops such as pineapples and bananas. It is also used to control weeds in irrigation channels and drainage ditches.

The APVMA Preliminary Review Findings Report identified that current uses of diuron posed risks to the environment. The findings of the Review that led to the APVMA's proposed ban on diuron were that:

- the toxic impurities in the active constituent diuron at the current very small concentration levels do not pose a risk to human health;
- there is a risk to the environment caused by diuron in water and soil run-off from use in sugarcane, cotton, citrus, horticultural crops and in irrigation channels and drainage ditches;
- the risk to the environment can be reduced by decreasing the environmental load (through reducing application of diuron); and
- product labels do not contain instructions for spray drift buffers.

In 2002, the APVMA began a review of diuron because of environmental and human health concerns, specifically regarding the potential for diuron to contaminate the marine environment through agricultural runoff.

In 2005 the APVMA released the Diuron Preliminary Review Findings Report. Following publication of the report, the APVMA received and assessed, through the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), a large body of new information.

In July 2011 the APVMA released the diuron environmental assessment report and the diuron human health assessment report.

In November 2011 the APVMA suspended the registration of selected diuron products while it considered additional information and submissions provided to the review. One hundred and thirteen submissions were received in response to the release of the 2011 environmental assessment report. A number contained new studies and information about the use and impacts of diuron. The submissions came from registrants, diuron chemical users, user groups, state governments and environmental groups.

In March 2012 the APVMA finalised the review for:

- active constituent approvals (approval of suppliers of diuron to product manufacturers);
- antifouling paints (continued registration with variations to two label instructions);
- pond and aquarium products (continued registration); and
- cotton defoliation products (continued registration after variations to label instructions).

At the same time, the APVMA continued the suspension of selected diuron products until 30 November 2012.

In September 2012 the APVMA published the final diuron environmental assessment report received from The Department of Sustainability, Environment, Water, Population and Communities and proposed to finalise the review based on the findings of this assessment. Diuron product registrants were asked to show cause as to why the review should not be finalised in the manner proposed.

Taking into consideration comments from registrants, the APVMA revised the review recommendations and completed the review of diuron on 29 November 2012. The outcomes included:

- cancellation of selected registrations;
- varied label approvals to specify amended instructions for use; and
- confirmation of affirmed product registrations and consequently cancellation of approvals of old labels.

Some uses are no longer approved, including industrial applications and use in non-agricultural situations, citrus, apples, pears, ornamentals and selected tropical crops (tea, coffee, and pawpaw). Other uses have been significantly restricted.

At the time the APVMA was making its decision it was not aware of any new products currently being registered for sugarcane.

The LNP Shadow Minister for Agriculture in 2012 Andrew Cripps challenged the move by the APVMA to ban the use of Diuron saying: "Since the unexpected announcement, there has been some belated consultation with industry groups – but there is still enormous uncertainty facing the agricultural sector".

Mr Cripps said that if growers lost diuron, for which there was no effective replacement product, there would be significant economic losses, in the form of lost productivity and the higher costs of alternative weed control methods.

He said banning Diuron would actually have perverse environmental outcomes as its withdrawal would force farmers to control pest weeds with alternative products and farming practices.”

“The fact is, alternative products are not as effective as Diuron in managing broad leaf weeds and vines in cropping areas, and may have to be applied more frequently to achieve effective control,” Mr Cripps said. “Farmers could also be forced into mechanical control methods by cultivating soil more often than is currently necessary. This risks increasing sediment and chemical residue run-off into the aquatic ecosystems – the very thing the APVMA is supposedly concerned about. The voluntary efforts of farmers to reduce the amount of agricultural chemicals being used, such as Diuron, have once again been ignored.”

Like the proposed ban on fenthion, the APVMA’s initial assessment was that diuron would be banned for use on sugarcane. After concerted lobbying by cane growers, under the new diuron rules sugarcane and pineapple growers will be allowed to spray outside strict seasonal “no-spray” windows with lower spray rates.

### **Regulate – why and when**

It is important to recognise the forces behind the growth in regulation in Australia if we are to find sustainable solutions. Perhaps the primary force has been the changing needs and expectations of our society.

Some of this is a natural and desirable consequence of rising affluence and increased scientific knowledge. However, a more problematic influence has been the increasing ‘risk aversion’ intruding into many areas of our lives.

Regulation has come to be seen as a panacea for many of society’s ills and as a means of protecting people from inherent risks of daily life. Any adverse event, especially where it involves loss of life, possessions, amenity or money is laid at government’s door for a regulatory fix. The pressure on government to ‘do something’ is heightened by intense, if short-lived, media attention.

British Prime Minister Tony Blair perhaps best summed it up when he said (2005): *“In my view, we are in danger of having a wholly disproportionate attitude to the risks we should expect to see as a normal part of life. This is putting pressure on policy making [and] regulatory bodies ... to act to eliminate risk in a way that is out of all proportion to the potential damage. The result is a plethora of rules, guidelines, and responses to ‘scandals’ of one nature or another, that ends up having utterly perverse consequences”.*

In responding to such pressures, governments themselves are often attracted to regulatory solutions, both as a tangible demonstration of government concern and because the costs are typically ‘off-budget’, diffuse and hard to measure. Each regulatory solution tends to be devised within individual government agencies. With such isolated policy formulation, the cumulative impact of regulation across government is poorly understood and rarely taken into account.

A ‘regulate first, ask questions later’ culture appears to have developed. Even where regulatory action is clearly justified, options and design principles that could lessen compliance costs or side-effects are given little consideration. Further, agencies

responsible for administering and enforcing regulation have tended to adopt strict and often prescriptive or legalistic approaches, to lessen their own risks of exposure to criticism. This, in turn, has contributed in some areas to excessively defensive and costly actions by business to ensure compliance.

Quantifying the excessive burdens stemming from all regulation is difficult. However, even the more conservative estimates put gross compliance costs at tens of billions of dollars annually.

The costs of regulation to business involve not just extra time, paperwork and capital outlays, but also diverts management from the core activities of the business. The impact is even greater for small businesses, which generally do not have the in-house capacity to deal with and keep abreast of the regulatory quagmire. Regulation can stifle innovation and crowd out productive activity in Australia's economy. At the same time, it involves substantial government resources and thus significant burdens on taxpayers.

Regulation of chemicals and their usage in the horticultural industry has over time:

- expanded its area of coverage;
- witnessed regulation creep;
- created overlapping and inconsistent regulatory requirements across jurisdictions;
- seen regulation that is redundant or not justified by policy intent;
- given rise to unintended or perverse outcomes;
- allowed ineffective or unnecessary regulation to continue without regard to circumstances that have changed over time;
- imposed excessive reporting or recording burdens and information demands;
- duplicated regulatory burden across agencies; and
- developed variations in definitions and reporting requirements.

The Australian Government has put food regulation and chemical regulation in the production of food as a priority area for reform. Since 2003 there have been a number of reports and reviews concerning the APVMA which point to ongoing concern over the performance of the APVMA.

Good regulatory process requires governments to apply the following six principles (Report of the Taskforce on Reducing Regulatory Burdens on Business January 2006):

- Governments should not act to address 'problems' through regulation unless a case for action has been clearly established. This should include evaluating and explaining why existing measures are not sufficient to deal with the issue.
- A range of feasible policy options - including self-regulatory and co-regulatory approaches - need to be assessed within a cost-benefit framework (including analysis of compliance costs and, where relevant, risk).
- Only the option that generates the greatest net benefit for the community, taking into account all the impacts, should be adopted.
- Effective guidance should be provided to regulators and regulated parties to ensure that the policy intent of the regulation is clear, as well as what is needed to be compliant.
- Mechanisms such as sunset clauses or periodic reviews need to be built in to legislation to ensure that regulation remains relevant and effective over time.
- There needs to be effective consultation with regulated parties at the key stages of regulation-making and administration.

HOIG does not consider that the requirements for good regulatory process have generally been well discharged.

HOIG considers that the culture and behaviour of regulators compounds the problems they face with regulation itself. Regulators respond to the incentives in their operating environments and the APVMA has tended to promote unduly risk-averse approaches without regard to cost-benefit analysis. Changes are required to promote a more balanced approach. There is also scope to improve the way regulators interact and consult with growers.

Regulators need clearer guidance about the policy intent behind regulation, including in enabling legislation. Regulated entities should also have timely access to internal and third-party review on the merits of key decisions.

### **Over regulated?**

The chemicals and plastics sector is regulated by a complex web of legislation. It is estimated that there are 144 pieces of Commonwealth, state and territory legislation governing the sector. The purpose of regulation is to ensure an appropriate balance between the benefits to society, such as increased agricultural and industrial productivity, and the risks to human health and the environment associated with exposure to potentially harmful substances.

The three main Australian Government regulatory agencies are the Therapeutic Goods Administration (TGA); the National Industrial Chemicals Notification and Assessment Scheme (NICNAS); and the Australian Pesticides and Veterinary Medicines Authority (APVMA). Other relevant national regulators include the Australian Safety and Compensation Council; Foods Standards Australia New Zealand; the Australian Consumer and Competition Commission; the Australian Quarantine Inspection Service; the Australian Customs Service; and the Australian Security Intelligence Organisation.

In each area of regulation, state and territory governments have their own arrangements for regulation, administration, policy development and enforcement. Local government authorities carry some enforcement responsibilities for jurisdictional legislation. They also exercise some planning approval powers potentially affecting chemical facilities or small businesses using chemicals.

Industry has for a number of years raised its concerns about the need for the APVMA, TGA, NICNAS and the Australian Government DSeWPAC to streamline their assessment processes and data requirements so that relevant information can be more freely exchanged between regulatory agencies, hence reducing the reporting and cost burden on industry seeking approval for the same chemical for different purposes from different regulatory agencies.

Given that Australia is a small player in the chemicals world (representing less than one per cent of global production), it is important that regulatory reform in Australia is aligned to the maximum extent possible with international standards, and that the opportunity is taken to draw on testing and research undertaken in other countries in relation to chemicals safety and use.

The sector also claims that many of the requirements for labelling agricultural and veterinary products exceed those of over-the-counter medicines administered by the TGA. Stakeholder feedback to APVMA on the issue of packaging and labelling led to duplication of regulation across the supply chain and work by the Product Safety Integrity Committee on the scope of products regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Industry feedback to the CPLG indicates that, despite its similar intent, experience with the equivalent APVMA LRCC reforms is that these have failed to deliver on the promise of cutting red-tape. The APVMA process can be more complex (and potentially more costly) for companies than simply continuing to meet the requirements associated with normal product registration.

## **Food security**

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 supply 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. 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.

As an industry, we recommend that 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 maximum residue level for fenthion of .2mg/kg seven days after harvest is based on a mathematical formula that predicts should a child aged two to six eat approximately 900gm of sprayed peaches in one sitting there is a risk that he/she may be exposed to a level of residue that constitutes an acute dietary exposure. The safety margin built in to this level of .2mg/kg is a factor of 10 and this potential risk of acute dietary exposure does not apply to any other age group. Fruit sold in shops throughout Australia over the past 50 years has been eaten by children with no recorded ill effects.

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 stonefruit 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.

### **Efforts to improve the efficiency of the APVMA**

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.

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.

The Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) is the primary Act regulating agricultural chemicals in Australia.

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, who's 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.

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, domestic 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 from 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 imposed by the APVMA 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. 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, 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.

Industry comments about the APVMA in a variety of studies suggest that the APVMA is not as clearly focused on the objective of net community benefit as it might be.

HOIG is of the view that there should be a formal obligation on the APVMA to set its assessment requirements to be commensurate with the risks and to appropriately direct its assessment and regulatory effort to managing risks in the most effective way.

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.

### **Predictions about the impacts of reduced pesticide use**

Legislation before the Federal Parliament will require the re-registration of all currently registered Agvet chemicals. In other jurisdictions where this policy has been adopted, numerous chemicals have been removed from the market not for safety reasons but because their manufacturers wouldn't undertake the cost of registration for old products.

In evidence to the Senate Rural and Regional Affairs and Transport Legislation Committee inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 the National Farmers Federation advised that in the EU approximately half the products ended up off the market through the re-registration process. This is likely to be more common in Australia because the size of the market does not justify the substantial cost of re-registering products that are out of patent or that have been superseded by newer, more expensive chemicals. The impact on the competitiveness of Australian farming will be serious.

Any reduction in the use of pesticides without suitable alternatives is likely to create economic risks resulting in reduced food production, higher production costs, increased food prices and higher levels of poor nutrition. While developed economies may choose to accept such impacts, as is arguably the case for certain interest groups in Australia, there are adverse consequences for the poor and globally for food security. The unintended economic and nutritional consequences of banning pesticides or allowing their registration to lapse receives little or no consideration in the current Australian regulatory strategy and debate.

When the use of pesticides is reduced or removed then both yields and costs of production decline but they do not decline at similar rates. Yields decline to a greater extent than costs and therefore the unit costs of production rise.

HOIG believes that there is a significant difference when we talk about a percentage reduction in yield and percentage change in production. While you may still get a crop without pesticide cover it may not be financially viable to continue trying.

Pesticide use reduction scenarios would in our opinion result in:

- the broader the group of pesticides eliminated the greater the yield impacts;
- fruit and vegetable are more likely to be adversely affected by a broad based reduction in pesticides than in broadacre crops;
- there would be substantial variability among the crops; and
- livestock, poultry, and dairy producers' net income would decline with higher feed prices.

There is likely to be negative economic effects on Australian consumers in terms of higher prices, which we predict will be substantial.

HOIG also believes that as supply is restricted demand will remain the same and prices will rise. This price increase will offset a portion of the loss of income from yield reduction. But as prices rise and demand is not being met, overseas products will fill the vacuum on the supply side. Overseas produce, which in some cases will have lower or no pesticide regulation, will be eaten by Australians.

The relative magnitude of yield and cost changes across crops will influence not only what crops will be grown but where they will be grown. HOIG members in the Perth Hills where fruit fly infestation is well documented are likely to have severe impacts on soft skinned stonefruit production. Citrus, pome and other stonefruit production is likely to be reduced.

The capability of farmers and growers to adjust their production between commodities when relative prices and profitability are changing as a result of pesticide availability and pest infestation and other policy changes is unpredictable. Changing economic variables such as production, prices, domestic demand, exports, imports and incomes are a vexed set of variables to compare and from those predictions form a policy and planting scenario. For growers there is also a three year window when changing varieties will return little from juvenile trees. In this scenario the only constant will be reduced pesticide use.

The result when you isolate the economic impacts of a specified change in pesticide policy on producers and consumers appears bleak.

The analysis to this point has not considered nutritional impacts. Reduced domestic production will result in higher prices which, in turn, will see a reduction in the intake of almost all vitamins and minerals. An analysis of the health effects of pesticide use reduction suggest that there is a need to consider a broader set of risks than is utilised by the APVMA. Its risk analysis only considers the direct effects of the target pesticide on health. To capture these additional or countervailing risks requires a much broader approach to pesticide policy.

Perhaps most important, it would be a serious mistake for Australia to make decisions regarding banning a broad range of pesticides without considering the effects on the poor, resource allocation, and on food security. That is, higher prices and reduced



consumption run counter to health policies advanced by state and Federal Governments over the past decade in the various “5 veg and 2 fruit” campaigns designed to encourage people to eat more fruits and vegetables.

There are still wider economic effects than the effect on farmers and growers. Rural communities are supported by the productivity of farmers and growers; national nutrition is impacted by the quality and quantity of food supply, the nation’s food security; and capacity to supply developing countries are all relevant to pesticide policy. These are issues that need serious attention by policy makers.

The emphasis on individual pesticides means that broad analyses are largely ignored. HOIG’s position has been to extensively criticise the APVMA for making decisions not being based on sound science. The reason for the absence of broader-based field trials lies in the regulatory process itself. In addition, there are no incentives for analysing the countervailing risks.

There is increasingly a need for interdisciplinary interaction, particularly in the health and environmental arenas. Government funding agencies can break down these rigidities, but only if they are overtly pursued. It will not happen naturally or by evolution. The interaction of the economic, nutritional, and health effects of reduced pesticide use needs to be pursued on the basis of national, multinational, and global policies. Making national decisions regarding pesticide use based on only national effects is as erroneous as making decisions on the basis of single pesticide effects.

The complexities and unforeseen consequences of regulatory action is not something that we have seen influence the decision making of the APVMA.

### **Addressing the terms of reference**

HOIG is hopeful that the Productivity Commission’s study will consider the approach adopted by the APVMA in its relationship to HOIG and its members. The regulator’s dealings with industry in this case created unnecessary tension, increased compliance costs and created foreseeable consequences that jeopardise the sustainability of orchards. To illustrate a foreseeable consequence, the APVMA banned the use of fenthion by home gardeners in October and, quite predictably, the number of fruit fly increased significantly this season.

Reviews of the APVMA over time and HOIG’s own experience suggest there is a clear pattern of behaviour adopted by the regulator to those that it regulates, whether they are small businesses or not.

#### **Term of reference - “provide evidence on the variety of approaches used by regulators to engage with small business”**

#### **Comment**

The APVMA announced just days before the commencement of picking this season’s crop that it would ban the use of the chemical fenthion on a wide range of fruits on October 31 2012. While this was its public position, the APVMA assured growers that submissions objecting to this step would be taken into account before a final decision was made about banning fenthion. Contrary to the stated position to HOIG, we were advised by the Department of Agriculture and Food Western Australia, pesticide manufacturers and by the Minister’s office that the ban would proceed, even though the submission period had not closed or submissions considered.

During this period HOIG had regular contact with the APVMA and put to them that there was no alternative to fenthion. The response of senior officers was that under the Act they had no responsibility or obligation to consider alternatives to fenthion. They put the responsibility on to orchardists to develop a new pesticide to replace fenthion.

They made the argument that they had been reviewing the use of fenthion for fifteen years and that was surely enough forewarning for growers to secure an alternative. The obvious point seemed to be lost on them that chemical manufacturers have not been able to develop one in spite of their best efforts. This was shrugged off with no interest or concern.

They publicly said they did not care about the impact of the decision. They were only obliged to do and consider what the Act required.

While grower groups wanted to highlight industry practice and the different application rates adopted from region to region across Australia, the APVMA demonstrated it was not aware of the differences nor were they particularly interested.

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, influence or veto.

HOIG contends the APVMA failed to apply the legal rules of procedural fairness and natural justice or the principles of scientific method in its review of fenthion.

The APVMA does not communicate on a regular basis with growers. 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. It uses its "statutory independence" to avoid accountability and scrutiny.

As its costs are recovered from industry it appears to feel that it is at arms' length from government control. Although growers ultimately pay the levies and fees to maintain the APVMA it appears to disregard them as stakeholders.

On the basis of historical evidence it appears to HOIG that the APVMA is only committed to improving its relationship with stakeholders and efficiency when it is under scrutiny. It pays lip service to political and administrative reform. For example, when the ANAO report made a number of recommendations about corporate governance, the APVMA did not implement two important recommendations directed towards improving timeframes. Both recommendations were aimed at streamlining assessments and reducing delays. It is difficult to understand why such procedural improvements were not implemented and why undue delays continue.

It is well established that the APVMA has struggled to maintain a timely and effective regulatory regime. APVMA evaluations have caused a considerable cost burden on Australian applicants which has led to delays and increased costs - all of which are passed onto growers. Growers are price takers in the market and susceptible to being squeezed financially with only a limited ability to pass costs on.

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 APVMA relies on overseas research to support a conclusion to restrict a chemical but not to approve one. By demanding the same work is repeated for assessment in Australia, costs to applicants for registration is higher than necessary.

For example, Organic Crop Protectants Pty Ltd has been trying to register a product AzaMax based on neem oil as an insecticide on horticultural and cotton crops since 2000. The APVMA has taken the position that neem is unsafe even though products like AzaMax have been registered in food crops overseas for over ten years without any adverse effects. Neem-based products are approved for use on food crops in the EU, the US and New Zealand.

APVMA has claimed the information provided to them has been insufficient to establish an ADI (Average Daily Intake) when regulators have used the same data to establish, with the 2011 evaluation report published by the EU regulator EFSA giving values for the ADI.

No regulatory action is being taken to stop the unrestricted use of crude neem oil products and extracts as “fertilisers” in this country. The APVMA actually released a document in 2010 which defined neem products with a concentration of Azadirachtin of 850ppm or less as not requiring registration and could be used as “fertilisers” in food crops. This further places into question APVMA’s arguments that neem based products are unsafe, especially when the proposed rate of use of AzaMax as an insecticide on food crops is almost 24 times less concentrated than neem “fertilisers” (2-3ml/L or 24-36ppm).

Australian food growers meanwhile are denied access to a competitive botanical insecticide.

**Term of reference – “the balance of facilitative, educative and compliance based approaches, including the use of risk-based compliance and enforcement strategies”**

#### **Comment**

The APVMA is the sole national regulator of pesticides and veterinary medicines industries. The enforcement of pesticide usage is conducted by the various state and territory governments. Additionally, it has responsibility for developing regulation and/or policy-making in addition to administering regulation.

The APVMA is both a policy advisor and regulator. It would appear that it has never enjoyed a particularly close or reasonable working relationship with industry. Over time the coverage of regulation has broadened. Governments of the day have delayed in responding to regulatory problems although they have been well aware of their existence. The APVMA approach to decision-making in the regulation of pesticides appears to be extremely risk averse, both historically and in our recent dealings with them regarding fenthion.

The regulatory approach doesn’t allow for discretion but is based on mathematical equations. Whether a pesticide residue falls above or below an arbitrary line it is either registered or not. In the case of fenthion, HOIG was told that there was no room for discretion. However, when the catastrophic impact on growers was highlighted to politicians and the public through the media the APVMA showed considerable room for discretion. This discretion resulted in the inconsistent regulatory decision to allow one spray regime for fruit sprayed with fenthion on one side of the country and another spray regime on the same fruit on the other side.

The APVMA’s behaviour towards growers in the initial stages of our negotiations was intimidatory and overbearing.

The APVMA appears to adopt a traditional compliance based approach of conformity or obedience to the regulations and legislation. The compliance of stakeholders should,

according to the APVMA operate according to expected norms and values that the APVMA establishes.

In the fenthion and other reviews, the APVMA did not adopt a facilitative approach - that is an approach to make something easier to do or understand. They commenced their engagement with HOIG on the basis that the decision had been made and this is how it was made. Alternative approaches or methodologies were not going to be considered.

The APVMA did not contemplate a broad knowledge set in its evaluation of fenthion. It had its own views and they were the only ones initially considered. It was as if the compliance approach of the regulator carried over into all aspects of the behaviour and conduct of the organisation. Obedience, agreement and acquiescence were required. If an educative approach of sorts was adopted it was characterised by hectoring, bullying, intimidation and badgering.

No consideration was going to be given to the real world use of the pesticide or the fact its use has not resulted in harm to orchard workers or consumers in 50 years that fenthion has been in use in the horticultural industry. The regulator denied itself the means to tailor its responses to local or particular circumstances. It did not want to take into account that it is mandatory that all stonefruit imported into Victoria must be sprayed with fenthion five times or it cannot enter the state.

The issue with this regulator is not corruption and/or discrimination but bureaucratic arrogance. As an independent regulator blindly following other like-minded regulators – i.e. The EU and USA – the APVMA views its actions as beyond question. The underlying cost implications to this approach are significant and dangerous in the future.

While many factors impact on a regulator's posture toward small business and sometimes these factors lie outside the control of regulators, HOIG believes that there is a framework within which the APVMA can engage in a much more collaborative fashion. There needs to be a new focus on how they discharge their responsibilities and how they use their powers, resources, tools and available discretion. This requires a cultural change, not merely legislative change.

**Term of reference - "whether approaches appropriately consider the characteristics of small business"**

**Comment**

The APVMA's engagement with growers revolves around:

- regulatory requirements;
- compliance and enforcement strategies; and
- consultation and feedback mechanisms.

As the APVMA is a fully cost recovered agency, all its compliance costs eventually flow to the users of Agvet chemicals – the primary producers. The APVMA's unpredictable and excessive demands for information for chemical registrants add to the compliance burden without necessarily adding to the efficiency of the process.

On the consultation and feedback side, the transparency and accountability of engagement by the APVMA with growers is minimal.

The quality of the APVMA's engagement with growers and the industry is a major determinant of regulatory compliance costs.

HOIG would hope that our submission has provided examples and historical evidence that the APVMA is:

- excessively prescriptive in interpreting statutes;
- not risk-based when assessing chemicals;
- excessive or unpredictable in its demands for information;
- adversarial in its attitude to industry and growers;
- lacking effective communication with growers and business about proposed regulatory changes, interpretations or investigations;
- failing to provide guidance on what constitutes adequate compliance and;
- over-reaching in its attempt to mirror or even exceed international standards.

The Commission in its “Issues Paper” says it will seek to identify particular regulator practices that minimise the cost of compliance for small business — that is, the costs incurred in meeting requirements are only those necessary to achieve regulatory outcomes.

Compliance costs for business can usually be divided into two broad categories:

- one-off costs, such as businesses acquiring sufficient knowledge to meet their regulatory obligations, purchasing/leasing additional equipment and buildings, legal/consultancy fees and training expenses; and
- recurring and ongoing costs, such as staff costs, consumable materials, inspection fees/licences and costs arising from the need to devote additional time and resources to satisfying regulatory requirements.

HOIG is of the view that there is at least a third major cost when dealing with the APVMA – the potential loss of significant sectors of Australia’s agricultural and veterinary medicines industries and loss of access to safe Agvet chemicals. This risks a loss of investment, innovation, jobs and communities. The repercussions of the APVMA’s decisions are enormous.

The potential economic cost of APVMA decisions which provide no demonstrable protection to health or the environment is clearly not well understood by government or it would act to reform the agency.

Growers faced with the loss of effective chemical tools and subsequent income loss will in the short term abstain from investment and pursuing innovations or creating new jobs, reducing production and profits. These effects have repercussions in the broader society in general, in the form of a net loss in primary production, closure of businesses, job losses, to the foreseeable increase in bankruptcies and people just walking off their properties.

The longer term impact will be the loss of primary production land to other uses and increased reliance on food imports.

Without effective Agvet chemicals, primary production will become uncompetitive. With the potential loss of fenthion on the horizon, Hills growers are feeling economic pressure to subdivide their orchards into smaller lots for sale or walk off the orchard. The Department of Agriculture and Food WA is opposing zoning changes to allow subdivision into smaller lots while refusing to support the continued use of fenthion.

Government’s policy objective of making Australia the food bowl of Asia is in direct conflict with the approach taken by the APVMA of regulating Agvet chemicals.

**Term of reference - “the extent to which regulatory engagement approaches vary with the nature and objectives of regulations and with the way the regulatory regime is defined by policy makers”**

### **Comment**

The APVMA has a web-site page titled “Our regulatory Posture” where it describes its posture as *“the behavioural stance of an organisation. Posture is driven by organisational values and is evident in the individual interactions of staff and the collective behaviours exhibited by the agency. For the APVMA posture is the character we project when interacting with stakeholders and with each other”*.

The APVMA defines its conduct as *“meeting a diverse set of responsibilities efficiently and effectively while using innovative leadership, nurturing professional and collaborative relationships, fostering public participation and being accountable to government and the broader community.”*

The APVMA goes on to say that it needs to inform the regulated community on how to comply; and also need to conduct enforcement activities with sufficient rigour to ensure lasting compliance.

The APVMA’s regulatory posture is to be ‘firm and fair’, delivering regulatory activities to protect the health and safety of people, animals and crops, the environment and trade. The APVMA says its regulatory posture enables it to be flexible and retain regulatory integrity, while ensuring that regulatory activities are thoughtfully developed, and then conducted with sufficient vigour to ensure that the strategic intent of the regulatory framework is achieved.

The operational characteristics and capabilities that support this regulatory posture are to:

- make consistent and predictable science based decisions based on evidence;
- demonstrate fairness and exercise good judgment;
- be responsive and innovative to adjust to changing operating environment;
- communicate and consult as extensively as appropriate with stakeholders;
- act independently and maintain the integrity of the regulatory framework; and
- deliver regulatory functions in a timely manner.

The APVMA has consistently failed its own charter. In our experience its behaviour is the exact opposite of its claimed regulatory posture and operational characteristics. Our view is supported by numerous reviews of the agency and comments by industry.

The APVMA also says that it is committed to ensuring regulatory activities are conducted fairly and describes its values as:

- “Scrutiny - will it withstand scrutiny from the community, media, industry groups, executive management and government;
- Ethical - is it truly impartial and without bias or prejudice and have any personal views or beliefs been properly identified and managed;
- Lawful - is it according to law, is it likely to be supported by the courts and is it within my delegations; and
- Fair - Is it fair to those involved, Is it reasonably consistent with policy and practice, Is it proportionate to risk, Is it respectful of individual and company reputations, and is it in any way unduly prejudicial or detrimental to other stakeholders?”

HOIG is not the only stakeholder to disagree with these descriptions of the conduct of the regulator. In the Business Spectator of May 2010 it was alleged that chemical industry

organisations placed stories in the media to make their complaints about the APVMA's conduct public.

The APVMA responded with an article on its website entitled "Animal health sector encouraged to develop an international perspective", in which it accused the animal health industry of being slow to adopt an approach it claims is followed by the crop protection industry.

The APVMA said that the crop protection companies generate one package of information which is submitted at the same time to regulators around the world... According to the APVMA "the agencies coordinate their assessments, share the work and produce a commonly agreed monograph that each country uses to undertake its risk assessment and make its decision".

Industry sources responded saying "to put it politely, utter garbage. Furthermore, the APVMA is being deliberately disingenuous. Australia might look big on the map but in global market terms it is a drop in the bucket. The suggestion that a chemical company would delay submitting a new product application in Europe or the USA while it generates data to allow a simultaneous submission in Australia defies reason".

The APVMA will not accept the assessment of American or European regulators and insists on undertaking its own evaluation despite claiming that it "accepts international chemistry assessment reports", placing an additional cost burden on registrants.

The bottom line is, Australian farmers and growers are paying the price through delayed access to modern farm chemicals that are available to their overseas competitors, and the chemical industry is paying for a regulator that is notorious for delays.

### **Term of reference – "how the use of particular engagement approaches might shape regulatory culture"**

#### **Comment**

HOIG agrees with the Commission that in principle, measures to ease compliance burdens should be broad-based and aimed at eliminating arbitrary, ineffective or badly designed features of regulations - irrespective of whether this affects small or large businesses.

HOIG applauds the Commission's suggestion that a well-structured risk-based approach to regulation by deploying resources based on an evidence-based assessment of risk should lead to an appropriate framework for a regulator to deal with small businesses. The challenge for the APVMA is after more than 15 years to develop a culture and attitude within its organisation that delivers in practice.

Compliance with regulations can impose proportionally greater administrative burdens on small businesses than on larger ones. It should also be remembered that the risks of poor or capacious regulation is also much greater for small business.

If there is not some change to the regulatory approach that has been adopted by the APVMA then growers and consumers are likely to be the losers on several fronts. Allowing the APVMA to continue the current approach to regulating is likely to risk incorrect targeting of its powers and delivering adverse regulatory outcomes that will have consequences to small and large businesses.

HOIG does not support the EU approach of 'Think Small First'. We suggest an approach that would provide the necessary protection that the agency was designed to provide with an additional element "think of Australia as well". The APVMA's policy objectives must be

broadened, it has to consider alternative options, respect and consider alternative points of view, deliberate on the cost-benefit analysis of its decisions and consult more widely with those that its decisions are likely to affect.

The small size of the Australian market restricts the ability of firms to recoup the costs of registration and accordingly, some firms claim that they are deterred from introducing new chemicals that may be more beneficial to users and the environment than the chemicals currently used.

The delays and data costs of assessments could be reduced through the greater recognition of appropriate overseas assessments and more extensive utilisation of international data and modelling tools. The APVMA is currently explicitly required by its legislation to manage risk within a cost-benefit framework although that is not a factor ever mentioned to HOIG.

The claim by the APVMA that it uses international best practice is said by Competitive Advantage (November 2011) as not being correct. Publication of the Risk Analysis Framework contains examples of approaches that are no longer considered 'best practice' being used e.g. use of NOEL (No Observed Effect Level) rather than the internationally accepted measures such as NOAEL (No Observed Adverse Effect Level) and Benchmark dose methodology.

To be truly effective, it is claimed that the Framework would need to be supported by comprehensive documentation on the procedures and policies that arise from the Framework.

The policies and procedures need to articulate:

- the criteria to be used by APVMA in determining when there is acceptable versus unacceptable doubt;
- how APVMA will deal with uncertainty, remembering that uncertainty should not be an excuse for inaction in relation to decision-making;
- APVMA's approach to 'weight of evidence' especially in relation to the need to do 'guideline' toxicity studies and APVMA's stated aim to minimise use of laboratory animals; and
- what the APVMA considers being 'unacceptable' harm.

The effectiveness of the Agvet scheme is limited given that all existing chemicals were grandfathered, without modern assessment, at the inception of the schemes. These constitute the vast majority of chemicals 'approved' for use in Australia. The APVMA has programs for assessing existing chemicals, with review priorities determined on the basis of perceived health and environmental risks. So far only a tiny fraction of existing chemicals have been assessed. Initiatives to greatly accelerate the pace of review under both programs are warranted.

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

HOIG has long supported Regulatory Impact Analysis as critical to informing regulatory decision making.

## **Conclusion**

Broadacre farmers, dairy farmers, horticulturists and orchardists make up the bulk of Australia's farmers and a significant number are doing it hard with many on the edge of financial collapse.



There is a complex and inter-related group of problems facing farmers and growers in Australia that come under three broad headings:

- the development of management systems to maintain or increase agricultural productivity while preserving soil and water resources;
- the need for plant improvement programs for current and potential crops; and
- socially-related factors like the cost of labour and the consumer's demand for a quality product.

Management systems include soil degradation through cropping or erosion, water quality and related problems, as well as pest control in a changing climate. One of the most pressing problems is to make better use of increasingly scarce and costly water supplies.

Plant improvement to meet the demand for higher-yielding, disease-resistant varieties with desirable agronomic characteristics is essential. Many breeders are largely occupied with maintaining yield and quality standards to meet new disease strains and new market requirements. It is to be expected that additional exotic pests and diseases will be inadvertently introduced to Australia in spite of strict quarantine provisions. Authorities have a responsibility to anticipate potential new pest threats and to develop contingency plans to overcome them. This includes introducing resistant materials to breeding programs wherever possible.

In horticultural crops there is a continuing need for virus-tested planting material and often for further introduction and evaluation of overseas strains. This applies to established crops such as stonefruits, which are facing market changes, as well as to crops not at present being grown commercially in Australia. There is enormous scope for genetic improvement in crops.

With rising labour costs, new plant types and management techniques must be developed to suit mechanical harvesting. Picking, packing and handling constitute a major cost. Consumers are demanding access to a full range of quality fruit and vegetables throughout the year and further improvements in storage and production in new areas is required. There is a need to improve the presentation and quality of fruit and vegetables, not only for the home market, but to take advantage of export opportunities.

Consumers in Australia have been educated to expect higher standards in the produce they buy. This increases pressures on growers to adopt spray programs that minimise the effects of pests and diseases. At the same time pesticide residues must be reduced. There is a place for greater development of integrated pest management programs and disease forecasting systems. Biological control is one answer, to reduce the amount of pesticide applied, but it is a complex problem and requires thorough studies of the control agent and target species.

Add to these physical challenges faced by primary producers is the regulatory burden, including:

- administrative costs;
- substantive compliance costs;
- financial costs; and
- indirect costs.

These costs may be borne by businesses, individuals, the community more broadly or government. Regulatory costs are money paid directly to the agencies or government and include fees, levies and fines. Substantive charges are the costs associated with providing background information or research to the regulator, training of staff to perform in accordance with the requirements of the regulator and providing equipment that is stipulated

by the regulator. Administrative costs are the costs associated with compliance and include record keeping, testing and form completion costs. Indirect costs are delays, altered patterns of consumption, holding costs and restrictions on innovation.

While providing detailed information on regulatory costs takes time and effort, such information HOIG acknowledges can assist decision-makers to better supervise:

- the many pesticides and veterinary medicines products so they will not only work, but will not harm growers and farmers, workers, crops, animals or the environment;
- chemicals which are used in the household, such as insect sprays, personal insect repellents, products for treating diseases in home garden plants, and medicines for companion animals such as dogs, cats and horses; and
- the full impacts of the regulation such as whether regulation is proportional, needs reform, or imposes excessive compliance costs.

When governments impose regulations on small business that usually drives up the cost of doing business, and in some ways is like imposing a tax or demanding a compulsory contribution to state revenue. This cost impacts on salaries, business profits and the cost of goods and services.

Regulations adversely impact small business in four ways:

- regulatory compliance puts a disproportionately large burden on small companies because they don't have as much revenue to spread the costs over;
- regulations make small business less competitive against foreign competition;
- regulations add uncertainty which stops small business investing in capital purchases, services and hiring; and
- new regulations add complexity and often have unintended consequences.

Farmers and growers, like so many small businesses, have a vast array of regulations to deal with - taxation, superannuation, workplace relations, insurance and health and safety obligations.

In addition, industry specific regulatory requirements can vary significantly. Farmers and growers are likely to face a number of State and Territory based requirements as well as the commonwealth obligations. Local councils can have their own specific requirements, for example, in Western Australia they monitor and police fruit fly infestation.

HOIG members identify that a significant source of unnecessary regulatory burden is imposed through the APVMA's lack of engagement with growers as part of the development of regulation and in its implementation. The seeming lack of transparency, contestability and accountability in the regulatory processes were identified as playing a significant role in the excessive regulatory burden on growers.

Agriculture is going to get more complex, there will be more controls, more community pressures and higher costs. Farmers and growers will be better educated and will be asking for detailed technical information on a wider range of subjects. In such a climate it is essential that the component parts of the industry co-operate and communicate as effectively as possible to ensure the sustainability of one Australia's most vital production sectors - a sector dominated by small businesses.

The ABS reports that in 2001, 91% of farmers in Australia were family-operated small businesses, with around 99% of farms operated by owner-managers. Since then the number of farming families has declined by more than 22%.

The APVMA has exhibited practices that threaten sectors of the industry, add additional unwarranted cost, delay the introduction of better Agvet chemicals into Australia and create

barriers to the development and production of new chemicals in Australia. This is a situation that has to be arrested if Australian horticulture is to survive.